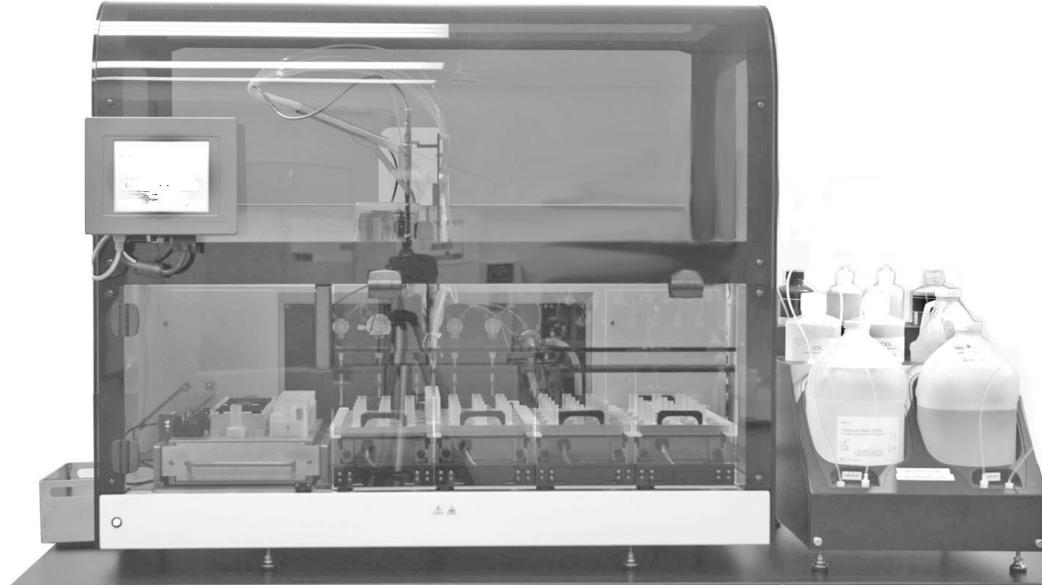


# BD Totalys™ SlidePrep Instrument User's Manual



CE  IVD  Rx Only

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# Change History

Revision	Date	Change Summary
08	2020-10	Removed information on operating conditions for BD PrepMate™ Automated Accessory. Updated Symbols Glossary.
09	2020-11	Updated Change Summary description.
10	2022-03	Updated for IVDR 2017/746 Updated ISO Symbol Updated EC Rep symbol and address. Added CH REP symbol and address. Added Technical Service and Support. Added Safe Disposal statement Updated BD Trademark and Copyright statement. Updated section 3.1 General.

Training by BD Diagnostics-authorized personnel is required before operating the BD Totalys™ SlidePrep. All operators should read this manual before operating the BD Totalys™ SlidePrep or using any BD SurePath™ reagents.

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# 1 – Introduction

## 1.1 Intended Use

The BD Totalys™ SlidePrep (SlidePrep) is an automated liquid-based thin layer cell preparation system which produces BD SurePath™ Liquid-based Pap Test slides intended as replacements for conventional gynecologic Pap smears. BD SurePath™ Liquid-based Pap Test slides (formerly AutoCyte® PREP slides) are intended for use in the screening and detection of cervical cancer, pre-cancerous lesions, atypical cells and all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

## 1.2 Overview

There are three main phases in the sample and slide preparation process:

- Specimen collection
- Cell enrichment / Pre-processing
- Slide preparation and staining

Both gynecological and non-gynecological specimens can be collected for use on the SlidePrep. For gynecological specimens, once samples are received from the collection site, cell enrichment is performed in order to remove obscuring debris such as blood and mucus to create an enriched pellet of diagnostically relevant cells. Cell enrichment consists of several steps including vortexing, processing using the BD PrepMate™ Automated Accessory, and centrifugation. Alternatively, the steps of cell enrichment can be completed using the fully automated BD Totalys™ Multiprocessor (MultiProcessor).

The pre-processing steps for non-gynecological specimens vary and are performed according to the laboratory's approved standard operating procedures or BD provided preprocessing protocols.

The SlidePrep then prepares either stained or unstained slides from the cell pellet using a robotic processor to transfer cell samples to a settling chamber mounted on a microscope slide. Additionally, the SlidePrep can solely stain slides that already have a mounted cell layer.

Two tests may be run on the SlidePrep.

### **BD SurePath™ Liquid-based Pap Test**

The BD Totalys™ SlidePrep system generates BD SurePath™ Liquid-based Pap Test slides with or without Papanicolaou staining chemistry from gynecological specimens. After cell samples are transferred to the settling chamber, they are rinsed and counterstained with hematoxylin and EA/OG for morphologic screening and detection of cells derived from cervical cancer, pre-cancerous lesions, benign atypia, and all other cytologic categories as defined by The Bethesda System (TBS) for Reporting Cervical/Vaginal Cytologic Diagnosis.

### **Non-Gyn Protocol**

Non-gynecological specimens may also be processed on the SlidePrep for slides with or without Papanicolaou staining chemistry. The Non-Gyn protocol runs similarly to the BD SurePath™ Liquid-based Pap Test but multiple slides can be prepared from one sample. In addition, sample transfer volumes are customizable per sample type.

The following sections introduce the BD Totalys™ SlidePrep system. One of the first items in the training agenda is a demonstration of the SlidePrep system in the training lab. You may find it useful to annotate the illustrations in this section as the demonstration proceeds.

Illustrations of each component in the SlidePrep process are introduced in the order they would be encountered in the routine laboratory process.

## 1.3 Specimen Collection

### Gynecological Specimens

The BD SurePath™ process begins with specimen collection using either a broom-type sampling device with detachable head (e.g., Cervex Brush®) or a combination endocervical brush/plastic spatula-type device with detachable head (e.g., Cytobrush Plus® GT and Pap Perfect®) to collect a gynecological specimen.

With the broom-type device, the longer central bristles of the device are inserted far enough into the cervical os to obtain cells from the endocervix. As the device is pushed towards the cervix, the lateral bristles splay out over the ectocervix. The device is rotated five times in a clockwise direction to sweep cells from the ectocervix and transformation zone. When using the spatula-type device, the contoured end of the spatula is inserted into the cervical os and rotated 360° around the entire ectocervix. Then the brush is inserted into the endocervix until only the bottom-most bristles are exposed at the os and is rotated 1/4 to 1/2 turn in one direction.



**Figure 1-1 – Collection devices**

The heads of the sampling devices detach from the handle and are placed into a BD SurePath™ Collection Vial (specimen vial) for shipment to the laboratory. See Figure 1-2. The sampling device heads are never removed from the vial containing the collected sample.



**Figure 1-2 – Detachable collection head**

### **BD SurePath™ Preservative Fluid**

BD SurePath™ Preservative Fluid is intended for use in the collection and transportation of gynecologic specimens and for storage of residual cervical cytology specimens.

The BD SurePath™ Collection Vials are pre-filled with 10mL of BD SurePath™ Preservative fluid. When gynecologic specimens are collected, the head of the sampling device is detached and deposited in the vial containing BD SurePath™ Preservative Fluid (preservative fluid) to preserve, transport and store the patient sample. The preservative fluid is a buffered 24% ethanol solution used to fix diagnostic cells and is bactericidal for gram negative enterics, gram positive cocci, and fungi.

### **Non-Gynecological Specimens**

Various types of non-gynecological specimens including washings, brushings, sputum, and urine may be used for slide preparation on the SlidePrep. Samples should be collected according to the manufacturer's recommended protocols.

## **1.4 Manual Pre-Processing Components**

The components used in manual pre-processing for cell enrichment of gynecological specimens are described in this section. These components can be used if the MultiProcessor is offline or is not available.

- Refer to your laboratory's approved standard operating procedures for the components involved in pre-processing non-gyn specimens.

During the cell enrichment phase of the BD SurePath™ slide preparation process, the clinical materials in the collected cervicovaginal samples are randomized and the clinical content of the sample is enriched. In this process, the sample is prepared in a series of manual steps that include vortexing to mix and disaggregate the sample, homogenizing, layering onto BD Density Reagent (density reagent), and centrifugation.

The major components of the pre-processing steps needed for cell enrichment are listed below and discussed further in the following sections.

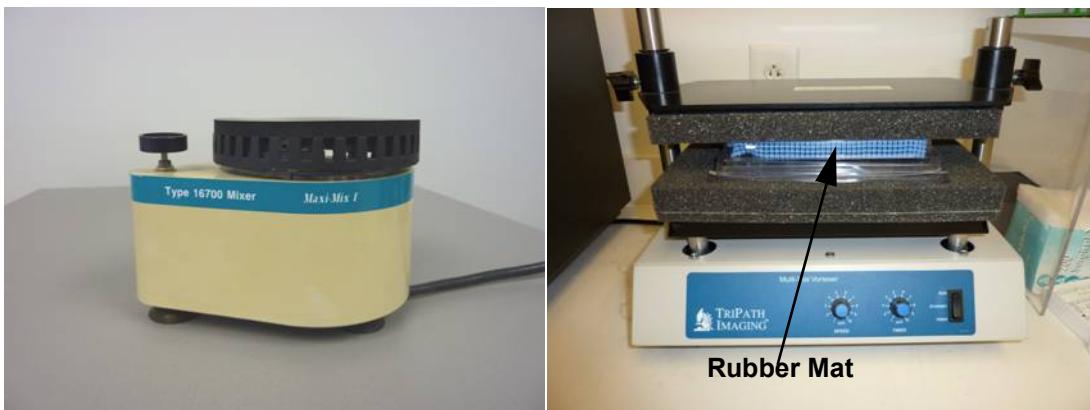
- Single and multi-vial vortexer
- BD PrepMate™ Automated Accessory
- Centrifuge
- Easy Aspirator fluid aspiration system

### **1.4.1 Vortexer**

Single and/or multi-vial vortexers mix specimens into a homogeneous cell solution prior to processing on the BD PrepMate™ Automated Accessory.

- The single-vial vortexer (not provided with the SlidePrep system) mixes one specimen vial at a time. It is also used to vortex the centrifuge tube rack (c-tube rack) after the second centrifuge cycle.

- The multi-vial vortexer mixes up to 25 specimen vials in a clamshell at a time.



**Figure 1-3 – Single (left) and multi-vial (right) vortexers**

**CAUTION**

**Vortexing represents two critical steps in the cell enrichment process.  
Failure to vortex may impact the quality of the sample.**

**NOTE**

Attention must be paid to place the rubber mat inside the lid of the clamshell in order to secure the vial in place during vortexing.

## 1.4.2 BD PrepMate™ Automated Accessory

Figure 1-4 shows the BD PrepMate™ Automated Accessory that homogenizes and transfers cell solution from the BD SurePath™ Collection Vial to a BD Centrifuge Tube (c-tube) containing density reagent.

The c-tubes contain the sample throughout the cell enrichment process.

Up to 12 BD SurePath™ Collection Vials can be processed during a single run.

Used with the BD PrepMate™ Automated Accessory are: specimen vials, density reagent, specimen rack, BD PrepMate™ Syringing Pipettes (syringeing pipettes), c-tubes and c-tube racks.

To eliminate the possibility of specimen contamination, syringeing pipettes and c-tubes are disposable and not re-used.



**Figure 1-4 – BD PrepMate™ Automated Accessory**

**WARNING**

**THE OPERATOR'S MANUAL FOR THE BD PREPMATE™ IS SEPARATE FROM THIS MANUAL AND SHOULD BE READ BEFORE OPERATING THE BD PREPMATE™.**

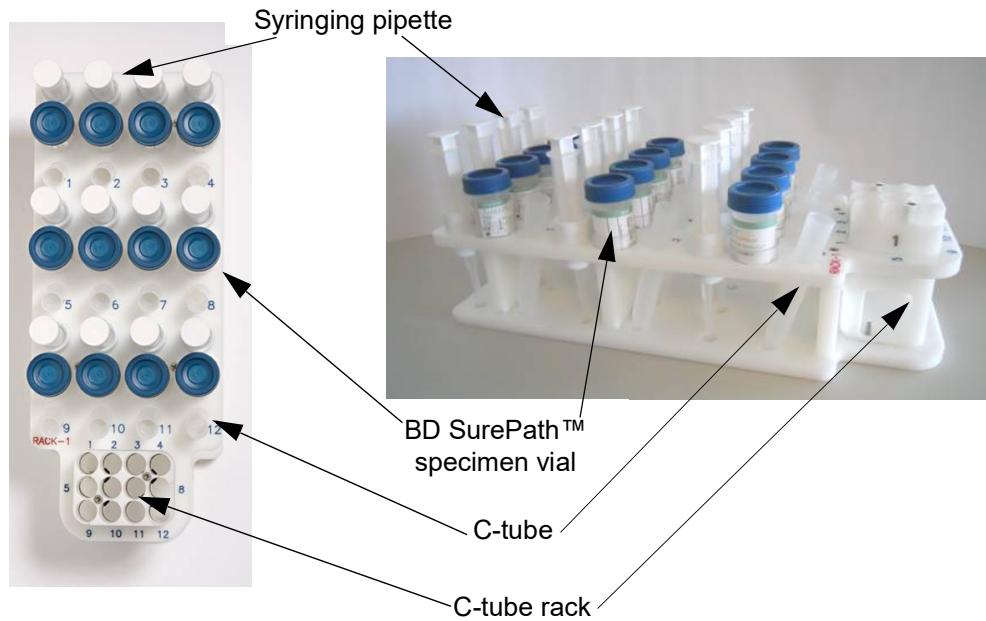
#### 1.4.2.1 BD PrepMate™ Specimen Rack

The BD PrepMate™ specimen rack holds specimen vials, c-tubes (mounted at a slant), syringing pipettes and c-tube racks. The specimen rack and c-tube racks are uniquely keyed to each other, for example, c-tube rack 1 only fits in specimen rack 1.

The specimen rack slides into the metal tray at the base of the BD PrepMate™ Automated Accessory. The syringing pipettes mix and then transfer specimen solution from the specimen vials onto the pre-aliquotted density reagent in the c-tubes. The density reagent is a polysaccharide solution with sodium azide added as a preservative.

After the run, the c-tubes are manually moved from the specimen rack to the c-tube rack. C-tube positions on both the specimen rack and the c-tube rack are numbered for maintaining chain of custody.

Depicted in Figure 1-5 are two views of a BD PrepMate™ specimen rack fully loaded with a c-tube rack, c-tubes, specimen vials, and syringing pipettes.



**Figure 1-5 – BD PrepMate™ specimen rack, top view (left) and side view (right)**

#### 1.4.2.2 BD C-tube rack

After samples are processed on the BD PrepMate™ Automated Accessory, the c-tubes are moved to the c-tube rack that is then placed into the centrifuge. After centrifugation steps, the c-tube racks are moved to the SlidePrep for cell transfer and staining.



**Figure 1-6 – C-tube rack**

### 1.4.3 Centrifuge

During two different centrifugation steps, the centrifuge spins the sample in the c-tube to form an enriched and concentrated cell pellet for use on the SlidePrep. The centrifuge is shipped pre-programmed for proper specimen processing, however the model of centrifuge may vary among installations dependent on power requirements and availability.

Figure 1-7 illustrates loading the c-tube racks and placing the centrifuge bucket lid onto the centrifuge bucket.



**Figure 1-7 – Placement of c-tube racks in centrifuge buckets**

**WARNING**

**THE OPERATOR'S MANUAL FOR THE CENTRIFUGE IS SEPARATE FROM THIS MANUAL AND SHOULD BE READ BEFORE OPERATING THE CENTRIFUGE.**

## 1.4.4 Easy Aspirator Fluid Aspiration System

Following the first centrifuge spin, the fluid aspiration system (Easy Aspirator block and a vacuum pump also called the *tube vac*) is used to aspirate the top fluid layer or supernatent from the c-tube. This top layer that was unable to pass through the density reagent contains obscuring agents that would otherwise inhibit proper visualization of cells.

The user-held Easy Aspirator block has prongs for attaching 12 tips that aspirate the top fluid layer from the c-tubes.



**Figure 1-8 – Easy Aspirator block with tips**

The tube vac is connected to the Easy Aspirator block and provides the suction to draw off the top fluid layer from the c-tube. Fluid is aspirated from the c-tube into a waste bottle.



**Figure 1-9 – Vacuum pump**

### WARNING

THE VACUUM PUMP EXHAUSTS ALCOHOL VAPORS DURING NORMAL OPERATION THAT COULD CAUSE A FLAMMABLE ATMOSPHERE IF THE PUMP IS KEPT IN AN ENCLOSED SPACE E.G. CABINET. DO NOT KEEP THE VACUUM PUMP IN ANY ENCLOSED SPACES THAT ARE NOT WELL-VENTILATED. THE VACUUM PUMP SHOULD BE USED IN A WELL-VENTILATED SPACE THAT IS FREE OF IGNITION SOURCES CLOSE TO THE EXHAUST.

## 1.5 Automated Pre-Processing Components

The BD Totalys™ SlidePrep can be used with the BD PrepMate™ semi-automated pre-processing procedure or with the automated pre-processing option used with the MultiProcessor system. The MultiProcessor automates the manual pre-processing steps described in the sections above to include:

- decapping the vial
- sample aliquot
- density reagent transfer to c-tubes
- sample transfer to c-tubes
- centrifugation
- aspiration
- decanting
- recapping

Several processing protocols are available on the MultiProcessor:

- Cytology Preparation and Molecular Aliquot
- Cytology Preparation only
- Molecular Aliquot only
- Reprocessing

The MultiProcessor system utilizes two work areas: a remote station (computer) for logging in or editing sample trays and the MultiProcessor system itself where sample trays are loaded for processing.

Inside the MultiProcessor, instrument functions are divided into two areas: the “front end” and the “back end.” The front end of the instrument contains: an input/output station for loading and unloading trays, an elevator and tray shelf assembly for positioning trays before and after processing, and a STaRD (sample transfer and reagent dispense) area to perform the specimen and density reagent transfer steps.

The back end of the instrument contains: a centrifuge that performs the two centrifugation steps, a centrifuge rack gripper (c-rack gripper) that transports the c-racks, and an aspirate/decant station where samples are handled after centrifugation.

Also part of the instrument is a waste/reagent tray which holds the liquid waste container, the solid waste container, the TBW bottle and the density reagent bottle.

Specimen processing for the MultiProcessor occurs on the sample tray. Each sample tray has its own tracking barcode and all specimens, c-tubes, syringing pipettes, and molecular tubes, if applicable, are loaded onto the tray prior to placement on the MultiProcessor. Once trays are setup, they are logged in at the remote station and loaded onto the MultiProcessor for processing.

### NOTE

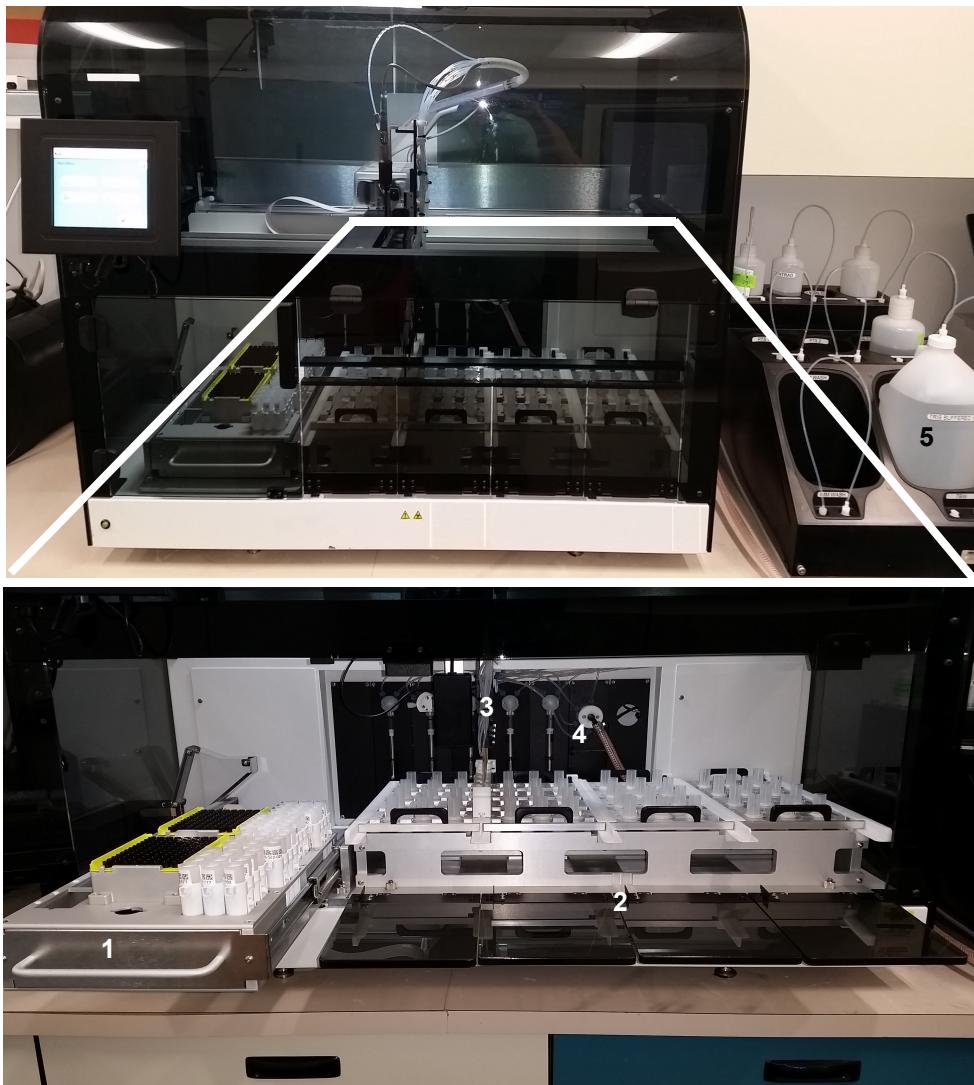
Refer to the *BD Totalys™ MultiProcessor User’s Manual* (8089991) for details on pre-processing using the MultiProcessor.

## 1.6 BD Totalys™ SlidePrep Components

A fully automated Tecan robotic processor is the base unit of the SlidePrep. The major components of the SlidePrep are listed and shown below in Figure 1-10 with further discussion in the following sections.

- 1 Deck accessories support rack (DASR)
- 2 Slide tray support (STS) with slide trays
- 3 Robotic arm containing the quad arm assembly and disposable tip (DiTi)
- 4 Rinsing and staining syringes
- 5 Bulk reagent station

A waste station is also attached to the SlidePrep (see Section 1.6.7: Waste Station).



**Figure 1-10 – Components of the BD Totalys™ SlidePrep**

### 1.6.1 Deck Accessories Support Rack (DASR)

The DASR holds disposable pipette tips and the centrifuge tube racks containing specimens. The remaining features of the DASR are not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol. When the door in front of the DASR is opened, the DASR can be slid forward using the handle for easy access. Figure 1-11 displays the primary elements of the DASR:

- 1 **Tip waste chute:** located at the back left corner of the DASR, discards used tips to a waste container. The tip waste chute does not slide forward with the DASR tray.
- 2 **Reagent kit rack:** located on the left side of the DASR, holds a (reagent/control) kit that is not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol.
- 3 **Control kit rack:** located in front of the reagent kit rack and holds a (reagent/control) kit that is not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol.
- 4 **C-tube rack holders (4):** hold the racks containing the enriched cell samples in c-tubes.

The c-tube racks used with the BD PrepMate™ Automated Accessory are shaped differently than the c-tube racks used with the MultiProcessor. Therefore the SlidePrep DASR is different depending on whether it is used with the BD PrepMate™ Automated Accessory for manual pre-processing or with the MultiProcessor for automated pre-processing.

- **With manual pre-processing:** the c-tube rack holders are sized to fit the c-tube racks used with the BD PrepMate™ Automated Accessory (see Figure 1-11). To help ensure chain of custody, there are four designated positions, uniquely pinned to hold their corresponding c-tube rack (c-tube rack 1 will only fit into holder position 1).
- **With automated pre-processing:** the c-tube rack holders are sized to fit the c-tube racks used with the MultiProcessor (Figure 1-12).



**Figure 1-11 – Components of the DASR (shown with BD PrepMate™ c-tube rack holders)**

- 5 **Tip rack holders (2):** hold racks of BD Totalys™ Transfer Tips (transfer tips).

- 6 **Mixing tube holder:** positioned in front of the tip racks and holds a mixing tube that is not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol.



**Figure 1-12 – DASR with the MultiProcessor c-tube rack holders**

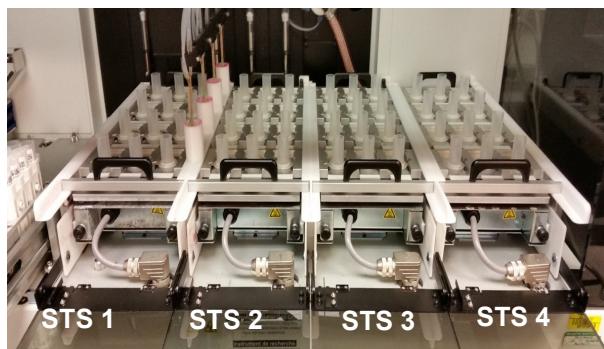
**NOTE**

Refer to Section 7.6.2 if you need to change or replace the DASR.

## 1.6.2 Slide Tray Support (STS)

There are four modules on the STS, located to the right of the DASR. Each module is numbered from left to right, with module 1 being closest to the DASR. Each module is uniquely channeled to its corresponding slide tray whereby slide tray 1 will only fit into module 1, slide tray 2 will only fit into module 2, etc.

Previous versions of the SlidePrep instrument may be equipped with heater modules that are located under the slide tray. The heater modules are not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test.



**Figure 1-13 – STS modules**

### 1.6.3 BD SurePath™ PreCoat Slides and Slide Trays

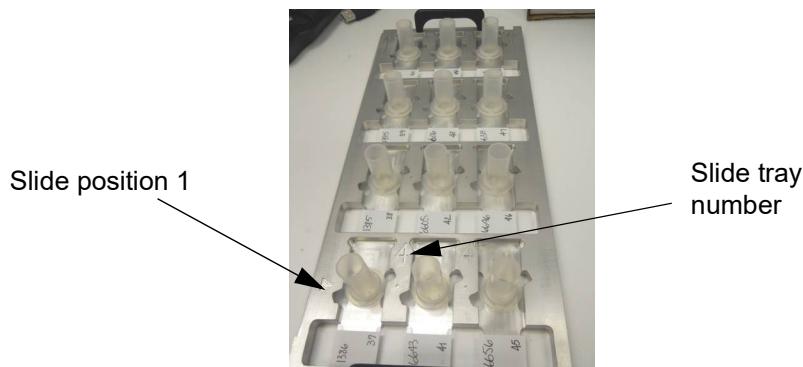
BD SurePath™ PreCoat Slides are proprietary microscope slides coated to create a positive charge on the slide surface. This positive charge enables adhesion of the negatively charged diagnostic cytologic material to the slide throughout the slide preparation process. Slides fit into wells of the SlidePrep slide trays as shown in Figure 1-14.

**NOTE**

Use only BD SurePath™ PreCoat Slides on the BD Totalys™ SlidePrep.

Each slide is mounted on the rack with the frosted or identifying end of the slide oriented towards the front of the tray. On each slide, a BD Settling Chamber (settling chamber) is placed and secured with a clockwise twist. The settling chamber's O-ring and the slide form a seal that prevents leaking when the chamber is filled with liquid. The sedimentation of cells onto the slide's surface and the subsequent staining takes place within the settling chamber. After staining, the settling chamber is removed and discarded. The slide is removed and cover slipped for subsequent screening.

The triangle on the lower left of the slide tray denotes slide 1 of the tray. The number engraved on each tray (1, 2, 3, or 4 depending on the slide tray) denotes into which slide tray support (STS) on the SlidePrep the slide tray will fit.



**Figure 1-14 – Slide tray**



**Figure 1-15 – Settling chamber**

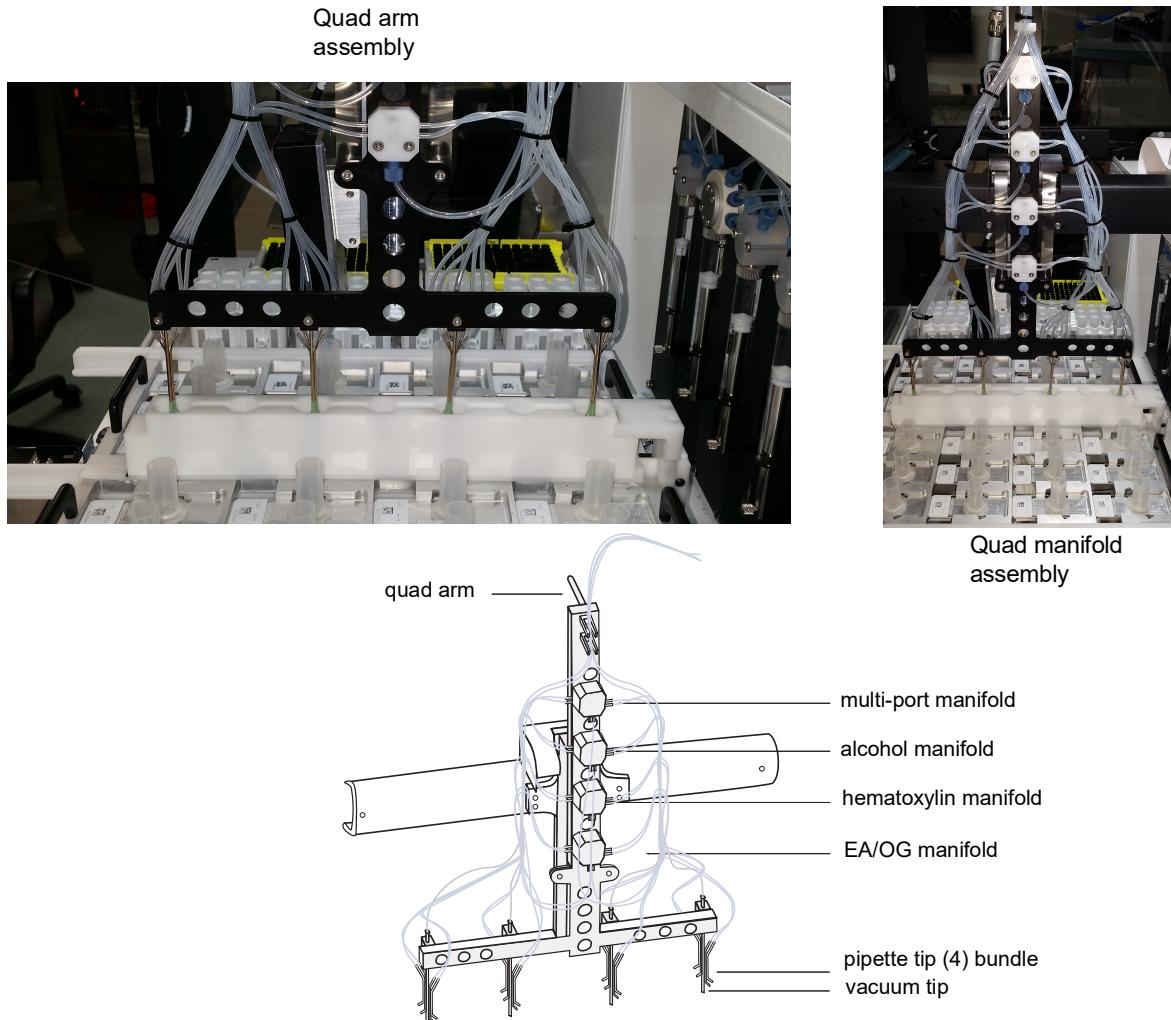
## 1.6.4 Robotic Arm

The delivery and removal of reagents to the slides is accomplished through a robotic arm. This arm is guided by software-controlled electronics that manipulate motors to move the arm in the X, Y, and Z coordinates (left-right, forward-backward, and up-down directions, respectively). Various components are attached to the arm for their specific directional movement.

### Quad Arm Assembly

The quad arm assembly mounts to the robotic arm and contains four pipette bundles (for simultaneous processing of four slides) that are lowered into the settling chambers to deliver and remove reagents during a run. There are four pipette tips and one vacuum tip on each bundle. The longest tip is the vacuum which vacuums used reagents. The four pipette tips are grouped in sets of two: the middle dual-prong extension delivers stains and the top dual-prong extension delivers the non-stain reagents.

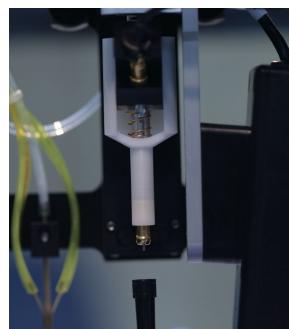
Mounted on the robotic arm above the quad arm assembly are quad manifold assemblies that contain the tubing that routes reagents and vacuum lines to pipette bundles. Of the four quad manifolds, three are dedicated to a particular reagent and the fourth is associated with the multi-port syringe that can dispense multiple reagents. Tubing from each manifold is routed to each pipette bundle.



**Figure 1-16 – Quad arm and manifold assemblies**

### Disposable Tip (DiTi) Assembly

The DiTi is mounted on the Z-rod of the robotic arm and is made up of a hollow cone to deliver buffered deionized water, a sleeve to hold the transfer tip, and a pipette tip ejection mechanism. A fresh pipette tip is used to mix and transfer an aliquot of each sample, for contamination-free transfers. After the sample is transferred (from tube to slide), the tip is discarded and a new tip is picked up for the next transfer. When the quad arm assembly is not in use, it remains clear of DiTi operations.



**Figure 1-17 – DiTi assembly detail**

### Birdbaths

Between STS 1 and 2 are collection wells called birdbaths. The quad arm is positioned over the wells during priming when any reagents are switched and also during any vacuum checks. The wells are cleaned as part of weekly maintenance (see Section 8).

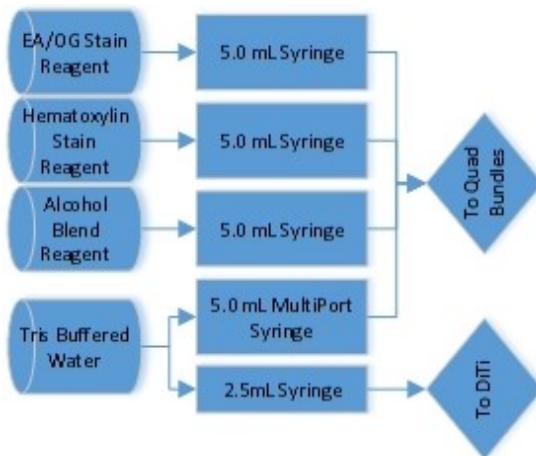
### 1.6.5 Rinsing and Staining Syringes

Five rinsing and staining syringes are mounted on the back wall of the SlidePrep. Metal plungers in the syringes are used to pump reagents to the quad arm assembly. On four of the syringes, one valve connects to the quad manifold tubing and one to a reagent container. The fifth syringe (multi-port syringe) is multi-valved and programmed to dispense four different reagents, some of which are not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test. All parts that contact liquid are made of inert materials (glass, Teflon, or Fluoroethylpropylene [FEP]).



**Figure 1-18 – Rinsing and staining syringes**

The reagent inputs to the syringes on the SlidePrep are shown in schematic form in Figure 1-19. Reagent lines enter the SlidePrep through a hole at the upper portion on the back right side panel of the instrument.



**Figure 1-19 – BD Totalys™ SlidePrep reagent connection to syringes**

(This diagram is intended to show what each syringe is used for, not the actual plumbing of each line.)

## 1.6.6 Bulk Reagent Station

The bulk reagent station holds the reagent bottles used by the SlidePrep, some of which are not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test. The bulk reagent station is shown in Figure 1-20. Some bottles in the figure contain colored solutions for visual purposes.

The bulk reagent station is installed with labels for the appropriate reagents at each of the reagent locations.

In front of each bulk reagent are tubing and two ports. On one end of each tubing is a quick disconnect port that can be switched between the station base and the cap on the reagent bottle.

- 1 Tris buffered water (TBW)
- 2 Auxiliary (AUX) 3 reagent – *Not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol*
- 3 EA/OG stain
- 4 Hematoxylin stain
- 5 BD Alcohol Blend Rinse (alcohol blend rinse)
- 6 Auxiliary (AUX) 1 reagent – *Not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol*
- 7 Auxiliary (AUX) 2 reagent – *Not used with the BD SurePath™ Liquid-based Pap Test or Non-gynecological slide preparation protocol*
- 8 Cleaning Contrad solution (provided by user)
- 9 Cleaning (DI) water (provided by user)

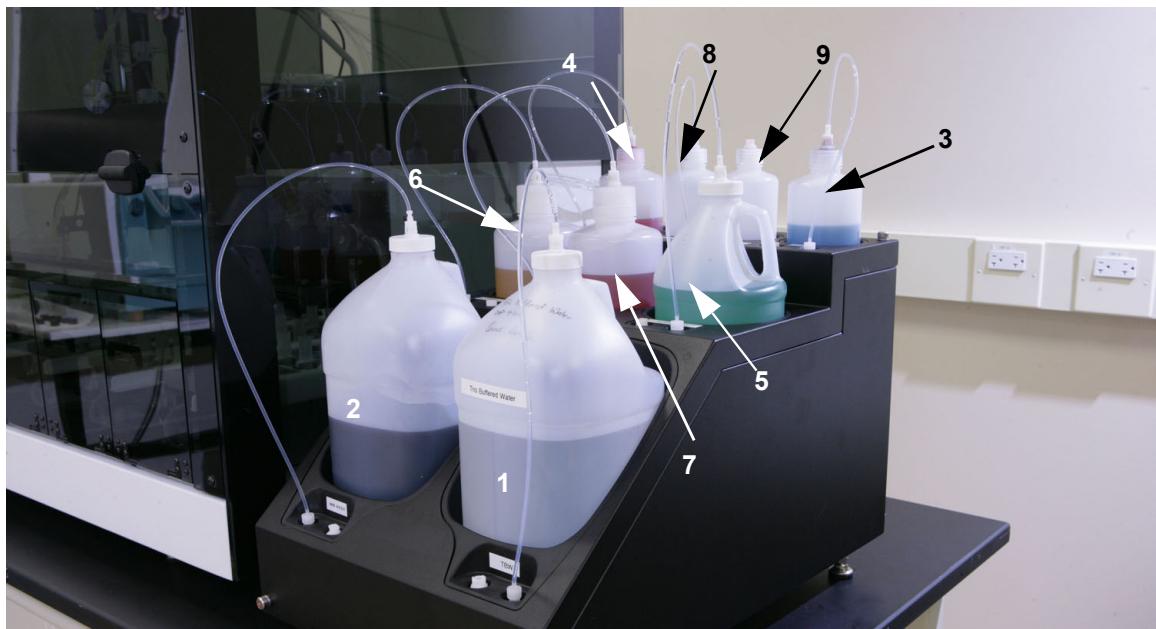


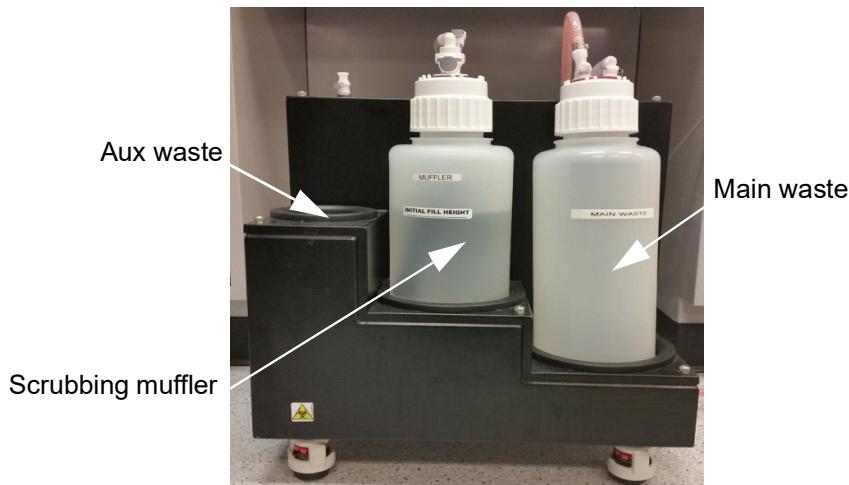
Figure 1-20 – Bulk reagent station

### 1.6.7 Waste Station

Liquid waste is generated on the SlidePrep when reagents and rinse liquids are aspirated from the settling chambers, or during priming steps. The liquid waste is stored in containers on the waste station. The main waste container holds all reagent wastes and the auxiliary (aux) waste container is not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test. Also on the waste station is a scrubbing muffler that removes volatile organic fumes from the exhaust tubing.

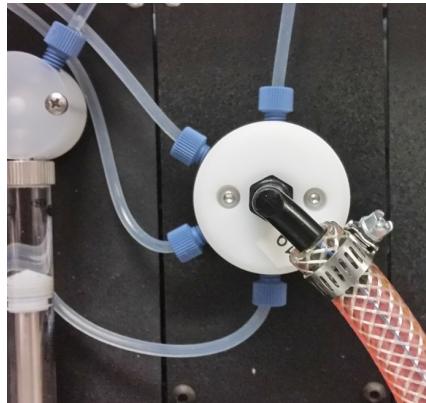
**NOTE**

The scrubbing muffler bottle does not need to be filled if the option to redirect the vacuum exhaust is selected.

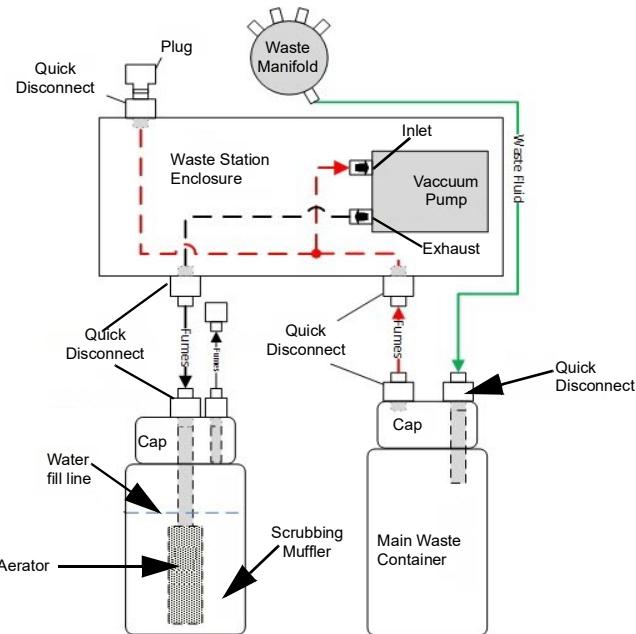


**Figure 1-21 – Waste station**

Inside the waste station is a vacuum pump that provides the aspiration for liquid waste. A vacuum line connects the pump to the waste bottle and the waste bottle connects to a manifold located to the right of the syringe assemblies on the SlidePrep (Figure 1-22). From the vacuum lines of the quad arm pipette bundles, waste goes through the manifold to the main waste container. An additional line from the vacuum pump exhaust connects to the scrubbing muffler. The vacuum pump exhaust is either bubbled through water in the scrubbing muffler to absorb volatile organic compounds (e.g., alcohol vapors) or passes through an empty scrubbing muffler and optional tubing that redirects the vacuum exhaust to an external fume hood. A schematic of the entire waste system is shown in Figure 1-23.



**Figure 1-22 – Waste Manifold**



**Figure 1-23 – Waste station system schematic**

**WARNING**

THE EA/OG REAGENT, ALCOHOL BLEND RINSE AND MAIN WASTE CONTAIN FLAMMABLE LIQUIDS. PROPER PRECAUTIONS, INCLUDING LOCAL INSTITUTIONAL GUIDELINES, SHOULD BE FOLLOWED TO REDUCE THE RISK OF IGNITION OF ANY FLAMMABLE LIQUIDS.

### 1.6.8 Screening Thin-Layer Preparations

The SlidePrep produces a 13 mm diameter circle of stained cells. The sample layer and sample distribution may be variable depending on sample physiology. The sample layer contains single cells, groups and clusters. When processed as instructed in this manual, the amount of mucus, inflammation and blood (obscuring elements) are significantly reduced allowing better visualization of the diagnostic cells.

The entire slide preparation is screened using a 10x objective by scanning across the slide in a serpentine method. When first learning BD SurePath™ morphology, it is a good idea to screen each slide twice, moving once horizontally and once vertically across the preparation area as depicted below. Once comfortable with screening BD SurePath™, the double screening method can be eliminated.



**Figure 1-24 – Serpentine, double screening method**

All diagnostic criteria in current cytology laboratories used for conventional Pap smears are applicable to BD SurePath™ thin-layer preparations. Standard procedures should be followed in reporting results.

## 1.7 Use of this Manual

This user's manual is designed as a reference tool for trained laboratory personnel who operate and maintain the SlidePrep on a regular basis. Every attempt has been made to include all information which would be required during normal use and maintenance of the instrument. Should a question arise which is not answered in this manual please contact:

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Other documentation required for proper SlidePrep operation includes:

*Reagent Package Inserts* - These documents contain important information on specimen preparation and the use, storage, performance, and limitation of reagents. A package insert is included with each reagent pack, and is available upon request from BD.

*BD PrepMate™ Automated Accessory Operator's Manual* - This manual contains specifications, operating instructions, maintenance and important safety warnings for the separate BD PrepMate™ Automated Accessory.

*Centrifuge Operator's Manual* - The manual supplied with each centrifuge model contains specifications, operating instructions, maintenance and important safety warnings for the separate centrifuge.

*BD Totalys™ MultiProcessor User's Manual* - This manual contains specifications, operating instructions, maintenance and important safety warnings for the separate and optional MultiProcessor.

## 1.8 Conventions

### 1.8.1 Buttons and Displays

The following typographical conventions are used to aid in discriminating words used in special context.

Usage	Convention	Example
Display names	<b>Bold</b>	The <b>Select Protocol</b> display
Button or menu	ALL CAPITALS	Click the RUN SELECTED PROTOCOL button
Navigating through menus and submenus	Angle bracket	Select UTILITIES>LOGS

## 1.8.2 Symbols Used on the Equipment

The following symbols appear on the SlidePrep:

	General warning sign
	Caution, risk of electrical shock
	Biological risks
	Hot Surface
	Serial Number

## 1.8.3 Notes, Cautions, and Warnings

Throughout this manual, important information is presented in boxes offset from the regular text and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following significance:

### NOTE

Important information about instrument use worthy of special attention is presented as a NOTE.

### CAUTION

Information on an activity which potentially could cause damage to the instrument is presented as a CAUTION.

### WARNING

INFORMATION ON AN ACTIVITY WHICH POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.



# 2 – Installation

## 2.1 General

This section provides the specifications for the pre-processing components and the BD Totalys™ SlidePrep, and instructions for system configuration. The following major topics are included:

- Pre-processing component specifications (Section 2.2)
- BD Totalys™ SlidePrep specifications (Section 2.3)
- Instrument installation (Section 2.4)
- Materials required for use (Section 2.5)

### WARNING

FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN, OR ANY OTHER PRACTITIONER LICENSED BY THE LAW OF THE STATE IN WHICH THE PRACTITIONER PRACTICES TO USE OR ORDER THE USE OF THE DEVICE AND ARE TRAINED AND EXPERIENCED IN THE USE OF THE BD TOTALYS™ SLIDEPREP.

### WARNING

THIS EQUIPMENT GENERATES AND USES RADIO FREQUENCY ENERGY. IT HAS BEEN TYPE TESTED AND FOUND TO COMPLY WITH THE EMISSION AND IMMUNITY REQUIREMENTS DESCRIBED IN IEC 61326 PART 2-6 ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE, EMC REQUIREMENTS: PARTICULAR REQUIREMENTS - IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT. THIS EQUIPMENT HAS BEEN DESIGNED AND TESTED CISPR 11 CLASS A. IN A DOMESTIC ENVIRONMENT IT MAY CAUSE RADIO INTERFERENCE, IN WHICH CASE YOU MAY NEED TO TAKE MEASURES TO MITIGATE THE INTERFERENCE.

THE ELECTROMAGNETIC ENVIRONMENT SHOULD BE EVALUATED PRIOR TO OPERATING THE DEVICE. DO NOT USE THIS DEVICE IN CLOSE PROXIMITY TO SOURCES OF STRONG ELECTROMAGNETIC RADIATION (E.G. UNSHIELDED INTENTIONAL RF SOURCES), AS THESE MAY INTERFERE WITH THE PROPER OPERATION.

**WARNING**

**PROTECTION PROVIDED BY THIS EQUIPMENT MAY BE IMPAIRED IF  
THE EQUIPMENT IS USED IN A MANNER NOT CONSISTENT WITH  
THE INSTRUCTIONS IN THIS MANUAL.**

## 2.2 Pre-processing Components Specifications

### 2.2.1 Multi-vial Vortexer

The model of multi-vial vortexer supplied depends on the voltage requirements in your area. Specifications for both available models are provided below:

Electrical Requirements	110	220
Voltage	100–120 VAC	220–240 VAC
Frequency	50–60 Hz	50–60 Hz
Power	100 Watts	100 Watts
5 mm x 20 mm Fuse	5 Amp quick acting (F)	1 Amp quick acting (F)

Non-Operating Conditions	
Ambient Temperature	-20 °C – 65 °C (-4 °F – 149 °F)
Ambient Humidity	20–85% RH, non-condensing

Operating Conditions	
Ambient Temperature	18–33 °C (64–91 °F)
Ambient Humidity	20–85% RH, non-condensing
Altitude	up to 2,000 m (6,562 ft)
Indoor Use only	
Installation Category II and Pollution Degree 2 in accordance with IEC 664.	

General	
Weight	16.3 kg (36 lb)
Width	38.1 cm (15 in)
Depth	30.5 cm (12 in)
Note: to reduce the effects of vibration, consider locating automated components on a counter top that is separate from the one that supports the SlidePrep.	

## 2.2.2 Single Vial Vortexer

A single vial vortexer is required but not provided. The single vial vortexer must be capable of developing 3000 RPM.

Electrical Requirements	
Voltage	100–120 VAC
Frequency	50–60 Hz
Power	40 Watts

Note: to reduce the effects of vibration, consider locating automated components on a counter top that is separate from the one that supports the SlidePrep.

## 2.2.3 BD PrepMate™ Automated Accessory

For BD PrepMate™ specifications, please refer to *BD PrepMate™ User's Manual*.

## 2.2.4 Centrifuge

Centrifuge specifications vary with the model shipped with your system. Typical values are listed below. Refer to your system's centrifuge operator's manual for exact technical specifications.

Electrical Requirements	Jouan	Hettich Rotina
Voltage	120 VAC	110–240 VAC
Power	400 Watts	

General	Jouan	Hettich Rotina
Height	43.2 cm (17 in)	40.6 cm (16 in)
Overhead Clearance (for full lid opening)	96.5 cm (38 in)	94 cm (37 in)
Width	61 cm (24 in)	45.7 cm (18 in)
Depth	71.1 cm (28 in)	58.4 cm (23 in)

## 2.3 BD Totalys™ SlidePrep Specifications

Electrical Requirements	
Voltage	100–240 VAC
Frequency	50–60 Hz
Power	1,000 Watts
Current	12 A

Operating Conditions	
Temperature	18–30 °C (64–86 °F)
Relative Humidity	20–80% RH, non-condensing
Altitude	up to 2,000 m (6,562 ft)
Installation Category II and Pollution Degree 2 as per IEC 664.	

Non-Operating Conditions	
Temperature	-20 °C – 65 °C (-4 °F – 149 °F)
Relative Humidity	20–80% RH, non-condensing

General	
Weight	124.7 kg (275 lb)
Height	86.4 cm (34 in)
Width (includes bulk reagent station and disposable tip waste container)	182.9 cm (72 in)
Depth	62.2 cm (24.5 in)
Rear Clearance (essential for the power cords, vacuum pumps, and the CPU air intake grills)	10.2 cm (4 in)
Overhead Clearance	88.9 cm (35 in)
The waste station sits separately from the SlidePrep and has dimensions of 40.6 x 33 x 58.4 cm (16 x 13 x 23 in).	
The bulk reagent station sits to the right of the SlidePrep and has dimensions of 35.6 x 55.9 x 35.6 cm (14 x 22 x 14 in). However, 61 cm (24 in) overhead clearance is needed to access the bottles and allow room for the tubing.	

## 2.4 Instrument Installation

### 2.4.1 Site Preparation

The SlidePrep should be installed in an area that is free from undue vibration, high humidity, dust, temperature extremes, and corrosive or explosive vapors or gases.

Installation of the SlidePrep must only be performed by BD Diagnostics-authorized personnel. A service representative will work with key operators and perform initial verification and provide verification documentation of correct system installation.

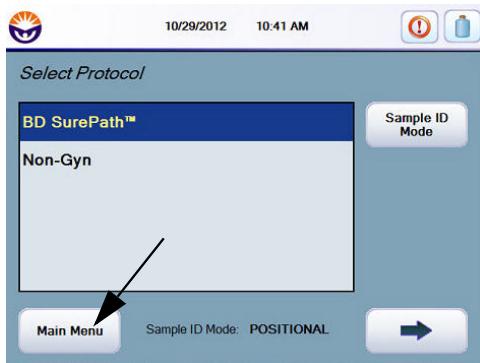
The SlidePrep system arrives in one or more shipping cartons.

### 2.4.2 System Setup

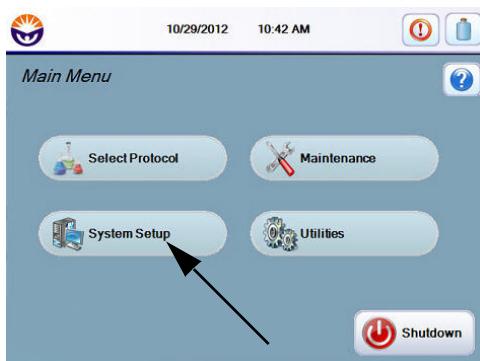
Before using the SlidePrep for preparation of BD SurePath™ or Non-Gyn slides, review the following setup parameters to see if they are suitable for your laboratory.

- Date and Time
- Default Printer
- Remote Station
- Select Language

After the system is turned on, the **Select Protocol** display appears. Select MAIN MENU > SYSTEM SETUP to access the **System Setup Menu** display.



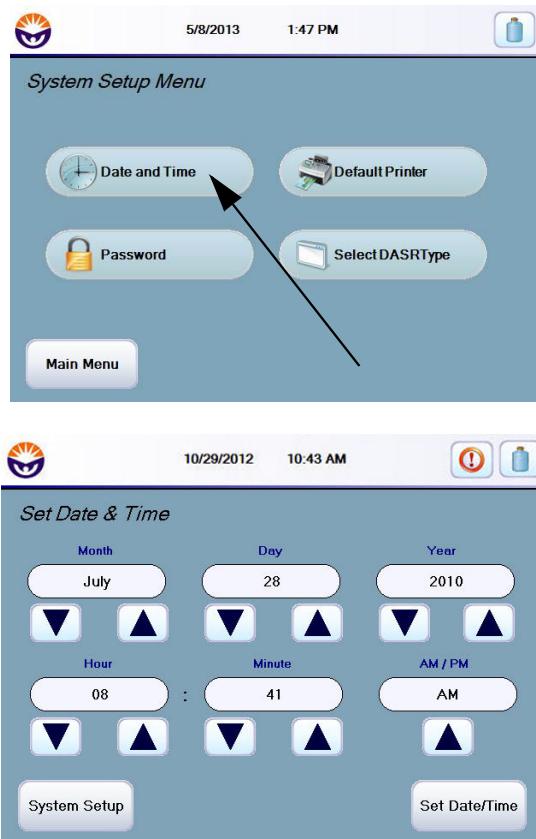
**Figure 2-1 – Select Protocol display**



**Figure 2-2 – Main Menu display**

#### 2.4.2.1 Date and Time

From the **System Setup Menu** display tap the DATE AND TIME button to set the time and date for the SlidePrep. A **Set Date & Time** display appears.

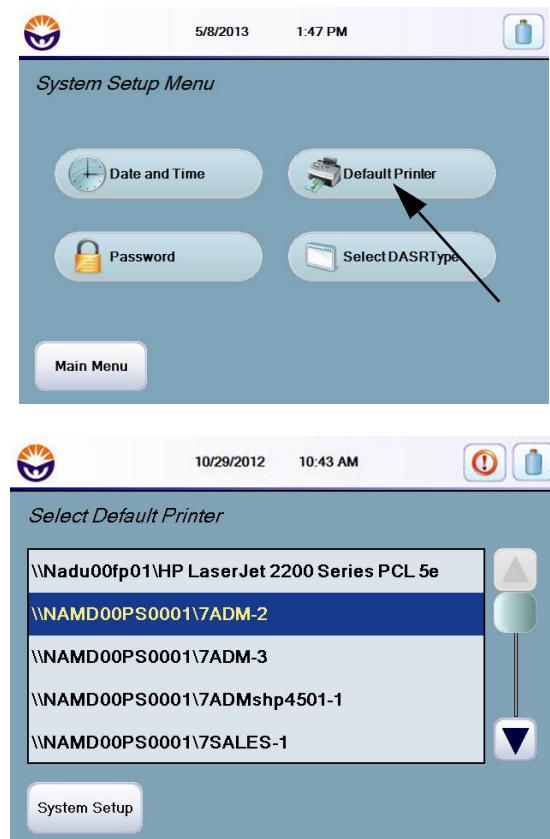


**Figure 2-3 – Set Date and Time**

To set the current date and time, use the up and down arrow buttons under each parameter. To save the new date/time entry, tap the SET DATE/TIME button. Tapping the SYSTEM SETUP button returns the program to the **System Setup Menu** display.

#### 2.4.2.2 Default Printer

From the **System Setup Menu** display tap the DEFAULT PRINTER button to set the printer for the SlidePrep. A **Select Default Printer** display appears.



**Figure 2-4 – Select Default Printer**

Use the up and down buttons to choose a printer displayed in the list. The selection will be highlighted. To save the new default printer and return the program to the **System Setup Menu** display, tap the SYSTEM SETUP button.

### 2.4.2.3 Remote station

The remote station application allows for connectivity with the MultiProcessor. The parameters for this connection are setup by BD installation personnel.

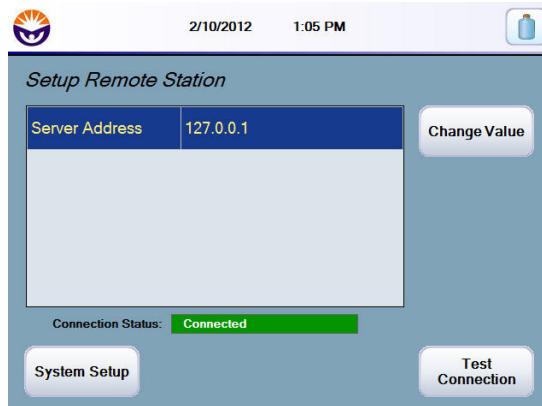


Figure 2-5 – Setup Remote Station

### 2.4.2.4 Select Language

The SlidePrep user interface is available in multiple languages. Although the preferred language will be set up at the time of installation, it is possible to select up to nine alternate languages.

From the **System Setup Menu** display use the down button to view the SELECT LANGUAGE option. Tap the SELECT LANGUAGE button.

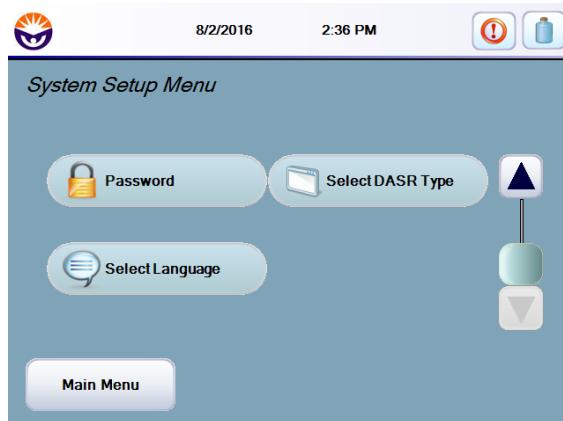


Figure 2-6 – Select Language

Scroll through the ten language options by using the down button on the right.

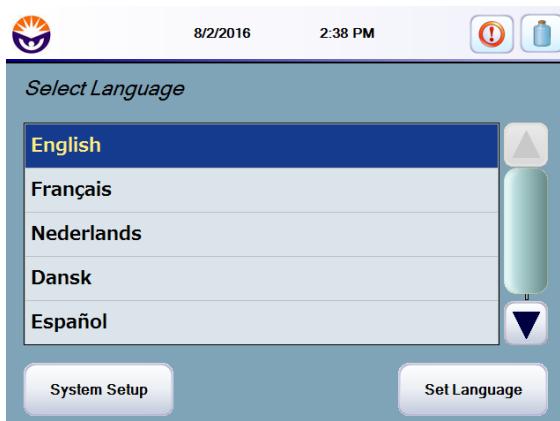


Figure 2-7 – Select Language options, screen one

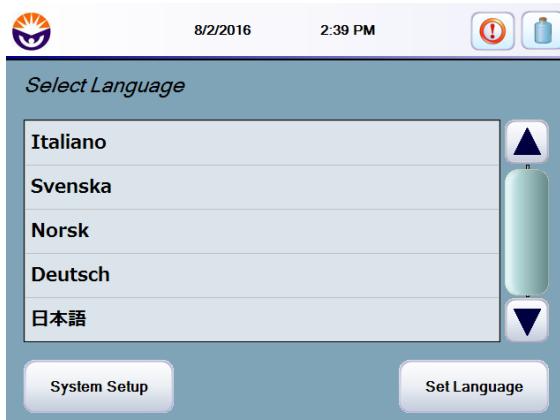


Figure 2-8 – Select Language options, screen two

Tap the desired language, and then select SET LANGUAGE to change the preference. Once the new language is set, exit by selecting **System Setup** and then the **Main Menu** button in the lower left-hand corner of the screen.

## 2.5 Materials Required for Use

### 2.5.1 Materials Available from BD

The following materials are available from BD and required for proper operation of the pre-processing components and the SlidePrep:

- BD Totalys™ SlidePrep
- BD PrepMate™ Automated Accessory
- Multi-vial vortexer
- BD SurePath™ Collection Vial
- Broom-type or brush/plastic spatula-type collection device
- BD SurePath™ Preservative Fluid
- BD Density Reagent
- BD SurePath™ PreCoat Slides
- BD Settling Chambers
- Centrifuge
- BD Centrifuge Tubes (c-tubes)
- BD Syringing Pipettes
- Fluid aspiration system (Easy Aspirator)
- BD Aspirator Tips (clear)
- Slide trays and c-tube racks
- BD Alcohol Blend Rinse
- BD Cytology Stain Kit (Hematoxylin 0.75 and EA/OG)
- BD Hematoxylin 0.5 (for BD CytoRich™ nonGyn)
- BD Totalys™ Transfer Tips (black)
- Tris buffered saline packets
- BD Totalys™ MultiProcessor (optional)

### 2.5.2 Materials Not Provided by BD

The following materials are not provided by BD but are required for proper operation of the pre-processing components and the SlidePrep:

- Single vial vortexer
- Deionized water
- Isopropanol and reagent grade alcohol
- Clearing agent, mounting media and glass coverslips
- Contrad 70



# 3 – Controls and Indicators

## 3.1 General

This section describes the meaning and use of the controls and indicators of the BD Totalys™ SlidePrep. Information for the centrifuge and BD PrepMate™ Automated Accessory may be found in their respective operator's manuals.

The following controls and indicators are discussed:

- Main power supply (Section 3.2)
- Monitor and touchscreen (Section 3.3)
- Computer connections and ports (Section 3.4)
- Barcode readers (Section 3.5)
- Instrument doors and trays (Section 3.6)
- Audible tones and alerts (Section 3.7)

### WARNING

**ALL USERS SHOULD BE THOROUGHLY FAMILIAR WITH ALL CONTROLS AND INDICATORS BEFORE ATTEMPTING TO OPERATE THE BD Totalys™ SLIDEPREP.**

### NOTE

Physical access to the system should be limited to only authorized individuals (BD Authorized service personnel). Additionally, the Microsoft Windows authentication controls can be used to restrict access. Passwords are used by authorized service personnel for system access and users (with the appropriate password) to create new protocol variations.

## 3.2 Main Power Supply

The main instrument power switch is on the lower left side of the SlidePrep, at the back. When in the lower off position (denoted by a circle), power is removed from the system. When in the upper on position (denoted by a vertical line), power is applied to the instrument. Power must be turned on for slide processing to occur.

The main instrument AC power port is located just below the power switch.



**Figure 3-1 – Main power switch and AC power port**

## 3.3 Monitor and Touchscreen

The touchscreen is mounted on the left side of the SlidePrep, above the DASR, outside of the instrument covering.

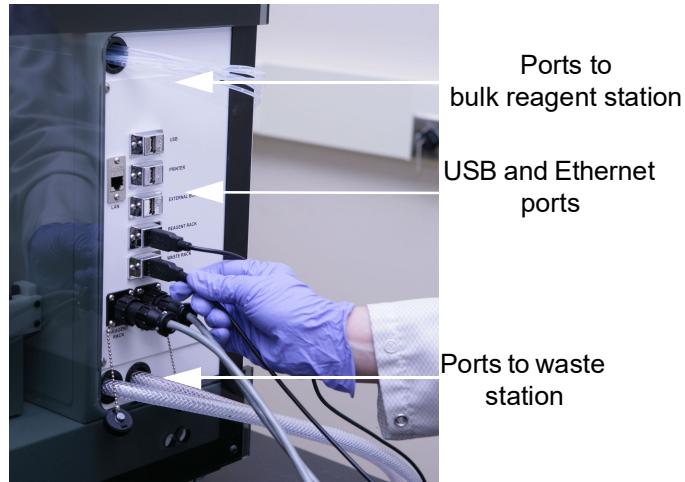
A touch-sensitive screen enables you to issue commands and to enter information into the SlidePrep simply by tapping buttons and fields that appear on the display. For more information on using the instrument interface, refer to Section 5.3 or Section 6.4.



**Figure 3-2 – Monitor and touchscreen**

## 3.4 Computer Connections and Ports

Computer connections and tubing ports for the SlidePrep are together on the same panel located on the right side of the SlidePrep, toward the back. There are five USB ports, an Ethernet (LAN) port, and ports connected to either the bulk reagent station or waste station. The USB ports are configured to specific devices. During installation, BD Diagnostic installation personnel will couple the correct devices to their proper port.



**Figure 3-3 – Computer connections and ports**

## 3.5 Barcode Readers

There are two barcode readers associated with the SlidePrep.

A handheld reader is plugged into a USB port on the panel in Figure 3-3. This reader can be used during assay setup to scan barcodes on c-tubes. For more information, refer to Section 5 or Section 6.

An internal automatic reader is also used on the SlidePrep. This reader is mounted on the robotic arm and can be used during assay setup to scan barcodes on slides. For more information, refer to Section 5 or Section 6.

## 3.6 Instrument Doors and Trays

To access the internal parts of the SlidePrep, the following doors and trays are used:

- DASR door – located on the left side of the SlidePrep, opens outward to provide access to the DASR and tip waste chute.
- DASR tray – once the DASR door is open, the DASR tray slides forward for easy loading and unloading of c-racks.
- Transom tray door – located on the right side of the SlidePrep, opens upward to provide full access to all four STS, the robotic arm, and syringes. This door is typically only needed for internal instrument access during maintenance and cleaning.
- Tray doors – four individual doors in front of each STS that are opened downward to allow insertion and removal of slide trays during SlidePrep setup and operation. Each tray door can be opened separately.

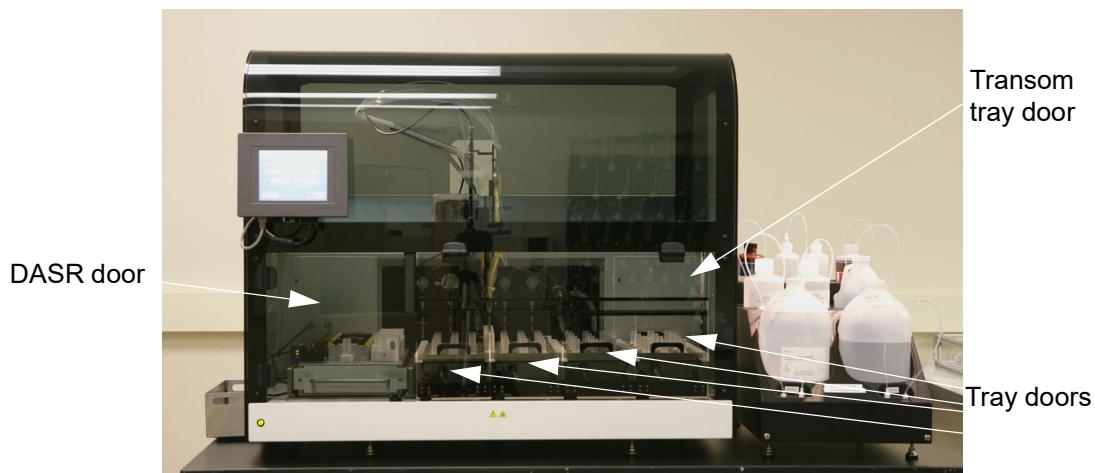


Figure 3-4 – BD Totalys™ SlidePrep doors

## 3.7 Audible Tones and Alerts

The following table provides information on the audible tones and alerts issued in various circumstances by the SlidePrep.

Type	Number of alerts	Usage Examples
Notification	One	Maintenance complete Tray complete (resounds every 30 seconds) Protocol complete
Warning	Two	Check Deck warning (resounds every 30 seconds) No USB drive installed during export (resounds every 30 seconds)
Error	Three	Robotic arm is unable to move to the requested position (resounds every 30 seconds)

# 4 – Pre-Processing Operation

## 4.1 General

This section discusses specimen pre-processing for cell enrichment and provides the procedures used to prepare gynecological specimens for use by the BD Totalys™ SlidePrep. The following major topics are discussed:

- Chain of custody (Section 4.2)
- Pre-processing for cell enrichment (Section 4.3)
- Reprocessing samples (Section 4.4)

The pre-processing for cell enrichment operation described in this section does not apply to non-gynecological specimens. For pre-processing of these samples, refer to Section 6 and use the laboratory's approved standard operating procedures or BD provided protocols.

### 4.1.1 Pre-Processing with the MultiProcessor

#### NOTE

Refer to the *BD Totalys™ MultiProcessor User's Manual* (8089991) for automated pre-processing for cell enrichment with the MultiProcessor.

## 4.2 Chain of Custody

In order to maintain test sample chain of custody, all specimen vials, c-tubes and glass slides are loaded in their respective racks in a specific order.

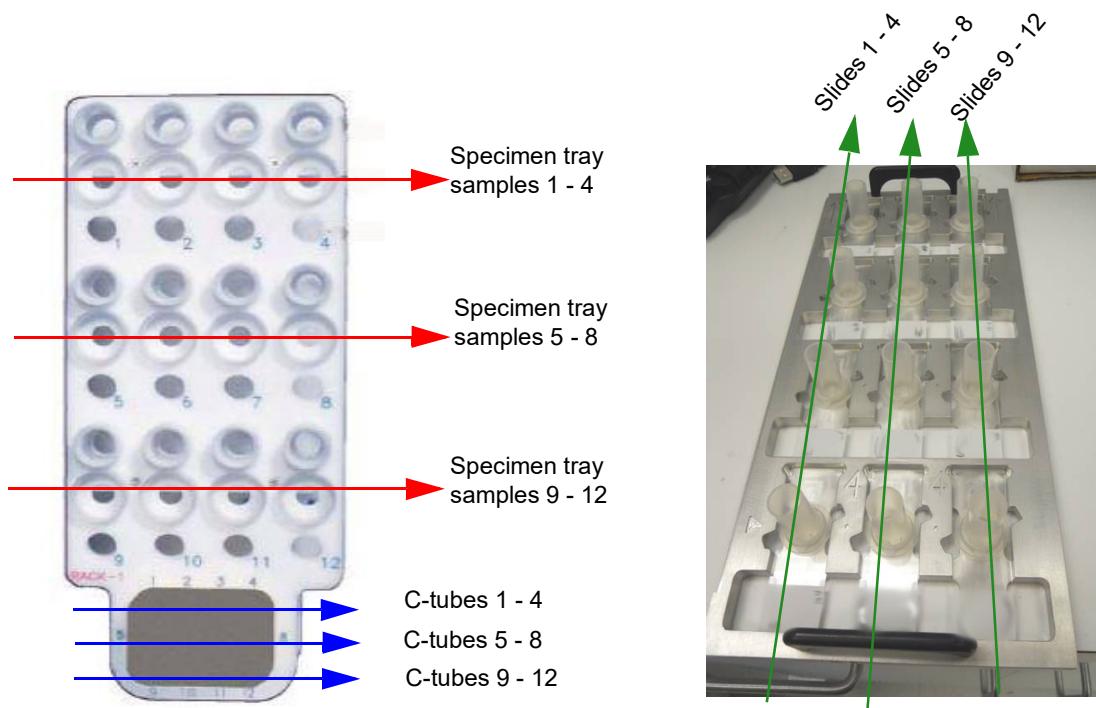
### Sample Placement

On the BD PrepMate™ specimen tray, sample positions 1 to 12 are numbered on the rack for the sets of specimen vials, syringing pipettes, and c-tubes. Ordering starts in the top row (furthest from the c-tube rack) and proceeds left to right.

On the c-tube rack, sample position for c-tubes 1 to 12 are numbered outside the c-tube rack on the specimen tray. Ordering is the same as the specimen tray, starting in the top row and proceeding left to right.

On the slide tray, individual slide positions are not numbered; instead an engraved arrow indicates the position of the first slide. Ordering proceeds from the first slide front to back, then continues to subsequent rows left to right.

The correspondence among rows in the specimen tray, c-tube rack, and slide tray is illustrated in Figure 4-1.



**Figure 4-1 – Specimen and slide placement for chain of custody**

**NOTE**

Samples in the BD PrepMate™ specimen tray and c-tube rack must be oriented correctly with matching slide trays to maintain chain of custody. Correct placement of specimens, c-tubes and slides must be verified by the operator.

**NOTE**

Positioning pins on the c-tube rack and SlidePrep c-tube rack holders are present for proper alignment. This ensures the sample in the c-tube rack is deposited on the correct slide on the slide tray.

## 4.3 Pre-Processing for Cell Enrichment

### WARNING

#### STANDARD PRECAUTIONS

**CONSIDER ALL ORGANISMS AS POTENTIALLY INFECTIOUS AND HANDLE ACCORDING TO STANDARD MICROBIOLOGICAL PRACTICES, SPECIAL PRACTICES, AND SAFETY EQUIPMENT RECOMMENDED FOR BIOSAFETY LEVEL 2 (BSL-2) CONTAINMENT.<sup>1</sup>**

**BSL-2 PRACTICES INCLUDE, BUT ARE NOT LIMITED TO THE FOLLOWING:**

- WEAR GLOVES AND LAB COAT WHEN HANDLING POTENTIALLY INFECTIOUS MATERIAL OR CONTAMINATED INSTRUMENT COMPONENTS. WEAR ANY OTHER PERSONAL PROTECTIVE EQUIPMENT ACCORDING TO LOCAL POLICY.
- DECONTAMINATE WORK SURFACES AFTER COMPLETION OF WORK AND AFTER ANY SPILL OR SPLASH OF POTENTIALLY INFECTIOUS MATERIAL WITH APPROPRIATE DISINFECTANT.
- DECONTAMINATE ALL CULTURES, STOCKS, AND OTHER POTENTIALLY INFECTIOUS MATERIALS BEFORE DISPOSAL USING AN EFFECTIVE METHOD.
- PERFORM ALL PROCEDURES TO MINIMIZE THE CREATION OF SPLASHES AND/OR AEROSOLS.
- LABORATORY EQUIPMENT SHOULD BE ROUTINELY DECONTAMINATED, AS WELL AS, AFTER SPILLS, SPLASHES, OR OTHER POTENTIAL CONTAMINATION.
- SPILLS INVOLVING INFECTIOUS MATERIALS MUST BE CONTAINED, DECONTAMINATED, AND CLEANED UP BY STAFF PROPERLY TRAINED AND EQUIPPED TO WORK WITH INFECTIOUS MATERIAL.
- EQUIPMENT MUST BE DECONTAMINATED BEFORE REPAIR, MAINTENANCE, OR REMOVAL FROM THE LABORATORY.
- DECONTAMINATE AND DISPOSE OF ALL POTENTIALLY CONTAMINATED MATERIALS AS REGULATED MEDICAL WASTE IN ACCORDANCE WITH LOCAL, STATE, AND FEDERAL REGULATIONS.

<sup>1</sup> *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition. 2007. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, US Government Printing Office, Washington, DC.

Web site: <http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm>

**WARNING**

**ALL OTHER HAZARDOUS MATERIALS SHOULD BE DEALT WITH IN ACCORDANCE WITH LOCAL, STATE, AND FEDERAL REGULATIONS. THIS INCLUDES, BUT IS NOT LIMITED TO**

- **DECONTAMINATION IN CASES OF HAZARDOUS SPILLAGE**
- **REMOVAL, TRANSPORTATION, AND DISPOSAL OF HAZARDOUS MATERIALS, INCLUDING THE BD TOTALYS™ SLIDEPREP UNIT**
- **ENSURING THE PROPER HANDLING, CONTAINMENT AND EXHAUST OF HAZARDOUS SUBSTANCES**

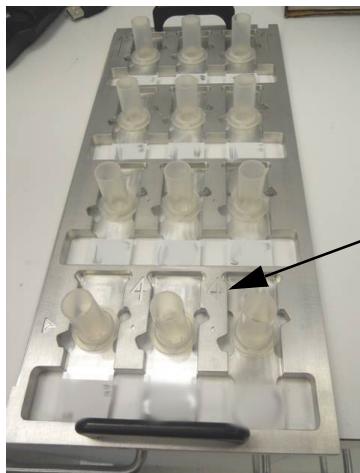
#### 4.3.1 Setup for Cell Enrichment

- 1 For each sample to be tested, label the test requisition, specimen vial, c-tube, and slide with a unique identifier or place barcode labels on each. If hand-labeled, use a solvent resistant marker.

**CAUTION**

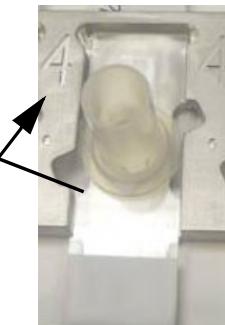
**Recheck labels on specimen vials, slides and c-tubes in their specific preparation rack positions to ensure that each sample set matches the correct sample.**

- 2 Set up slide trays (to be used later on the SlidePrep) with slides corresponding to the number of specimens being processed.
  - a Load slides with the frosted side up and toward the front of the rack (toward user).



**Figure 4-2 – Loading slides into slide tray**

- b Add settling chambers to slides by aligning tabs on settling chambers with slots in slide trays and lock into place by twisting counter-clockwise.



**Figure 4-3 – Loading settling chambers into slide tray**

- c If there are less than four specimens in a column, place blank slides and settling chambers in the corresponding spaces.

### 4.3.2 Sample Randomization

Sample randomization via vortexing is the first step of cell enrichment. The shearing forces free cells and cell clusters from the specimen collection device and partially disaggregate cell clusters.

**WARNING**

**BD SUREPATH™ PRESERVATIVE FLUID IN THE SPECIMEN VIALS  
CONTAINS AN AQUEOUS SOLUTION OF DENATURED ETHANOL.  
THE MIXTURE CONTAINS SMALL AMOUNTS OF METHANOL AND  
ISOPROPANOL. DO NOT INGEST.**

- 1 Vortex specimen vials for  $15 \pm 5$  seconds at 3,000 rpm (or appropriate speed to cause a funnel in the specimen vial).

The detachable head(s) of the collection device must be in the specimen vial for proper sample and slide processing.

Either the single or multi-vial vortexer may be used for sample randomization. If using a single vial vortexer, only one specimen vial at a time may be vortexed. If using the multi-vial vortexer, specimen vials must be placed in their plastic “clam-shell” container (with the shelving liner covering the specimen vials in the container). There is no minimum number of specimen vials that may be vortexed when using the multi-vial vortexer.

NOTE

Vortexing is a critical step in the process and is required in order to:

- 1 Re-distribute cells that may have settled during transportation
- 2 Dislodge cells that may be on the sampling device
- 3 Blend and homogenize the sample assisting in the cell enrichment process to manage obscuring elements so the relevant diagnostic cells can be available for testing.

Failure to vortex as instructed may impact slide quality.

NOTE

An aliquot of fluid may be removed from the specimen vial(s) immediately after vortexing for use with the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays. For this procedure, refer to Section 12.

NOTE

Place rubber mat (shelving liner) inside the clamshell lid to secure the vials to prevent spinning during vortexing. Failure to do so will prohibit the vortexing action in the vial.



**Figure 4-4 – Sample randomization**

### 4.3.3 Mixing and Layering

Mixing samples and layering onto density reagent is the second step of cell enrichment and is performed by the BD PrepMate™ Automated Accessory. Density reagent is a polysaccharide solution with sodium azide preservative that is used to remove obscuring agents in the sample during centrifugation.

#### WARNING

**THE OPERATOR'S MANUAL FOR THE BD PREPMATE™ AUTOMATED ACCESSORY IS SEPARATE FROM THIS MANUAL AND SHOULD BE READ BEFORE OPERATING THE BD PREPMATE™ AUTOMATED ACCESSORY.**

- 1 Transfer the vortexed specimen vials to BD PrepMate™ specimen trays. Do not remove the caps from the specimen vials.  
Reconfirm that each c-tube is labeled the same as its corresponding specimen vial.
- 2 Load c-tubes onto the specimen tray(s) adjacent to any present specimen vials.
- 3 Add  $4 \pm 0.1$  mL of density reagent to each c-tube in the specimen tray.

#### WARNING

**BD PREPSTAIN DENSITY REAGENT CONTAINS SODIUM AZIDE. DO NOT INGEST. SODIUM AZIDE MAY REACT WITH LEAD OR COPPER PLUMBING TO FORM HIGHLY EXPLOSIVE METAL AZIDES. ON DISPOSAL, FLUSH WITH A LARGE VOLUME OF WATER TO PREVENT BUILDUP OF AZIDE.**

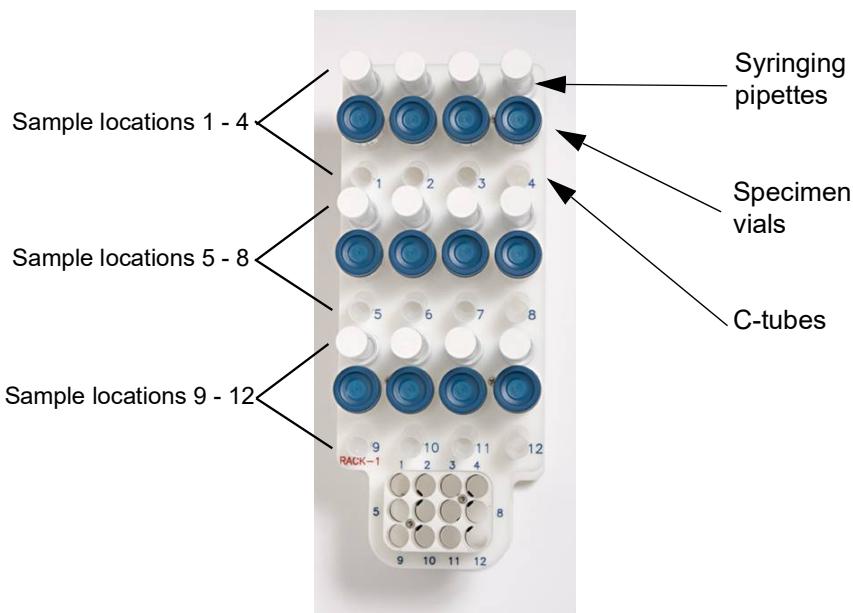
**FOR FURTHER INFORMATION, REFER TO PUBLICATION DHHS (NIOSH) NO. 78-127 CURRENT 13, ISSUED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION.  
SEE WEBSITE: [WWW.CDC.GOV/NIOSH/DOCS/1970/78127\\_13.HTML](http://WWW.CDC.GOV/NIOSH/DOCS/1970/78127_13.HTML).**

- a Remove tubing from the port on the end of the density reagent pump.
- b Hold tubing over c-tube. Be careful to not touch tubing to the inside of the c-tube.
- c Dispense 4 mL of density reagent. The pump is pre-set to deliver 4 mL of density reagent. If you do not have a pre-set pump, set the pump or other device to deliver 4 mL.
- d When finished adding density reagent to all c-tubes, put tubing back onto the port on the end of the density reagent pump.
- 4 Load syringing pipettes onto the specimen tray(s) adjacent to any present specimen vials.

#### CAUTION

**Ensure syringing pipettes, plungers in the syringing pipettes, and c-tubes are fully seated in the specimen tray before proceeding.**

Specimen vials, syringing pipettes and c-tube locations are shown in Figure 4-5.



**Figure 4-5 – Specimen rack loading locations**

- 5 Add a c-tube rack to the specimen rack. C-tube racks and specimen racks are uniquely keyed to specifically fit together. Therefore, add c-tube rack 1 to specimen rack 1, etc.
- 6 Run samples on the BD PrepMate™ Automated Accessory.

**NOTE**

The *BD PrepMate™ Automated Accessory Operator's Manual* is separate from this manual. Operators should become thoroughly familiar with the BD PrepMate™ Automated Accessory before operation. The full operation procedure is detailed in the *BD PrepMate™ Automated Accessory manual*, and a summary of the steps is below.

- a Make sure the BD PrepMate™ Automated Accessory is connected to an AC power source.
- b Turn on the BD PrepMate™ Automated Accessory via the toggle switch on the right side of the instrument.  
Make sure the vial hold-down door is in the vertical, latched position.
- c Allow the instrument to initialize before loading a specimen tray. The operator interface will indicate when trays can be loaded.
- d Turn and hold the tray latch at the front left corner of the instrument so that it lays flat to allow loading of the specimen tray.
- e Load the specimen tray (with specimen vials, syringing pipettes, c-tubes and c-tube rack) onto the instrument.  
Push the specimen tray all the way forward until the tray latch engages and locks the specimen tray into place.

- f The BD PrepMate™ Automated Accessory processes specimens by row. Specimens 1–4 are row 1 and processed first; specimens 5–8 are row 2 and processed next; specimens 9–12 are row 3 and processed last. A row does not have to be entirely full to be processed.
- If processing fewer than three rows of specimens, press the DEC button to decrease the number of specimen rows the BD PrepMate™ Automated Accessory will process. The number of rows to be processed appears on the user interface.
- During any subsequent runs, if the number of rows needs to be increased, press the INC button until the appropriate number of rows appears on the user interface.
- g Press START to begin processing.
- The BD PrepMate™ Automated Accessory mixes and removes 8 mL of sample from the specimen vial and layers it onto the density reagent in the c-tube. Because of the special cap on the specimen vial, the BD PrepMate™ Automated Accessory punctures, mixes, and removes specimens without having to remove the cap.
- 7 When the specimen tray processing cycle completes, an audible tone sounds. Remove the rack by turning and holding flat the latch at the front left corner of the instrument until the specimen tray is clear of the instrument.
  - 8 Inspect the c-tubes to verify that the correct amount of sample has been transferred from the specimen vials. There should be  $12 \pm 1$  mL in the c-tubes (4 mL of density reagent and 8 mL of sample).
  - 9 Repeat steps 6–8 for all specimen trays that need pre-processing (Racks 2–4).
  - 10 Discard the syringing pipettes.

Keep the specimen vials in the specimen trays until pre-processing is complete for all racks. The specimen trays will be used later to confirm c-tubes and slides are oriented in the proper locations.

#### CAUTION

**To obtain optimum results, after the specimen sample has been layered onto the density reagent by the BD PrepMate™ Automated Accessory, samples should be centrifuged and the supernatant aspirated within 30 minutes.**

#### 4.3.4 Centrifugation and Aspiration

The centrifugation steps of cell enrichment are performed to remove debris and obscuring agents leaving an enriched cell pellet for use on the SlidePrep. Centrifugation consists of three steps:

- a “soft spin” pulls sample cell solution through the density reagent
- the tube vac removes the supernatant
- a “hard spin” concentrates diagnostic cellular materials in the bottom of the c-tube

#### WARNING

**THE OPERATOR'S MANUAL FOR THE CENTRIFUGE IS SEPARATE FROM THIS MANUAL AND SHOULD BE READ BEFORE OPERATING THE CENTRIFUGE.**

- 1 Transfer c-tubes (that have been processed with the BD PrepMate™ Automated Accessory) from the specimen tray to the c-tube rack.

Make sure to keep tubes in their proper position for chain of custody. For example, a c-tube that is in specimen tray 1 position 3 should be moved to c-tube rack 1 position 3.
- 2 Place c-tube racks into centrifuge buckets and cover with bucket lids. Ensure c-tube racks are balanced before starting the centrifuge.
  - a Place the c-tube racks on a twin pan balance.
  - b If the tube count between the two racks is not matched, add blank tube(s) and balance with DI water.
  - c If necessary, balance by adding preservative fluid to one of the tubes.
- 3 Centrifuge samples at  $2 \pm 0.25$  minutes at  $200 \pm 25$  rcf (Program 1).

This “soft spin” is used to trap debris and obscuring agents above the interface between the density reagent and the supernatant preservative fluid.
- 4 Aspirate the supernatant preservative fluid using the Easy Aspirator system and tube vac. An entire c-tube rack is aspirated at the same time.
  - a Turn on the tube vac for the aspirator system using the on/off switch on the vacuum.
    - For a Schuco vacuum pump, adjust the pressure to 8–10 in. Hg.
    - For a KNF pump, adjust the pressure to 5.5 in. Hg.

Allow the pump to come to equilibrium vacuum pressure before beginning aspiration.
  - b Place the Easy Aspirator block on a rack of disposable BD Aspirator Tips (aspirator tips) (clear) so that the tip adaptors on the block fit down into 12 tips. Apply moderate pressure to attach the tips onto the Easy Aspirator block.

**NOTE**

Do not bury the post seal too deeply into the tip hub. The tip hub should not be flush with the metal post on the Easy Aspirator block.

- Since the Easy Aspirator block is designed to aspirate all 12 c-tubes of a c-tube rack at once, all 12 tips are needed on the aspirator block even if the c-tube rack is not full.
- Ensure that the 12 aspirator tips are securely attached to the posts on the Easy Aspirator block.
- c Hold the Easy Aspirator block with tips over the c-tubes to be aspirated. **Slowly** lower the aspirator tips into the supernatant, staying just below the dropping fluid level, until the aspirator head rests evenly across the tops of the c-tubes. At this point you should hear the tips drawing air into the vacuum tubing.
- This process removes the top supernatant layer and interface between the supernatant and density reagent layers. There is approximately 8 mL of volume in the top layer, and when removed, the vacuum tubing flows clear.

**NOTE**

Be careful to not disturb the lower density reagent layer during the aspiration process, or aspirate quickly to avoid inadvertent removal of diagnostic cells.

- d Carefully withdraw the aspirator head with tips from the c-tube rack.
- e Repeat steps b–d for all c-tube racks that have been centrifuged on Program 1 ( $2 \pm 0.25$  minutes at  $200 \pm 25$  rcf). Tips may either be discarded or re-used for additional aspirations.
  - If tips are not re-used for additional aspirations, follow steps g and h below to eject tips. Then replace with new tips as described in step b above.
  - If tips are used for additional aspirations, rinse them with DI water after each c-tube rack. Discard tips after aspirating four c-tube racks (48 samples).
- f To prevent clogs, run water through the aspirator before shutting off the vacuum pump. Perform this rinse after the last c-tube rack is aspirated and with tips still seated on the aspirator block.
- g When aspiration is complete, load the Easy Aspirator block onto the tip ejector.
  - Hold the aspirator head in front of and at the same plane as the white Delrin wedge in the top of the tip ejector. Slide the aspirator head along the top of the wedge so that the posts align into the slots of the tip ejector.

**NOTE**

When new, the tip ejector slots may seem tight. The tightness decreases over time as the white Delrin wedge material wears and adjusts.

- h Sliding the aspirator head into the tip ejector should eject all of the tips into the disposal tray. Withdraw the aspirator head by pulling it up and out of the tip ejector.
  - i Turn off the vacuum using the on/off switch on the vacuum. This will stop the vacuum and release the tips from the Easy Aspirator block into the waste bucket below the tip ejector.
    - Empty the tip waste container when it becomes half full. Follow local requirements for disposal of hazardous wastes.
- 5 Place c-tube racks into centrifuge buckets and cover with bucket lids. Make sure racks are balanced as described above before starting the centrifuge.
- 6 Centrifuge samples at  $10 \pm 1$  minutes at  $800 \pm 50$  rcf (Program 2).
- This “hard spin” concentrates the diagnostic cellular materials and creates a pellet in the bottom of the c-tube.

- 7 Remove c-tube racks from the centrifuge and decant remaining fluid in c-tubes. One c-tube rack can be decanted at a time.
  - a In a single, rapid motion, decant the supernatant by inverting each c-tube rack 180 degrees so as not to disturb the cell pellet.

Do not shake the c-tube rack or turn back upright until all fluid is decanted as this may loosen or resuspend the pellet.



**Figure 4-6 – Decant tubes**

- b While inverted, carefully blot the mouth of all tubes in the rack with an absorbent pad.

The absorbent pad is used to prevent drips of fluid onto the c-tube rack, other c-tubes, and/or the operator.
  - c Flip the c-tube rack back over after 3–5 seconds.
  - 8 Still holding the absorbent pad over the c-tubes, vortex the c-tube rack on a single vial vortexer for  $15 \pm 5$  seconds at 3,000 rpm.
  - 9 Repeat steps 7 and 8 for all c-tube racks that have been centrifuged on Program 2 ( $10 \pm 1$  minutes at  $800 \pm 50$  rcf).
  - 10 Discard, or store for reuse, any blank c-tubes that were used to balance c-tube racks.
  - 11 Compare the labels on the specimen vials that are still in the specimen trays with the c-tubes and slides to confirm that sample position remains the same for each.
- Samples are now ready for the SlidePrep.**
- 12 After sample confirmation, store the specimen vials according to the package insert instructions and the laboratory's protocols.
  - 13 Clean the wells beneath the syringing pipettes positions on the BD PrepMate™ specimen trays by wiping with a paper towel damped with Contrad 70 solution.

## 4.4 Reprocessing Samples

Additional and/or repeat testing of samples may be performed using the cell pellet that remains after initial slide processing (as described in Sections 5.7.5 or 6.8.5). However, several pre-processing steps must be re-performed.

For automated reprocessing using the MultiProcessor, refer to the *BD Totalys™ MultiProcessor User's Manual*.

- 1 If refrigerated, allow specimen(s) to come to room temperature (approximately 30 minutes). Add samples in c-tubes to a c-tube rack.
- 2 Set up slide trays with slides corresponding to the number of specimens being processed.

- 3 For each sample, label the c-tube (if not labeled already) and slide with a unique identifier or place barcode labels on each. If hand-labeled, use a solvent resistant marker.
- 4 Place c-tube racks into centrifuge buckets and cover with bucket lids. Ensure racks are balanced before starting the centrifuge.
- 5 Centrifuge samples at  $10 \pm 1$  minutes at  $800 \pm 50$  rcf (Program 2).  
This “hard spin” concentrates the diagnostic cellular materials and creates a pellet in the bottom of the c-tube.
- 6 Remove c-tube racks from the centrifuge and decant remaining fluid in c-tubes. One c-tube rack can be decanted at a time.
  - a In a single, rapid motion, decant the supernatant by inverting each c-tube rack 180 degrees so as not to disturb the cell pellet.  
Do not shake the c-tube rack or turn back upright until all fluid is decanted as this may loosen or resuspend the pellet.
  - b While inverted, carefully blot the mouth of all tubes in the rack with an absorbent pad.  
The absorbent pad is used to prevent drips of fluid onto the c-tube rack, other c-tubes, and/or the operator.
  - c Flip the c-tube rack back over after 3–5 seconds.
- 7 Still holding the absorbent pad over the c-tubes, vortex the c-tube rack on a single vial vortexer for  $15 \pm 5$  seconds at 3,000 rpm.
- 8 Discard, or store for reuse, any blank c-tubes that were used to balance c-tube racks.
- 9 Compare the labels on the c-tubes and slides to confirm that sample position remains the same for each.

Samples are now ready for repeat testing on the SlidePrep.



# 5 – BD SurePath™ Slide Processing Operation

## 5.1 General

This section describes the procedures required to operate the BD Totalys™ SlidePrep for generating BD SurePath™ Liquid-based Pap Test slides. The following major topics are discussed:

- Preparation of tris buffered water (Section 5.2)
- Using the instrument interface (Section 5.3)
- Powering up the SlidePrep (Section 5.4)
- BD SurePath™ slide processing (Section 5.5)
- Assay progress reports (Section 5.6)
- Completed slide trays and samples (Section 5.7)
- Cleanup and shutdown (Section 5.8)

### NOTE

When using the SlidePrep in conjunction with the MultiProcessor for automated pre-processing, DO NOT switch or move around the c-tubes when transferring c-racks from the MultiProcessor to the BD SlidePrep.

The chain of custody between the two systems will be broken if the c-tubes are not in the same location.

## 5.2 Preparation of Tris Buffered Water

Tris buffered water (TBW) is one of the bulk reagents used on the bulk reagent station and must be made prior to operation of the SlidePrep.

### 5.2.1 Materials Required

- 1 L volumetric flask
- Deionized (DI) or distilled water
- Tris buffered saline packet, pH 8.0
- 200 mL measuring device
- 1 gallon container

## 5.2.2 Production of Stock Solution

One liter of tris buffered water stock solution is made first, and can be used to prepare multiple batches of working solution tris buffered water which is used on the SlidePrep.

**CAUTION**

**The tris buffered water stock solution must be prepared before the working solution can be made.**

- 1 Fill a 1 L flask approximately half full with DI or distilled water.
- 2 Empty 1 packet of tris buffered saline, pH 8.0 into flask and swirl until dissolved.
- 3 Fill flask to the 1 L mark with DI or distilled water and seal with Parafilm.
- 4 Invert flask several times to ensure complete mixing.
- 5 Transfer stock solution to the 1 L bottle provided during installation.
- 6 Label bottle with:
  - Tris Buffered Water Stock Solution, pH 8.0
  - Preparation date
  - Expiration date

The stock solution is stable for one month refrigerated (2–10 °C). Discard after one month.

Clean or replace container before making a new batch of stock solution. Wash containers using appropriate labware cleaner (do not use bleach). Rinse container thoroughly with DI or distilled water after cleaning or before using any brand new container.

## 5.2.3 Production of Working Solution

Working solution is prepared from the previously made stock solution and is then used in the bulk reagent station on the SlidePrep.

- 1 Measure 200 mL of tris buffered water stock solution and pour into the 1 gallon container provided during installation.
- 2 Add 3,400 mL of DI or distilled water.
- 3 Cap, invert, and mix well.
- 4 Label gallon container with:
  - Tris Buffered Water Working Solution, pH 8.0
  - Preparation date
  - Expiration date

The working solution is stable for two weeks at room temperature (15–30 °C). Discard after two weeks.

Clean or replace container before making a new batch of working solution. Wash containers using appropriate labware cleaner (do not use bleach). Rinse container thoroughly with DI or distilled water after cleaning or before using any brand new container.

## 5.3 Using the Instrument Interface

The touchscreen presents all the information needed to view system status and operate the SlidePrep. The information is presented on the touchscreen with icons that represent system operations. The display presents general information, progress information, and prompts for the operations currently being performed. The screen is touch sensitive, meaning you can simply touch or tap the button or icon on the screen itself to perform the associated action.

As you initiate system activities, new buttons may appear that present additional options. Icon definitions and buttons are presented in this section and in Section 7. Do not use pens or sharp implements to tap the screen; this can cause damage to the screen. You can use your fingertip or fingernail for greater precision, or a pencil eraser to tap buttons on the screen without causing damage to the screen.

## 5.4 Powering up the BD Totalys™ SlidePrep

To power on the SlidePrep, close all the doors and press the power switch on the left back side of the SlidePrep to the on position.

The first display upon startup is the Select Protocol display. However, if maintenance is required, the first display is a notification that indicates whether any user actions are required (For example: “Weekly Maintenance needs to be performed”). Note the action(s) required and press the CLOSE button.

## 5.5 BD SurePath™ Slide Processing

This section describes the routine operation of the SlidePrep for generating BD SurePath™ slides.

Setup can be performed using one of three sample ID modes:

- **Positional** (Section 5.5.1)
- **Barcode** (Section 5.5.2)
- **Remote Station** (Section 5.5.2)

Protocol setup for barcode and remote station sample ID mode are almost identical and are therefore presented in the same section. Refer to Section 5.5.2 for more information. Remote station sample ID mode is activated by BD service or installation personnel (see Section 2.4.2.3).

### NOTE

When using the SlidePrep in conjunction with the MultiProcessor for automated pre-processing, remote station sample ID mode is typically used and chain of custody as well as processing information is automatically transferred to the SlidePrep.

The system software presents a series of displays on setup and starting the run. At the bottom left side of each display, click  $\Rightarrow$  to continue to the next setup display or the  $\leftarrow$  (“Previous”) button to return to the previous display.

## 5.5.1 Positional Sample ID Mode

Use positional sample ID mode to generate slides without using any barcode labels on slides. Samples in this mode must be tracked manually.

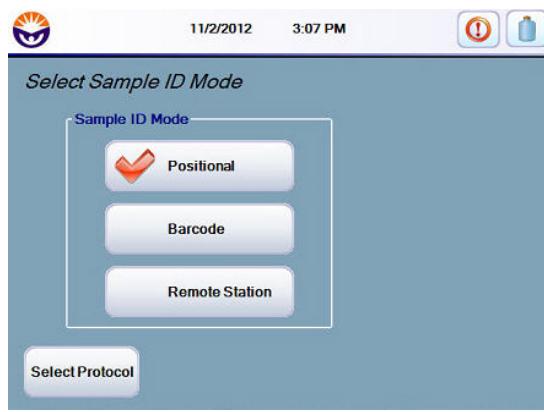
- 1 The initial display after start up and notifications is the **Select Protocol** display. Select “BD SurePath™” by tapping the name, if it is not already highlighted.  
Setup for a system run will initiate from this display, however, if desired the MAIN MENU button brings the user to the **Main Menu** display where the user can choose among System Setup, Utilities, Maintenance, Select Protocol, and Shutdown.



**Figure 5-1 – Select Protocol display**

- 2 Tap the SAMPLE ID MODE button to adjust sample input.

In the **Select Sample ID Mode** window, if POSITIONAL is already selected, indicated by the red checkmark, tap the SELECT PROTOCOL button to return to the previous display. If positional mode needs to be selected, tap on the button. You will be returned to the previous display automatically.



**Figure 5-2 – Select Sample ID Mode display**

On the **Select Protocol** display, “POSITIONAL” appears on the bottom of the display.

- 3 Tap ⇒ on the **Select Protocol** display to continue.
- 4 On the **Select Protocol Variation** display, select the desired run variation.



**Figure 5-3 – Select Protocol Variation display**

*Prep Only:* the SlidePrep prepares slides from specimen samples, but does not stain with hematoxylin and EA/OG.

*Stain Only:* the SlidePrep only stains slides (that already have a cell layer) with hematoxylin and EA/OG. For this protocol, the SlidePrep does not transfer specimen from c-tubes onto slides.

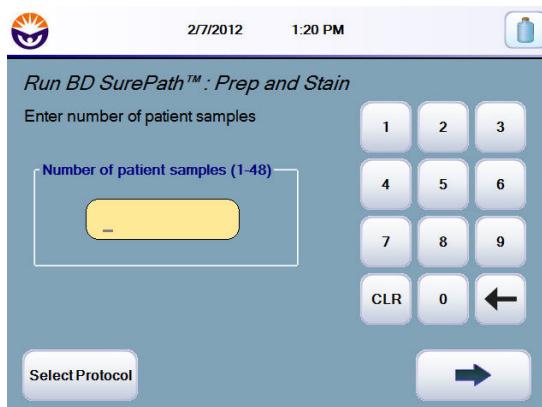
*Prep and Stain:* the SlidePrep transfers specimen from c-tubes onto slides and stains with hematoxylin and EA/OG.

- If no additional protocol variations have been created, the above three options are the only ones listed. Select the desired protocol and tap the SETUP RUN button to continue.
- If any additional protocol variations have been created, they will also appear in list form. Select the desired protocol variation by tapping the name in the list and tap the SETUP RUN button to continue.
- To modify or create a protocol variation, tap the MODIFY button. The user will be prompted for a password and information on the new protocol modification. See Section 7.4.1 for more information on modifying protocol variations.
- To remove an existing protocol variation, tap the name desired and hit the REMOVE button. The Prep Only, Stain Only, and Prep and Stain protocols cannot be removed, and the REMOVE button is gray/not functional when any of these protocols is selected. Also, once you remove a modified protocol variation, any run reports reprinted after that will not show the run parameters. Therefore, always print any necessary run reports before removing that modified protocol.

5 Enter number of patient samples.

- a Use the keypad to enter the number of patient samples from 1 to 48 (up to 48 slides can be prepared in one run, no slides are reserved for controls).

The CLR button erases the entire entry and the ← button on the keypad deletes the last entered digit.



**Figure 5-4 – Enter Number of Patient Samples display**

- b After a sample number in the appropriate range (1-48) has been entered, tap ⇒ to continue.

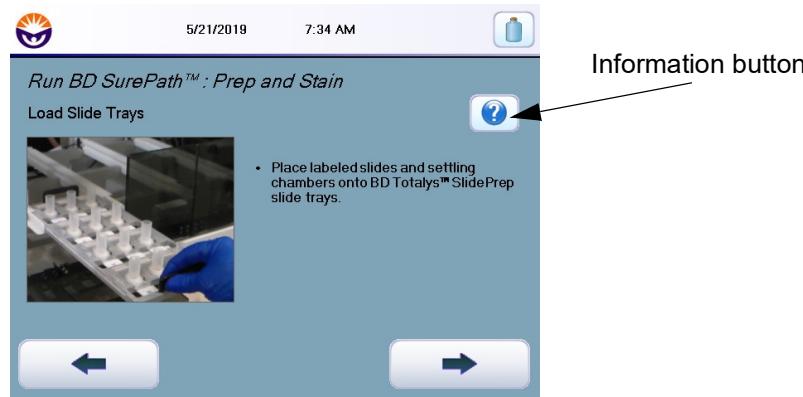
Because the SlidePrep processes an entire row of four slides at a time, if the total number of samples would leave a slide row partially empty, a popup information box instructs the user to fill empty slide slots on a partial row with blank slides and settling chambers. When finished, tap the CLOSE button to continue.

6 Load slide trays.

- a Place labeled slides, with settling chambers, onto slide trays if not already done during pre-processing. For Stain Only runs, the slides should already have a cell layer inside the settling chamber.  
Ensure that the labeled slides correspond to labels or patient identification on the c-tubes.
- b Open slide tray doors and slide the slide trays into their corresponding STS. Slide the trays back until they lock into place. Trays should be loaded so that the engraved triangle that indicates position 1 is towards the user.

**NOTE**

Trays are channeled so that they fit properly into position only if they are placed in the proper orientation and correct STS in the SlidePrep.



**Figure 5-5 – Load Slide Trays display**

- c Close the slide tray doors.
- If needed, a summary of the load slide trays steps can be found by clicking on the information button. The Load Slide Trays message box appears. Use the slide bar to scroll the instruction list. Tap the CLOSE button to exit the information box.
- d Tap  $\Rightarrow$  to continue.
- 7 Verify slide trays.
- Compare c-tube racks and slide trays to this display to verify the placement of samples, sample slides, and any blank slides. This display is generated based on the number of patient samples that was entered previously.
- C-tube rack graphics on the left side of the display indicate sample locations (green).
  - Slide tray graphics in the center of the display show where all sample slides (green) and blank slides (orange) should be located.
  - The light green color shows which sample and slide are linked. Each time the c-tube rack graphic is tapped, the next sample and slide are highlighted light green.



**Figure 5-6 – Verify Slide Trays display**

NOTE

In Stain Only runs, there are no c-tube racks associated with the slide trays and therefore, no c-tube racks appear on this display.

8 Load DASR.

NOTE

For Stain Only runs, there are no c-tube racks to load and this display does not appear.

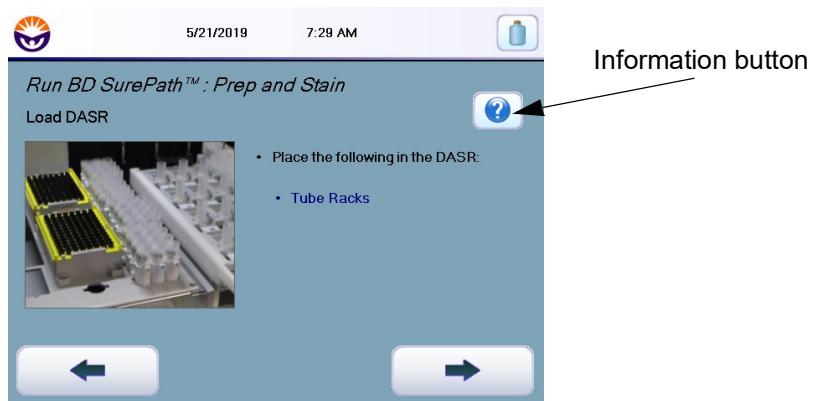


Figure 5-7 – Load DASR display

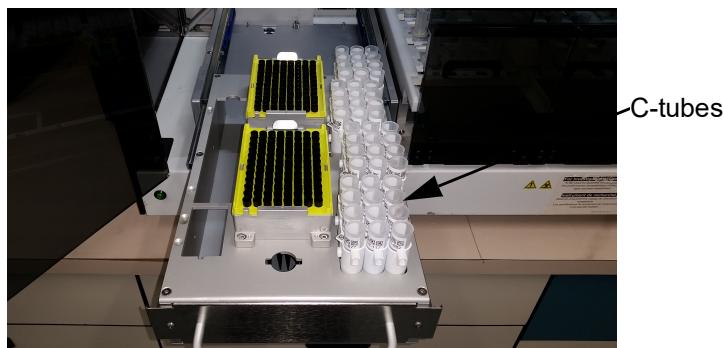


Figure 5-8 – DASR contents

- a Open the DASR door and slide the drawer to its outermost position.
- b Load the c-tube racks containing specimens into the c-tube rack holders. C-tube rack 1 is in front. C-tube racks fit into their correctly aligned position only with the proper rack number and orientation (tube 1 at lower left). If the rack does not slip into place, check for proper c-tube rack slot and orientation.

- c Ensure there is one full rack of tips (verifying tip racks will also be performed later).

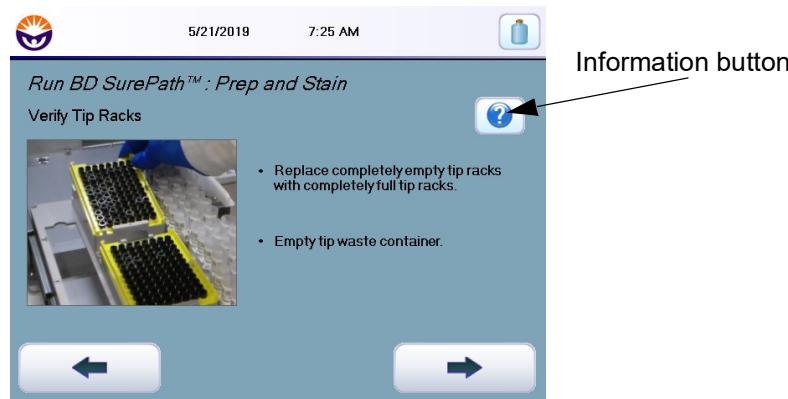
**NOTE**

There are several locations on the DASR for loading a reagent kit, a control kit, and a mixing tube. These reagents are not used in a BD SurePath™ Liquid-based Pap Test and do not need to be loaded onto the DASR.

- d Slide the DASR drawer back into position until it locks in place.
  - e Close the DASR door.  
If needed, additional information for loading the DASR can be found by clicking on the information button. The Load DASR message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.
  - f Tap to continue.
- 9 Verify tip racks and empty the tip waste container.

**CAUTION**

**Load only BD Totalys™ Transfer Tips in the SlidePrep.**



**Figure 5-9 – Verify Tip Racks display**

- a Open the DASR door and slide the drawer to its outermost position.
- b Ensure that there is at least one full rack of tips. Replace any completely empty tip racks with a completely full rack. If one rack is empty and one rack is partially full, leave the partially full rack in place as the SlidePrep remembers where it last used a tip and will restart there (the slot holding the full rack will vary from run to run depending on usage).
- c Slide the DASR drawer back into position until it locks in place and close the DASR door.

- d Empty the tip waste container. The tip waste container sits on the left side of the SlidePrep, outside of the instrument enclosure and is secured to the SlidePrep on two prongs. Slide the tip waste container up off the prongs and dispose of the tips in an appropriate waste container. Place the container back on the side of the SlidePrep by locking onto prongs.

If needed, a summary of the verify tip racks steps can be found by clicking on the information button. The Verify Tip Racks message box appears. Tap the CLOSE button to exit the details box.

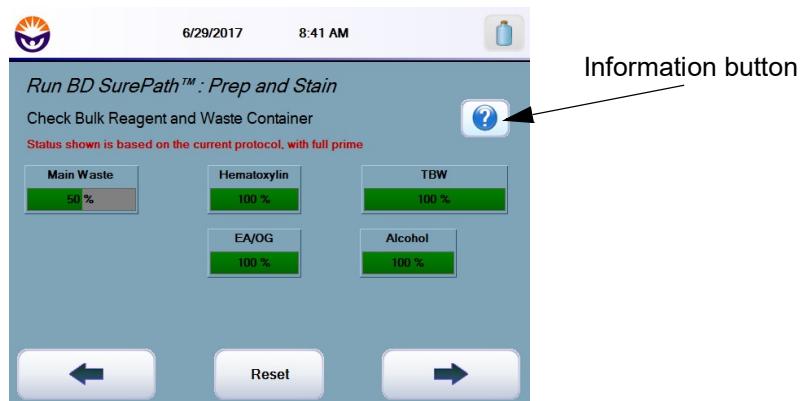
- e Tap to continue.

#### 10 Check bulk reagent and waste containers.

The **Check Bulk Reagent and Waste Container** display shows the percentage volume in each container.

##### NOTE

If you switch reagents between tests (e.g., use a different hematoxylin) you must rely on visual confirmation of volume if the new reagent bottle is not full because the counters only reset to 100%.



**Figure 5-10 – Check Bulk Reagent and Waste Container display**

- a Prepare and fill the bulk reagent containers as needed for the following reagents:
- Tris buffered water (TBW)
  - Alcohol blend rinse
  - Hematoxylin
  - EA/OG

**NOTE**

Other bulk reagent bottle positions are present on the bulk reagent station (AUX 1, 2, and 3 reagents), however these reagents are not used for a BD SurePath™ test and do not need to be checked for volume or connected to tubing.

In locations where no reagent bottle is present, leave the tubing connected to the bulk reagent station base.

**NOTE**

For Prep Only runs, hematoxylin and EA/OG reagents are not used and do not need to be checked for volume or connected to tubing.

- b Verify the waste containers have sufficient capacity. Empty as needed into an appropriate waste collection container.

- c Verify all tubing is correctly connected to its respective container.

Reagent containers: if the tubing quick disconnect port is attached to the bulk reagent station base, remove it by turning the port counter-clockwise. Attach the quick disconnect port to the reagent container's lid by turning the port clockwise onto the lid.

Main waste container: Attach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

Aux waste container: Some older instruments support the use of two waste streams and have a secondary "Aux" waste container. For those systems, attach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid. All tubing must be connected to the appropriate waste bottle for proper vacuum function.

Scrubbing muffler container: Attach the tubing from the SlidePrep to the clip on the scrubbing muffler lid.

- d For any reagent containers that were filled, or waste containers that were emptied, tap the appropriate area on the **Check Bulk Reagent and Waste Container** display and hit the RESET button. This will return the reagent to 100% (indicating 100% full) or the waste to 0% (indicating 0% full).

The fill volumes are then adjusted automatically by the SlidePrep based on use.

If needed, a summary of the check bulk containers steps can be found by clicking on the information button. The Check Bulk Reagent and Waste Container message box appears. Use the slide bar to navigate the instructions list. Tap the CLOSE button to exit the information box.

- e Tap ⇒ to continue.

## 11 Prime Fluids.

A full prime is required if this is the first run after any cleaning event, the first run after power-on, or if the RUN PROTOCOL button on the **Prime Fluids** display is inactive. This action primes the fluid lines and eliminates any air bubbles in the lines.

- When this display first appears, the PRIME FLUIDS button is already selected\*, and the RUN PROTOCOL button is grayed out and inactive.

\*If this is not the first run after a cleaning event or power-on the RUN PROTOCOL button is active and selected:

- Unless you notice any air bubbles in the fluid lines or have just replaced a reagent, you do not need to perform the prime fluids when the RUN PROTOCOL button is already active. Proceed to step 12.
- If you do notice any air bubbles or have just replaced a reagent, tap the PRIME FLUIDS button to select it and follow the rest of the steps in this procedure.

- Tap the START PRIME button to prime the fluid lines. The SlidePrep automatically performs the fluid prime.



**Figure 5-11 – Prime Fluids display**

- Once prime fluids is complete, the RUN PROTOCOL button becomes active with a red checkmark and the START PRIME button changes to START RUN.

### NOTE

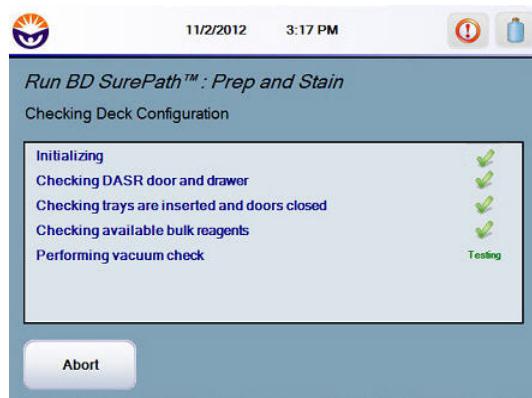
If you need to re-run the prime fluids protocol, tap on the PRIME FLUIDS button so that it is highlighted with the red checkmark, then tap the START PRIME button on the bottom of the display.

- 12 Tap the START RUN button on the **Prime Fluids** display to start the run. The **Checking Deck Configuration** display appears (Figure 5-12).

The SlidePrep starts operating at this point. However, **do not walk away from the instrument**; if the check deck configuration fails, additional action(s) may be required.



For the check deck configuration, the SlidePrep checks that configured slide trays and the DASR drawer are completely inserted and that all tray and DASR doors are closed. The levels of the bulk reagents are checked and a vacuum check is performed on all tubing. Figure 5-12 shows the **Checking Deck Configuration** display.



**Figure 5-12 – Checking Deck Configuration display**

The operator can abort the check deck configuration by tapping the ABORT button.

For each deck component tested the status appears as Pending, Testing, Error (test failed), Aborted (operator aborted check), or a green checkmark for passing the test. If a condition fails, an error message is shown indicating which check failed. An intermittent alarm sounds to alert the operator of the failure. Choose CLOSE to exit the message box. The ABORT button changes to SELECT PROTOCOL and the RETRY button is added. If the condition is remedied, tap the RETRY button to begin the check deck configuration again. Otherwise tap the SELECT PROTOCOL button to return to the **Main Menu** display and reset conditions for the run.

A warning may also pop up if monthly or weekly maintenance needs to be performed. Note the information and tap the CLOSE button. Either tap SELECT PROTOCOL to return to the **Main Menu** display and perform the required maintenance procedures, or tap RETRY to continue the run. The first check deck configuration step, "Initializing," will then have a status of Ignored.

- 13 Once the check deck configuration process is completed successfully, the selected protocol immediately starts.

Information on sample processing during the run (Section 5.5.3), assay progress reports (Section 5.6), and completed slide trays and samples (Section 5.7) are below.

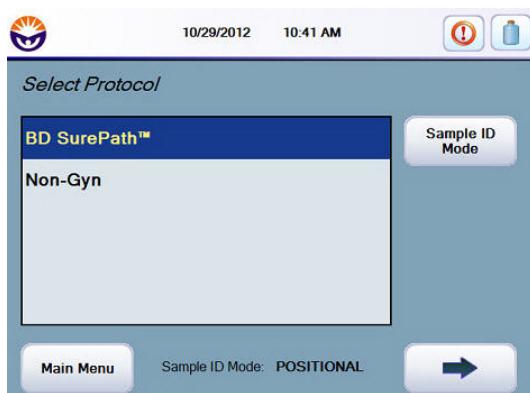
## 5.5.2 Barcode and Remote Station Sample ID Modes

Use barcode sample ID mode to generate slides using barcode tracking.

If your system is set up with a MultiProcessor, use remote station sample ID mode to link with the remote station from the MultiProcessor and transfer chain of custody information to the SlidePrep.

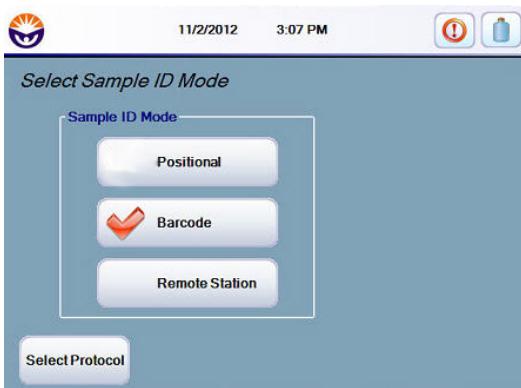
Almost all of the protocol setup steps for barcode and remote station sample ID mode are the same. Follow the steps below whether you are processing in either barcode or remote station sample ID mode. Any differences in protocol setup are noted. Additionally, any major differences in displays are presented; but small variations that do not affect set up are not shown separately.

- 1 The initial display after start up and notifications is the **Select Protocol** display. Select "BD SurePath™" by tapping the name, if it is not already highlighted. Setup for a system run will initiate from this display, however, if desired the MAIN MENU button brings the user to the **Main Menu** display where the user can choose among System Setup, Utilities, Maintenance, Select Protocol, and Shutdown.



**Figure 5-13 – Select Protocol display**

- 2 Tap the SAMPLE ID MODE button to adjust sample input to either barcode or remote station sample ID. In the **Select Sample ID Mode** window, if the desired mode is already selected, indicated by the red checkmark, tap the SELECT PROTOCOL button to return to the previous display. If barcode or remote station mode needs to be selected, tap on the appropriate button. You will be returned to the previous display automatically.



**Figure 5-14 – Select Sample ID Mode display**

On the **Select Protocol** display, either “BARCODE” or “REMOTE” appears on the bottom of the display, depending on your selection.

- 3 Tap  $\Rightarrow$  on the **Select Protocol** display to continue.
- 4 On the **Select Protocol Variation** display, select the desired run variation.



**Figure 5-15 – Select Protocol Variation display**

*Prep Only:* the SlidePrep prepares slides from specimen samples, but does not stain with hematoxylin and EA/OG.

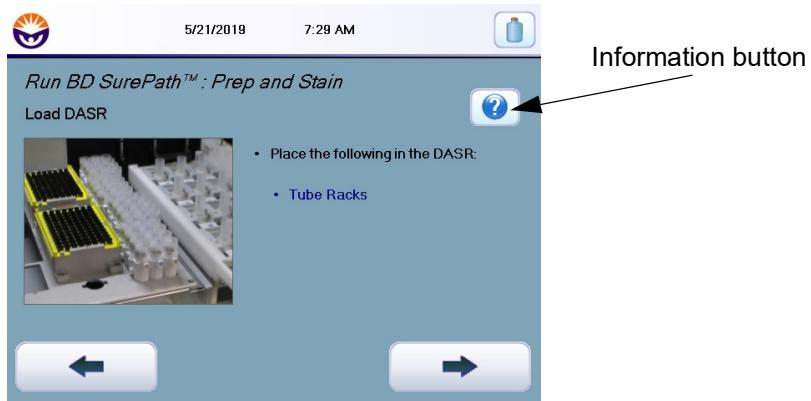
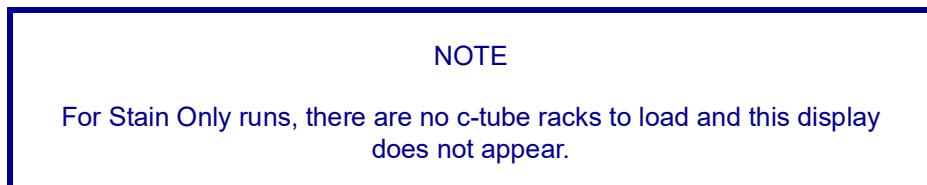
*Stain Only:* the SlidePrep only stains slides (that already have a cell layer) with hematoxylin and EA/OG. For this protocol, the SlidePrep does not transfer specimen from c-tubes onto slides.

*Prep and Stain:* the SlidePrep transfers specimen from c-tubes onto slides and stains with hematoxylin and EA/OG.

- If no additional run variation protocols have been created, the above three options are the only ones listed. Select the desired protocol and tap the SETUP RUN button to continue.
- If any additional run variations have been created, they will also appear in list form. Select the desired variation by tapping the name in the list and tap the SETUP RUN button to continue.
- To modify a protocol, tap the MODIFY button. The user will be prompted for a password and information on the new protocol modification. See Section 7.4.1 for more information on modifying protocol variations.

- To remove an existing protocol variation, tap the name desired and hit the REMOVE button. The Prep Only, Stain Only, and Prep and Stain protocols cannot be removed, and the REMOVE button is gray/not functional when any of these protocols is selected. Also, once you remove a modified protocol, any run reports reprinted after that will not show the run parameters. Therefore, always print any necessary run reports before removing that modified protocol.

5 Load DASR.



**Figure 5-16 – Load DASR display**



**Figure 5-17 – DASR contents**

- Open the DASR door and slide the drawer to its outermost position.
- Load the c-tube racks containing specimens into the c-tube rack holders. C-tube rack 1 is in front. C-tube racks fit into their correctly aligned position only with the proper rack number and orientation (tube 1 at lower left). If the rack does not slip into place, check for proper c-tube rack slot and orientation.

If operating the SlidePrep in conjunction with a MultiProcessor, make sure the c-racks from the MultiProcessor are snapped together before inserting into the c-tube rack on the DASR. For more information, refer to the *BD Totalys™ MultiProcessor User's Manual*.

- c Ensure there is one full rack of tips (verifying tip racks will also be performed later).

**NOTE**

There are several locations on the DASR for loading a reagent kit, a control kit, and a mixing tube. These reagents are not used in a BD SurePath™ test and do not need to be loaded onto the DASR.

- d Slide the DASR drawer back into position until it locks in place.

- e Close the DASR door.

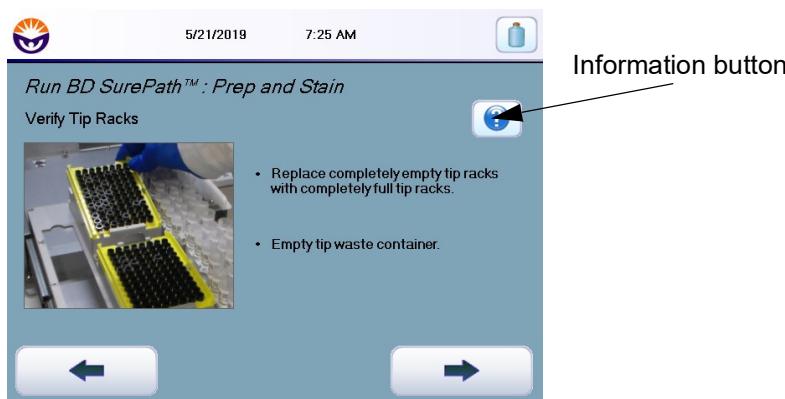
If needed, additional information for loading the DASR can be found by clicking on the information button. The Load DASR message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

- f Tap  $\Rightarrow$  to continue.

- 6 Verify tip racks and empty the tip waste container.

**CAUTION**

**Load only BD Totalys™ Transfer Tips in the SlidePrep.**



**Figure 5-18 – Verify Tip Racks display**

- a Open the DASR door and slide the drawer to its outermost position.
- b Ensure that there is at least one full rack of tips. Replace any completely empty tip racks with a completely full rack. If one rack is empty and one rack is partially full, leave the partially full rack in place as the SlidePrep remembers where it last used a tip and will restart there (the slot holding the full rack will vary from run to run depending on usage).
- c Slide the DASR drawer back into position until it locks in place and close the DASR door.

- d Empty the tip waste container. The tip waste container sits on the left side of the SlidePrep, outside of the instrument enclosure and is secured to the SlidePrep on two prongs. Slide the tip waste container up off the prongs and dispose of the tips in an appropriate waste container. Place the container back on the side of the SlidePrep by locking onto prongs.

If needed, a summary of the verify tip racks steps can be found by clicking on the information button. The Verify Tip Racks message box appears. Tap the CLOSE button to exit the details box.

- e Tap to continue.

7 Scan sample tubes.

*For Stain Only runs, there are no sample tubes to scan and this display does not appear.*

**NOTE**

This step and the Scan Sample Tubes display varies depending on whether sample ID mode is set up for barcode or remote station. Follow the procedure in the appropriate section below.

**WHEN IN BARCODE SAMPLE ID MODE:**

The **Scan Sample Tubes** display allows for either barcode reader or manual entry of sample identification (Figure 5-19).

A c-tube rack picture is depicted toward the left of the display, with an identification display depicted to its right. As barcodes are entered from the c-tube samples, the barcode is filled in at the appropriate spot on the identification display.

Sample tube barcodes must be scanned in the correct sequence, as depicted on the display.

To enter sample identification using the barcode reader:

- a Verify all c-tubes have a valid barcode attached to the outside of the tube and the barcode contains only one sample ID.
- b Starting with c-tube rack 1, pick up the first c-tube to be scanned and scan the label using the handheld barcode reader.

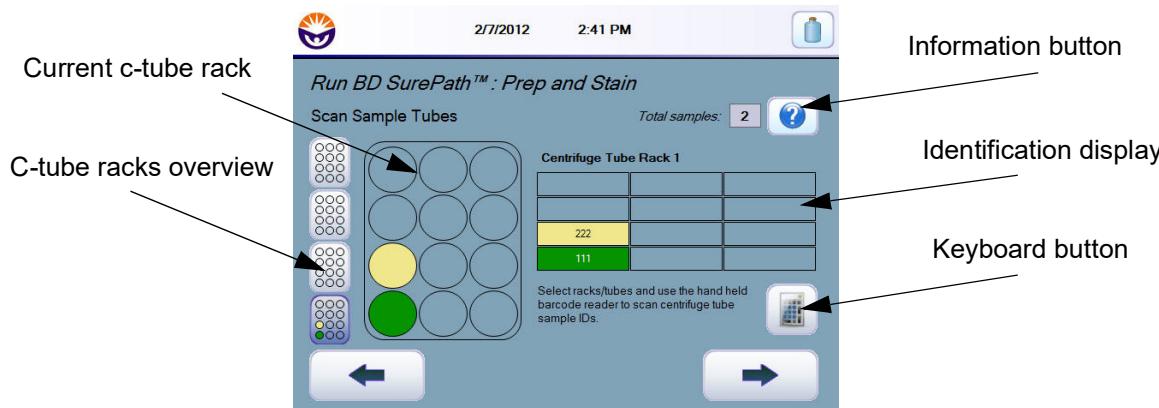
The barcode reader normally operates in "continuous mode" where it automatically reads the presented barcode. To switch to trigger mode, where the barcode trigger must be depressed to scan a barcode, simply press and release the trigger.

- c As a barcode is scanned, the information appears in the display. Repeat scanning for all barcodes to be scanned. The display highlights the next c-tube position by default. Scan c-tubes in the sequence highlighted on the display.

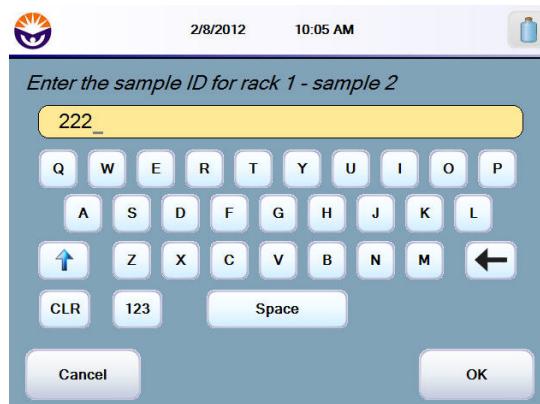
If the wrong barcode is accidentally scanned, correct it by following the procedure below for manual entry.

To enter sample identification using the manual-entry keyboard:

- a Tap the desired location on the identification display then tap the keyboard button on the bottom right side of the display (See Figure 5-19).
- b Using the virtual keyboard that appears (Figure 5-20), enter the desired sample identification, up to 18 characters. Both letters and numbers can be used; the keyboard is switched using either the “123” or “ABC” button at the bottom of the keyboard. Certain characters, as present on the display, are also available.
- c Press OK on the keyboard when finished to return to the **Scan Sample Tubes** display.
- d Repeat these steps for all samples that require keyboard entry for identification.



**Figure 5-19 – Scan Sample Tubes display (barcode sample ID mode)**



**Figure 5-20 – Sample identification keyboard**

Samples not yet entered have no fill color. A sample that is currently selected for identification is colored yellow. And a sample that has already been entered is colored green.

On the far left side of the display, the highlighted c-tube rack indicates which c-tube rack (1, 2, 3, or 4) is currently being entered. C-tube rack 1 is highlighted first. When one rack is completed, tap the picture for the next rack to start scanning or entering barcodes. On the display, c-tube rack 1 is at the bottom, and c-tube rack 4 is at the top.

On the top right of the display a box indicates the total number of specimen samples that have been scanned.

If needed, a summary of the scan sample tubes steps can be found by clicking on the information button. The Scan Sample Tubes message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

When all barcode reader or keyboard entry of samples is complete, tap  $\Rightarrow$  on the **Scan Sample Tubes** display.

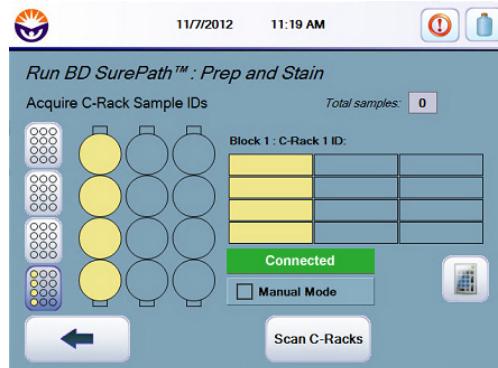
### WHEN IN REMOTE STATION SAMPLE ID MODE:

In remote station sample ID mode, the SlidePrep automatically acquires the c-rack (and c-tube) identification information from the MultiProcessor remote station.

- Tap the SCAN C-RACKS button on the display.
- The SlidePrep scans and fills in the c-rack and c-tube identification information.
  - C-racks not yet entered have no fill color.
  - A c-rack that is currently selected for identification is colored yellow.
  - A c-rack that has already been entered is colored green.

On the far left side of the display, the highlighted c-rack indicates which c-rack (1, 2, 3, or 4) is currently being entered. C-tube rack 1 is highlighted first. On the display, c-rack 1 is at the bottom, and c-rack 4 is at the top.

- On the top right of the display a box indicates the total number of specimen samples that have been scanned.
- If information cannot be acquired from the remote station, or if the “connected” text in green changes to “not connected” in red (indicating that the SlidePrep is not communicating with the remote station), enter the c-rack barcode information manually:
    - Tap the MANUAL MODE button.
    - Use the hand scanner to scan the barcode of the c-rack (not each individual c-tube). The c-rack and c-tube identification information is filled in on the display.



**Figure 5-21 – Acquire C-Rack Sample IDs display (remote station sample ID mode)**

8 Load slide trays.

- a Place labeled slides, with settling chambers, onto slide trays if not already done during pre-processing. For Stain Only runs, the slides should already have a cell layer inside the settling chamber.

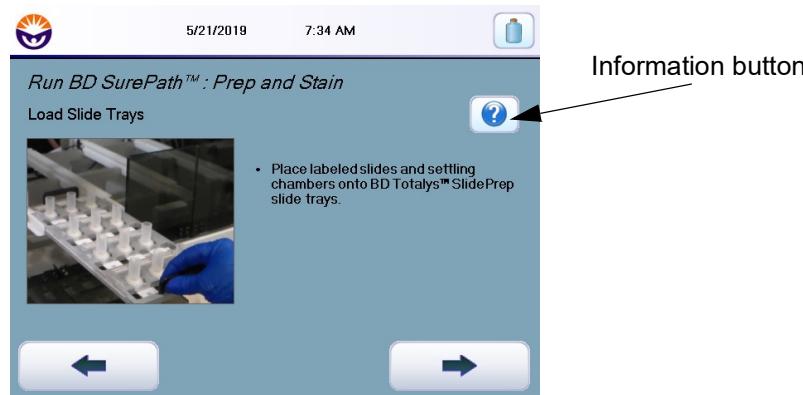
Ensure that the labeled slides correspond to labels or patient identification on the c-tubes.

Load slides onto slide trays without spaces in between.

- b Open slide tray doors and slide the slide trays into their corresponding STS. Slide the trays back until they lock into place. Trays should be loaded so that the engraved triangle that indicates position 1 is towards the user.

**NOTE**

Trays are channeled so that they fit properly into position only if they are placed in the proper orientation and correct STS in the SlidePrep.



**Figure 5-22 – Load Slide Trays display**

- c Close the slide tray doors.

If needed, a summary of the load slide trays steps can be found by clicking on the information button. The Load Slide Trays message box appears. Use the slide bar to scroll the instruction list. Tap the CLOSE button to exit the information box.

- d Tap ⇒ to continue.

9 Scan slides.

The **Scan Slides** display allows for either automatic scanning, handheld barcode reader or manual entry of slide identification (Figure 5-23).

C-tube racks are depicted on the left side of the display, with a slide tray identification display depicted to the right. As barcodes are entered from the slides, the barcode will be filled in at the appropriate spot on the slide tray rack. The c-tube racks have colored circles in any sample position where a sample ID was entered.

For automatic scanning of slide barcodes:

- Verify all slides have a valid barcode label attached containing a single sample ID.
- Press the SCAN SLIDES button.

All slides are scanned until slide barcodes match specimen samples.

For handheld barcode reader entry of slide barcodes:

- Verify all slides have a valid barcode label attached containing a single sample ID.
  - Starting with slide tray 1, slide the tray out and scan the label using the handheld barcode reader.
- The barcode reader normally operates in “continuous mode” where it automatically reads the presented barcode. To switch to trigger mode, where the barcode trigger must be depressed to scan a barcode, simply press and release the trigger.
- As a barcode is scanned, the information appears in the display. Repeat scanning for all barcodes to be scanned.

To enter sample identification using the manual-entry keyboard:

- Tap the desired slide tray location on the **Scan Slides** display then tap the keyboard button on the bottom right side of the display (See Figure 5-23).
- Using the virtual keyboard that appears, enter the desired sample identification, up to 18 characters. Both letters and numbers can be used; the keyboard is switched using either the “123” or “ABC” button at the bottom of the keyboard. Certain characters, as present on the display, are also available.
- Press OK on the keyboard when finished to return to the main **Scan Slides** display.
- Repeat these steps for all samples that require keyboard entry for identification.

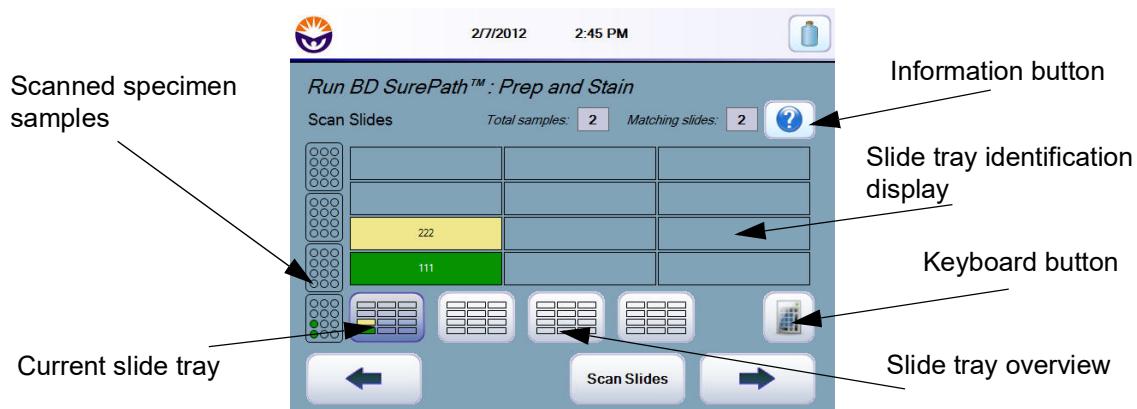


Figure 5-23 – Scan Slides display

Slides not yet entered have no fill color. A slide that is currently selected for identification is colored yellow. A slide that has already been entered is colored green if the barcode matches the specimen/c-tube barcode, but is red if the barcode does not match the specimen/c-tube barcode. A slide will also be colored red if there were any errors from the MultiProcessor.

The “Next” button to proceed to the next display does not appear until the slide barcodes match the previously entered specimen barcodes.

Across the bottom of the display, the highlighted slide tray indicates which slide tray (1, 2, 3, or 4) is currently being entered. Slide tray 1 is highlighted first. When one tray is completed, tap the picture for the next tray to start scanning. On the display, slide tray 1 is on the left, and slide tray 4 is on the right.

On the top right of the display a box indicates the total number of specimen samples that have been scanned as well as the number of matching slide identifications.

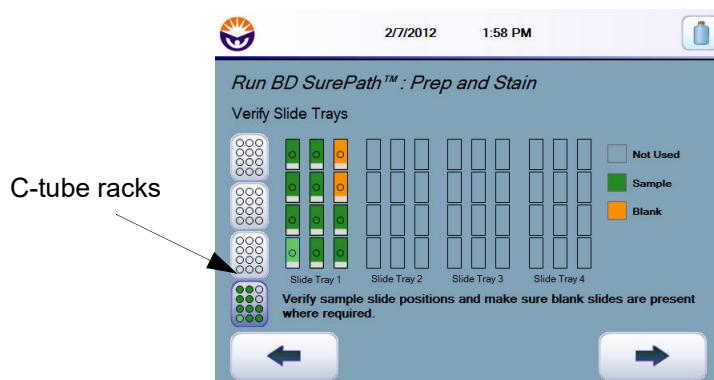
If needed, a summary of the scan slides steps can be found by clicking on the information button. The Scan Slides message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

When all automatic or keyboard entry of samples is complete, tap  $\Rightarrow$  on the **Scan Slides** display.

#### 10 Verify slide trays.

Compare c-tube racks and slide trays to this display to verify the placement of samples, sample slides, and any blank slides. This display is generated based on the number of patient samples that was entered previously.

- C-tube rack graphics on the left side of the display indicate sample locations (green).
- Slide tray graphics in the center of the display show where all sample slides (green) and blank slides (orange) should be located.
- The light green color shows which sample and slide are linked. Each time the c-tube rack graphic is tapped, the next sample and slide are highlighted light green.
- Samples will be colored red if there were any errors from the MultiProcessor.



**Figure 5-24 – Verify Slide Trays display**

**NOTE**

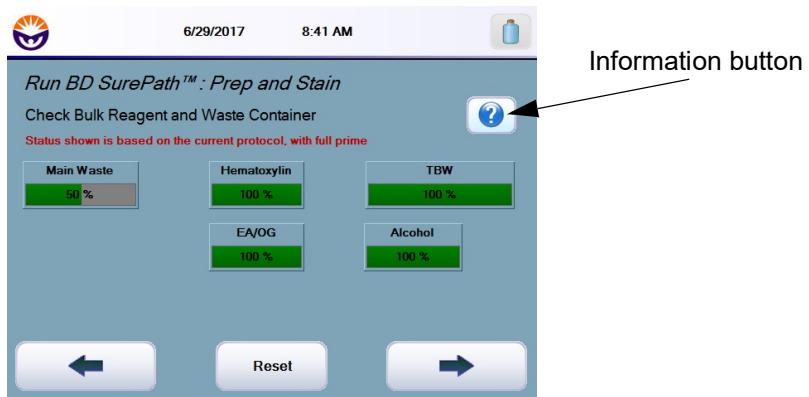
In Stain Only runs, there are no c-tube racks associated with the slide trays and therefore, no c-tube racks appear on this display.

## 11 Check bulk reagent and waste containers.

The **Check Bulk Reagent and Waste Container** display shows the percentage volume in each container.

**NOTE**

If you switch reagents between tests (e.g., use a different hematoxylin) you must rely on visual confirmation of volume if the new reagent bottle is not full because the counters only reset to 100%.



**Figure 5-25 – Check Bulk Reagent and Waste Container display**

- Prepare and fill the bulk reagent containers as needed for the following reagents:
  - Tris buffered water (TBW)
  - Alcohol blend rinse
  - Hematoxylin
  - EA/OG

**NOTE**

Other bulk reagent bottle positions are present on the bulk reagent station (AUX 1, 2, and 3 reagents), however these reagents are not used for a BD SurePath™ test and do not need to be checked for volume or connected to tubing.

In locations where no reagent bottle is present, leave the tubing connected to the bulk reagent station base.

**NOTE**

For Prep Only runs, hematoxylin and EA/OG reagents are not used and do not need to be checked for volume or connected to tubing.

- b Verify the waste containers have sufficient capacity. Empty as needed into an appropriate waste container.

- c Verify all tubing is correctly connected to its respective container.

Reagent containers: if the tubing quick disconnect port is attached to the bulk reagent station base, remove it by turning the port counter-clockwise. Attach the quick disconnect port to the reagent container's lid by turning the port clockwise onto the lid.

Main waste container: Attach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

Aux waste container: Some instruments have a waste diverter valve that supports two liquid waste containers. For those instruments, attach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid. All tubing must be connected to the appropriate waste bottle for proper vacuum function.

Scrubbing muffler container: Attach the tubing from the SlidePrep to the clip on the scrubbing muffler lid.

- d For any reagent containers that were filled, or waste containers that were emptied, tap the appropriate area on the **Check Bulk Reagent and Waste Container** display and hit the RESET button. This will return the reagent to 100% (indicating 100% full) or the waste to 0% (indicating 0% full).

The fill volumes are then adjusted automatically by the SlidePrep based on use.

If needed, a summary of the check bulk containers steps can be found by clicking on the information button. The Check Bulk Reagent and Waste Container message box appears. Use the slide bar to navigate the instructions list. Tap the CLOSE button to exit the information box.

- e Tap ⇒ to continue.

## 12 Prime Fluids.

A full prime is required if this is the first run after any cleaning event, the first run after power-on, or if the RUN PROTOCOL button on the **Prime Fluids** display is inactive. This action primes the fluid lines and eliminates any air bubbles in the lines.

- a When this display first appears, the PRIME FLUIDS button is already selected\*, and the RUN PROTOCOL button is grayed out and inactive.

\*If this is not the first run after a cleaning event or power-on the RUN PROTOCOL button is active and selected:

- Unless you notice any air bubbles in the fluid lines or have just replaced a reagent, you do not need to perform the prime fluids when the RUN PROTOCOL button is already active. Proceed to step 13.
- If you do notice any air bubbles or have just replaced a reagent, tap the PRIME FLUIDS button to select it and follow the rest of the steps in this procedure.

- b Tap the START PRIME button to prime the fluid lines. The SlidePrep automatically performs the fluid prime.



**Figure 5-26 – Prime Fluids display**

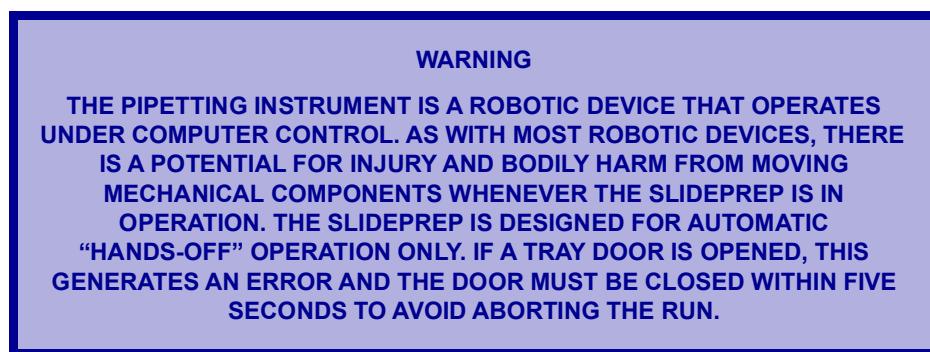
- c Once prime fluids is complete, the RUN PROTOCOL button becomes active with a red checkmark and the START PRIME button changes to START RUN.

### NOTE

If you need to re-run the prime fluids protocol, tap on the PRIME FLUIDS button so that it is highlighted with the red checkmark, then tap the START PRIME button on the bottom of the display.

- 13 Tap the START RUN button on the **Prime Fluids** display to start the run. The **Checking Deck Configuration** display appears (Figure 5-27).

The SlidePrep starts operating at this point. However, **do not walk away from the instrument**; if the check deck configuration fails, additional action(s) may be required.



For the check deck configuration, the SlidePrep checks that configured slide trays and the DASR drawer are completely inserted and that all tray and DASR doors are closed. The levels of the bulk reagents are checked and a vacuum check is performed on all tubing. Figure 5-27 shows the **Checking Deck Configuration** display.



**Figure 5-27 – Checking Deck Configuration display**

The operator can abort the check deck configuration by tapping the ABORT button.

For each deck component tested the status appears as Pending, Testing, Error (test failed), Aborted (operator aborted check), or a green checkmark for passing the test. If a condition fails, an error message is shown indicating which check failed. An intermittent alarm sounds to alert the operator of the failure. Choose CLOSE to exit the message box. The ABORT button changes to SELECT PROTOCOL and the RETRY button is added. If the condition is remedied, tap the RETRY button to begin the check deck configuration again. Otherwise tap the SELECT PROTOCOL button to return to the **Main Menu** display and reset conditions for the run.

A warning may also pop up if monthly or weekly maintenance needs to be performed. Note the information and tap the CLOSE button. Either tap SELECT PROTOCOL to return to the **Main Menu** display and perform the required maintenance procedures, or tap RETRY to continue the run. The first check deck configuration step, "Initializing," will then have a status of Ignored.

- 14 Once the check deck configuration process is completed successfully, the selected protocol immediately starts.

Information on sample processing during the run (Section 5.5.3), assay progress reports (Section 5.6), and completed slide trays and samples (Section 5.7) are below.

## 5.5.3 Sample Processing

### Prep and Stain Runs

During a BD SurePath™ Prep and Stain run, the following steps are performed by the SlidePrep:

- 450 µL of tris buffered water is added to each settling chamber, and tris buffered water is added to each c-tube.
- A transfer tip is used to mix the cell pellet 8 times, then 200 µL is transferred to the settling chamber where it is allowed to settle for a minimum of 10 minutes. During this time cells bond with the BD SurePath™ PreCoat Slides to form a thin layer of cells.
- Rinsing steps with incubations are performed to remove unbound cells: 600 µL of alcohol blend rinse with incubation and 600 µL of tris buffered water with incubation.
- 300 µL of hematoxylin and 300 µL of EA/OG are added to slides for Papanicolaou staining (interleaved with incubations, tris buffered water and alcohol blend rinse steps).

### Prep Only Runs

During a BD SurePath™ Prep Only run, the following steps are performed by the SlidePrep:

- 450 µL of tris buffered water is added to each settling chamber, and tris buffered water is added to each c-tube.
- A transfer tip is used to mix the cell pellet 8 times, then 200 µL is transferred to the settling chamber where it is allowed to settle for a minimum of 10 minutes. During this time cells bond with the BD SurePath™ PreCoat Slides to form a thin layer of cells.
- Rinsing steps with incubations are performed to removed unbound cells: 600 µL of alcohol blend rinse with incubation, one 300 µL wash of tris buffered water with incubation, three 300 µL washes of tris buffered water, and 300 µL of alcohol blend rinse.

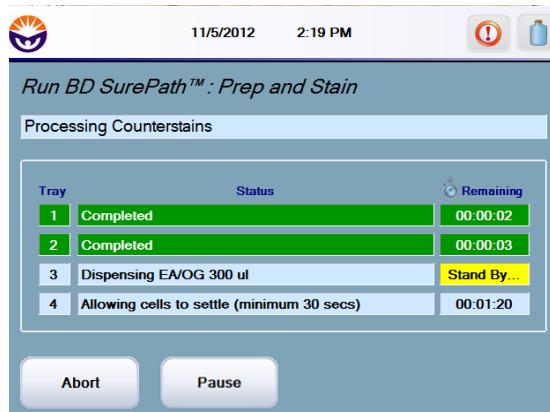
### Stain Only Runs

During a BD SurePath™ Stain Only run, the following steps are performed by the SlidePrep:

- 600 µL of alcohol blend rinse and two 600 µL washes of tris buffered water are added to slides (interleaved with incubations) to prepare the samples for staining.
- 300 µL of hematoxylin and 300 µL of EA/OG are added to slides for Papanicolaou staining (interleaved with incubations, tris buffered water and alcohol blend rinse steps).

## 5.6 Assay Progress Reports

While a BD SurePath™ Liquid-based Pap Test is underway, monitor the current status of the process on the SlidePrep display (Figure 5-28).



**Figure 5-28 – Assay Progress Report display**

The **Assay Progress Report** display shows the current step performed. For each slide tray, the sub process is displayed in the tray's corresponding status field. The remaining (ESTIMATED) time to process completion for each tray is displayed. When a tray is completed, its reporting fields turn green and a message appears stating that the tray is completed and to remove the tray. Refer to Section 5.7 for information on completed slide trays.

“Standby” indicates that the tray is nearing completion. However, DO NOT open the door until the message appears that the tray is completed.

Clicking on the clock will change the estimated amount of time remaining to the estimated time the trays will be completed.

After completion of a tray, a count-up timer will show the time since completion.

There is typically nine to ten minutes between trays for completion.

### Pausing a Run

At any point, the protocol may be paused by tapping the PAUSE button. The system finishes its current action, then pauses and the reporting status field turns red. Tap the RESUME button to resume the protocol.

The pause and resume times appear on the run report.

If the system was paused during a step involving the vacuum pump, the pump will automatically shut off after 2.5 minutes.

**NOTE**

Pausing the SlidePrep for extended periods of time once the staining process has started could impact the quality of the slides produced, including but not limited to increased background staining. The impact on stain quality of pausing the system once the staining process has started has not been evaluated as part of the performance claims. Therefore, users are responsible for determining the acceptability of slides when using the pause function.

**Aborting a Run**

At any point, the protocol may be aborted by tapping the ABORT button. A display appears to confirm the abort. If the run is aborted, the reporting status field turns red.

**NOTE**

Once aborted, the run cannot be restarted.

## 5.7 Completed Slide Trays and Samples

### 5.7.1 Completed Slide Trays

- When **each** slide tray is finished processing, its status is indicated as completed with an audible alert that continues every 30 seconds until acknowledged.

Open the appropriate slide tray door and remove the slide tray from the SlidePrep and follow the procedure below for rinsing and clearing the slides or staining slides, as needed.

**CAUTION**

**Leaving samples in alcohol for an extended length of time can cause the cells to de-stain.**

If an incorrect door (the door of an uncompleted slide tray) is opened during the run, an alarm sounds. **The door must be closed within five seconds to avoid an aborted run. Furthermore, actually pulling out a slide tray before it is completed instantly aborts the run.**

- 2 When the SlidePrep finishes processing **all** trays, “Protocol Completed” appears in the status message, an alarm briefly sounds, the ABORT button disappears, and the PRINT REPORT and DONE buttons appear.
  - Tapping the PRINT REPORT button prints the run report to the default printer (see Section 2.4.2). Tapping the DONE button returns the program to the **Select Protocol** display.
  - See Section 7.7.4, Figure 7-27 for a sample run report.
  - If unable to print, the file in pdf format can be saved to a USB drive for printing elsewhere (see Section 7.7.4).

## 5.7.2 Quality Control Evaluation

Perform quality control slide evaluation on selected slides per the laboratory's protocols.

## 5.7.3 Rinsing and Clearing Slides

These steps apply to slides prepared during Stain Only or Prep and Stain protocols of BD SurePath™ runs.

- 1 After removing a slide tray from the SlidePrep, invert the slide tray to decant the alcohol from the slides. Before returning to an upright position, blot the excess alcohol from the settling chambers with an absorbent pad. Turn the slide tray right side up.
- 2 Taking one slide at a time, remove and discard the settling chamber, then follow the steps below.

### NOTE

Do not remove all settling chambers at one time. This will result in air-drying of the slides.

- 3 Dehydrate the slide with 100% alcohol. This can be done by directing a stream of alcohol over the preparation using a squirt bottle or by dipping the slide in an alcohol bath.
- 4 Once the slide has been dehydrated, immediately clear the slide with xylene or xylene substitute. This can be done by directing a stream over the preparation using a squirt bottle or by placing the slide into a xylene or xylene substitute bath. If using the latter method, at least two xylene or xylene substitute baths are recommended.  
Leaving samples in alcohol for an extended length of time can cause the cells to de-stain.
- 5 Slides may be coverslipped one at a time or batched together.  
Slides may be coverslipped manually or with an automated coverslipper.

### CAUTION

Do not allow slides to dry prior to coverslapping.

## 5.7.4 Staining Slides

This procedure applies to slides prepared using the Prep Only protocol variation for BD SurePath™ runs.

- 1 After removing a slide tray from the SlidePrep, invert the slide tray to decant the alcohol from the slides. Before returning to an upright position, blot the excess alcohol from the settling chambers with an absorbent pad. Turn the slide tray right side up.
- 2 Taking one slide at a time, remove and discard the settling chamber. To prevent slides from drying out, prepare them according to the laboratory's standard procedures, such as placing them into 95% alcohol.

**NOTE**

Do not remove all settling chambers at one time. This will result in air-drying of the slides.

- 3 Perform staining procedures as needed according to the laboratory's standard protocols.

## 5.7.5 Completed Samples

After completion on the SlidePrep, samples may be re-run if needed. To prepare samples for any potential retesting, perform the following steps:

- 1 Open the DASR door and remove c-tube racks from the SlidePrep.
- 2 Add 2 mL of preservative fluid from the bulk preservative fluid bottle to each c-tube.  
Set the plunger on the bulk preservative fluid bottle to 2 mL. Remove the tubing from the port on the bottle and hold over a c-tube. Pull up on the plunger, then press down until the plunger stops. Repeat as needed for additional c-tubes.
- 3 Cap c-tubes with stopper caps.
- 4 Store samples according to the BD SurePath™ product insert:
  - Room Temperature up to one month from the collection date.
  - 2–8 °C up to six months from collection date.
- 5 See Section 4.4 for the pre-processing steps needed for retesting.

## 5.8 Cleanup and Shutdown

### 5.8.1 Instrument and Reagent Cleanup

Once you have removed slides and slide trays from the SlidePrep, you can either run another batch or perform any required maintenance (below).

- Perform the daily maintenance procedure if appropriate (Section 8.3).
- Perform the weekly maintenance procedure if appropriate (Section 8.4).
- Perform the monthly maintenance procedure if appropriate (Section 8.5).

### 5.8.2 Instrument Shutdown

The steps below describe the procedure for shutting down the SlidePrep. However, the instrument power should remain on at all times unless directed by BD service personnel.

- 1 From the **Main Menu** display, tap the SHUTDOWN button.
- 2 A popup information box asks to confirm the shutdown procedure. Tap YES to continue or NO to return to the **Main Menu** display.
- 3 After tapping YES an additional popup information box appears with instructions to turn off power to the SlidePrep after the screen goes blank. Tap CONTINUE to proceed or CANCEL to return to the **Main Menu** display.
- 4 After tapping CONTINUE, wait for the software to shutdown and the screen to go blank. Turn off power to the SlidePrep pressing the toggle switch on the back left side of the SlidePrep to the off position.



# 6 – Non-Gynecological Operation

## 6.1 General

This section describes the procedures required to operate the BD Totalys™ SlidePrep for generating slides with the Non-Gyn protocol. Pre-processing and operation for the Non-Gyn mode are described in different sections. The following major topics are discussed:

- Non-Gynecological pre-processing (Section 6.2)
- Preparation of tris buffered water (Section 6.3)
- Using the instrument interface (Section 6.4)
- Powering up the SlidePrep (Section 6.5)
- Non-Gyn slide processing (Section 6.6)
- Assay progress reports (Section 6.7)
- Completed slide trays and samples (Section 6.8)
- Cleanup and shutdown (Section 6.9)

## 6.2 Non-Gynecological Pre-Processing

Perform pre-processing of non-gyn samples according to your laboratory's approved standard operating procedures and/or the BD provided protocols.

Non-gyn sample processing on the SlidePrep begins once a cell pellet has been prepared for each sample.

## 6.3 Preparation of Tris Buffered Water

Tris buffered water (TBW) is one of the bulk reagents used on the bulk reagent station and must be made prior to operation of the SlidePrep.

### 6.3.1 Materials Required

- 1 L volumetric flask
- Deionized (DI) or distilled water
- Tris buffered saline packet, pH 8.0
- 200 mL measuring device
- 1 gallon container

### 6.3.2 Production of Stock Solution

One liter of tris buffered water stock solution is made first, and can be used to prepare multiple batches of working solution tris buffered water which is used on the SlidePrep.

**CAUTION**

**The tris buffered water stock solution must be prepared before the working solution can be made.**

- 1 Fill a 1 L flask approximately half full with DI or distilled water.
- 2 Empty 1 packet of tris buffered saline, pH 8.0 into flask and swirl until dissolved.
- 3 Fill flask to the 1 L mark with DI or distilled water and seal with Parafilm.
- 4 Invert flask several times to ensure complete mixing.
- 5 Transfer stock solution to the 1 L bottle provided during installation.
- 6 Label bottle with:
  - Tris Buffered Water Stock Solution, pH 8.0
  - Preparation date
  - Expiration date

The stock solution is stable for one month refrigerated (2–10 °C). Discard after one month.

Clean or replace container before making a new batch of stock solution. Wash containers using appropriate labware cleaner (do not use bleach). Rinse container thoroughly with DI or distilled water after cleaning or before using any brand new container.

### 6.3.3 Production of Working Solution

Working solution is prepared from the previously made stock solution and is then used in the bulk reagent station on the SlidePrep.

- 1 Measure 200 mL of tris buffered water stock solution and pour into the 1 gallon container provided during installation.
- 2 Add 3,400 mL of DI or distilled water.
- 3 Cap, invert, and mix well.
- 4 Label gallon container with:
  - Tris Buffered Water Working Solution, pH 8.0
  - Preparation date
  - Expiration date

The working solution is stable for two weeks at room temperature (15–30 °C). Discard after two weeks.

Clean or replace container before making a new batch of working solution. Wash containers using appropriate labware cleaner (do not use bleach). Rinse container thoroughly with DI or distilled water after cleaning or before using any brand new container.

## 6.4 Using the Instrument Interface

The touchscreen presents all the information needed to view system status and operate the SlidePrep. The information is presented on the touchscreen with icons that represent system operations. The display presents general information, progress information, and prompts for the operations currently being performed. The screen is touch sensitive, meaning you can simply touch or tap the button or icon on the screen itself to perform the associated action.

As you initiate system activities, new buttons may appear that present additional options. Icon definitions and buttons are presented in this section and in Section 7. Do not use pens or sharp implements to tap the screen; this can cause damage to the screen. You can use your fingertip or fingernail for greater precision, or a pencil eraser to tap buttons on the screen without causing damage to the screen.

## 6.5 Powering up the BD Totalys™ SlidePrep

To power on the SlidePrep, press the power switch on the left back side of the SlidePrep to the on position.

The first display upon startup is the Select Protocol display. However, if maintenance is required, the first display is a notification that indicates whether any user actions are required (For example: “Weekly Maintenance needs to be performed”). Note the action(s) required and press the CLOSE button.

## 6.6 Non-Gyn Slide Processing

This section describes the routine operation of the SlidePrep for generating Non-Gyn slides. Setup can be in either Positional (Section 6.6.1) or Barcode (Section 6.6.2) sample ID mode.

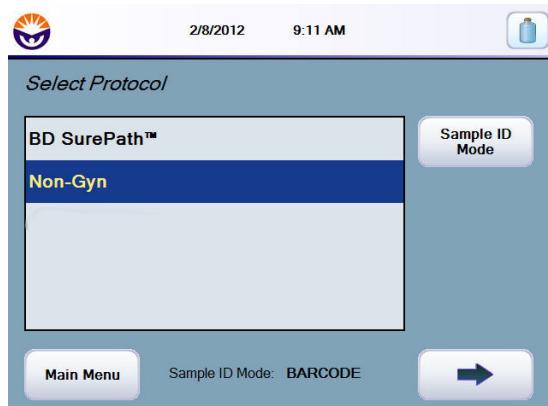
The system software presents a series of displays on setup and starting the run. At the bottom left side of each display, click  $\Rightarrow$  to continue to the next setup display or the  $\leftarrow$  (“Previous”) button to return to the previous display.

## 6.6.1 Positional Sample ID Mode

Use positional sample ID mode to generate slides without using any barcode labels on slides. Samples in this mode must be tracked manually.

- 1 The initial display after start up and notifications is the **Select Protocol** display. Select "Non-Gyn" by tapping the name, if it is not already highlighted.

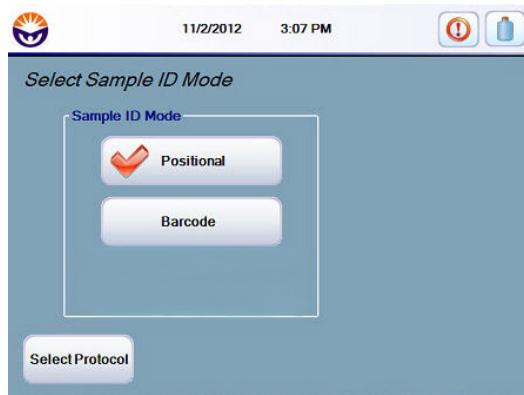
Setup for a system run will initiate from this display, however, if desired the **MAIN MENU** button brings the user to the **Main Menu** display where the user can choose among System Setup, Utilities, Maintenance, Select Protocol, and Shutdown.



**Figure 6-1 – Select Protocol display**

- 2 Tap the SAMPLE ID MODE button to adjust sample input.

In the **Select Sample ID Mode** window, if POSITIONAL is already selected, indicated by the red checkmark, tap the SELECT PROTOCOL button to return to the previous display. If positional mode needs to be selected, tap on the button. You will be returned to the previous display automatically.



**Figure 6-2 – Select Sample ID Mode display**

On the **Select Protocol** display, "POSITIONAL" appears on the bottom of the display.

- 3 Tap ⇒ on the **Select Protocol** display to continue.

- 4 On the **Select Protocol Variation** display, select the desired run variation.



**Figure 6-3 – Select Protocol Variation display**

**Prep Only:** the SlidePrep will prepare slides from specimen samples, but not stain with hematoxylin and EA/OG.

**Stain Only:** the SlidePrep will only stain slides (that already have a cell layer) with hematoxylin and EA/OG. For this protocol, the SlidePrep will not transfer specimen from c-tubes onto slides.

**Prep and Stain:** the SlidePrep will transfer specimen from c-tubes to slide and stain with hematoxylin and EA/OG.

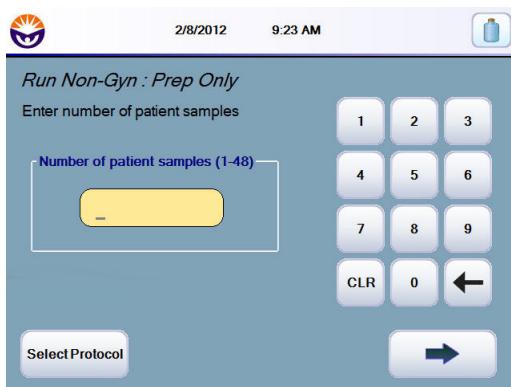
- If no additional protocol variations have been created, the above three options are the only ones listed. Select the desired protocol variation and tap the SETUP RUN button to continue.
- If any additional protocol variations have been created, they will also appear in list form. Select the desired protocol variation by tapping the name in the list and tap the SETUP RUN button to continue.
- To modify or create a protocol variation, tap the MODIFY button. The user will be prompted for a password and information on the new protocol modification. See Section 7.4.1 for more information.

**NOTE**

You must use a modified protocol variation if you are planning on processing more than 2 slides per sample. This is because the default Prep Only and Prep and Stain protocols have a default transfer volume of 300 µL per slide. Processing more than 2 slides per sample would exceed the maximum 800 µL transfer volume.

Follow the procedure in Section 7.4.1 to create a new protocol with a smaller transfer volume per slide.

- To remove an existing protocol variation, tap the name desired and hit the REMOVE button. The Prep Only, Stain Only, and Prep and Stain protocols cannot be removed, and the REMOVE button is gray/not functional when any of these protocols is selected. Also, once you remove a modified protocol variation, any run reports reprinted after that will not show the run parameters. Therefore, always print any necessary run reports before removing that modified protocol.
- 5 Enter number of patient samples.
- a For Stain Only runs: Following protocol selection, a display appears to enter the number of slides to stain. Use the keyboard on the display to enter the number of slides, then tap the Next button. Proceed to Step 7.
  - b For Prep Only and Prep and Stain runs: Use the keypad to enter the number of patient samples from 1 to 48 (up to 48 slides can be prepared in one run, no slides are reserved for controls).
- The CLR button erases the entire entry and the ← button on the keypad deletes the last entered digit.



**Figure 6-4 – Enter Number of Patient Samples display**

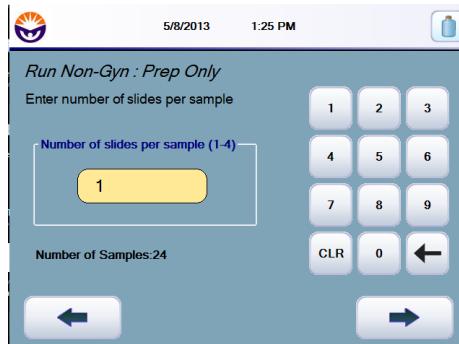
- c After a sample number in the appropriate range (1–48) has been entered, select ⇒ to continue.

Because the SlidePrep processes an entire row of four slides at a time, if the total number of samples would leave a slide row partially empty, a popup information box instructs the user to fill empty slide slots on a partial row with blank slides and settling chambers. When finished, tap the CLOSE button to continue.

6 Enter number of slides.

After entering the number of patient samples, a display appears to enter the number of slides per sample. Use the keyboard on the display to enter from 1 to 4 slides per sample.

Only 48 slides total can be processed between the combination of samples and slides per sample. For example, if processing 24 samples, no more than 2 slides per sample can be processed. The display shows the number of samples entered on the previous display.



**Figure 6-5 – Enter Number of Slides per Sample display**

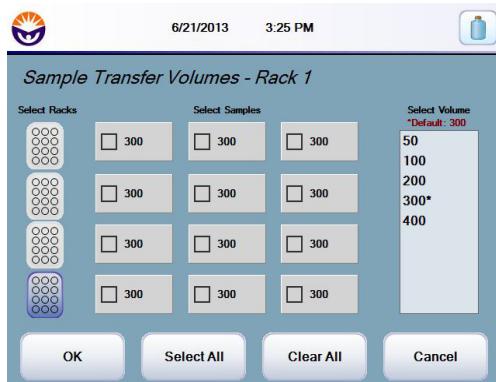
Tap ➔ to continue.

7 Select slide trays to be stained and edit sample transfer volume.

The **Select Slide Trays to be Stained** display allows you to select stain options and edit the sample transfer volume if needed.



**Figure 6-6 – Select Slide Trays to be Stained display**



**Figure 6-7 – Sample Transfer Volumes display**

- C-tube rack graphics on the left side of the display indicate sample locations (green)

**NOTE**

In Stain Only runs, there are no c-tube racks associated with the slide trays and therefore, no c-tube racks appear on this display.

- Slide tray graphics in the center of the display show where all sample slides (green) and blank slides (orange) should be located.
  - The light green color shows which sample and slide are linked. Each time the c-tube rack graphic is tapped, the next sample and slide are highlighted light green.
- To deselect staining (Prep and Stain runs) for a particular tray, click on the box below that slide tray. A checkmark in the box indicates that tray is selected for staining.
  - To adjust the sample transfer volume for any samples in the run, tap the EDIT SAMPLE VOLUME button at the bottom of the display.
  - On the **Sample Transfer Volumes** display (Figure 6-7), the sample transfer volume for each slide are presented.
    - C-tube rack graphics on the left side of the display show all four c-tube racks.
    - The graphic in the center of the display shows the sample transfer volume for each c-tube in the selected c-tube rack.
    - The options for sample transfer volume are shown in the column on the right side of the display (the options that are available vary depending on the number of slides per sample selected).
  - To change the volume, tap on the desired c-tube rack:

**NOTE**

All slides for a particular sample use the same sample transfer volume.

- If all samples in the rack need the same sample transfer volume, tap the SELECT ALL button at the bottom of the display, then tap the desired sample transfer volume from the list on the right. When finished, tap the OK button.
  - If only particular samples need a different sample transfer volume, tap the sample, then tap the desired sample transfer volume from the list on the right. Repeat for all necessary samples, then tap the OK button.
  - Repeat for all c-tube racks that contain samples not using the default sample transfer volume.
- e Tap ➔ to continue.

8 Load slide trays.

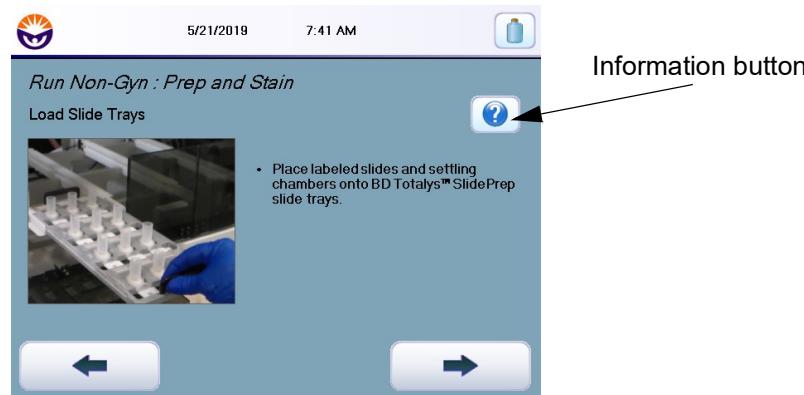
- a Place labeled slides, with settling chambers, onto slide trays if not already done during pre-processing. For Stain Only runs, the slides should already have a cell layer inside the settling chamber.

Ensure that the labeled slides correspond to labels or patient identification on the c-tubes. If you are processing more than one slide per sample, load each slide onto a different slide tray (do not load all slides for one sample onto the same slide tray). An example of this layout is shown in Figure 6-6.

- b Open slide tray doors and slide the slide trays into their corresponding STS. Slide the trays back until they lock into place. Trays should be loaded so that the engraved triangle that indicates position 1 is towards the user.

**NOTE**

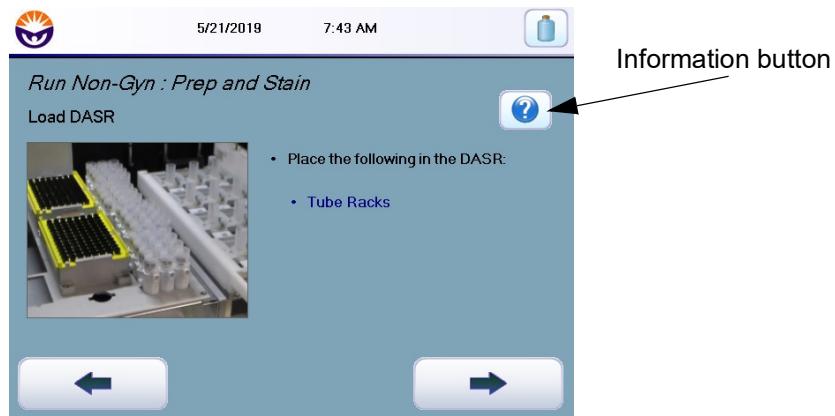
Trays are channeled so that they fit properly into position only if they are placed in the proper orientation and correct STS in the SlidePrep.



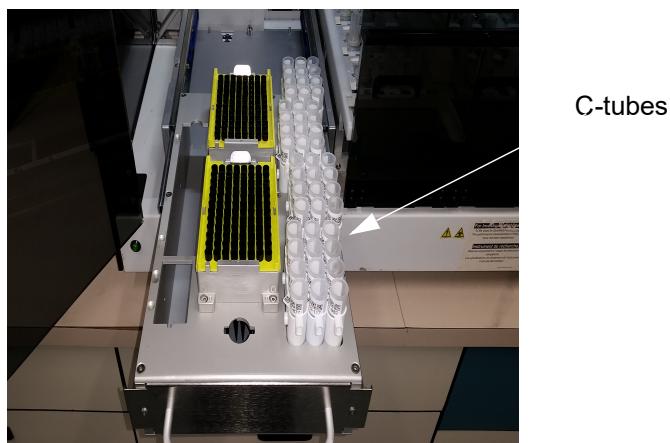
**Figure 6-8 – Load Slide Trays display**

- c Close the slide tray doors.
- If needed, a summary of the load slide trays steps can be found by clicking on the information button. The Load Slide Trays message box appears. Use the slide bar to scroll the instruction list. Tap the CLOSE button to exit the information box.
- d Tap  $\Rightarrow$  to continue.
- 9 Load DASR.

*For Stain Only runs, there are no c-tube racks to load and this display does not appear.*



**Figure 6-9 – Load DASR display**



**Figure 6-10 – DASR contents**

- a Open the DASR door and slide the drawer to its outermost position.
- b Load the c-tube racks containing specimens into the c-tube rack holders. C-tube rack 1 is in front. C-tube racks fit into their correctly aligned position only with the proper rack number and orientation (tube 1 at lower left). If the rack does not slip into place, check for proper c-tube rack slot and orientation.

- c Ensure there is one full rack of tips (verifying tip racks will also be performed later).

**NOTE**

There are several locations on the DASR for loading a reagent kit, a control kit, and a mixing tube. These reagents are not used in the Non-Gyn protocol and do not need to be loaded onto the DASR.

- d Slide the DASR drawer back into position until it locks in place.

- e Close the DASR door.

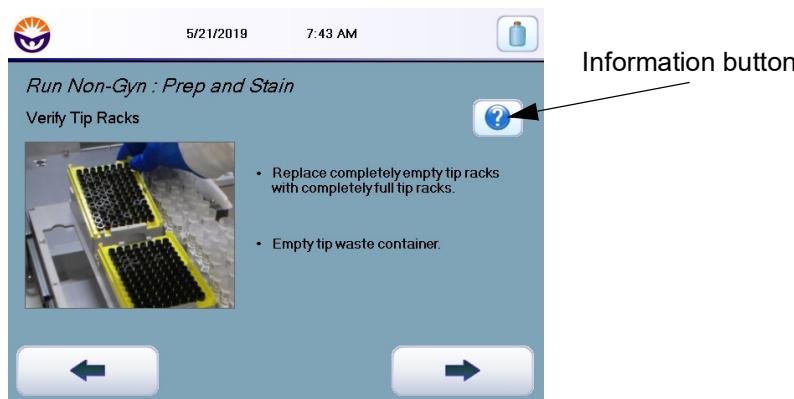
If needed, additional information for loading the DASR can be found by clicking on the information button. The Load DASR message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

- f Tap to continue.

- 10 Verify tip racks and empty the tip waste container.

**CAUTION**

**Load only BD Totalys™ Transfer Tips in the SlidePrep.**



**Figure 6-11 – Verify Tip Racks display**

- a Open the DASR door and slide the drawer to its outermost position.
- b Ensure that there is at least one full rack of tips. Replace any completely empty tip racks with a completely full rack. If one rack is empty and one rack is partially full, leave the partially full rack in place as the SlidePrep remembers where it last used a tip and will restart there (the slot holding the full rack will vary from run to run depending on usage).
- c Slide the DASR drawer back into position until it locks in place and close the DASR door.

- d Empty the tip waste container. The tip waste container sits on the left side of the SlidePrep, outside of the instrument enclosure and is secured to the SlidePrep on two prongs. Slide the tip waste container up off the prongs and dispose of the tips in an appropriate waste container. Place the container back on the side of the SlidePrep by locking onto prongs.

If needed, a summary of the verify tip racks steps can be found by clicking on the information button. The Verify Tip Racks message box appears. Tap the CLOSE button to exit the details box.

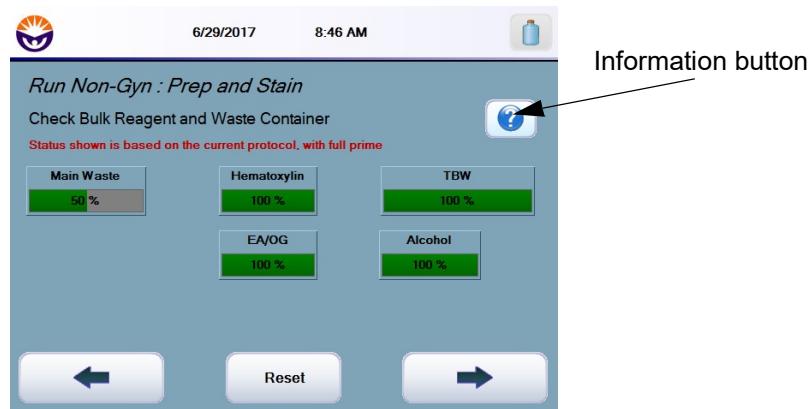
- e Tap to continue.

#### 11 Check bulk reagent and waste containers.

The **Check Bulk Reagent and Waste Container** display shows the percentage volume in each container.

##### NOTE

If you switch reagents between tests (e.g., use a different hematoxylin) you must rely on visual confirmation of volume if the new reagent bottle is not full because the counters only reset to 100%.



**Figure 6-12 – Check Bulk Reagent and Waste Container display**

- a Prepare and fill the bulk reagent containers as needed for the following reagents:
- Tris buffered water (TBW)
  - Alcohol blend rinse
  - Hematoxylin
  - EA/OG

**NOTE**

Other bulk reagent bottle positions are present on the bulk reagent station (AUX 1, 2, and 3 reagents), however these reagents are not used for the Non-Gyn protocol and do not need to be checked for volume or connected to tubing.

In locations where no reagent bottle is present, leave the tubing connected to the bulk reagent station base.

**NOTE**

For Prep Only runs, hematoxylin and EA/OG reagents are not used and do not need to be checked for volume or connected to tubing.

- b Verify the waste containers have sufficient capacity. Empty as needed into an appropriate waste collection container.
- c Verify all tubing is correctly connected to its respective container.

Reagent containers: if the tubing quick disconnect port is attached to the bulk reagent station base, remove it by turning the port counter-clockwise. Attach the quick disconnect port to the reagent container's lid by turning the port clockwise onto the lid.

Main waste container: Attach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

Aux waste container: Some instruments have a waste diverter valve that supports two liquid waste containers. For those instruments, attach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid. All tubing must be connected to the appropriate waste bottle for proper vacuum function.

Scrubbing muffler container: Attach the tubing from the SlidePrep to the clip on the scrubbing muffler lid.

- d For any reagent containers that were filled, or waste containers that were emptied, tap the appropriate area on the **Check Bulk Reagent and Waste Container** display and hit the RESET button. This will return the reagent to 100% (indicating 100% full) or the waste to 0% (indicating 0% full).

The fill volumes are then adjusted automatically by the SlidePrep based on use.

If needed, a summary of the check bulk containers steps can be found by clicking on the information button. The Check Bulk Reagent and Waste Container message box appears. Use the slide bar to navigate the instructions list. Tap the CLOSE button to exit the information box.

- e Tap ⇒ to continue.

## 12 Prime Fluids.

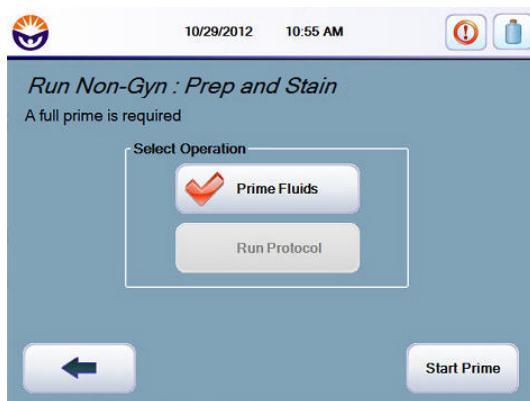
A full prime is required if this is the first run after any cleaning event, the first run after power-on, or if the RUN PROTOCOL button on the **Prime Fluids** display is inactive. This action primes the fluid lines and eliminates any air bubbles in the lines.

- When this display first appears, the PRIME FLUIDS button is already selected\*, and the RUN PROTOCOL button is grayed out and inactive.

\*If this is not the first run after a cleaning event or power-on the RUN PROTOCOL button is active and selected:

- Unless you notice any air bubbles in the fluid lines or have just replaced a reagent, you do not need to perform the prime fluids when the RUN PROTOCOL button is already active. Proceed to step 13.
- If you do notice any air bubbles or have just replaced a reagent, tap the PRIME FLUIDS button to select it and follow the rest of the steps in this procedure.

- Tap the START PRIME button to prime the fluid lines. The SlidePrep automatically performs the fluid prime.



**Figure 6-13 – Prime Fluids display**

- Once prime fluids is complete, the RUN PROTOCOL button becomes active with a red checkmark and the START PRIME button changes to START RUN.

### NOTE

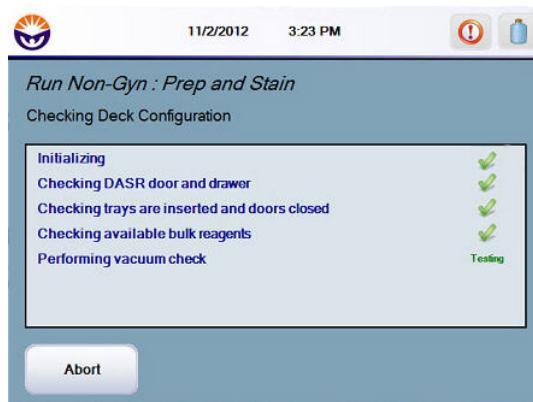
If you need to re-run the prime fluids protocol, tap on the PRIME FLUIDS button so that it is highlighted with the red checkmark, then tap the START PRIME button on the bottom of the display.

- Tap the START RUN button on the **Prime Fluids** display to start the run. The **Checking Deck Configuration** display appears (Figure 6-14).

The SlidePrep starts operating at this point. However, **do not walk away from the instrument**; if the check deck configuration fails, additional action(s) may be required.



For the check deck configuration, the SlidePrep checks that configured slide trays and the DASR drawer are completely inserted and that all tray and DASR doors are closed. The levels of the bulk reagents are checked and a vacuum check is performed on all tubing. Figure 6-14 shows the **Checking Deck Configuration** display.



**Figure 6-14 – Checking Deck Configuration display**

The operator can abort the check deck configuration by tapping the ABORT button.

For each deck component tested the status appears as Pending, Testing, Error (test failed), Aborted (operator aborted check), or a green checkmark for passing the test. If a condition fails, an error message is shown indicating which check failed. An intermittent alarm sounds to alert the operator of the failure. Choose CLOSE to exit the message box. The ABORT button changes to SELECT PROTOCOL and the RETRY button is added. If the condition is remedied, tap the RETRY button to begin the check deck configuration again. Otherwise tap the SELECT PROTOCOL button to return to the **Main Menu** display and reset conditions for the run.

A warning may also pop up if monthly or weekly maintenance needs to be performed. Note the information and tap the CLOSE button. Either tap SELECT PROTOCOL to return to the **Main Menu** display and perform the required maintenance procedures, or tap RETRY to continue the run. The first check deck configuration step, “Initializing,” will then have a status of Ignored.

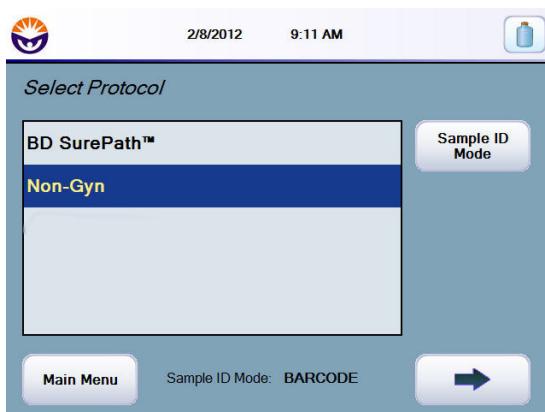
- 14 Once the check deck configuration process is completed successfully, the selected protocol immediately starts.

Information on sample processing during the run (Section 6.6.3), assay progress reports (Section 6.7) and completed slide trays and samples (Section 6.8) are below.

## 6.6.2 Barcode Sample ID Mode

Use barcode sample ID mode to track specimens using barcoded c-tubes and slides.

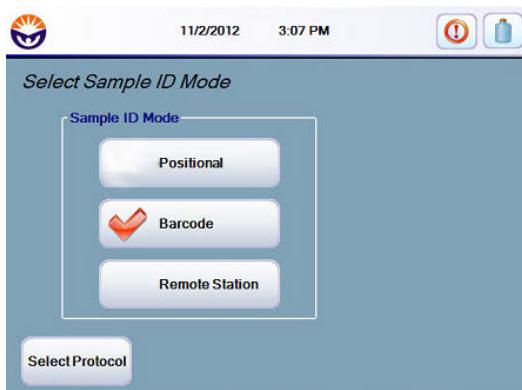
- The initial display after start up and notifications is the **Select Protocol** display. Select "Non-Gyn" by tapping the name, if it is not already highlighted.  
Setup for a system run will initiate from this display, however, if desired the MAIN MENU button brings the user to the **Main Menu** display where the user can choose among System Setup, Utilities, Maintenance, Select Protocol, and Shutdown.



**Figure 6-15 – Select Protocol display**

- Tap the SAMPLE ID MODE button to adjust sample input.

In the **Select Sample ID Mode** window, if BARCODE is already selected, indicated by the red checkmark, tap the SELECT PROTOCOL button to return to the previous display. If barcode mode needs to be selected, tap on the button. You will be returned to the previous display automatically.



**Figure 6-16 – Select Sample ID Mode display**

On the **Select Protocol** display, "BARCODE" appears on the bottom of the display.

- 3 Tap  on the **Select Protocol** display to continue.
- 4 On the **Select Protocol Variation** display, select the desired run variation.



**Figure 6-17 – Select Protocol Variation display**

*Prep Only:* the SlidePrep will prepare slides from specimen samples, but not stain with hematoxylin and EA/OG.

*Stain Only:* the SlidePrep will only stain slides (that already have a cell layer) with hematoxylin and EA/OG. For this protocol, the SlidePrep will not transfer specimen from c-tubes onto slides.

*Prep and Stain:* the SlidePrep will transfer specimen from c-tubes to slide and stain with hematoxylin and EA/OG.

- If no additional run variation protocols have been created, the above three options are the only ones listed. Select the desired protocol and tap the SETUP RUN button to continue.
- If any additional run variations have been created, they will also appear in list form. Select the desired variation by tapping the name in the list and tap the SETUP RUN button to continue.
- To modify a protocol, tap the MODIFY button. The user will be prompted for a password and information on the new protocol modification. See Section 7.4.1 for more information on modifying protocol variations.
- To remove an existing protocol variation, tap the name desired and hit the REMOVE button. The Prep Only, Stain Only, and Prep and Stain protocols cannot be removed, and the REMOVE button is gray/not functional when any of these protocols is selected. Also, once you remove a modified protocol, any run reports reprinted after that will not show the run parameters. Therefore, always print any necessary run reports before removing that modified protocol.

- 5 Load DASR.

**NOTE**

For Stain Only runs, there are no c-tube racks to load and this display does not appear.



Figure 6-18 – Load DASR display



Figure 6-19 – DASR contents

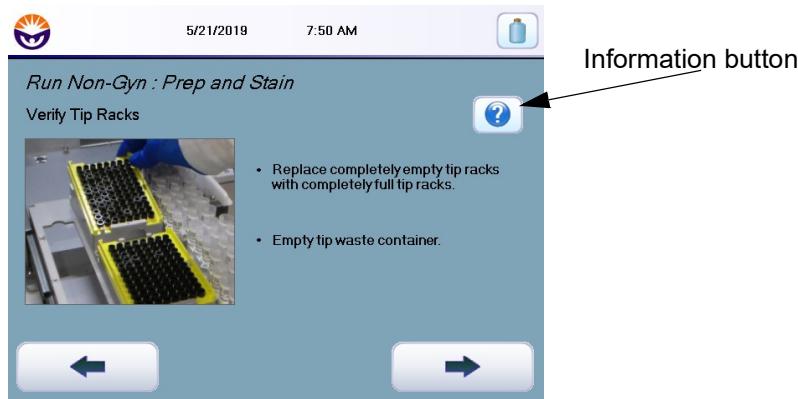
- a Open the DASR door and slide the drawer to its outermost position.
- b Load the c-tube racks containing specimens into the c-tube rack holders. C-tube rack 1 is in front. C-tube racks fit into their correctly aligned position only with the proper rack number and orientation (tube 1 at lower left). If the rack does not slip into place, check for proper c-tube rack slot and orientation.
- c Ensure there is one full rack of tips (verifying tip racks will also be performed later).

**NOTE**

There are several locations on the DASR for loading a reagent kit, a control kit, and a mixing tube. These reagents are not used in the Non-Gyn protocol and do not need to be loaded onto the DASR.

- d Slide the DASR drawer back into position until it locks in place.
- e Close the DASR door.  
If needed, additional information for loading the DASR can be found by clicking on the information button. The Load DASR message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.
- f Tap ⇒ to continue.

- 6 Verify tip racks and empty the tip waste container.



**Figure 6-20 – Verify Tip Racks display**

- Open the DASR door and slide the drawer to its outermost position.
- Ensure that there is at least one full rack of tips. Replace any completely empty tip racks with a completely full rack. If one rack is empty and one rack is partially full, leave the partially full rack in place as the SlidePrep remembers where it last used a tip and will restart there (the slot holding the full rack will vary from run to run depending on usage).
- Slide the DASR drawer back into position until it locks in place and close the DASR door.
- Empty the tip waste container. The tip waste container sits on the left side of the SlidePrep, outside of the instrument enclosure and is secured to the SlidePrep on two prongs. Slide the tip waste container up off the prongs and dispose of the tips in an appropriate waste container. Place the container back on the side of the SlidePrep by locking onto prongs.

If needed, a summary of the verify tip racks steps can be found by clicking on the information button. The Verify Tip Racks message box appears. Tap the CLOSE button to exit the details box.

- Tap to continue.

- Scan sample tubes.

*For Stain Only runs, there are no sample tubes to scan and this display does not appear.*

The **Scan Sample Tubes** display allows for either barcode reader or manual entry of sample identification (Figure 6-21).

A c-tube rack picture is depicted toward the left of the display, with an identification display depicted to its right. As barcodes are entered from the c-tube samples, the barcode is filled in at the appropriate spot on the identification display.

Sample tube barcodes must be scanned in the correct sequence, as depicted on the display.

To enter sample identification using the barcode reader:

- Verify all c-tubes have a valid barcode attached to the outside of the tube and the barcode contains only one sample ID.
- Starting with c-tube rack 1, pick up the first c-tube to be scanned and scan the label using the handheld barcode reader.

The barcode reader normally operates in “continuous mode” where it automatically reads the presented barcode. To switch to trigger mode, where the barcode trigger must be depressed to scan a barcode, simply press and release the trigger.

- As a barcode is scanned, the information appears in the display. Repeat scanning for all barcodes to be scanned. The display highlights the next c-tube position by default. Scan c-tubes in the sequence highlighted on the display.

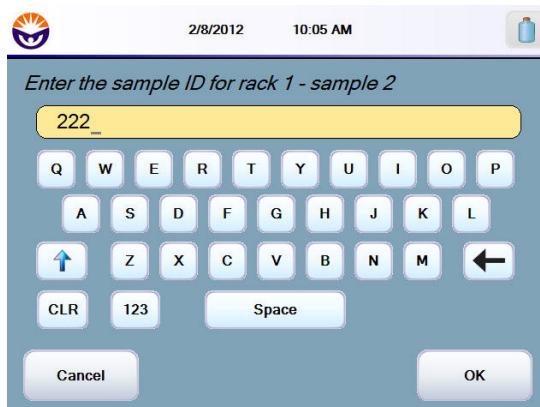
If the wrong barcode is accidentally scanned, correct it by following the procedure below for manual entry.

To enter sample identification using the manual-entry keyboard:

- Tap the desired location on the identification display then tap the keyboard button on the bottom right side of the display (See Figure 6-21).
- Using the virtual keyboard that appears (Figure 6-22), enter the desired sample identification, up to 18 characters. Both letters and numbers can be used; the keyboard is switched using either the “123” or “ABC” button at the bottom of the keyboard. Certain characters, as present on the display, are also available.
- Press OK on the keyboard when finished to return to the **Scan Sample Tubes** display.
- Repeat these steps for all samples that require keyboard entry for identification.



**Figure 6-21 – Scan Sample Tubes display**



**Figure 6-22 – Sample identification keyboard**

Samples not yet entered have no fill color. A sample that is currently selected for identification is colored yellow. And a sample that has already been entered is colored green.

On the far left side of the display, the highlighted c-tube rack indicates which c-tube rack (1, 2, 3, or 4) is currently being entered. C-tube rack 1 is highlighted first. When one rack is completed, tap the picture for the next rack to start scanning or entering barcodes. On the display, c-tube rack 1 is at the bottom, and c-tube rack 4 is at the top.

On the top right of the display a box indicates the total number of specimen samples that have been scanned.

If needed, a summary of the scan sample tubes steps can be found by clicking on the information button. The Scan Sample Tubes message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

When all barcode reader or keyboard entry of samples is complete, tap the “Next” button on the **Scan Sample Tubes** display.

- 8 Load slide trays.
  - a Place labeled slides, with settling chambers, onto slide trays if not already done during pre-processing. For Stain Only runs, the slides should already have a cell layer inside the settling chamber.  
Ensure that the labeled slides correspond to labels or patient identification on the c-tubes.  
Load slides onto slide trays without spaces in between.  
If you are processing more than one slide per sample, load slides onto separate slide trays. For example, if you are generating one unstained, and two stained slides, load these slides onto separate slide trays.
  - b Open slide tray doors and slide the slide trays into their corresponding STS. Slide the trays back until they lock into place. Trays should be loaded so that the engraved triangle that indicates position 1 is towards the user.

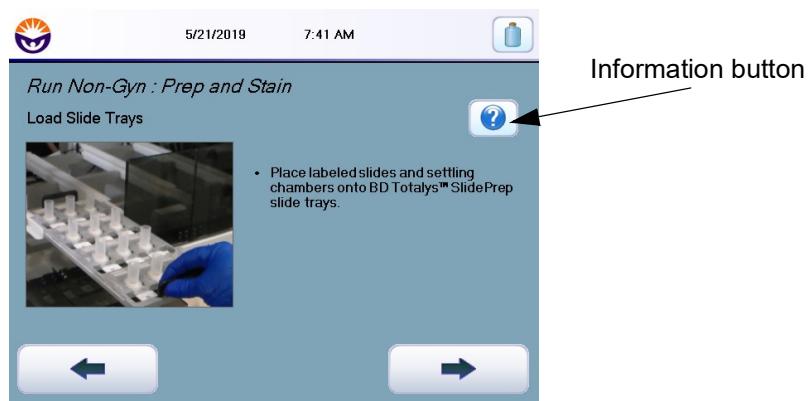
**NOTE**

Trays are channeled so that they fit properly into position only if they are placed in the proper orientation and correct STS in the SlidePrep.

- c Close the slide tray doors.

If needed, a summary of the load slide trays steps can be found by clicking on the information button. The Load Slide Trays message box appears. Use the slide bar to scroll the instruction list. Tap the CLOSE button to exit the information box.

- d Tap ➔ to continue.



**Figure 6-23 – Load Slide Trays display**

- 9 Scan slides.

The **Scan Slides** display allows for either automatic scanning or manual entry of slide identification (Figure 6-24).

C-tube racks are depicted on the left side of the display, with a slide tray identification display depicted to the right. As barcodes are entered from the slides, the barcode will be filled in at the appropriate spot on the slide tray rack. The c-tube racks have colored circles in any sample position where a sample ID was entered.

For automatic scanning of slide barcodes:

- Verify all slides have a valid barcode label attached containing a single sample ID.
  - Press the SCAN SLIDES button.
- All slides are scanned until slide barcodes match specimen samples.

For handheld barcode reader entry of slide barcodes:

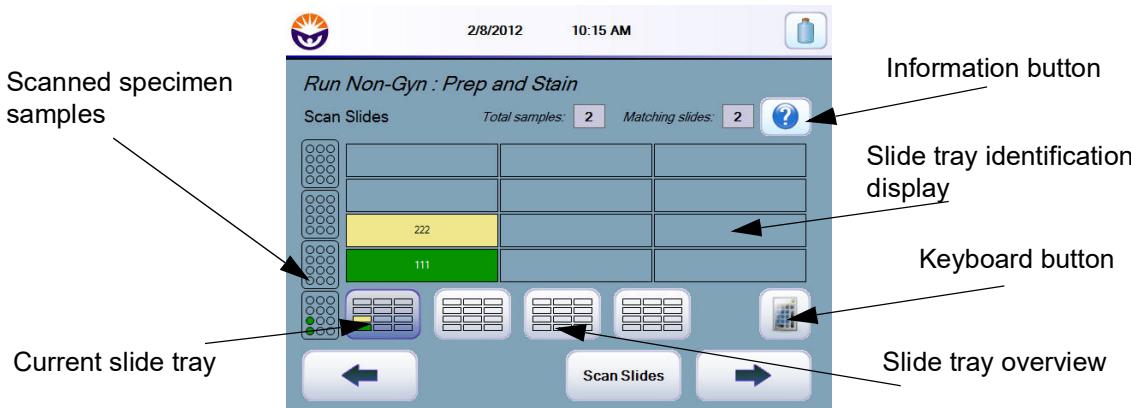
- Verify all slides have a valid barcode label attached containing a single sample ID.
- Starting with slide tray 1, slide the tray out and scan the label using the handheld barcode reader.

The barcode reader normally operates in “continuous mode” where it automatically reads the presented barcode. To switch to trigger mode, where the barcode trigger must be depressed to scan a barcode, simply press and release the trigger.

- As a barcode is scanned, the information appears in the display. Repeat scanning for all barcodes to be scanned.

To enter sample identification using the manual-entry keyboard:

- a Tap the desired slide tray location on the **Scan Slides** display then tap the keyboard button on the bottom right side of the display (See Figure 6-24).
- b Using the virtual keyboard that appears, enter the desired sample identification, up to 18 characters. Both letters and numbers can be used; the keyboard is switched using either the “123” or “ABC” button at the bottom of the keyboard. Certain characters, as present on the display, are also available.
- c Press OK on the keyboard when finished to return to the main **Scan Slides** display.
- d Repeat these steps for all samples that require keyboard entry for identification.



**Figure 6-24 – Scan Slides display**

Slides not yet entered have no fill color. A slide that is currently selected for identification is colored yellow. A slide that has already been entered is colored green if the barcode matches the specimen/c-tube barcode, but is red if the barcode does not match the specimen/c-tube barcode. The “Next” button to proceed to the next display does not appear until the slide barcodes match the previously entered specimen barcodes.

Across the bottom of the display, the highlighted slide tray indicates which slide tray (1, 2, 3, or 4) is currently being entered. Slide tray 1 is highlighted first. When one tray is completed, tap the picture for the next tray to start scanning. On the display, slide tray 1 is on the left, and slide tray 4 is on the right.

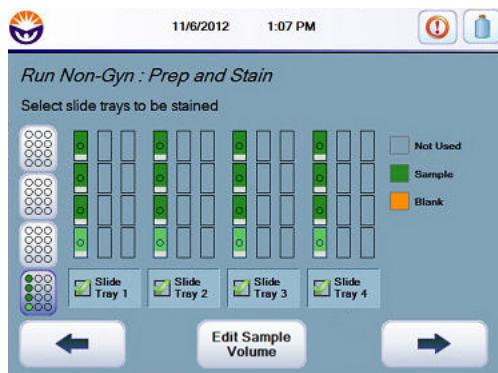
On the top right of the display a box indicates the total number of specimen samples that have been scanned as well as the number of matching slide identifications. The matching slide identification is counted for the first slide’s sample ONLY (i.e. if there is more than one slide per sample, the matching slide is counted after the first’s slide’s barcode matches).

If needed, a summary of the scan slides steps can be found by clicking on the information button. The Scan Slides message box appears. Use the slide bar to scroll the instructions list. Tap the CLOSE button to exit the information box.

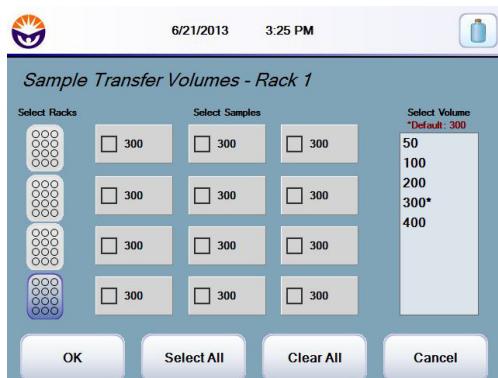
When all automatic or keyboard entry of samples is complete, tap the “Next” button on the **Scan Slides** display.

10 Select slide trays to be stained and edit sample transfer volume.

The **Select Slide Trays to be Stained** display allows you to select stain options and edit the sample transfer volume if needed.



**Figure 6-25 – Select Slide Trays to be Stained display**



**Figure 6-26 – Sample Transfer Volumes display**

- C-tube rack graphics on the left side of the display indicate sample locations (green).

**NOTE**

In Stain Only runs, there are no c-tube racks associated with the slide trays and therefore, no c-tube racks appear on this display.

- Slide tray graphics in the center of the display show where all sample slides (green) and blank slides (orange) should be located.
  - The light green color shows which sample and slide are linked. Each time the c-tube rack graphic is tapped, the next sample and slide are highlighted light green.
- To deselect staining (Prep and Stain runs) for a particular tray, click on the box below that slide tray. A checkmark in the box indicates that tray is selected for staining.
  - To adjust the sample transfer volume for any samples in the run, tap the EDIT SAMPLE VOLUME button at the bottom of the display.

- c On the **Sample Transfer Volumes** display (Figure 6-25), the sample transfer volume for each slide are presented.
  - C-tube rack graphics on the left side of the display show all four c-tube racks.
  - The graphic in the center of the display shows the sample transfer volume for each c-tube in the selected c-tube rack.
  - The options for sample transfer volume are shown in the column on the right side of the display (the options that are available vary depending on the number of slides per sample selected).
- d To change the volume, tap on the desired c-tube rack:

**NOTE**

All slides for a particular sample use the same sample transfer volume.

- If all samples in the rack need the same sample transfer volume, tap the SELECT ALL button at the bottom of the display, then tap the desired sample transfer volume from the list on the right. When finished, tap the OK button.
- If only particular samples need a different sample transfer volume, tap the sample, then tap the desired sample transfer volume from the list on the right. Repeat for all necessary samples, then tap the OK button.
- Repeat for all c-tube racks that contain samples not using the default sample transfer volume.

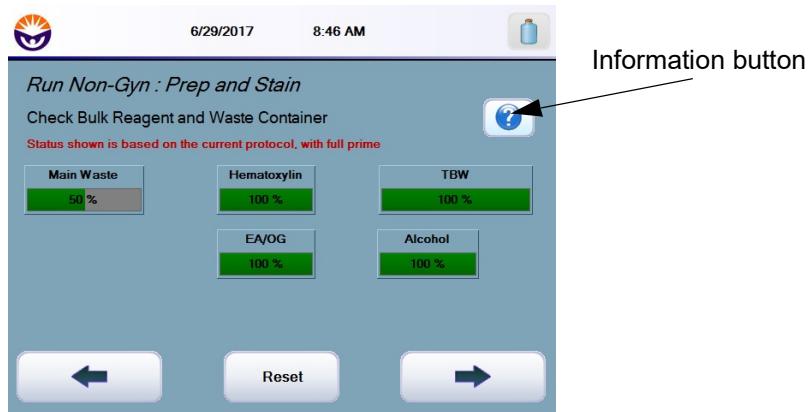
- e Tap  $\Rightarrow$  to continue.

- 11 Check bulk reagent and waste containers.

The **Check Bulk Reagent and Waste Container** display shows the percentage volume in each container.

**NOTE**

If you switch reagents between tests (e.g., use a different hematoxylin) you must rely on visual confirmation of volume if the new reagent bottle is not full because the counters only reset to 100%.



**Figure 6-27 – Check Bulk Reagent and Waste Container display**

- Prepare and fill the bulk reagent containers as needed for the following reagents:
  - Tris buffered water (TBW)
  - Alcohol blend rinse
  - Hematoxylin
  - EA/OG

**NOTE**

Other bulk reagent bottle positions are present on the bulk reagent station (AUX 1, 2, and 3 reagents), however these reagents are not used for the Non-Gyn protocol and do not need to be checked for volume or connected to tubing.

In locations where no reagent bottle is present, leave the tubing connected to the bulk reagent station base.

**NOTE**

For Prep Only runs, hematoxylin and EA/OG reagents are not used and do not need to be checked for volume or connected to tubing.

- Verify the waste containers have sufficient capacity. Empty as needed into an appropriate waste collection container.
- Verify all tubing is correctly connected to its respective container.

Reagent containers: if the tubing quick disconnect port is attached to the bulk reagent station base, remove it by turning the port counter-clockwise. Attach the quick disconnect port to the reagent container's lid by turning the port clockwise onto the lid.

Main waste container: Attach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

Aux waste container: Some instruments have a waste diverter valve that supports two liquid waste containers. For those instruments, attach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid. All tubing must be connected to the appropriate waste bottle for proper vacuum function.

Scrubbing muffler container: Attach the tubing from the SlidePrep to the clip on the scrubbing muffler lid.

- d For any reagent containers that were filled, or waste containers that were emptied, tap the appropriate area on the **Check Bulk Reagent and Waste Container** display and hit the RESET button. This will return the reagent to 100% (indicating 100% full) or the waste to 0% (indicating 0% full).

The fill volumes are then adjusted automatically by the SlidePrep based on use.

If needed, a summary of the check bulk containers steps can be found by clicking on the information button. The Check Bulk Reagent and Waste Container message box appears. Use the slide bar to navigate the instructions list. Tap the CLOSE button to exit the information box.

- e Tap  $\Rightarrow$  to continue.

## 12 Prime Fluids.

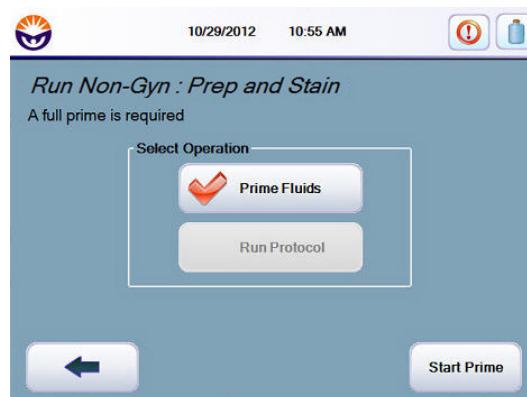
A full prime is required if this is the first run after any cleaning event, the first run after power-on, or if the RUN PROTOCOL button on the **Prime Fluids** display is inactive. This action primes the fluid lines and eliminates any air bubbles in the lines.

- a When this display first appears, the PRIME FLUIDS button is already selected\*, and the RUN PROTOCOL button is grayed out and inactive.

\*If this is not the first run after a cleaning event or power-on the RUN PROTOCOL button is active and selected:

- Unless you notice any air bubbles in the fluid lines or have just replaced a reagent, you do not need to perform the prime fluids when the RUN PROTOCOL button is already active. Proceed to step 13.
- If you do notice any air bubbles or have just replaced a reagent, tap the PRIME FLUIDS button to select it and follow the rest of the steps in this procedure.

- b Tap the START PRIME button to prime the fluid lines. The SlidePrep automatically performs the fluid prime.



**Figure 6-28 – Prime Fluids display**

- c Once prime fluids is complete, the RUN PROTOCOL button becomes active with a red checkmark and the START PRIME button changes to START RUN.

**NOTE**

If you need to re-run the prime fluids protocol, tap on the PRIME FLUIDS button so that it is highlighted with the red checkmark, then tap the START PRIME button on the bottom of the display.

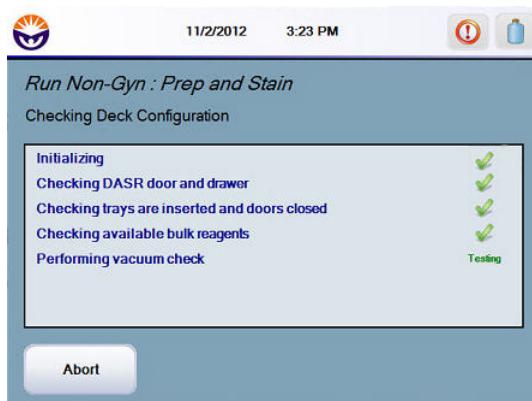
- 13 Tap the START RUN button on the **Prime Fluids** display to start the run. The **Checking Deck Configuration** display appears (Figure 6-29).

The SlidePrep starts operating at this point. However, **do not walk away from the instrument**; if the check deck configuration fails, additional action(s) may be required.

**WARNING**

**THE PIPETTING INSTRUMENT IS A ROBOTIC DEVICE THAT OPERATES UNDER COMPUTER CONTROL. AS WITH MOST ROBOTIC DEVICES, THERE IS A POTENTIAL FOR INJURY AND BODILY HARM FROM MOVING MECHANICAL COMPONENTS WHENEVER THE SLIDEPREP IS IN OPERATION. THE SLIDEPREP IS DESIGNED FOR AUTOMATIC "HANDS-OFF" OPERATION ONLY. IF A TRAY DOOR IS OPENED, THIS GENERATES AN ERROR AND THE DOOR MUST BE CLOSED WITHIN FIVE SECONDS BEFORE OPERATIONS CEASE.**

For the check deck configuration, the SlidePrep checks that configured slide trays and the DASR drawer are completely inserted and that all tray and DASR doors are closed. The levels of the bulk reagents are checked and a vacuum check is performed on all tubing. Figure 6-29 shows the **Checking Deck Configuration** display.



**Figure 6-29 – Checking Deck Configuration display**

The operator can abort the check deck configuration by tapping the ABORT button.

For each deck component tested the status appears as Pending, Testing, Error (test failed), Aborted (operator aborted check), or a green checkmark for passing the test. If a condition fails, an error message is shown indicating which check failed. An intermittent alarm sounds to alert the operator of the failure. Choose CLOSE to exit the message box. The ABORT button changes to SELECT PROTOCOL and the RETRY button is added. If the condition is remedied, tap the RETRY button to begin the check deck configuration again. Otherwise tap the SELECT PROTOCOL button to return to the **Main Menu** display and reset conditions for the run.

A warning may also pop up if monthly or weekly maintenance needs to be performed. Note the information and tap the CLOSE button. Either tap SELECT PROTOCOL to return to the **Main Menu** display and perform the required maintenance procedures, or tap RETRY to continue the run. The first check deck configuration step, “Initializing,” will then have a status of Ignored.

- 14 Once the check deck configuration process is completed successfully, the selected protocol immediately starts.

Information on sample processing during the run (Section 6.6.3), assay progress reports (Section 6.7) and completed slide trays and samples (Section 6.8) are below.

### 6.6.3 Sample Processing

#### Non-Gyn Prep and Stain Runs

During a Non-Gyn Prep and Stain run, the following steps are performed by the SlidePrep:

- 100 µL of tris buffered water is added to each settling chamber, followed by 1,000 µL of tris buffered water to each c-tube.
- A transfer tip is used to mix the cell pellet 8 times, then 300 µL (default sample transfer volume) is transferred to the settling chamber where it is allowed to settle for a minimum of 10 minutes. During this time cells adhere to the BD SurePath™ PreCoat Slides to form a thin layer of cells.
- 600 µL of alcohol blend rinse and 600 µL of tris buffered water are added to rinse slides.
- 300 µL of hematoxylin and 300 µL of EA/OG are added to slides for Papanicolaou staining.

#### Non-Gyn Prep Only Runs

During a Non-Gyn Prep Only run, the following steps are performed by the SlidePrep:

- 100 µL of tris buffered water is added to each settling chamber, followed by 1,000 µL of tris buffered water to each c-tube.
- A transfer tip is used to mix the cell pellet 8 times, then 300 µL (default sample volume) is transferred to the settling chamber where it is allowed to settle for a minimum of 10 minutes. During this time cells adhere to the BD SurePath™ PreCoat Slides to form a thin layer of cells.
- Rinsing steps are performed: 600 µL of alcohol blend rinse, 300 µL of tris buffered water, and 300 µL of alcohol blend rinse.

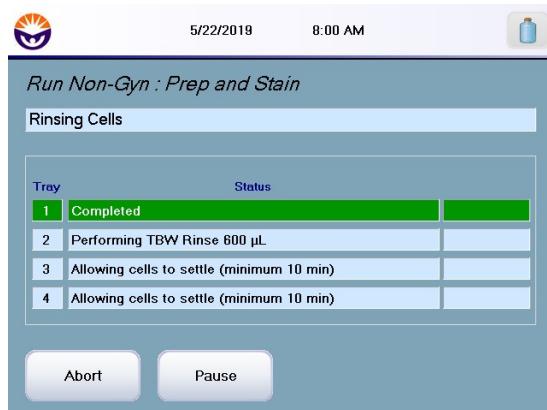
#### Non-Gyn Stain Only Runs

During a Non-Gyn Stain Only run, the following steps are performed by the SlidePrep:

- 600 µL of alcohol blend rinse and 600 µL of tris buffered water are added to rinse slides.
- 300 µL of hematoxylin and 300 µL of EA/OG are added to slides for Papanicolaou staining.

## 6.7 Non-Gyn Protocol Progress Reports

While a Non-Gyn protocol is underway, monitor the current status of the process on the SlidePrep display (Figure 6-30).



**Figure 6-30 – Non-Gyn Protocol Progress Report display**

The **Non-Gyn Protocol Progress Report** display shows the current step performed. For each slide tray, the sub process is displayed in the tray's corresponding status field. When a tray is completed, its reporting fields turn green and a message appears stating that the tray is completed and to remove the tray. Refer to Section 6.8 for information on completed slide trays.

There is typically nine to ten minutes between trays for completion.

### Pausing a Run

At any point, the protocol may be paused by tapping the PAUSE button. The system finishes its current action, then pauses and the reporting status field turns red. Tap the RESUME button to resume the protocol.

The pause and resume times appear on the run report.

If the system was paused during a step involving the vacuum pump, the pump will automatically shut off after 2.5 minutes.

#### NOTE

Pausing the SlidePrep for extended periods of time once the staining process has started could impact the quality of the slides produced, including but not limited to increased background staining. The impact on stain quality of pausing the system once the staining process has started has not been evaluated as part of the performance claims. Therefore, users are responsible for determining the acceptability of slides when using the pause function.

### Aborting a Run

At any point, the protocol may be aborted by tapping the ABORT button. A display appears to confirm the abort. If the run is aborted, the reporting status field turns red.

#### NOTE

Once aborted, the run cannot be restarted.

## 6.8 Completed Slide Trays and Samples

### 6.8.1 Completed Slide Trays

- When **each** slide tray is finished processing, its status is indicated as completed with an audible alert that continues every 30 seconds until acknowledged.

Open the appropriate slide tray door and remove the slide tray from the SlidePrep and follow the procedure below for rinsing and clearing the slides or staining slides, as needed.

#### CAUTION

**Leaving samples in alcohol for an extended length of time can cause the cells to de-stain.**

If an incorrect door (the door of an uncompleted slide tray) is opened during the run, an alarm sounds. **The door must be closed within five seconds to avoid an aborted run. Furthermore, actually pulling out a slide tray before it is completed instantly aborts the run.**

- When the SlidePrep finishes processing **all** trays, “Protocol Completed” appears in the status message, an alarm briefly sounds, the ABORT button disappears, and the PRINT REPORT and DONE buttons appear.
  - Tapping the PRINT REPORT button prints the run report to the default printer (see Section 2.4.2). Tapping the DONE button returns the program to the **Select Protocol** display.
  - See Section 7.7.4, Figure 7-27 for a sample run report.
  - If unable to print, the file in pdf format can be saved to a USB drive for printing elsewhere (see Section 7.7.4).

### 6.8.2 Quality Control Evaluation

Perform quality control slide evaluation on selected slides per the laboratory’s protocols.

### 6.8.3 Rinsing and Clearing Slides

These steps apply to slides prepared during Stain Only or Prep and Stain protocols of Non-Gyn runs.

- 1 After removing a slide tray from the SlidePrep, invert the slide tray to decant the alcohol from the slides. Before returning to an upright position, blot the excess alcohol from the settling chambers with an absorbent pad. Turn the slide tray right side up.
- 2 Taking one slide at a time, remove and discard the settling chamber, then follow the steps below.

**NOTE**

Do not remove all settling chambers at one time. This will result in air-drying of the slides.

- 3 Dehydrate the slide with 100% alcohol. This can be done by directing a stream of alcohol over the preparation using a squirt bottle or by dipping the slide ten times in an alcohol bath.
- 4 Once the slide has been dehydrated, immediately clear the slide with xylene or xylene substitute. This can be done by directing a stream over the preparation using a squirt bottle or by placing the slide into a xylene or xylene substitute bath. If using the latter method, at least two xylene or xylene substitute baths are recommended.  
Leaving samples in alcohol for an extended length of time can cause the cells to de-stain.
- 5 Slides may be coverslipped one at a time or batched together.  
Slides may be coverslipped manually or with an automated coverslipper.

**CAUTION**

Do not allow slides to dry prior to coverslapping.

### 6.8.4 Staining Slides

This procedure applies to slides prepared using the Prep Only protocol variation for Non-Gyn runs.

- 1 After removing a slide tray from the SlidePrep, invert the slide tray to decant the alcohol from the slides. Before returning to an upright position, blot the excess alcohol from the settling chambers with an absorbent pad. Turn the slide tray right side up.
- 2 Taking one slide at a time, remove and discard the settling chamber. To prevent slides from drying out, prepare them according to the laboratory's standard procedures, such as placing them into 95% alcohol.

**NOTE**

Do not remove all settling chambers at one time. This will result in air-drying of the slides.

- 3 Perform staining procedures as needed according to the laboratory's standard protocols.

### 6.8.5 Completed Samples

After completion on the SlidePrep, samples may be re-run if needed. To prepare samples for any potential retesting, perform the following steps:

- 1 Open the DASR door and remove c-tube racks from the SlidePrep.
- 2 Prepare and store samples according to the laboratory's approved standard operating procedures.
- 3 Refer to the laboratory's approved standard operating procedures for the pre-processing steps needed for retesting.

## 6.9 Cleanup and Shutdown

### 6.9.1 Instrument and Reagent Cleanup

Once you have removed slides and slide trays from the SlidePrep, you can either run another batch or perform any required maintenance (below).

- Perform the daily maintenance procedure if appropriate (Section 8.3).
- Perform the weekly maintenance procedure if appropriate (Section 8.4).
- Perform the monthly maintenance procedure if appropriate (Section 8.5).

### 6.9.2 Instrument Shutdown

The steps below describe the procedure for shutting down the SlidePrep. However, the system power should remain on at all times unless directed by BD service personnel.

- 1 From the **Main Menu** display, tap the SHUTDOWN button.
- 2 A popup information box asks to confirm the shutdown procedure. Tap YES to continue or NO to return to the **Main Menu** display.
- 3 After tapping YES an additional popup information box appears with instructions to turn off power to the SlidePrep after the screen goes blank. Tap CONTINUE to proceed or CANCEL to return to the **Main Menu** display.
- 4 After tapping CONTINUE, wait for the software to shutdown and the screen to go blank. Turn off power to the SlidePrep pressing the toggle switch on the back left side of the SlidePrep to the off position.



# 7 – Reference

## 7.1 General

This section presents reference material on the BD Totalys™ SlidePrep user interface as well as information to perform the various available utility tests on the SlidePrep. The following information is presented:

- Software tree (Section 7.2)
- Main Menu display (Section 7.3)
- Select Protocol display (Section 7.4)
- Maintenance display (Section 7.5)
- System Setup display (Section 7.6)
- Utilities Menu display (Section 7.7)

## 7.2 Software Tree

The following is a hierarchical list of the SlidePrep displays/functions.

### Main Menu display

#### Select Protocol display

BD SurePath™ Liquid-based Pap Test

Non-Gyn

#### Maintenance display

Daily Maintenance

Weekly Maintenance

Monthly Maintenance

#### System Setup display

Date and Time

Default Printer

Password

Select DASR Type

### Utilities Menu display

- Reporting
- Logs
- Run Reports
- Random XYZ Test
- Disposable Tip Handling Test
- Vacuum Deck
- Prime Syringe
- Barcode Test

## 7.3 Main Menu Display

The main menu is used to access all functions of the SlidePrep as well as perform system shutdown.



**Figure 7-1 – Main Menu display**

#### SlidePrep function buttons

These buttons are used to access the system's activities: Select Protocol, Maintenance, System Setup and Utilities.

#### Information header

This bar at the top of the Main Menu display presents the system name, software version, and the date and time as set up in System Setup (see Section 2.4.2).

#### Shutdown button

This button is used for system shutdown. Refer to Section 5.8 or Section 6.9 for the shutdown procedure.

### Other buttons

Several other functional and informational buttons are present on the Main Menu display, some of which may also be present on other displays:

Button Icon	Name and Function
	<p>Warning button Appears on displays to provide any warning information and/or whether any user action is required. Often this button appears when maintenance is required. When the indicated user action is performed, the button disappears from displays.</p>
	<p>Bulk Reagent and Waste Management button This button appears on all displays and can be pressed to view the status of the bulk reagent and waste containers. This button cannot be selected during an assay run or during the daily or weekly maintenance tubing flushing steps. For any reagent containers that were filled, or waste containers that were emptied, tap the appropriate area and hit the RESET button. This will return the reagent to 100% (indicating 100% full) or the waste to 0% (indicating 0% full). Tap the CLOSE button to exit.</p>
	<p>System Information button This button presents a read-only display with system information including: serial number, software version, last cleaning events, and last run events. Tap the CLOSE button to exit.  Note: when present anywhere other than the <b>Main Menu</b> display, this button provides a summary of the steps used in that display.</p>

## 7.4 Select Protocol Display

Tap the SELECT PROTOCOL button on the **Main Menu** display to access the BD SurePath™ and Non-Gyn protocols for SlidePrep operation.

Refer to any of the slide processing operation sections for further information on SlidePrep operation for the various assays.

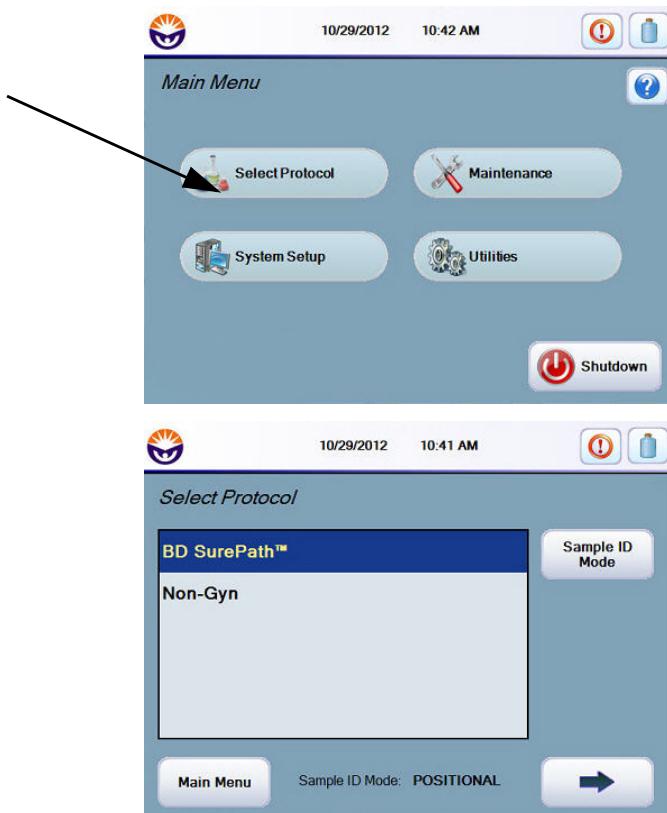


Figure 7-2 – Main Menu and Select Protocol display

### 7.4.1 Modify Protocol Variation

From the **Select Protocol** display for either BD SurePath™ or Non-Gyn, tap the  $\Rightarrow$  to view the **Select Protocol Variation** display.



**Figure 7-3 – Select Protocol Variation display**

To create new protocol variations:

**NOTE**

Any setting modified from the original protocol variations (prep only, stain only, and prep and stain) must be independently validated in accordance with your site's procedures. All performance claims made by BD were validated utilizing default parameters only.

- 1 Tap the desired protocol to modify.
- 2 Tap the MODIFY button.
- 3 Enter the password that was setup during installation.
- 4 On the list that appears, tap the desired parameter to modify and tap CHANGE VALUE.
- 5 Use the keyboard to enter a new value and tap OK.
- 6 Tap either SAVE NEW to save the protocol variation and apply a name, or START RUN to process only that particular run with the new parameter(s).

**NOTE**

The original protocol variations (prep only, stain only, and prep and stain) are always saved as-is and cannot be overwritten.

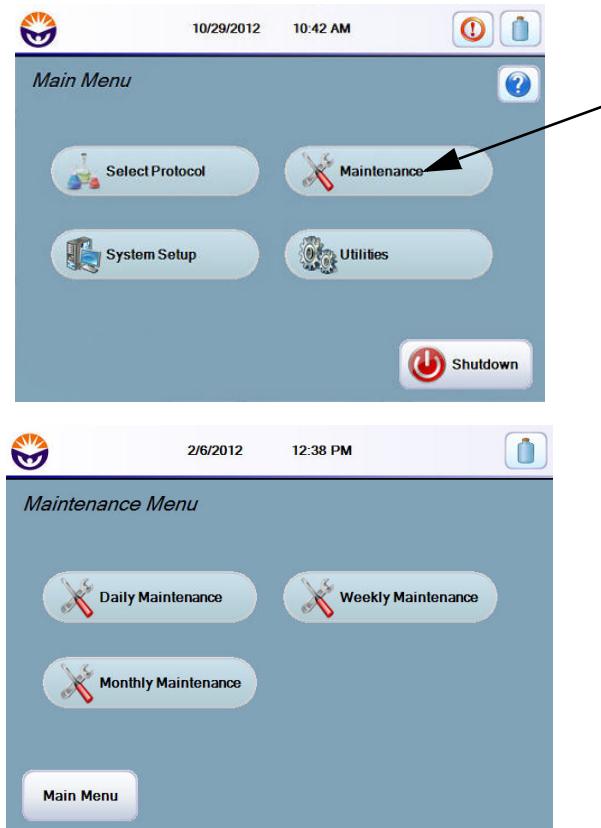
The table below lists the defaults and allowable limits for the various protocol variation parameters.

<u>Parameter Name</u>	<u>Limits</u>	<u>Prep Only Default</u>	<u>Stain Only Default</u>	<u>Prep and Stain Default</u>	<u>Definition</u>
<b>BD SurePath™ Liquid-based Pap Test</b>					
Mix Cycles	8–15	8	n/a	8	The number of times that the diluted sample is pumped in and out of the disposable tip to resuspend the cell pellet.
Sample Volume	100–500 µL	200 µL	n/a	200 µL	The amount of sample transferred to the settling chamber.
Drying Time	55–300 secs (Prep and Stain / Stain Only) 70–300 secs (Prep Only)	70 secs	60 secs	60 secs	The amount of time allowed for the cells to dry onto the BD SurePath™ PreCoat Slide.
Hematoxylin Time	55–180 secs	n/a	85 secs	85 secs	The amount of time allowed for cells to absorb the hematoxylin stain.
EA/OG Time	55–180 secs	n/a	75 secs	75 secs	The amount of time allowed for the cells to absorb the EA/OG stain.
TBW Wash Cycles	1–9	n/a	2	2	The number of TBW cycles used to wash the slide after hematoxylin staining is complete.
Alcohol Wash Cycles	1–9	n/a	3	3	The number of alcohol cycles used to wash the slide after EA/OG staining is complete.
<b>Non-Gyn Protocol</b>					
Mix Cycles	1–15	8	n/a	8	The number of times that the diluted sample is pumped in and out of the disposable tip to resuspend the cell pellet.
Sample Volume	50–800 µL	300 µL	n/a	300 µL	The amount of sample transferred to the settling chamber.
Sedimentation Time	0–1,200 secs	600 secs	n/a	600 secs	The amount of time allowed for the cells to settle onto the BD SurePath™ PreCoat Slide.
Drying Time	55–300 secs	60 secs	n/a	60 secs	The amount of time allowed for the cells to dry onto the BD SurePath™ PreCoat Slide.
Hematoxylin Time	55–180 secs	n/a	55 secs	55 secs	The amount of time allowed for cells to absorb the hematoxylin stain.
EA/OG Time	55–360 secs	n/a	65 secs	65 secs	The amount of time allowed for the cells to absorb the EA/OG stain.
TBW Wash Cycles	1–9	n/a	3	3	The number of TBW cycles used to wash the slide after hematoxylin staining is complete.
Alcohol Wash Cycles	1–9	n/a	5	5	The number of alcohol cycles used to wash the slide after EA/OG staining is complete.

## 7.5 Maintenance Display

Tap the MAINTENANCE button on the **Main Menu** display to access the daily, weekly and monthly maintenance procedures for the SlidePrep.

Refer to Section 8 for further information on SlidePrep maintenance.

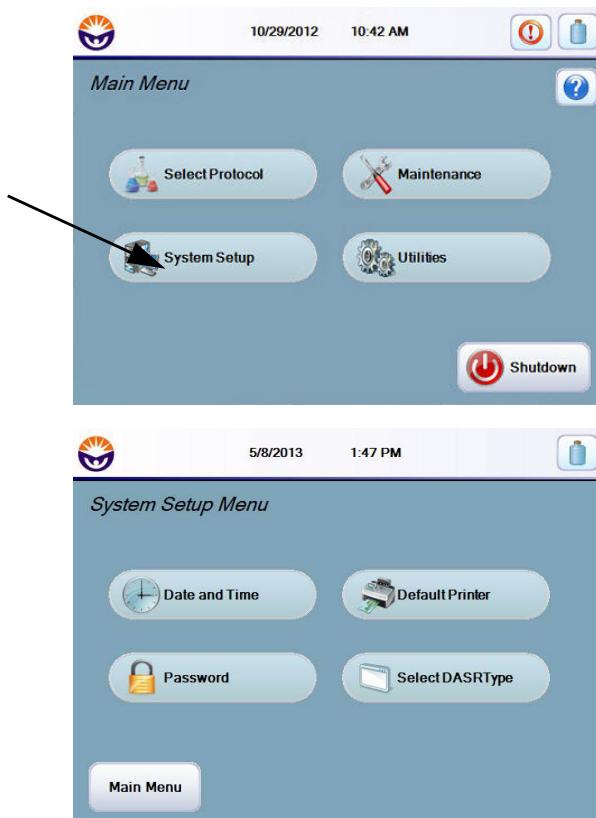


**Figure 7-4 – Main Menu and Maintenance displays**

## 7.6 System Setup Display

Tap the SYSTEM SETUP button on the **Main Menu** display to access the default printer, date and time, password setup, and select DASR type features for the SlidePrep.

Refer to Section 2.4.2 for further information on selecting the default printer and setting the date and time.



**Figure 7-5 – Main Menu and System Setup displays**

### 7.6.1 Passwords

On the **System Setup** display, tap the **PASSWORD** button to access password entry keypads for both service access and protocol variation. These passwords are used by service personnel for system access and users (with the appropriate password) to create new protocol variations.

## 7.6.2 Changing the DASR

If you need to switch your system's DASR from the MultiProcessor DASR to the Manual DASR (compatible with the BD PrepMate™ Automated Accessory), or vice versa, follow the procedure below. Once the DASR is changed, you must confirm the change using the **System Setup** display.

### CAUTION

**If you switch the DASR but do not confirm the DASR change in the software (step 5 below), the DASR setup will be incomplete and a system crash can result. Complete all steps in this section whenever changing between DASRs to avoid causing any system damage.**

#### Remove existing DASR

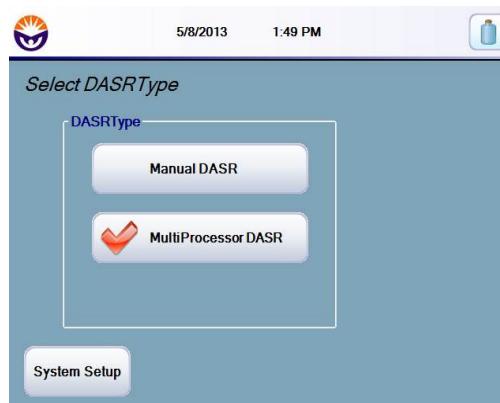
- 1 Open the DASR door and slide out the DASR to its outermost position.
- 2 Press the tabs located on either side of the DASR at the same time to unlock the DASR from its slides.  
The tab on the right side of the DASR faces down and the tab on the left side of the DASR faces up.
- 3 Once unlocked, remove the DASR and store in a secure location.

#### Install new DASR

- 4 Align the DASR with its slides and push in completely to lock into place.  
You can check whether the DASR is installed completely by pulling it back out: it should stop without being completely removed. Then push in: the slides should automatically pull the drawer completely closed.

#### Confirm DASR change

- 5 From the **System Setup Menu** display tap the SELECT DASR TYPE button. A **Select DASR Type** display appears.



**Figure 7-6 – Select DASR Type display**

- 6 Tap on the name of the new DASR type. A red checkmark appears next to the selected DASR.

7 Tap the SYSTEM SETUP button to save the change and return to the previous display.

## 7.7 Utilities Menu Display

Tap the UTILITIES button on the **Main Menu** display to access the various utility and diagnostic features of the SlidePrep. Use the up and down arrow button on the **Utilities Menu** display to scroll through the menu.

Refer to the sections below for the information and procedures associated with these displays.

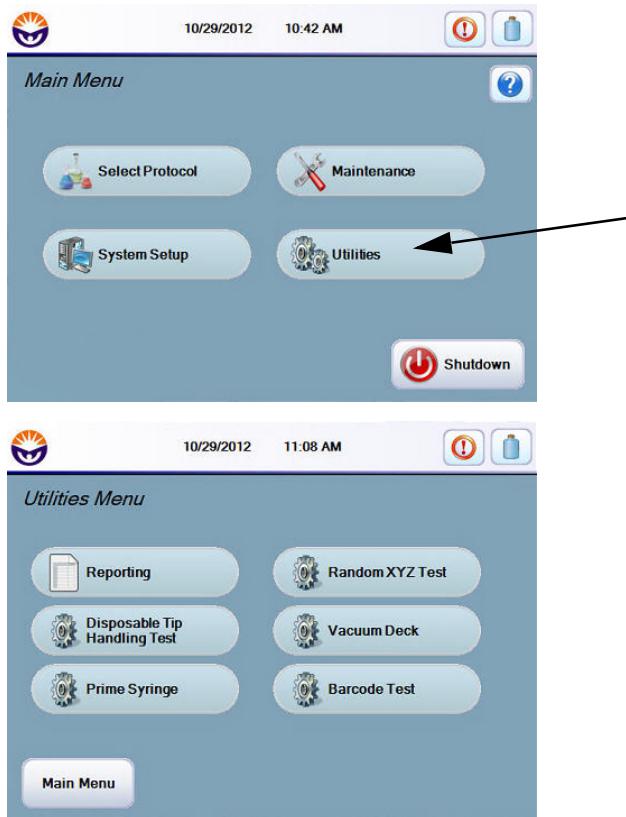
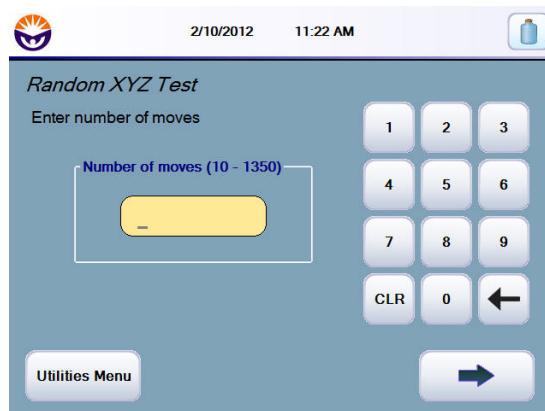


Figure 7-7 – Main Menu and Utilities Menu display

### 7.7.1 Random XYZ Test

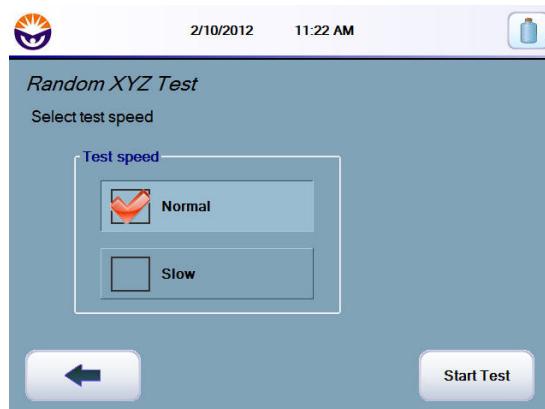
The Random XYZ Test automatically drives the robotic arm to random locations within the SlidePrep worktable, simultaneously recording information about errors, skipped steps, and the parameters of the current test cycle. This diagnostic tool will only be used when directed by service personnel.

- 1 From the **Utilities Menu** display, tap the RANDOM XYZ TEST button.
- 2 Enter the number of moves for the test (from 10–1,350 moves; 540 moves is recommended for a significant test). After entering the number of desired moves using the keypad, press  $\Rightarrow$  to continue.



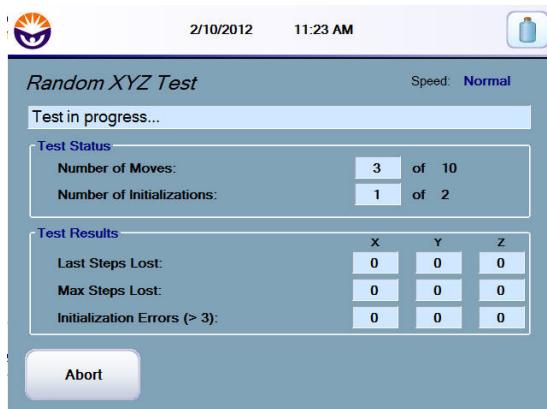
**Figure 7-8 – Random XYZ Test—Enter Number of Moves**

- 3 Choose either Normal or Slow test speed. “Normal” speed selection approximates the movement speed of the robotic arm during an assay run. Tap the START TEST button to begin.



**Figure 7-9 – Random XYZ Test—Select Test Speed**

- 4 The system runs the Random XYZ Test and shows the results on the Random XYZ Test Status display. To stop the run, choose ABORT. A display appears to confirm aborting the Random XYZ test. YES confirms the abort, NO continues the Random XYZ Test.



**Figure 7-10 – Random XYZ Test–Status display**

Figure 7-10 illustrates **Random XYZ Test Status** display. Listed in the table below are the acceptable test values for each parameter.

PARAMETER	ACCEPTABLE RESULTS
Number of moves	The number of moves completed by the arm out of the total number of moves entered. At least 540 moves should be completed in a random test.
Number of initializations	The number of initializations the arm has performed. A minimum of twenty initializations is recommended for a meaningful run.
Last steps lost	The number of steps lost between two initializations. This number must not exceed three.
Max steps lost	The number of steps lost during the entire test. This number must not exceed three.
Initialization errors	The number of errors occurring during an initialization cycle. This number must be zero (an error occurs if the number of steps lost between two initializations is greater than 3).

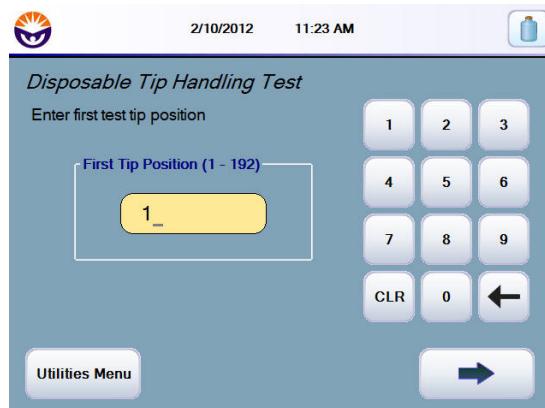
If acceptable results are not met, report to BD Technical Service and Support at: 1.800.638.8663, or contact your local BD representative.

- 5 When the test is completed, the status is displayed in the message bar. Tap the REPEAT button to repeat the test and navigate through the number of moves and speed dialog boxes again, or choose UTILITIES MENU to return to the **Utilities Menu** display.

## 7.7.2 Disposable Tip Handling Test

The Disposable Tip Handling Test records the pickup gaps associated with tip pickups and drop-offs. This diagnostic tool will only be used when directed by service personnel.

- 1 From the **Utilities Menu** display tap the DISPOSABLE TIP HANDLING TEST button.
- 2 Use the keypad on the display to enter the position of the first test tip to be handled (range is from 1–192). Tip one is in the tip rack 1 (furthest from the user on the DASR). It is the front left most tip in that rack. Press  $\Rightarrow$  to continue.



**Figure 7-11 – Disposable Tip Handling Test–Enter First Tip Position**

- 3 Use keypad to enter the number of tips to test (range is from 1–192). Tap the START TEST button to begin the tip handling test.



**Figure 7-12 – Disposable Tip Handling Test–Enter Number of Tip Positions**

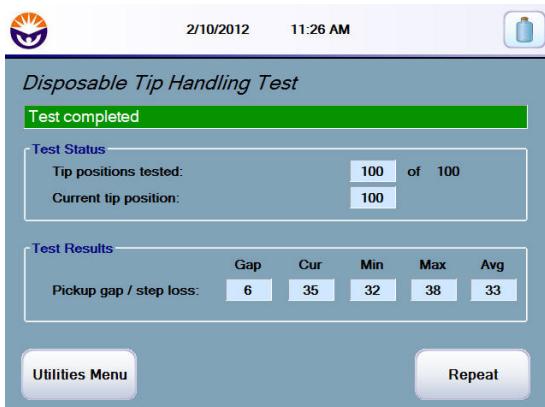
- 4 The system picks up a disposable tip, starting with the first test tip position entered, and drops it in the tip waste container. The DiTi performs a test to detect step losses after each drop off. To abort the run, choose ABORT. A display appears to confirm aborting the Disposable Tip Handling Test.
- 5 Figure 7-13 shows the **Disposable Tip Handling Test Status** display. The pickup gap should be six or fewer.

**If the pickup gap is not six or fewer, report to BD Technical Service and Support at: 1.800.638.8663, or your local BD representative.**



**Figure 7-13 – Disposable Tip Handling Test–Status display**

- 6 When the test is complete, the status is shown in the message bar. To repeat the test tap the REPEAT button and navigate through the tip position and number of tips dialog boxes again, or tap the UTILITIES MENU button to return to the **Utilities Menu** display.



**Figure 7-14 – Disposable Tip Handling Test–Completed display**

### 7.7.3 Logs

This utility is used for the management of logs that store information and errors from the processing run.

From the **Utilities Menu** tap REPORTING, then LOGS in the **Reporting Menu** display.

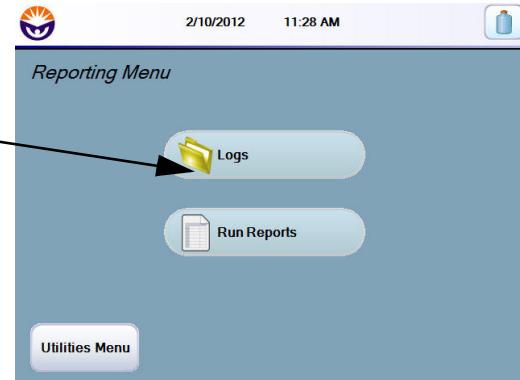


Figure 7-15 – Reporting Menu display

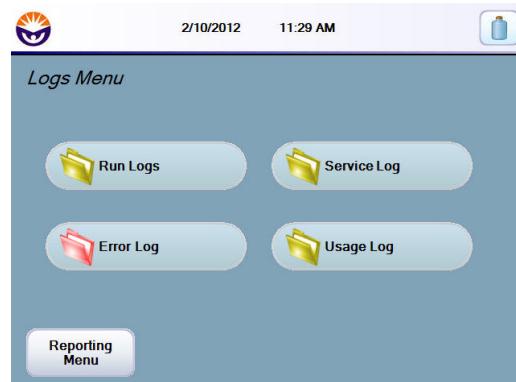
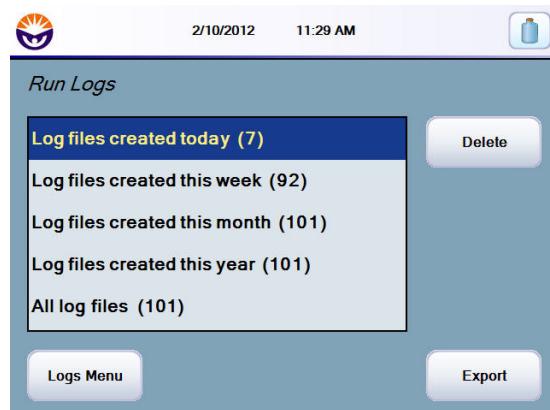


Figure 7-16 – Logs Menu display

### 7.7.3.1 Run Logs

Run logs are detailed logs of each run that contain all processing steps and any error information. These logs are typically many pages. Logs are kept for 90 days and are sorted by date.

- 1 In the **Logs Menu** display, tap the RUN LOGS button.
- 2 Select the desired set of logs by tapping the desired date range. Once selected, the logs can either be exported or deleted.



**Figure 7-17 – Run Logs display**

#### To delete the selected run logs:

Tap the DELETE button. A popup box asks for confirmation to permanently delete the file. Tap YES to continue with deletion or NO to abort the deletion.



**Figure 7-18 – Delete Log Files dialog box**

### To export the selected run logs:

Tap the EXPORT button. If no USB drive is detected, a dialog box appears requesting that one be inserted. After inserting a storage drive, click OK. In the **Run Logs** display, choose EXPORT again.



**Figure 7-19 – USB Drive Required dialog box**

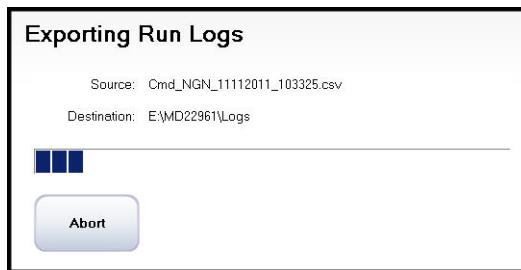
When exporting to a USB drive, a dialog box appears for selecting the USB drive to use for export. Select the drive from the list and save the run log by choosing OK or tap CANCEL to return to the **Run Logs** display.



**Figure 7-20 – Select USB Drive dialog box**

The **Exporting Run Logs** status dialog box appears with:

- a progress bar that indicates the status of the export
- text indicating the source (name) of the file being exported
- the destination and name given to the file being exported



**Figure 7-21 – Exporting Run Logs Status dialog box**

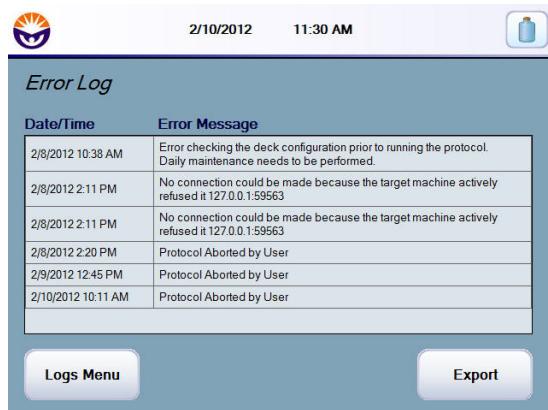
During the exporting process the export can be aborted by tapping the ABORT button. An **Abort Export Run Logs** message box appears asking confirmation to abort the export. Tap YES to abort the export or NO to continue with the export.

Tapping the LOGS MENU button returns the program to the **Logs Menu** display.

### 7.7.3.2 Error Log

The error log lists the date, time and specific error message for all recent errors.

- 1 In the **Logs Menu** display, tap the ERROR LOG button.
- 2 Use the up and down arrow buttons to scan the error message information.



**Figure 7-22 – Error Log display**

To export the error log, tap EXPORT. If no USB drive is detected, a dialog box appears requesting that one be inserted. After inserting a storage drive, click OK. In the **Error Log** display, choose EXPORT again.

**NOTE**

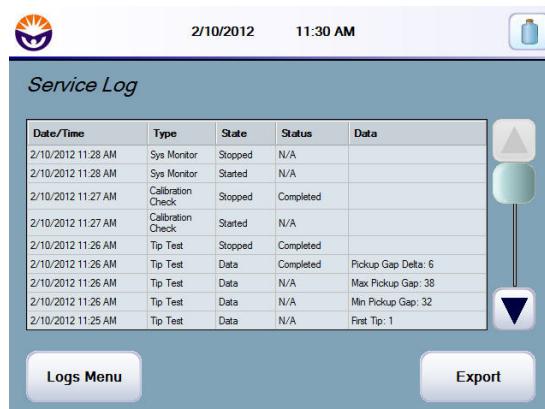
When exporting the error log, all logs are exported.

- 3 When exporting to a USB drive, a dialog box appears for selecting the USB drive to use for export. Select the drive from the list and save the error log by choosing OK or tap CANCEL to return to the **Error Log** display.
- 4 The **Exporting Error Log** dialog box appears with:
  - a progress bar indicating the status of the export
  - text indicating the source (name) of the file being exported
  - the destination and name given to the file being exported
 During the exporting process the export can be aborted by tapping the ABORT button. An **Abort Error Log** message box appears asking confirmation to abort the export. Tap YES to abort the export or NO to continue with the export.
- 5 Tapping the LOGS MENU button returns the program to the **Logs Menu** display.

### 7.7.3.3 Service Log

The service log lists the date, time and specific information for all actives that were performed to service the SlidePrep.

- 1 In the **Logs Menu** display, tap the SERVICE LOG button.
- 2 Use the up and down arrow buttons to scan the service information.



**Figure 7-23 – Service Log display**

- 3 To export the service log, tap EXPORT. If no USB drive is detected, a dialog box appears requesting that one be inserted. After inserting a storage drive, click OK. In the **Service Log** display, choose EXPORT again.

**NOTE**

When exporting the service log, all logs are exported.

- 4 When exporting to a USB drive, a dialog box appears for selecting the USB drive to use for export. Select the drive from the list and save the service log by choosing OK or tap CANCEL to return to the **Service Log** display.

- 5 The **Exporting Service/Audit Log** dialog box appears with:

- a progress bar indicating the status of the export
- text indicating the source (name) of the file being exported
- the destination and name given to the file being exported

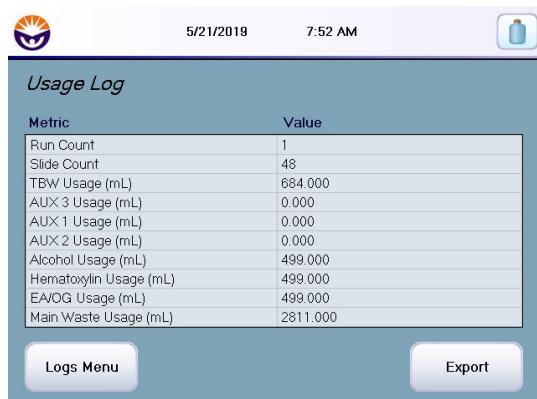
During the exporting process the export can be aborted by tapping the ABORT button. An **Abort Service/Audit Log** message box appears asking confirmation to abort the export. Tap YES to abort the export or NO to continue with the export.

- 6 Tapping the LOGS MENU button returns the program to the **Logs Menu** display.

### 7.7.3.4 Usage Log

The usage log contains a run count and a running log of the usage of various reagents and wastes for the SlidePrep.

- 1 In the **Logs Menu** display, tap the USAGE LOG button.
- 2 Use the up and down arrow buttons to scan the usage information.



The screenshot shows the 'Usage Log' display. At the top, there is a small circular logo, the date '5/21/2019', the time '7:52 AM', and a battery icon. Below this is a table titled 'Usage Log' with two columns: 'Metric' and 'Value'. The table lists the following data:

Metric	Value
Run Count	1
Slide Count	48
TBW Usage (mL)	684.000
AUX 3 Usage (mL)	0.000
AUX 1 Usage (mL)	0.000
AUX 2 Usage (mL)	0.000
Alcohol Usage (mL)	499.000
Hematoxylin Usage (mL)	499.000
E/A/Q Usage (mL)	499.000
Main Waste Usage (mL)	2811.000

At the bottom of the screen are two buttons: 'Logs Menu' on the left and 'Export' on the right.

**Figure 7-24 – Usage Log display**

- 3 To export the usage log, tap EXPORT. If no USB drive is detected, a message box will appear requesting that one be inserted. After inserting a storage drive, click OK. In the **Usage Log** display, choose EXPORT again.

**NOTE**

When exporting the usage log, all logs are exported.

- 4 When exporting to a USB drive, a dialog box appears for selecting the USB drive to use for export. Select the drive from the list and save the usage log by choosing OK or tap CANCEL to return to the **Usage Log** display.
- 5 The **Exporting Usage Log** dialog box appears with:
  - a progress bar indicating the status of the export
  - text indicating the source (name) of the file being exported
  - the destination and name given to the file being exported
 During the exporting process the export can be aborted by tapping the ABORT button. An **Abort Usage Log** message box appears asking confirmation to abort the export. Tap YES to abort the export or NO to continue with the export.
- 6 Tapping the LOGS MENU button returns the program to the **Logs Menu** display.

## 7.7.4 Run Reports

This utility allows management of the individual run reports that are generated during each processing run. Run reports can be printed at the end of each run (see Section 5.8 and Section 6.8) or from the **Reporting Menu** display.

- 1 From the **Utilities Menu** display tap REPORTING, then RUN REPORTS in the **Reporting Menu** display.



**Figure 7-25 – Reporting Menu display**

- 2 Select the desired run report. Use the up and down arrow buttons to scroll the list.
  - To select all reports tap the SELECT ALL button.
  - To choose a single or specific multiple files, select each file separately by tapping on the name in the list.
  - To deselect all files chosen, use the CLEAR ALL button.
  - To deselect specific files, tap the previously chosen file again to deselect it from the list.



**Figure 7-26 – Run Reports display**

Selecting the REPORTING MENU button returns the program to the **Reporting Menu** display.

**To print the selected run report(s):**

Tap the PRINT button. The reports are printed to the default printer (see Section 2.4.2 for setting the default printer).

**To export the selected run report(s):**

- 1 Tap the EXPORT button. If no USB drive is detected, a message box instructs insertion of a USB drive. When inserted, click OK. In the **Run Reports** display, choose EXPORT again.
- 2 When exporting to a USB drive, a dialog box appears for selecting the USB drive to store the exported file. Select the USB drive and continue by choosing OK.
- 3 The **Exporting Run Reports** dialog box appears with:
  - a a progress bar that indicates the status of the export
  - b text indicating the source (name) of the file being exported
  - c the destination and name given to the file being exported

During the exporting process the export can be aborted by tapping the ABORT button. An **Abort Export Run Reports** message box appears asking confirmation to abort the export. Tap YES to abort the export or NO to continue with the export.

Tapping the REPORTING MENU button returns the program to the **Reporting Menu** display.

Figures 7-27 and 7-28 show SAMPLE run reports. Run information, reagent information, any warnings or errors reported during the run, and slide tray information is presented. Additionally, a place to review, sign and date is provided.

11/5/2012 2:25:29 PM		Device: BUTPE4549W7																												
<b>BD Totalys™ SlidePrep Run Report</b>																														
<table border="1"> <tr><td>Protocol:</td><td>BD SurePath™</td><td>Status:</td><td>Completed</td></tr> <tr><td># Samples:</td><td>48</td><td>Software Version:</td><td>1.0.5.16-090</td></tr> <tr><td>Run Start Date:</td><td>11/5/2012 2:05:55 PM</td><td>Run Stop Date:</td><td>11/5/2012 2:25:02 PM</td></tr> <tr><td>Tray 1 Run Time:</td><td>00:08:47</td><td>Removal Time:</td><td>00:00:02</td></tr> <tr><td>Tray 2 Run Time:</td><td>00:12:13</td><td>Removal Time:</td><td>00:00:02</td></tr> <tr><td>Tray 3 Run Time:</td><td>00:15:38</td><td>Removal Time:</td><td>00:00:02</td></tr> <tr><td>Tray 4 Run Time:</td><td>00:19:03</td><td>Removal Time:</td><td>00:00:02</td></tr> </table>			Protocol:	BD SurePath™	Status:	Completed	# Samples:	48	Software Version:	1.0.5.16-090	Run Start Date:	11/5/2012 2:05:55 PM	Run Stop Date:	11/5/2012 2:25:02 PM	Tray 1 Run Time:	00:08:47	Removal Time:	00:00:02	Tray 2 Run Time:	00:12:13	Removal Time:	00:00:02	Tray 3 Run Time:	00:15:38	Removal Time:	00:00:02	Tray 4 Run Time:	00:19:03	Removal Time:	00:00:02
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Page 1 of 2																														

BD Totalys™ SlidePrep Run Report		Device: BUTPE4549W7	
Protocol: BD SurePath™		Run Start Date: 11/5/2012 2:05:55 PM	
Slide Tray Information			
Tray Location	Specimen ID	Tray Location	Specimen ID
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1-2		3-2	
1-3		3-3	
1-4		3-4	
1-5		3-5	
1-6		3-6	
1-7		3-7	
1-8		3-8	
1-9		3-9	
1-10		3-10	
1-11		3-11	
1-12		3-12	
2-1		4-1	
2-2		4-2	
2-3		4-3	
2-4		4-4	
2-5		4-5	
2-6		4-6	
2-7		4-7	
2-8		4-8	
2-9		4-9	
2-10		4-10	
2-11		4-11	
2-12		4-12	
<input type="checkbox"/> Pass <input type="checkbox"/> Fail    Signature: _____		Date: _____	
Page 2 of 2			

Figure 7-27 – SAMPLE BD SurePath™ Run Report

<p>5/8/2013 2:11:39 PM      Device: MD990887W7</p> <p><b>BD Totalys™ SlidePrep Run Report</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Protocol: Non-Gyn</td> <td style="width: 50%;">Status: Aborted</td> </tr> <tr> <td># Samples: 24</td> <td># Multiples: 2</td> </tr> <tr> <td>Run Start Date: 5/8/2013 2:10:58 PM</td> <td>Run Stop Date: 5/8/2013 2:11:28 PM</td> </tr> <tr> <td>Tray 1 Run Time: 00:00:29</td> <td>Removal Time: n/a</td> </tr> <tr> <td>Tray 2 Run Time: 00:00:29</td> <td>Removal Time: n/a</td> </tr> <tr> <td>Tray 3 Run Time: 00:00:29</td> <td>Removal Time: n/a</td> </tr> <tr> <td>Tray 4 Run Time: 00:00:29</td> <td>Removal Time: n/a</td> </tr> </table> <p>Non-Gyn - Prep and Stain</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Resuspension Volume</td> <td>1000 ul</td> <td style="width: 50%;">Mix Volume</td> <td>500 ul</td> </tr> <tr> <td>Mix Cycles</td> <td>8</td> <td>Sample Volume</td> <td>300 ul</td> </tr> <tr> <td>Dilution Volume</td> <td>100 ul</td> <td>Sedimentation Time</td> <td>600 secs</td> </tr> <tr> <td>Drying Time</td> <td>60 secs</td> <td>Hematoxylin Time</td> <td>56 secs</td> </tr> <tr> <td>E/A/QG Time</td> <td>65 secs</td> <td>TBW Wash Cycles</td> <td>3</td> </tr> <tr> <td>Alcohol Wash Cycles</td> <td>5</td> <td colspan="2"></td> </tr> </table> <p>Sample Transfer Overrides</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Tube</th> <th>Sample Position</th> <th>Transfer Volume (ul)</th> </tr> </thead> <tbody> <tr><td>1</td><td>1</td><td>200</td></tr> <tr><td>1</td><td>2</td><td>200</td></tr> <tr><td>1</td><td>3</td><td>200</td></tr> <tr><td>1</td><td>4</td><td>200</td></tr> <tr><td>1</td><td>5</td><td>200</td></tr> <tr><td>1</td><td>6</td><td>200</td></tr> <tr><td>1</td><td>7</td><td>200</td></tr> <tr><td>1</td><td>8</td><td>200</td></tr> <tr><td>1</td><td>9</td><td>200</td></tr> <tr><td>1</td><td>10</td><td>200</td></tr> <tr><td>1</td><td>11</td><td>200</td></tr> <tr><td>1</td><td>12</td><td>200</td></tr> </tbody> </table>	Protocol: Non-Gyn	Status: Aborted	# Samples: 24	# Multiples: 2	Run Start Date: 5/8/2013 2:10:58 PM	Run Stop Date: 5/8/2013 2:11:28 PM	Tray 1 Run Time: 00:00:29	Removal Time: n/a	Tray 2 Run Time: 00:00:29	Removal Time: n/a	Tray 3 Run Time: 00:00:29	Removal Time: n/a	Tray 4 Run Time: 00:00:29	Removal Time: n/a	Resuspension Volume	1000 ul	Mix Volume	500 ul	Mix Cycles	8	Sample Volume	300 ul	Dilution Volume	100 ul	Sedimentation Time	600 secs	Drying Time	60 secs	Hematoxylin Time	56 secs	E/A/QG Time	65 secs	TBW Wash Cycles	3	Alcohol Wash Cycles	5			Tube	Sample Position	Transfer Volume (ul)	1	1	200	1	2	200	1	3	200	1	4	200	1	5	200	1	6	200	1	7	200	1	8	200	1	9	200	1	10	200	1	11	200	1	12	200	<p>5/8/2013 2:11:39 PM      Device: MD990887W7</p> <p>Protocol: Non-Gyn</p> <p>Run Start Date: 5/8/2013 2:10:58 PM</p> <p><b>BD Totalys™ SlidePrep Run Report</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Reagent</td> <td style="width: 50%;">Lot Number</td> </tr> <tr> <td>TBV</td> <td></td> </tr> <tr> <td>Alcohol</td> <td></td> </tr> <tr> <td>Hematoxylin</td> <td></td> </tr> <tr> <td>EVOC</td> <td></td> </tr> </table> <p><b>Bulk Reagents Used During The Run</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Date/Time</td> <td>Error</td> </tr> <tr> <td>5/8/2013 2:11:06 PM</td> <td>Run/Stop protocol issued</td> </tr> <tr> <td>5/8/2013 2:11:12 PM</td> <td>Running protocol resumed</td> </tr> <tr> <td>5/8/2013 2:11:28 PM</td> <td>Protocol Aborted by User/Protocol Aborted</td> </tr> </table> <p><b>Warnings/Errors Reported During The Run</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Date/Time</td> <td>Error</td> </tr> <tr> <td>5/8/2013 2:11:06 PM</td> <td>Run/Stop protocol issued</td> </tr> <tr> <td>5/8/2013 2:11:12 PM</td> <td>Running protocol resumed</td> </tr> <tr> <td>5/8/2013 2:11:28 PM</td> <td>Protocol Aborted by User/Protocol Aborted</td> </tr> </table>	Reagent	Lot Number	TBV		Alcohol		Hematoxylin		EVOC		Date/Time	Error	5/8/2013 2:11:06 PM	Run/Stop protocol issued	5/8/2013 2:11:12 PM	Running protocol resumed	5/8/2013 2:11:28 PM	Protocol Aborted by User/Protocol Aborted	Date/Time	Error	5/8/2013 2:11:06 PM	Run/Stop protocol issued	5/8/2013 2:11:12 PM	Running protocol resumed	5/8/2013 2:11:28 PM	Protocol Aborted by User/Protocol Aborted
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<p>5/8/2013 2:11:39 PM      Device: MD990887W7</p> <p>Protocol: Non-Gyn</p> <p>Run Start Date: 5/8/2013 2:10:58 PM</p> <p><b>Slide Tray Information</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Tray Location</th> <th>Specimen ID</th> <th>Tray Location</th> <th>Specimen ID</th> </tr> </thead> <tbody> <tr><td>1-1</td><td></td><td>3-1</td><td></td></tr> <tr><td>1-2</td><td></td><td>3-2</td><td></td></tr> <tr><td>1-3</td><td></td><td>3-3</td><td></td></tr> <tr><td>1-4</td><td></td><td>3-4</td><td></td></tr> <tr><td>1-5</td><td></td><td>3-5</td><td></td></tr> <tr><td>1-6</td><td></td><td>3-6</td><td></td></tr> <tr><td>1-7</td><td></td><td>3-7</td><td></td></tr> <tr><td>1-8</td><td></td><td>3-8</td><td></td></tr> <tr><td>1-9</td><td></td><td>3-9</td><td></td></tr> <tr><td>1-10</td><td></td><td>3-10</td><td></td></tr> <tr><td>1-11</td><td></td><td>3-11</td><td></td></tr> <tr><td>1-12</td><td></td><td>3-12</td><td></td></tr> <tr><td>2-1</td><td></td><td>4-1</td><td></td></tr> <tr><td>2-2</td><td></td><td>4-2</td><td></td></tr> <tr><td>2-3</td><td></td><td>4-3</td><td></td></tr> <tr><td>2-4</td><td></td><td>4-4</td><td></td></tr> <tr><td>2-5</td><td></td><td>4-5</td><td></td></tr> <tr><td>2-6</td><td></td><td>4-6</td><td></td></tr> <tr><td>2-7</td><td></td><td>4-7</td><td></td></tr> <tr><td>2-8</td><td></td><td>4-8</td><td></td></tr> <tr><td>2-9</td><td></td><td>4-9</td><td></td></tr> <tr><td>2-10</td><td></td><td>4-10</td><td></td></tr> <tr><td>2-11</td><td></td><td>4-11</td><td></td></tr> <tr><td>2-12</td><td></td><td>4-12</td><td></td></tr> </tbody> </table> <p><input type="checkbox"/> Pass    <input type="checkbox"/> Fail    Signature: _____ Date: _____</p>	Tray Location	Specimen ID	Tray Location	Specimen ID	1-1		3-1		1-2		3-2		1-3		3-3		1-4		3-4		1-5		3-5		1-6		3-6		1-7		3-7		1-8		3-8		1-9		3-9		1-10		3-10		1-11		3-11		1-12		3-12		2-1		4-1		2-2		4-2		2-3		4-3		2-4		4-4		2-5		4-5		2-6		4-6		2-7		4-7		2-8		4-8		2-9		4-9		2-10		4-10		2-11		4-11		2-12		4-12		<p>5/8/2013 2:11:39 PM      Device: MD990887W7</p> <p>Protocol: Non-Gyn</p> <p>Run Start Date: 5/8/2013 2:10:58 PM</p> <p><b>Slide Tray Information</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Tray Location</th> <th>Specimen ID</th> <th>Tray Location</th> <th>Specimen ID</th> </tr> </thead> <tbody> <tr><td>1-1</td><td></td><td>3-1</td><td></td></tr> <tr><td>1-2</td><td></td><td>3-2</td><td></td></tr> <tr><td>1-3</td><td></td><td>3-3</td><td></td></tr> <tr><td>1-4</td><td></td><td>3-4</td><td></td></tr> <tr><td>1-5</td><td></td><td>3-5</td><td></td></tr> <tr><td>1-6</td><td></td><td>3-6</td><td></td></tr> <tr><td>1-7</td><td></td><td>3-7</td><td></td></tr> <tr><td>1-8</td><td></td><td>3-8</td><td></td></tr> <tr><td>1-9</td><td></td><td>3-9</td><td></td></tr> <tr><td>1-10</td><td></td><td>3-10</td><td></td></tr> <tr><td>1-11</td><td></td><td>3-11</td><td></td></tr> <tr><td>1-12</td><td></td><td>3-12</td><td></td></tr> <tr><td>2-1</td><td></td><td>4-1</td><td></td></tr> <tr><td>2-2</td><td></td><td>4-2</td><td></td></tr> <tr><td>2-3</td><td></td><td>4-3</td><td></td></tr> <tr><td>2-4</td><td></td><td>4-4</td><td></td></tr> <tr><td>2-5</td><td></td><td>4-5</td><td></td></tr> <tr><td>2-6</td><td></td><td>4-6</td><td></td></tr> <tr><td>2-7</td><td></td><td>4-7</td><td></td></tr> <tr><td>2-8</td><td></td><td>4-8</td><td></td></tr> <tr><td>2-9</td><td></td><td>4-9</td><td></td></tr> <tr><td>2-10</td><td></td><td>4-10</td><td></td></tr> <tr><td>2-11</td><td></td><td>4-11</td><td></td></tr> <tr><td>2-12</td><td></td><td>4-12</td><td></td></tr> </tbody> </table> <p><input type="checkbox"/> Pass    <input type="checkbox"/> Fail    Signature: _____ Date: _____</p>	Tray Location	Specimen ID	Tray Location	Specimen ID	1-1		3-1		1-2		3-2		1-3		3-3		1-4		3-4		1-5		3-5		1-6		3-6		1-7		3-7		1-8		3-8		1-9		3-9		1-10		3-10		1-11		3-11		1-12		3-12		2-1		4-1		2-2		4-2		2-3		4-3		2-4		4-4		2-5		4-5		2-6		4-6		2-7		4-7		2-8		4-8		2-9		4-9		2-10		4-10		2-11		4-11		2-12		4-12	
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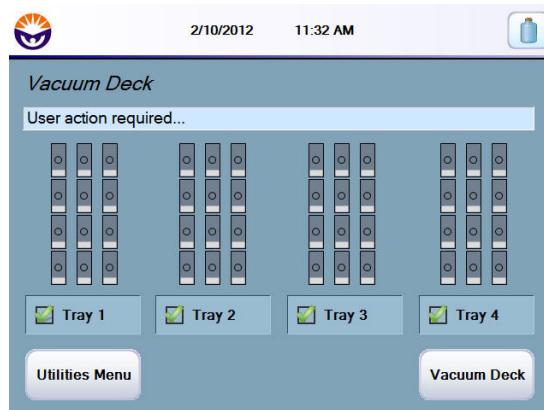
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**Figure 7-28 – SAMPLE Non-Gyn Run Report**

### 7.7.5 Vacuum Deck

The vacuum deck feature allows the user to vacuum any or all slide trays. This diagnostic tool will only be used when directed by service personnel.

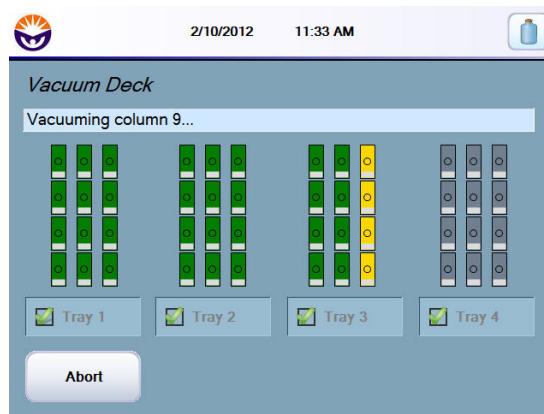
- 1 From the **Utilities Menu** display, tap the VACUUM DECK button.
- 2 On the **Vacuum Deck** display select the desired trays to be vacuumed by tapping on the appropriate tray button. Selected slide trays are indicated by a green checkmark. Selected trays can be deselected by tapping the tray button again.



**Figure 7-29 – Vacuum Deck display**

- 3 Tap the VACUUM DECK button to imitate the vacuum. Tray columns not yet vacuumed are gray, columns in process are yellow and completed tray columns are green. When all selected trays are vacuumed, all selected trays are green and the banner across the top of the display reads “Completed.”

During the vacuum deck, the process may be aborted by tapping the ABORT button. A dialog box asks to confirm the abort. Tap YES to abort or NO to return to the vacuum deck.



**Figure 7-30 – Vacuum Deck in process**

- 4 When the vacuum deck is completed, tap the UTILITIES MENU button to return to the **Utilities Menu** display.

## 7.7.6 Prime Syringe

The prime syringe feature allows all syringes to be primed in order to eliminate any air pockets in the tubing. This diagnostic tool will only be used when directed by service personnel.

- 1 From the **Utilities Menu** display, tap the PRIME SYRINGE button.
- 2 The **Prime Syringe** display allows three parameters to be set for priming.



**Figure 7-31 – Prime Syringe display**

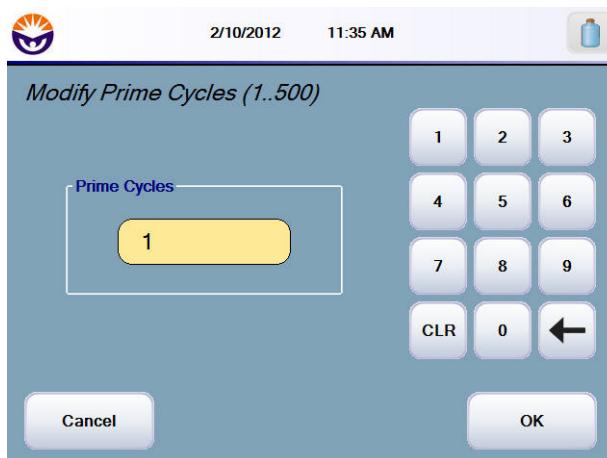
- a Tap Syringe Pump, then the MODIFY button to select which syringe pump to prime. Use the up and down arrow buttons to scroll the list of pumps: DiTi, multi-port, alcohol, hematoxylin or EA/OG.



**Figure 7-32 – Select Syringe Pump / Fluid display**

Once the desired syringe pump is selected, tap the OK button to return to the **Syringe Pump** display.

- b Tap Prime Cycles, then the MODIFY button to select the number of prime cycles on the keypad for priming. The number of prime cycles can range from 1–500.



**Figure 7-33 – Modify Prime Cycles display**

Once the desired number of prime cycles is entered, tap the OK button to return to the **Syringe Pump** display.

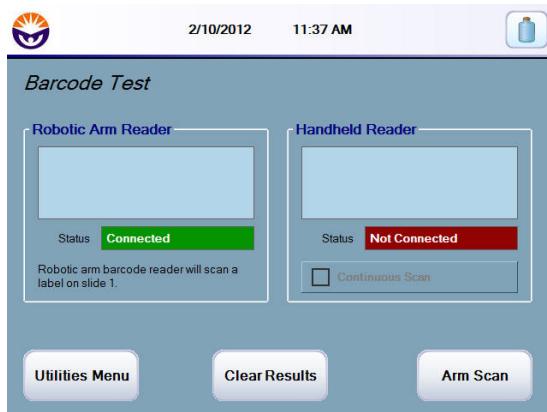
- 3 Tap the PRIME button. The SlidePrep primes according to the parameters selected. When completed, the banner at the top of the display reads “Completed.”
- 4 When finished priming syringes, tap the UTILITIES MENU button to return to the **Utilities Menu** display.

### 7.7.7 Barcode Test

The barcode test feature is used to test either the handheld barcode reader or the internal instrument reader.

- 1 From the **Utilities Menu** display, tap the BARCODE TEST button.
- 2 On the **Barcode Test** display, the left box provides information for the internal system scanner on the robotic arm. The right box provides information for the handheld barcode reader. For the handheld reader, tap Continuous Scan to perform the barcode test with a continuous scan.

If either reader is not attached or functioning the display status reads "Not Connected." Plug in the handheld barcode reader or, for the internal scanner, **contact BD Technical Service and Support at: 1.800.638.8663 or your local BD representative.**



**Figure 7-34 – Barcode Test display**

- 3 Place a slide with a barcode label in slide tray 1, position 1. This is the location of scanning for the internal reader.
- 4 To test the readers, tap the ARM SCAN button.

The internal reader scans the slide barcode automatically and the barcode appears in the open field.

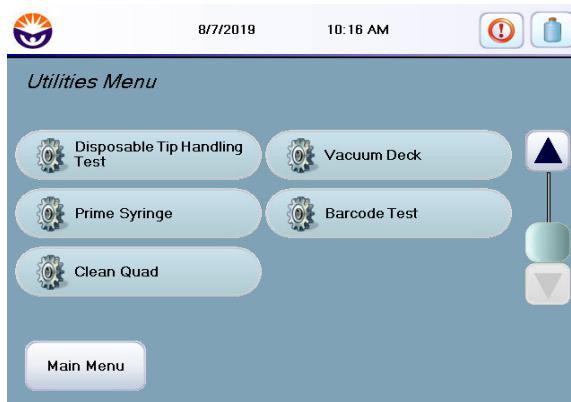
Hold the handheld reader to the barcode and either press the trigger or hold in place for continuous scanning. The barcode appears in the open field.

- 5 Once the scan is complete, the fields for each can be cleared by tapping the CLEAR RESULTS button.
- 6 When finished, tap the UTILITIES MENU button to return to the **Utilities Menu** display.

### 7.7.8 Clean Quad

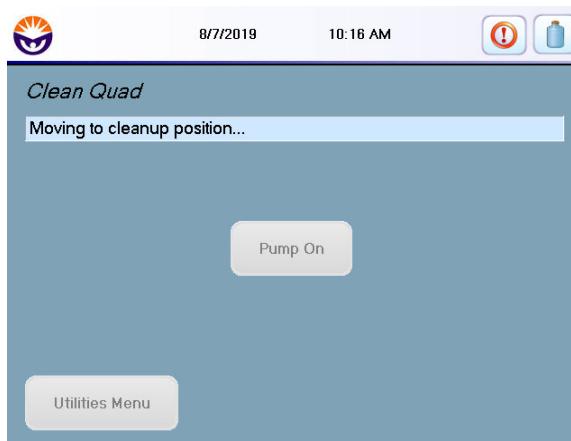
The clean quad feature allows the user to reposition the robot arm and the quad bundles to the far left side of the instrument behind the DASR door to provide user access to the quad bundle tubing for clearing a clog from any vacuum tubing. This feature is only accessible when a protocol run is not in progress.

- 1 From the Utilities Menu display, scroll down to the bottom of the menu and tap the CLEAN QUAD button.



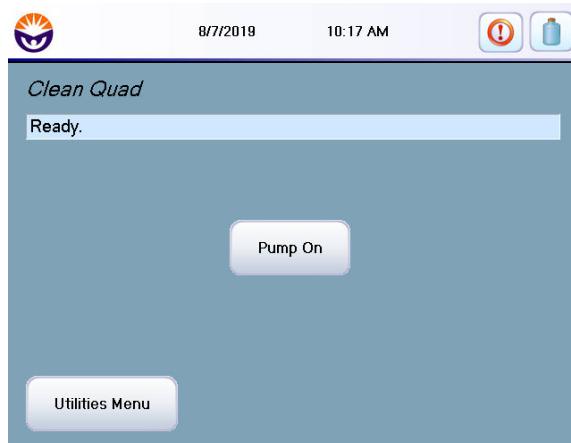
**Figure 7-35 – Clean Quad: Utilities Menu**

- 2 The status "Moving to cleanup position..." is displayed as the robot arm travels to the left side of the instrument.
- 3 The "Pump On" control button displayed in the center of the utility will remain inactive until the robotic arm travel is finished.



**Figure 7-36 – Clean Quad: Moving to cleanup position**

- 4 When the robotic arm travel is completed, the status "Ready" is displayed and the "Pump On" vacuum pump control button becomes active.



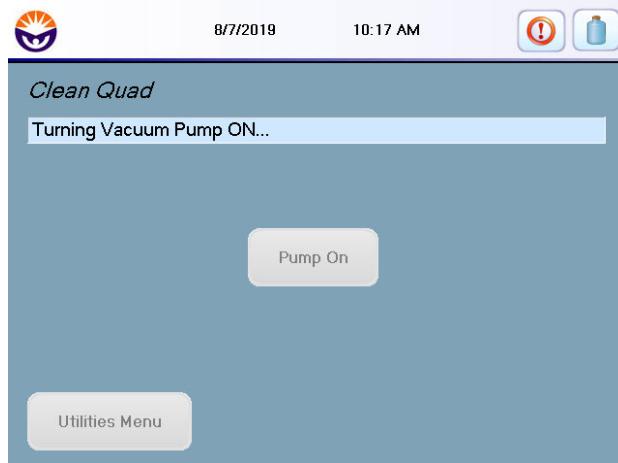
**Figure 7-37 – Clean Quad: Pump On Ready**

- 5 Open the DASR door to access the quad bundle tubing.

**NOTE**

Take precautions to prevent contaminating the pipette and or c-tube materials on the DASR while cleaning the quad bundle vacuum tubing.

- 6 Tap the "Pump On" button as needed while cleaning the vacuum tubing.

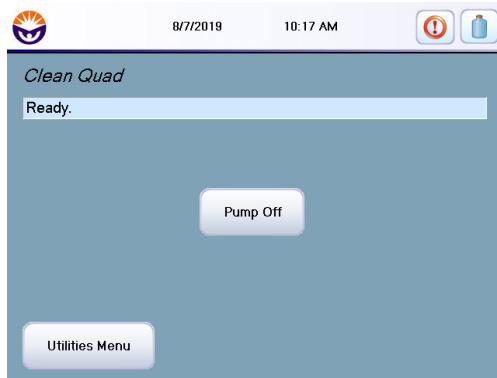


**Figure 7-38 – Clean Quad: Turning Vacuum Pump ON**

**NOTE**

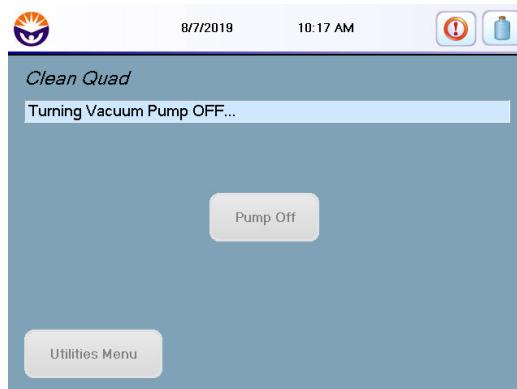
Use the recommended stylus to unclog the vacuum tube. When cleaning is finished, clean the pipette bundle with an alcohol wipe.

- 7 The "Pump Off" button can be used to stop vacuum pump operation when its active.



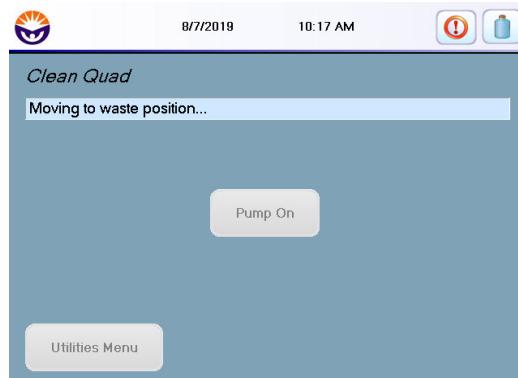
**Figure 7-39 – Clean Quad: Pump Off Ready**

- 8 The status displays "Turning Vacuum Pump OFF..." after tapping the "Pump Off" control button.



**Figure 7-40 – Clean Quad: Turning Vacuum Pump OFF**

- 9 When cleaning is finished, return all materials to the DASR and close the DASR door.
- 10 Tap the "Utilities Menu" to close the Clean Quad utility. The Clean Quad status displays "Moving to waste position..." as the robot arm repositions the quad bundles back to the Birdbath assembly.



**Figure 7-41 – Clean Quad: Moving to waste position**



# 8 – Maintenance

## 8.1 General

This section details the procedures for maintaining the BD Totalys™ SlidePrep. Proper maintenance is necessary for the SlidePrep to consistently produce quality slides. If neglected, the system's performance may deteriorate over time.

Once every 12 months, preventive maintenance is required to be performed by BD authorized service personnel.

The following major topics are discussed:

- Preparation of Cleaning Solution (Section 8.2)
- Daily Maintenance (Section 8.3)
- Weekly Maintenance (Section 8.4)
- Monthly Maintenance (Section 8.5)
- Replacing the Handheld Barcode Reader (Section 8.6)

A BD Totalys™ SlidePrep Maintenance Log is provided at the end of this section.

### WARNING

IT IS THE USER'S RESPONSIBILITY TO FOLLOW THE MAINTENANCE AND CLEANING GUIDELINES OUTLINED IN THIS SECTION. USING CLEANING AGENTS OTHER THAN DESCRIBED COULD RESULT IN HAZARDS AS A RESULT OF A REACTION WITH THE EQUIPMENT OR MATERIALS CONTAINED IN IT. ALL MAINTENANCE AND REPAIR OTHER THAN DESCRIBED IN THIS SECTION MUST BE PERFORMED BY BD QUALIFIED PERSONNEL.

### WARNING

FOLLOW ESTABLISHED STANDARD OPERATING PROCEDURES (SOPs) FOR CLEANING AND SAMPLE HANDLING AND DISPOSE OF ALL USED CLEANING MATERIALS PER THESE PROCEDURES.

### WARNING

THE EA/OG REAGENT, ALCOHOL BLEND RINSE AND MAIN WASTE CONTAIN FLAMMABLE LIQUIDS. PROPER PRECAUTIONS, INCLUDING LOCAL INSTITUTIONAL GUIDELINES, SHOULD BE FOLLOWED TO REDUCE THE RISK OF IGNITION OF ANY FLAMMABLE LIQUIDS.

## 8.2 Preparation of Cleaning Solution (10% Contrad 70)

The 10% Contrad 70 solution is used as the cleaning reagent during daily, weekly and monthly maintenance and must be prepared from Contrad 70.

- 1 Fill a gallon container with 2,700 mL of DI or distilled water.
- 2 Add 300 mL of Contrad 70 to the gallon container for a 10% cleaning solution.
- 3 Cap and invert gently to mix.
- 4 Label the gallon container with 10% Contrad 70 and the date prepared.

## 8.3 Daily Maintenance

### 8.3.1 Materials Required

- Cleaning water: deionized (DI) or distilled water
- SlidePrep cleaning water container
- 10% Contrad 70

### 8.3.2 Frequency

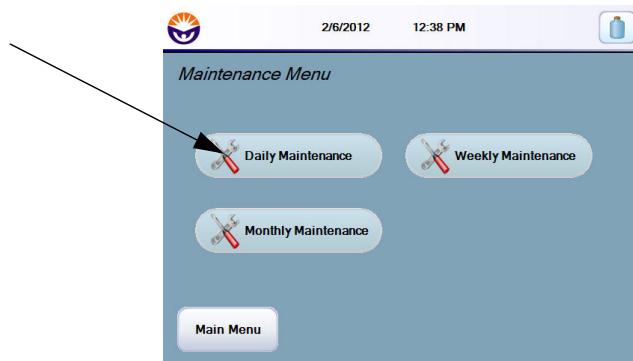
Perform daily maintenance at the end of each day the SlidePrep has been in use. This is an important maintenance procedure as some solutions can form precipitate that can shorten the life of the tubing, valves, and syringes, which in turn affects the precision and accuracy of the SlidePrep.

### 8.3.3 Procedure

- 1 Tap MAINTENANCE from the **Main Menu** display, then DAILY MAINTENANCE from the **Maintenance Menu** display.

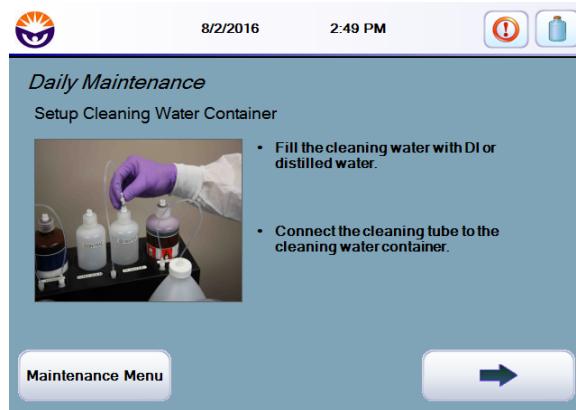


**Figure 8-1 – Main Menu display**



**Figure 8-2 – Maintenance Menu display**

- 2 Setup cleaning water container.
  - a Pour DI or distilled water into the cleaning water container until full. Attach the cap and place on the bulk reagent station.
  - b Connect the cleaning tube on the bulk reagent station to the cleaning water container. Attach the port to the cleaning water container's lid by turning the port clockwise onto the lid.



**Figure 8-3 – Setup Cleaning Water Container display**

- c Tap  $\Rightarrow$  to continue.

- 3 Connect ALL other tubes to cleaning connections.
  - a Connect all bulk reagents to the cleaning connection on the bulk reagent station base. If the tubing quick disconnect port is attached to the bulk reagent lid, remove it by turning the port counter-clockwise. Attach the port to the bulk reagent station base by turning the tubing clockwise onto the cleaning connection.

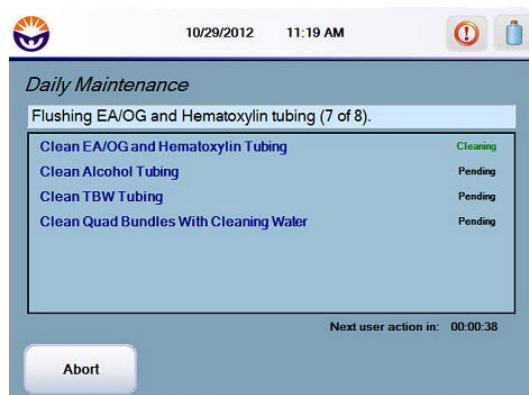


**Figure 8-4 – Connect All Tubes to Cleaning Connections display**

At this point the tubing for the cleaning water container should be attached to the cleaning water container's lid and all other tubing should be attached to the bulk reagent station base.

- 4 Press the START CLEANING button to initiate Daily Maintenance.

The SlidePrep automatically flushes the syringes and tubing for each reagent with the cleaning water. The quad arm pipette bundle tips and their drip wells (birdbaths) are also cleaned.



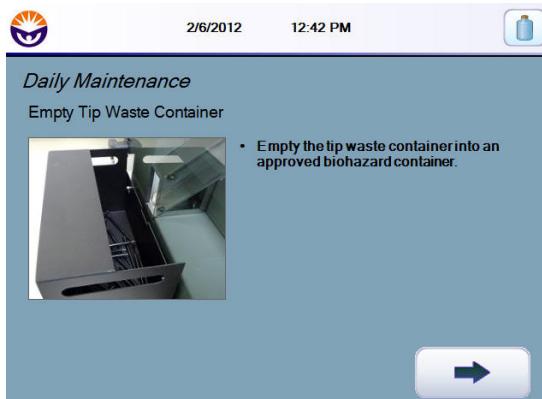
**Figure 8-5 – Daily Maintenance–Status display**

The display shows the sequential cleaning procedures in list form and the stage of the current procedure is shown in the status message box across the top. The status is indicated on the right of each procedure as Pending, Cleaning, or a checkmark to denote completed. An indicator at the bottom of the display shows how much time is remaining until the next user action is required.

An ABORT button is present at the bottom of the display during instrument cleaning. When selected, a message box appears asking confirmation to abort the current maintenance procedure. Tap YES to stop the maintenance procedure or NO to return to the current cleaning point in the sequence.

When the cleaning procedure is completed by the SlidePrep, the next display automatically appears.

- 5 Empty the tip waste container.
- a The tip waste container sits on the left side of the SlidePrep, outside of the instrument enclosure and is secured to the SlidePrep on two prongs. Slide the tip waste container up off the prongs and dispose of the tips in an appropriate waste container. Place the container back on the side of the SlidePrep by locking onto prongs.



**Figure 8-6 – Empty Tip Waste Container display**

- b Tap ➔ to continue.
- 6 Empty scrubbing muffler and liquid waste containers if necessary.

**NOTE**

If weekly or monthly maintenance is to immediately follow, this step does not need to be performed unless there is not sufficient capacity in any of the waste containers to complete maintenance.

- a To empty either the main or aux waste:

**Main waste**

Unhook both tubing clips on the lid of the main waste container. Remove lid and empty waste into an approved waste container. Flush container with tap water. Place container back on waste station and reattach lid. Reattach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

**Aux waste**

Some instruments have a waste diverter valve that supports two liquid waste containers. The aux waste is not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test, so it should not need to be emptied. If you do need to empty this container, follow the instructions below.

Unhook the tubing clips on the lid and tubing connected to the waste station base. Remove lid and empty waste into an approved waste container. Flush container with tap water. Place container back on waste station and reattach lid. Reattach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid.

- b To empty the scrubbing muffler bottle (if filled):

Disconnect the tubing clip on the cap of the scrubbing muffler and remove cap. Empty the contents of the scrubbing muffler into an approved waste container. Add 2.5 L of water to the scrubbing muffler. Do not overfill. Recap the scrubbing muffler and reconnect tubing clip to lid.

**NOTE**

Deionized water is recommended but not required.

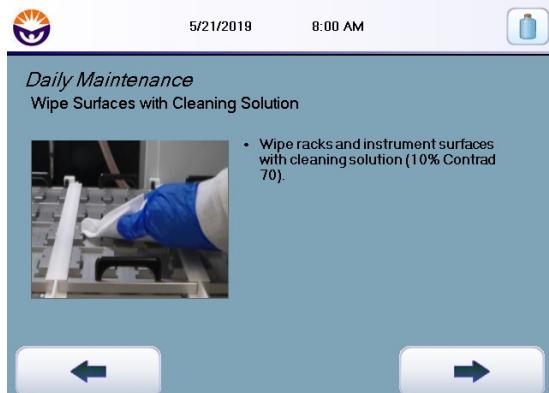
- c On the **Empty Muffler and Liquid Waste Container** display, tap the appropriate waste button and hit the RESET button. This returns the waste to 0% (indicating 0% full).
- d Tap  $\Rightarrow$  to continue.



**Figure 8-7 – Empty Muffler and Liquid Waste Container display**

- 7 Wipe surfaces with cleaning solution.

- a Wipe racks and internal instrument surfaces with a cleaning cloth dampened with 10% Contrad 70. Do not directly squirt the 10% Contrad 70 onto any internal instrument components.
- b Tap  $\Rightarrow$  to continue.



**Figure 8-8 – Wipe Surfaces with Cleaning Solution display**

- 8 Check tubing connectors and syringe tightness.
  - a Check the tubing connections to the syringe pumps, quad manifolds, and vacuum manifolds:
    - Tighten the blue and white plastic knobs on all four syringe pumps and the multi-port. Tighten by twisting clockwise; knobs should be finger-tight.
    - Tighten all knobs on the quad arm manifold assembly. Tighten by twisting clockwise; knobs should be finger-tight.
  - b Secure syringes:
    - Tighten the silver rings on the neck of all four syringe pumps and the multi-port. Tighten by twisting clockwise; rings should be finger-tight.
    - Tighten the silver metal knobs at the base of all four syringe pumps and the multi-port. Tighten by twisting clockwise; knobs should be finger-tight.
  - c Tap to continue

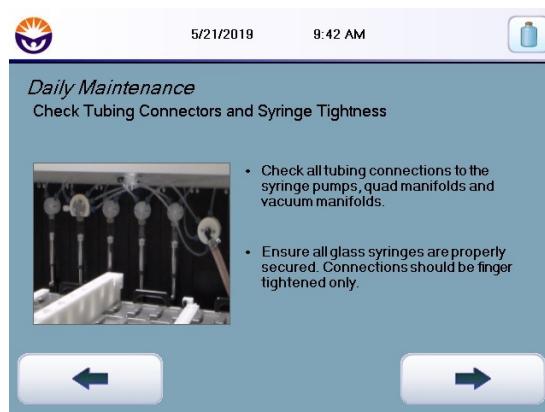


Figure 8-9 – Check Tubing Connectors and Syringe Tightness display

**NOTE**

If the Weekly Maintenance is not going to be performed immediately following the Daily Maintenance, the lines should be checked for any reagent residue. If some are noted, the Daily Maintenance can be run again.

- 9 Daily maintenance completed.

If maintenance is completed for the day (no weekly or monthly maintenance to follow) and more runs are scheduled to be performed, reconnect tubing from the bulk reagent station base to the reagent bottles. Remove the quick disconnect port from the cleaning connection on the bulk reagent station base by twisting counter-clockwise. Attach the quick disconnect port to the bulk reagent lid by turning the port clockwise onto the reagent lid. Leave the cleaning water container tubing attached to the cleaning water container.

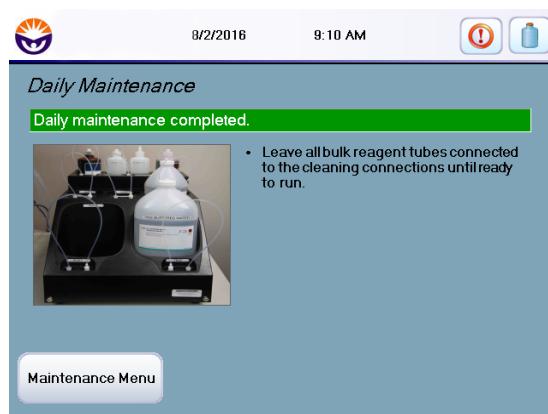
**NOTE**

If the reagent bottles are reconnected and the SlidePrep is not used, the reagents may cause capillary action in the tubing and subsequently dry out and crystallize. This may cause drips and decreased quality of slides.

Leave the tubing for the AUX 1, 2, and 3 reagents attached to the bulk reagent station base.

If weekly and/or monthly maintenance is to follow, leave all reagent tubing as is.

Tap the MAINTENANCE MENU button to return to the **Maintenance Menu** display.



**Figure 8-10 – Daily Maintenance–Completed display**

- 10 Once daily maintenance is complete the SlidePrep may be turned off if needed. Refer to the instrument shutdown procedure in any of the Operations sections.  
Document the daily maintenance on the Maintenance Log provided at the end of this section.

## 8.4 Weekly Maintenance

### 8.4.1 Materials required

- Cleaning water: Deionized (DI) or distilled water
- SlidePrep cleaning water container
- Lint free cloth
- 70% alcohol
- 10% Contrad 70
- SlidePrep 10% Contrad 70 container

### 8.4.2 Frequency

Perform weekly maintenance at the end of each week. This procedure is designed to IMMEDIATELY follow the daily maintenance procedure described in Section 8.3.

### 8.4.3 Procedure

- 1 From the **Main Menu** display, tap MAINTENANCE, then from the **Maintenance Menu** display tap WEEKLY MAINTENANCE.

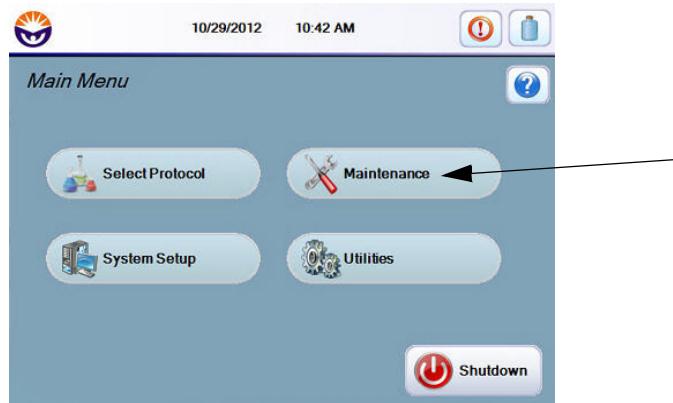


Figure 8-11 – Main Menu display

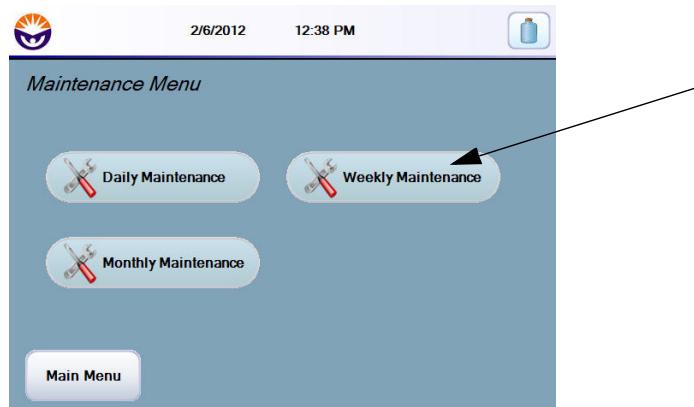
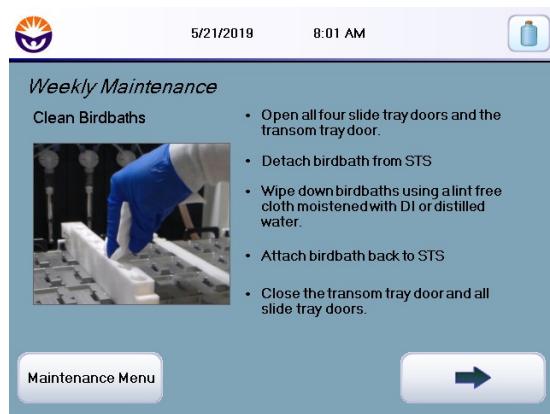


Figure 8-12 – Maintenance Menu display

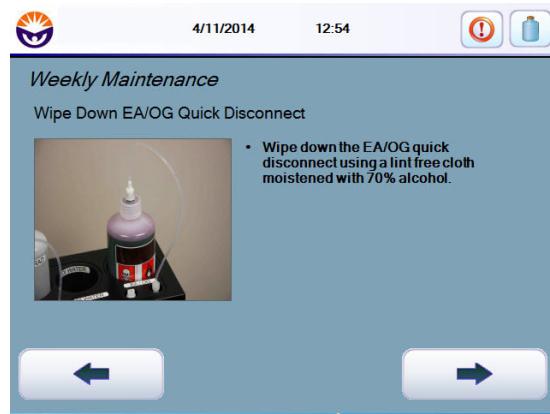
- 2 Clean the birdbaths.
  - a Open all four slide tray doors and the transom tray door.
  - b SlidePrep instruments installed with software version 1.5.0.0 and higher are equipped with a detachable birdbath assembly. Follow on-screen cleaning instructions. Wipe down the birdbaths using a lint-free cloth, moistened with DI or distilled water.
  - c Discard the cloth and close all the doors.

- d Tap ➔ to continue.



**Figure 8-13 – Clean Birdbaths display**

- 3 Wipe down the EA/OG quick disconnect port.
  - a Remove the EA/OG quick disconnect port from the bulk reagent station base by turning the port counter-clockwise.
  - b Wipe down the port using a lint free cloth moistened with 70% alcohol.
  - c Reattach the quick disconnect port to the bulk reagent station base by twisting clockwise.
  - d Tap ➔ to continue.



**Figure 8-14 – Wipe Down EA/OG Quick Disconnect display**

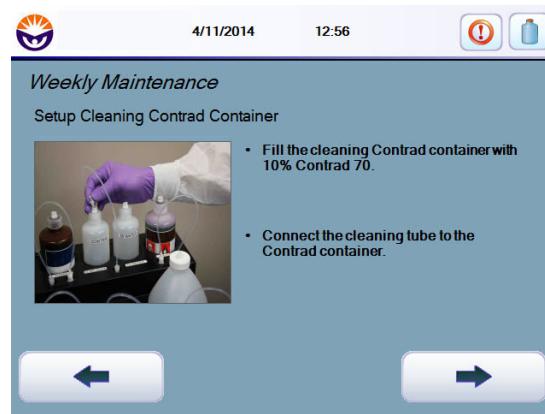
- 4 Wipe down the remaining quick disconnect ports.
  - a For the remaining reagents, remove the quick disconnect ports from the bulk reagent station base by turning the ports counter-clockwise.
  - b Wipe down all ports with a lint free cloth moistened with DI or distilled water. Use a fresh moistened cloth for each port.
  - c Reattach the quick disconnect ports to their respective locations on the bulk reagent station base by twisting clockwise.

- d Tap  to continue.



**Figure 8-15 – Wipe Down Remaining Quick Disconnects display**

- 5 Setup cleaning Contrad container.
- Fill the cleaning Contrad container with 10% Contrad 70 and attach cap.
  - Attach the cleaning tube (may be attached to the cleaning water container from the daily maintenance procedure) to the cleaning Contrad container. Remove port from either the bulk reagent station base or the cleaning water container by twisting counter-clockwise and attach to the cap of the cleaning Contrad container by twisting clockwise.
  - Tap  to continue.



**Figure 8-16 – Setup Cleaning Contrad Container display**

- 6 Setup cleaning water container.
- Fill the cleaning water container with DI or distilled water, place on bulk reagent station base and attach cap.  
Do not attach any tubing to the cleaning water container at this time. This container is used in a later step.

- b Tap ➔ to continue.



**Figure 8-17 – Setup Cleaning Water Container display**

- 7 Connect remaining tubes.

If not already completed in Step 1 and 2 of Weekly Maintenance, connect ports for the remaining reagents to the cleaning connection on the bulk reagent station base by twisting clockwise.

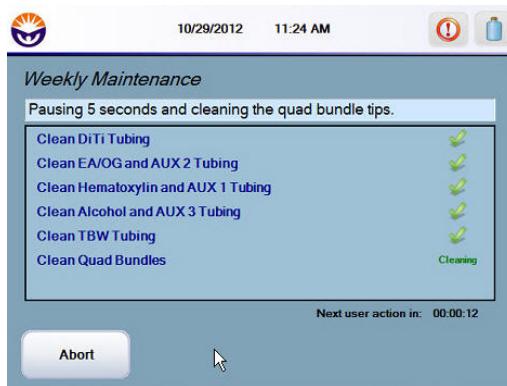
Although the AUX 1, 2, and 3 reagents are not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test, the tubing for each must be connected to the bulk reagent station base in order to clean the entire system.



**Figure 8-18 – Connect Remaining Tubes display**

- 8 Tap the START CLEANING button on the **Connect Remaining Tubes** display to start the cleaning procedure for Weekly Maintenance. Do not walk away from the SlidePrep, additional actions are required.

The SlidePrep automatically cleans the syringes and tubing for each reagent with the 10% Contrad 70 solution. The quad arm pipette bundle tips and their drip wells (birdbaths) are also cleaned.



**Figure 8-19 – Weekly Maintenance–Cleaning Status display**

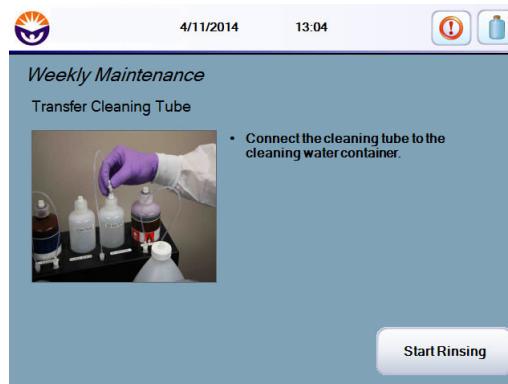
The display shows the sequential cleaning procedures in list form and the stage of the current procedure is shown in the status message box across the top. The status is indicated on the right of each procedure as Pending, Cleaning, or a checkmark to denote completed. An indicator at the bottom of the display shows how much time is remaining until the next user action is required.

An ABORT button is present at the bottom of the display during instrument cleaning. When selected, a message box appears asking confirmation to abort the current maintenance procedure. Tap YES to stop the maintenance procedure or NO to return to the current cleaning point in the sequence.

When the cleaning procedure is completed by the SlidePrep, the next display automatically appears.

9 Transfer cleaning tube.

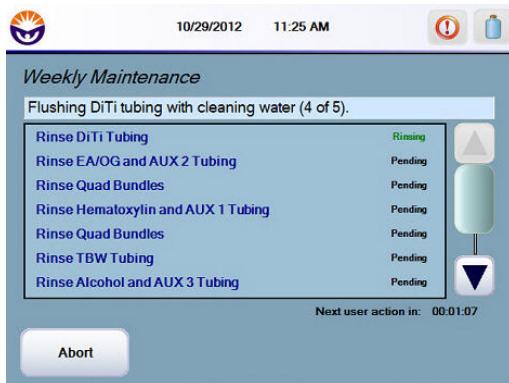
Transfer the cleaning tube from the cleaning Contrad container to the cleaning water container. Disconnect the port from the cap on the 10% Contrad 70 by twisting counter-clockwise and attach to the cap on the cleaning water by twisting clockwise.



**Figure 8-20 – Transfer Cleaning Tube display**

- 10 Tap the START RINSING button on the **Transfer Cleaning Tube** display to start the rinsing procedure for Weekly Maintenance. Do not walk away from the SlidePrep, additional actions are required.

The SlidePrep automatically rinses the syringes and tubing for each reagent with the cleaning water. The quad arm pipette bundle tips and their drip wells (birdbaths) are also rinsed.



**Figure 8-21 – Weekly Maintenance–Rinsing Status display**

The display shows the sequential rinsing procedures in list form and the stage of the current procedure is shown in the status message box across the top. The status is indicated on the right of each procedure as Pending, Cleaning, or a checkmark to denote completed. An indicator at the bottom of the display shows how much time is remaining until the next user action is required.

An ABORT button is present at the bottom of the display during instrument rinsing. When selected, a message box appears asking confirmation to abort the current maintenance procedure. Tap YES to stop the maintenance procedure or NO to return to the current point in the sequence.

When the rinsing procedure is completed by the SlidePrep, the next display automatically appears.

11 Replace scrubbing muffler contents (if filled).

**NOTE**

This step is not required if the option to redirect the vacuum exhaust is installed.

**NOTE**

If the muffler contents were just replaced per the daily maintenance instructions, or if monthly maintenance is to immediately follow, this step does not need to be performed.

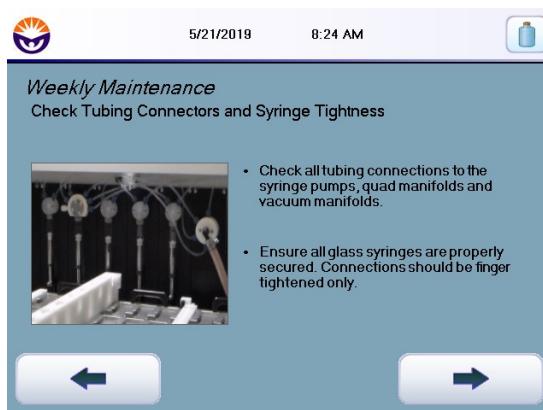
- a Disconnect the tubing clip on the cap of the scrubbing muffler and remove cap.
- b Empty the contents of the scrubbing muffler into an approved waste container.
- c Rinse the scrubbing muffler with tap water.
- d Add 2.5 L of water to the scrubbing muffler. Do not overfill.

- e Recap the scrubbing muffler and reconnect tubing clip to lid.
- f Tap  to continue.



**Figure 8-22 – Replace Muffler Contents display**

- 12 Check tubing connectors and syringe tightness.
  - a Check the tubing connections to the syringe pumps, quad manifolds, and vacuum manifolds:
    - Tighten the blue and white plastic knobs on all four syringe pumps and the multi-port. Tighten by twisting clockwise; knobs should be finger-tight.
    - Tighten all knobs on the quad arm manifold assembly. Tighten by twisting clockwise; knobs should be finger-tight.
  - b Secure syringes:
    - Tighten the silver rings on the neck of all four syringe pumps and the multi-port. Tighten by twisting clockwise; rings should be finger-tight.
    - Tighten the silver metal knobs at the base of all four syringe pumps and the multi-port. Tighten by twisting clockwise; knobs should be finger-tight.
  - c Tap  to continue.



**Figure 8-23 – Check Tubing Connectors and Syringe Tightness display**

- 13 Empty liquid waste containers if necessary.

**NOTE**

If waste containers were emptied per the daily maintenance instructions, or if monthly maintenance is to immediately follow, this step does not need to be performed.

- a To empty either the main or aux waste:

**Main waste**

Unhook both tubing clips on the lid of the main waste container. Remove lid and empty waste into an approved waste container. Flush container with tap water. Place container back on waste station and reattach lid. Reattach the tubing from the waste station base to one of the clips on the main waste container lid and attach the tubing from the SlidePrep to the other clip on the main waste container lid.

**Aux waste**

Some instruments have a waste diverter valve that supports two liquid waste containers. The aux waste is not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test, so it should not need to be emptied. If you do need to empty this container, follow the instructions below. Unhook the tubing clips on the lid and tubing connected to the aux waste. Remove lid and empty waste into an approved waste container. Flush container with tap water. Place container back on waste station and reattach lid. Reattach the tubing from the aux waste container lid to the clip on the waste station base and attach the tubing from the SlidePrep to the clip on the aux waste container lid.

- b On the **Empty Liquid Waste Containers** display, tap the appropriate waste button and hit the RESET button. This returns the waste to 0% (indicating 0% full).
- c Tap  $\Rightarrow$  to continue.



**Figure 8-24 – Empty Liquid Waste Containers display**

14 Weekly maintenance completed.

If maintenance is completed for the week (no monthly maintenance to follow) and more runs are scheduled to be performed, reconnect tubing from the bulk reagent station base to the reagent bottles. Remove the quick disconnect port from the cleaning connection on the bulk reagent station base by twisting counter-clockwise. Attach the quick disconnect port to the bulk reagent lid by turning the port clockwise onto the reagent lid. The tubing to the cleaning water container can be removed from the cleaning water container lid and reattached to the cleaning connection on the bulk reagent station base.

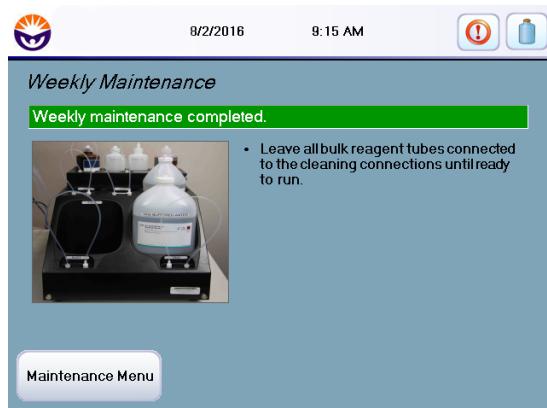
**NOTE**

If the reagent bottles are reconnected and the SlidePrep is not used, the reagents may cause capillary action in the tubing and subsequently dry out and crystallize. This may cause drips and decreased quality of slides.

Leave the tubing for the AUX 1, 2, and 3 reagents attached to the bulk reagent station base.

If monthly maintenance is to follow, leave all reagent tubing as is.

Tap the MAINTENANCE MENU button to return to the **Maintenance Menu** display.



**Figure 8-25 – Weekly Maintenance Completed display**

15 Once weekly maintenance is complete the SlidePrep may be turned off if needed. Refer to the system shutdown procedure in any of the Operations sections.

Document the weekly maintenance on the Maintenance Log provided at the end of this section.

## 8.5 Monthly Maintenance

### 8.5.1 Materials required

- Cleaning water: DI or distilled water
- Cleaning water squirt bottle
- Lint free cloth
- 100% Contrad 70
- 10% Contrad 70
- 10% Contrad 70 squirt bottle

### 8.5.2 Frequency

Perform monthly maintenance every 4 to 6 weeks. This procedure is designed to IMMEDIATELY follow the weekly maintenance procedure described in Section 8.4.

### 8.5.3 Procedure

- 1 From the **Main Menu** display, tap MAINTENANCE, then from the **Maintenance Menu** display tap MONTHLY MAINTENANCE.

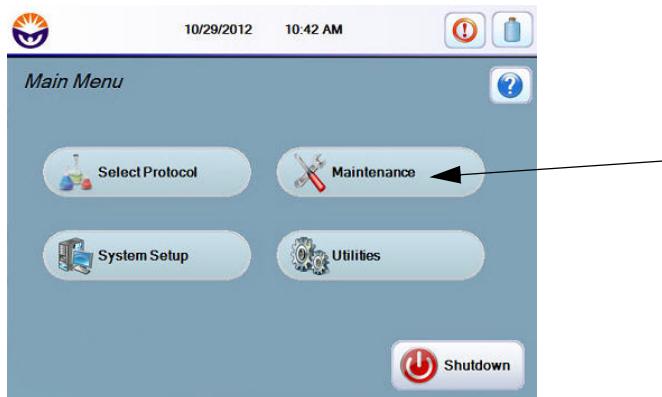


Figure 8-26 – Main Menu display

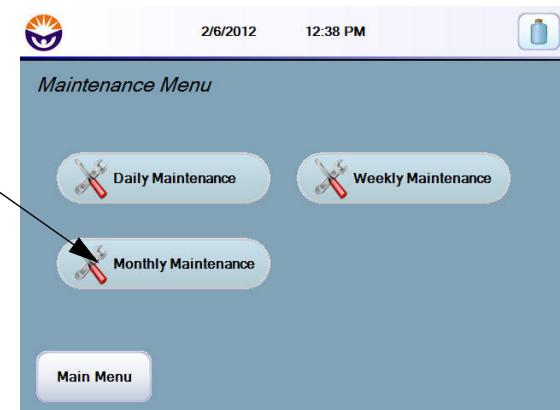
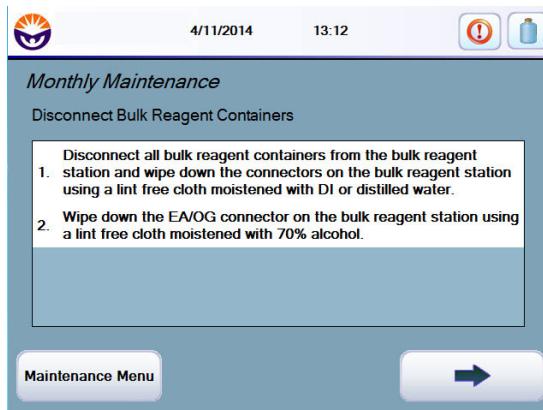


Figure 8-27 – Maintenance Menu display

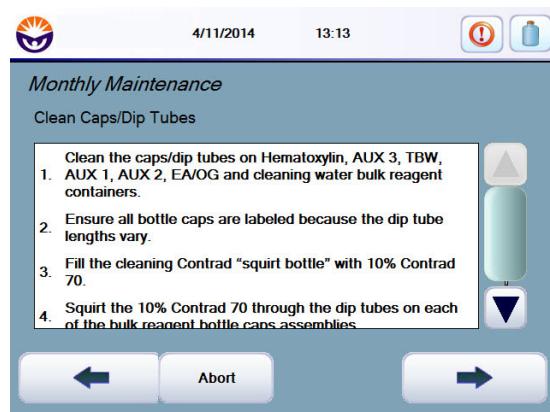
- 2 Disconnect and clean bulk reagent containers.
  - a If any of the bulk reagents have tubing attached to the lid, disconnect the quick disconnect port by turning counter-clockwise (the tubing for the bulk reagent containers should already be disconnected from the weekly maintenance procedure).
  - b Wipe down the EA/OG port using a lint free cloth moistened with 70% alcohol.
  - c Wipe down the other bulk reagent ports using a lint free cloth moistened with DI water. Although the AUX 1, 2, and 3 reagents are not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test, the tubing for each must be wiped down in order to clean the entire system.
  - d Tap  to continue.



**Figure 8-28 – Disconnect Bulk Reagent Containers display**

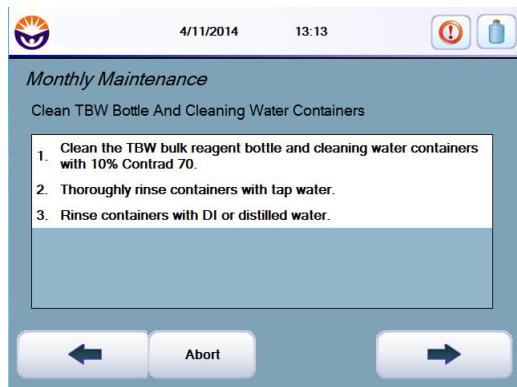
- 3 Clean caps/dip tubes on hematoxylin, AUX 3 reagent, TBW, AUX 1 and 2 reagents, EA/OG and alcohol blend rinse reagent containers. Use the up and down arrow buttons to scroll through the list on the display.
  - a Remove the caps/dip tubes from the reagent bottles. Ensure all caps/dip tubes are identified because the dip tube lengths vary.
  - b Fill the cleaning Contrad squirt bottle with 10% Contrad 70.
  - c Squirt the 10% Contrad 70 through the dip tubes on each of the bulk reagent bottle cap assemblies.
  - d Submerge bulk reagent cap/dip tube assemblies in a container of 10% Contrad 70 and let stand for 30 minutes.
  - e Fill the cleaning water squirt bottle with DI or distilled water.
  - f Rinse the outside of the cap/dip tube assemblies thoroughly with cleaning water and squirt cleaning water through the dip tubes making sure there is no residual 10% Contrad 70.
  - g Replace the bottle caps on the appropriate containers, making sure the dip tube lengths are appropriate for the bottle size.

- h Tap  $\Rightarrow$  to continue.



**Figure 8-29 – Clean Caps/Dip Tubes display**

- 4 Clean the TBW and cleaning water containers.
- Remove the TBW and cleaning water containers from the bulk reagent station.
  - Discard any remaining fluid and thoroughly rinse containers with 10% Contrad 70.
  - Rinse containers with DI or distilled water.
  - Tap  $\Rightarrow$  to continue.



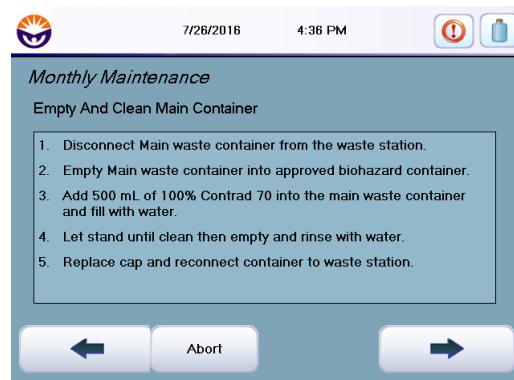
**Figure 8-30 – Clean TBW Bottle and Cleaning Water Containers display**

- 5 Empty and clean waste containers. Use the up and down arrow buttons to scroll through the list on the display.

Although the aux waste container is not used in either the BD SurePath™ Liquid-based Pap Test or the Non-Gyn test, if it is installed on the system, it should be cleaned periodically in order to clean the entire system.

- Disconnect the main and aux waste containers from waste station. For the main waste station, disconnect both clips from the container lid and remove lid. For the aux waste, disconnect one clip from the container lid and the other clip from the waste station base, then remove the lid.
- Empty waste containers into an approved waste container.
- Add 500 mL of 100% Contrad 70 solution into the main waste container.
- Add 100 mL of 100% Contrad 70 into the aux waste container.

- e Fill containers with tap water and let stand for 30 minutes (or until clean).
- f Rinse containers with tap water.
- g Replace caps and reconnect to waste station. For the main waste reconnect both clips to the container cap. For the aux waste reconnect one clip to the container cap and the other clip to the waste station base.
- h Tap to continue.



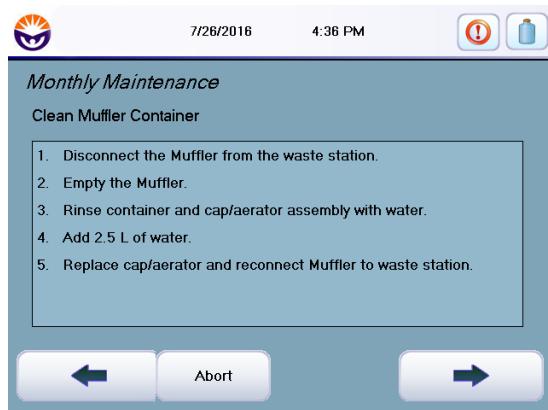
**Figure 8-31 – Empty and Clean Main Container display**

- 6 Empty and clean the scrubbing muffler (if filled).

**NOTE**

This step is not required if the option to redirect the vacuum exhaust is installed.

- a Disconnect the scrubbing muffler from the waste station by disconnecting the clip on the cap and remove the cap/aerator.
- b Empty the scrubbing muffler bottle into an approved waste container.
- c Rinse bottle, aerator and cap assembly thoroughly with the recommended detergent and water.
- d Add 2.5 L of water. Do not overfill.
- e Replace cap/aerator and re-connect to waste station by clipping the tubing to the cap.
- f Tap to continue.



**Figure 8-32 – Clean Muffler Container display**

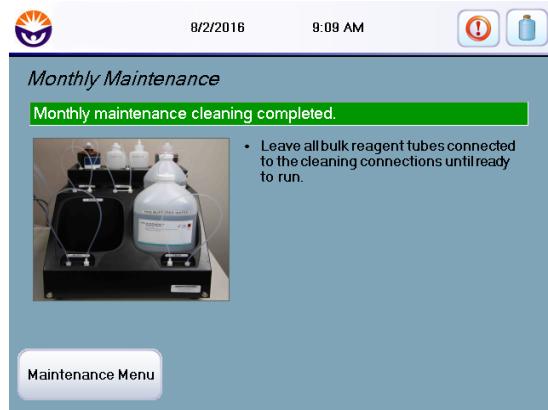
7 Monthly maintenance completed.

Reconnect the tubing from the bulk reagent station base to the reagent bottles if more runs are scheduled to be performed. Attach the quick disconnect port to the bulk reagent lid by turning the port clockwise onto the reagent lid. The tubing to the cleaning water container can be attached to the cleaning connection on the bulk reagent station base.

**NOTE**

If the reagent bottles are reconnected and the SlidePrep is not used, the reagents may cause capillary action in the tubing and subsequently dry out and crystallize. This may cause drips and decreased quality of slides.

Tap the MAINTENANCE MENU button to return to the **Maintenance Menu** display.



**Figure 8-33 – Monthly Maintenance–Completed display**

8 Once monthly maintenance is complete the SlidePrep may be turned off if needed. Refer to the system shutdown procedure in any of the Operations sections.

Document the monthly maintenance on the Maintenance Log provided at the end of this section.

## 8.6 Replacing the Handheld Barcode Reader

This procedure describes the steps necessary to install a new handheld barcode reader for use with the SlidePrep. See Section 11 – Ordering Information for handheld barcode reader ordering information.

To install the new barcode reader:

- 1 Turn off the SlidePrep (see Section 5.8.2 or Section 6.9.2).
- 2 Plug in the handheld barcode reader to the USB port marked “External BCR” on the right side of the SlidePrep.
- 3 Turn on the SlidePrep and allow the software to initialize.
- 4 Scan the 2-D barcode below.
  - a Point the barcode reader at the barcode then press and release the trigger.
  - b The reader sounds a beep to indicate that it has read the barcode successfully.



- 5 From the **Main Menu** display, tap UTILITIES > BARCODE TEST.
- 6 On the **Barcode Test** display, make sure the Handheld Reader status is “connected.”
- 7 Hold the barcode reader over any slide barcode label then press and release the trigger.  
A beep sounds and the barcode number appears in the display’s Handheld Reader window.
- 8 Tap the CLEAR RESULTS button on the display.
- 9 Tap the “Continuous Scan” checkbox on the display.
- 10 Hold the barcode reader over any slide barcode label.  
A beep sounds and the barcode number appears in the display’s Handheld Reader window.
- 11 Tap the CLEAR RESULTS button on the display.

Facility	Month	BD Totalys™ SlidePrep Maintenance Log																													
		BD Totalys™ SlidePrep Serial Number																													
Daily	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Run daily maintenance utility																															
Empty tip waste container																															
Empty liquid waste containers, if necessary, and (if installed) replace scrubbing muffler contents (2.5 L water)																															
Wipe surfaces with cleaning solution																															
<i>Initials</i>																															
<b>Weekly</b>																															
Clean birdbaths and reagent quick disconnect ports																															
Run weekly maintenance utility																															
Replace scrubbing muffler contents (2.5 L water) (if installed)																															
Check tubing connectors and syringe tightness																															
Empty liquid waste containers, if necessary																															
<i>Initials</i>																															
<b>Monthly</b>																															
Disconnect and clean bulk reagent containers																															
Clean caps/dip tubes																															
Clean TBS and cleaning water containers																															
Empty and clean waste containers																															
Empty and clean scrubbing muffler (Replace with 2.5 L water) (if installed)																															
<i>Initials</i>																															

# 9 – Troubleshooting

## 9.1 General

This section provides information on routine troubleshooting procedures.

### BD Technical Service and Support

Technical Information: In the United States contact BD Technical Service and Support at 1.800.638.8663 or [bd.com](http://bd.com).

Or contact your local BD representative.

## 9.2 Error Table

The following table describes situations that can occur during processing with the BD Totalys™ SlidePrep. The likely causes and potential corrective actions are listed next to each symptom. If the symptom is not corrected by the corrective action, contact BD Technical Service and Support for assistance.

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
<b>ALL SETTLING CHAMBERS DO NOT EMPTY</b>	The cap on a waste bottle is loose.	<ol style="list-style-type: none"><li>1. Ensure the lids on the waste bottles (main waste and scrubbing muffler) are tightened securely.</li><li>2. Ensure all tubing connections are secure.</li></ol>
	The vacuum pressure is too low.	<ol style="list-style-type: none"><li>1. Ensure all connections (blue plastic knobs) from the quad manifold are tight.</li><li>2. Check all reagent and waste bottles for hairline cracks.</li></ol>
	The vacuum line is clogged.	<ol style="list-style-type: none"><li>1. Examine all tubing to identify the vacuum line that is obstructed.</li><li>2. Use a stylus to unclog the vacuum line.</li></ol>
	The waste diverter valve or waste manifold is clogged.	Call BD Technical Service and Support for assistance.
	The vacuum pump is not on.	Call BD Technical Service and Support for assistance.
<b>DONUTTING</b> Macroscopically visible holes on slide.	The pipette bundles on the quad arm touch the slide surface during processing.	Call BD Technical Service and Support.

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
<b>DROPS FORM AT THE END OF THE DITI TIP OR PIPETTE STAINING BUNDLE</b>	The vacuum pressure is too low or air is present in tubing.	<ol style="list-style-type: none"> <li>1. If air is observed in any tubing, tighten the connections to that tubing line.</li> <li>2. Tighten all connections that carry liquids (knobs and rings on syringes, knobs on waste manifold, knobs on quad arm).</li> </ol>
<b>FAILURE TO PICK UP A TIP</b>	-----	Call BD Technical Service and Support.
<b>HYPOCCELLULARITY (TOO FEW CELLS)</b>	BD SurePath™ PreCoat Slides were not used.	Use BD SurePath™ PreCoat Slides on the SlidePrep.
	An inappropriate fixative was used to preserve the specimen.	Use BD SurePath™ Preservative Fluid.
	The BD SurePath™ PreCoat Slides are expired.	Discard expired BD SurePath™ PreCoat Slides and use BD SurePath™ PreCoat Slides that are within expiration date limits.
<b>NUCLEUS IS TOO DARK</b>	An inappropriate fixative was used to fix the specimen.	Use BD SurePath™ Preservative Fluid.
	Drying artifact; the setting chamber was removed and the cell surface dried before the mounting media and cover glass was added.	Complete dehydration clearing as soon as possible after slides are finished processing on the SlidePrep.
<b>OBSTRUCTION</b>	One of the quad arm pipette bundle tips is clogged.	<ol style="list-style-type: none"> <li>1. Identify the tip that is clogged.</li> <li>2. Use a stylus to unclog the tip.</li> <li>3. Clean the outside of the tip with an alcohol wipe.</li> </ol>
<b>ONE SETTLING CHAMBER DOES NOT EMPTY</b>	A vacuum line popped off of the quad manifold.	Call BD Technical Service and Support.
	One of the pipette bundles on the quad arm is clogged.	<ol style="list-style-type: none"> <li>1. Identify the pipette bundle that is obstructed.</li> <li>2. Use a stylus to unclog the pipette bundle.</li> <li>3. Clean the outside of the pipette bundle with an alcohol wipe.</li> </ol>

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
	The vacuum line is clogged.	<ol style="list-style-type: none"> <li>1. Isolate the vacuum line that is causing the obstruction.</li> <li>2. Refer to Section 7.7.8 for detailed instructions to resolve a clogged vacuum tube.</li> </ol>
<b>CLOGGED VACUUM TIP</b>	The vacuum line is clogged during a run.	<ol style="list-style-type: none"> <li>1. Use a stylus to unclog the vacuum line.</li> <li>2. If the quad arm and bundles are inside of the settling chambers, or in the birdbath when the clog occurs, hit pause on the touchscreen.</li> <li>3. Open slide doors.</li> <li>4. Open transom door.</li> <li>5. DO NOT SLIDE THE SLIDE TRAY OUT as this will immediately abort the run.</li> <li>6. Once you have identified the clogged line or lines, gently remove the tubing from the top of the vacuum line without moving the quad arm. Moving the quad arm to the left or right will result in additional errors.</li> <li>7. Insert the stylus into the tubing.</li> <li>8. Push the stylus down to dislodge the clog.</li> <li>9. Re-connect the tubing to the quad bundle.</li> <li>10. Close the transom door.</li> <li>11. Close the slide tray doors.</li> <li>12. Unpause and run.</li> <li>13. Verify that aspiration has begun.</li> <li>14. Repeat as necessary.</li> </ol> <p>Dry excess liquid from above or below the slide trays as well as below the STS, Excess water may cause a malfunction. If a malfunction occurs contact BD Technical Service and Support.</p>
	The vacuum line remains clogged.	Call BD Technical Service and Support.
<b>ONE SETTLING CHAMBER DOES NOT FILL</b>	One of the quad manifolds or quad arm pipette bundle tips is clogged.	<ol style="list-style-type: none"> <li>1. Identify the manifold or tip that is obstructed.</li> <li>2. Use a stylus to unclog.</li> <li>3. Clean the outside of the manifold or tip with an alcohol wipe.</li> </ol>
<b>PINK SPOTS</b>	Z-max of the slide quad is too high.	Call BD Technical Service and Support for adjustment.
	The quad arm pipette bundle tips are dripping.	Check all tubing connections.

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
<b>PIPETTE TIP MISSES TARGET</b>	DASR or slide tray are not fully seated.	<ol style="list-style-type: none"> <li>1. Ensure that the DASR and slide trays are fully seated.</li> <li>2. Start a run to test if a pipette tip is picked up.</li> </ol>
<b>RIMMING</b> Most of the cells are located on the outer edge of the 13 mm circle.	An inappropriate fixative was used.	Use BD SurePath™ Preservative Fluid.
	The settling chambers are not sealed on the slide.	Use BD SurePath™ PreCoat Slides and do not re-use the settling chambers.
	BD SurePath™ PreCoat Slides were not used.	Use BD SurePath™ PreCoat Slides.
	The Z dispense setting is incorrect.	Call BD Technical Service and Support.
	The pipette bundle position is incorrect.	Call BD Technical Service and Support.
<b>SLIDE BARCODES DO NOT MATCH SPECIMEN SAMPLES DURING SCAN SLIDES PROTOCOL SETUP</b>	-----	<ol style="list-style-type: none"> <li>1. If in remote station sample ID mode, return to the Select Sample ID Mode display and choose positional or barcode sample ID for this protocol.</li> <li>2. If in barcode sample ID mode, either scan manually with the handheld barcode reader or return to the Select Sample ID Mode display and choose positional ID for this protocol.</li> </ol>
<b>STAIN QUALITY IS INCONSISTENT</b>	One of the quad arm pipette bundle tips is clogged.	<ol style="list-style-type: none"> <li>1. Identify the tip that is clogged.</li> <li>2. Use a stylus to unclog the tip.</li> <li>3. Clean the outside of the tip with an alcohol wipe.</li> </ol>
	One or more of the reagent bottles is too low.	Check the levels of all reagent bottles prior to slide processing using the minimum volume gauge. Fill any reagents that are low. Refer to Section 5 or Section 6.
	Pausing the system once the staining process has started.	Allow the system to complete the run once the staining process has started. Determine the acceptability of slides when using the pause function.
<b>TIP IS NOT EJECTED</b>	-----	Call BD Technical Service and Support.
<b>TIP FALLS OFF DURING TRANSPORT</b>	-----	Call BD Technical Service and Support.

SYMPTOM	LIKELY CAUSE(S)	CORRECTIVE ACTION SEQUENCE
<b>VACUUM CHECK FAILS DURING CHECK DECK CONFIGURATION</b>	TBW reagent bottle is empty.	Fill the TBW reagent bottle and select the RETRY button to restart the Check Deck Configuration. If problem persists after restarting the Check Deck Configuration multiple times, contact BD Technical Service and Support.
	Vacuum connections and/or vacuum bottle lids not connected properly.	Ensure all tubing and caps are properly connected then select the RETRY button to restart the Check Deck Configuration. If problem persists after restarting the Check Deck Configuration multiple times, contact BD Technical Service and Support.
<b>VOLUME OF DISPENSED REAGENT VARIES</b>	-----	<ol style="list-style-type: none"> <li>1. If there are air bubbles in the tubing, tighten the tubing connections. Prime affected lines. See Section 7.7.6.</li> <li>2. Check the levels in the reagent containers using the minimum volume gauge. Fill any reagents that are low. Refer to Section 5, or Section 6.</li> </ol>
<b>REMOTE STATION ERRORS</b>	Various	Refer to the <i>BD Totalys™ MultiProcessor User's Manual</i> . Information is presented on sample and processing errors that may affect remote station data. Messages regarding these items appear on the MultiProcessor batch reports.
<b>OVERFLOWING MUFFLER CONTAINER</b>	Did not empty scrubbing muffler when main waste container was emptied	Empty container and refill with 2.5 L of water.



# 10 – Glossaries

## 10.1 Glossary of Terms

Refer to the following descriptions as a guide to the mechanical components that make up the BD Totalys™ SlidePrep and the terms used in the process.

Term	Description/Function
Alcohol blend rinse	A proprietary combination of alcohols, one of the reagents used on the bulk reagent station.
Base unit	Robotic sample processor. A system of microprocessor-controlled liquid handling components.
Centrifugation	A process to separate fluid(s) and solid(s) using centrifugal force.
Centrifuge bucket lids	A safety lid that snaps over the top of the small centrifuge bucket to prevent spills or creation of aerosols during centrifugation.
Cleaning Contrad solution	10% Contrad 70 (prepared from Contrad 70) for use during daily, weekly and monthly maintenance.
Cleaning water	DI or distilled water for use during daily, weekly and monthly maintenance.
Computer (CPU)	Hardware component that stores software applications (programs) and data. The SlidePrep CPU is built into the system.
C-tube rack	A centrifuge tube rack capable of holding twelve 12 mL c-tubes. The c-tube rack for the BD PrepMate™ Automated Accessory and the MultiProcessor are shaped differently. The SlidePrep DASR is setup to fit the appropriate c-tube rack.
Decant	Pour off supernatant (liquid).
DASR (Deck Accessories Support Rack)	Tray on the SlidePrep that holds reagent kit, control kit, tip racks, and c-tube racks. One of two different DASR modules is installed with the SlidePrep depending on whether it is set up with a MultiProcessor instrument.
DiTi (Disposable Tip)	A plastic pipette on the robotic arm that is used to mix and distribute the cell solution onto the glass slide.
Easy aspirator block	A 12 position block used to aspirate fluid from c-tubes while placed in the c-tube rack during pre-processing. Clear disposable pipette tips are used.
EA/OG stain	One component of the cytoplasmic Papanicolaou stain. The mixture contains a modified Eosin-50 and Orange G.

Term	Description/Function
Hematoxylin stain	Water based, nuclear stain used as part of the Papanicolaou stain. Designed specifically for use on the SlidePrep. Compatible for use with slides to be processed on the BD FocalPoint™ Slide Profiler.
Mounting media	Toluene or xylene based solution used to adhere the coverslip to the microscope slide.
Non-Gyn	An application for use on the SlidePrep for preparing slides for non-gynecological specimens.
Pipette bundle	Located on the quad arm and consists of four dispensing tips mounted around a longer vacuum tip. Dispenses stains, alcohol, bulk reagents, and water.
Quad arm assembly	A system of pipette bundles, tubing and manifolds mounted on the robotic arm of the SlidePrep. Allows staining operations to be performed on four samples at once. Reagents are dispensed through four pipette bundles and waste is removed through a vacuum pipette. Engaged to move by the quad engagement key on the Z-rod handle.
Quad engagement key	Engages the quad handle on the quad arm assembly.
Quad manifold	Four plastic housings mounted on the quad arm assembly. Holds tubing from syringes to pipette bundles.
Run report	Detailed description of events and reagents related to a specific run on the SlidePrep.
Settling chambers	Plastic chamber that fastens onto the slide in the slide tray. O-ring component creates a seal with the slide. Holds samples and other liquids during slide processing.
Scrubbing muffler	Located on the waste station, removes volatile organic fumes from exhaust tubing. There is an option to re-direct the vacuum exhaust to a fume hood rather than absorb the volatile organic fumes in water.
Slide tray	A metal tray fabricated with twelve rectangular cut-outs designed specifically to hold microscope slides. Each cut-out has a slotted track used to hold a settling chamber onto the slide surface. Four trays fit on the STS of the SlidePrep. Capacity of 12 glass slides in a 4 x 3 format.
STS (Slide Tray Support)	Holds the slide trays on the SlidePrep. Each STS is configured to specifically hold its own slide tray.

Term	Description/Function
Solvent resistant marker	A pen/marker with ink insoluble with alcohol, water, or xylene/xylene substitutes.
BD SurePath™ Liquid-based Pap Test	An <i>in vitro</i> diagnostic test intended for use on the SlidePrep for the screening and qualitative detection of cervical cancer and its precursors in cervical cytology specimens. Uses Papanicolaou staining.
BD SurePath™ PreCoat Slides	Microscope slide coated to create a positive charge on the slide surface. This positive charge enables adhesion of the negatively charged diagnostic cytological material to the slide throughout the slide preparation process.
BD SurePath™ Preservative Fluid	A proprietary fluid used to collect and preserve samples.
Syringe pump	A microprocessor-controlled pump with syringes and 2-way valves used to dispense liquids.
Syringes	A device used to draw in and then expel a liquid solution. On the SlidePrep, four syringes are used to move water, alcohol, hematoxylin, and EA/OG. A fifth syringe is multi-valved and used to dispense multiple reagents.
TBW (Tris Buffered Water)	A dilute tris buffered saline solution used during cellular deposition onto slides.
Vacuum pump	An electric pump that creates a vacuum and used for aspiration. There is one vacuum pump used with the Easy Aspirator block and one located in the waste station on the SlidePrep.
Vortexer	An electric device that vibrates cell samples in either the collection device or agitates cell pellets in the c-tubes.
Waste containers	Bottles used to collect waste liquids resulting from slide processing (main and aux waste).
Z-Rod	A vertical toothed rack that is raised or lowered by the Z-stepper motor. Holds the DiTi components. Z movement mechanism.

## 10.2 Symbol Glossary

	Manufacturer
	Catalogue number
	Authorized Representative in the European Community
	Authorised representative in Switzerland
	In vitro diagnostic medical device
	Biological risks
	Caution
	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	Date of manufacture
	CE marking; Signifies European technical conformity
	Do not use if package is damaged and consult <i>instructions for use</i>
	Serial number
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>

# 11 – Ordering Information

Below is a list of components and kits for use with the BD Totalys™ System. For product availability, refer to the product catalog or contact your local distributor or BD representative.

Catalog/Component Number	Item Description
443327	BD Totalys™ MultiProcessor
490510	BD Aspirator Tips, 96
490515	BD Centrifuge Tubes, 480
490518	Tris Buffered Saline Packet
491075	BD SurePath™ PreCoat Slides, 96 (Japan Only)
491103	BD PrepMate™ Automated Accessory
491120	BD Totalys™ Transfer Tips, 192
491457	BD Alcohol Blend Rinse, 1,700 mL
491137	Handheld 2D Barcode Reader
491248	BD SurePath™ PreCoat Slides, 96
491287	BD Totalys™ MultiProcessor DASR
491291	BD Totalys™ Standard DASR
491456	BD Totalys™ SlidePrep Consumables Kit Contains: BD SurePath™ PreCoat Slides, 480 BD Settling Chambers, 480 BD Totalys™ Transfer Tips, 576
491309	BD Totalys™ SlidePrep Consumables Kit (Japan Only)
491453	BD Totalys™ MultiProcessor Consumables Kit Contains: BD Density Reagent, 480 mL BD Density Reagent, 1.9 L Tris Buffered Saline Packets, 2 BD Centrifuge Tubes with 2D Barcode, 480 BD Syringing Pipettes, 480
491455	BD PrepMate™ Consumables Kit Contains: BD Density Reagent, 480 mL BD Centrifuge Tubes, 480 BD Syringing Pipettes, 480 BD Aspirator Tips, 480

Catalog/Component Number	Item Description
491323	BD Centrifuge Tubes with 2D Barcode, 480
491331	BD Syringing Pipettes, 240
491332	BD Density Reagent, 480 mL
491458	BD Cytology Stain Kit Contains: BD Hematoxylin Stain 0.75, 480 mL BD EA/OG Combo Stain, 480 mL
491337	BD SurePath™ Preservative Fluid, 3,600 mL
491346	BD Totalys™ SlidePrep
491348	BD Totalys™ SlidePrep Waste Station
491350	BD Totalys™ SlidePrep Bulk Reagent Station
443948	BD SlidePrep™ Exhaust Kit

Additional components and kits for Non-Gynecological use with the BD Totalys™ SlidePrep.

Catalog/Component Number	Item Description
490719	BD CytoRich™ Clear Preservative 3.6 L
491304	BD Totalys™ SlidePrep Non-GYN Test Kit Contains: BD Centrifuge Tubes, 192 BD SurePath™ PreCoat Slides, 192 BD Settling Chambers, 192 BD Totalys™ Transfer Tips, 192
491459	BD Non-GYN Stain Kit Contains: BD Hematoxylin Stain 0.5, 480 mL BD EA/OG Combo Stain, 480 mL
491335	BD CytoRich™ Blue Preservative, 3,600 mL
491336	BD CytoRich™ Red Preservative, 3,600 mL



# 12 – Ancillary Testing from the BD SurePath™ Collection Vial

## 12.1 Purpose

In order to perform *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) testing using the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays out of the BD SurePath™ Collection Vial (specimen vial), specific processing steps provided in this appendix must be followed.

An aliquot of collected specimen (up to 0.5 mL) may be removed from the BD SurePath™ Collection Vial for this ancillary testing *prior* to the BD Totalys™ SlidePrep test process.

## 12.2 Procedure

### NOTE

Sufficient volume is available in the BD SurePath™ Collection Vial to allow removal of up to 0.5 mL of homogenous mixture of cells and fluid for ancillary testing, while still being able to perform testing using the BD Totalys™ SlidePrep.

- 1 In order to ensure a homogenous mixture, the BD SurePath™ Collection Vial must be vortexed for 10–20 seconds (refer to Section 4.3.2) and the 0.5 mL aliquot must be removed within one minute of vortexing.
- 2 Use a polypropylene aerosol barrier pipette tip that is appropriately sized for the volume to withdraw the desired volume aliquot from the specimen vial. Dispense aliquot into desired tube or sample collection container.

### NOTE

A maximum 0.5 mL aliquot may be removed from the specimen vial prior to processing a BD SurePath™ Liquid-based Pap Test. Only one aliquot may be removed from the specimen vial prior to performing a BD SurePath™ Liquid-based Pap Test, regardless of the volume of the aliquot.

Do not use serological pipettes. Follow standard good laboratory practices to avoid introducing contaminants into the specimen vial or the aliquot.

Perform aliquot removal in an appropriate location away from any area where amplification is performed.

- 3 Visually check the aliquot material in the pipette for evidence of large particulates or semi-solids. If any aliquot has evidence of such material, return all of the aliquot to the specimen vial. These samples are not eligible for ancillary testing.
- 4 For instructions on dispensing and processing the aliquot for use with the BD ProbeTec™ *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays, consult the package inserts provided with the assay kits.

## 12.3 General Precautions

While there is no evidence that removal of an aliquot from the BD SurePath™ Collection Vial affects the quality of the specimen for cytology testing, rare instances of misallocation of pertinent diagnostic material may occur during this process. Healthcare providers may need to acquire a new specimen if the results do not correlate with the clinical history of the patient. Furthermore, cytology addresses different clinical questions than sexually transmitted disease (STD) testing; therefore, aliquot removal may not be suitable for all clinical situations. If necessary, a separate specimen may be collected for STD testing, rather than taking an aliquot from the BD SurePath™ Collection Vial.

Aliquot removal from low-cellularity specimens may leave insufficient material in the BD SurePath™ Collection Vial for preparation of a satisfactory BD SurePath™ Liquid-based Pap Test.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

## 13 – Contacts

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Report any serious incident that has occurred in relation to the device to your BD Representative (or Manufacturer) and EU National Competent Authority. For incidents occurring outside of the EU, contact your BD Representative.

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