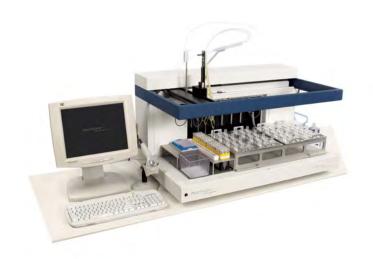


## **⇔** BD PrepStαin™ Slide Processor

### User's Manual







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> > 500005572(10) 2021-11 REF 490100, 491425

> > > **English**



bd.com/e-labeling

#### **Change History**

| Revision | Date    | Change Summary   |
|----------|---------|--|
| 08       | 2018-11 | Updated ordering information.  |
| 09       | 2020-04 | Updated operating conditions. Removed BD PrepMate <sup>™</sup> specifications and referenced the BD PrepMate <sup>™</sup> User Manual. Converted printed instructions for use to electronic format and added access information to obtain the document from bd.com/e-labeling. |
| 10       | 2021-11 | Updated images of the BD PrepStain™ instrument and its parts.  |

This User's Manual describes the function, operation and maintenance of the BD PrepStain™ Slide Processor for use in preparing BD SurePath™ Liquid-Based Pap Test Slides. Training by BD authorized personnel is required before operating the system. Please read this manual before using the BD PrepStain™ Slide Processor using BD SurePath™ reagents.

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#### **Preface**

#### About this manual

This manual is designed to be the primary resource for understanding how to use the BD PrepStain™ Slide Processor (BD PrepStain™) to produce BD SurePath™ Liquid-based Pap Test slides (BD SurePath™ slides). Users of this manual are expected to have received training by BD authorized personnel and to have had hands-on experience in processing samples.

#### **CAUTION**

- 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 PrepStain™ system.
- This equipment generates and uses radio frequency energy. It has been type tested and found to comply with the limits for ISM-equipment in accordance with the requirements for FCC Part 15 Subpart J, Class A and EN 55011, Class B, which are designed to provide protection against such interference in a residential installation. If the equipment is not used in strict accordance with the manufacturer's instructions, it may cause interference to radio and TV reception or the functionality of other electrical devices.

#### Formatting conventions

The following types of formatting are used in this document to identify important information.

- Type like this (This Key) indicates a reference to a key that you press.
- Type like this (Type This) is a reference to a keystroke that you type.
- Type like this (screen Text) is a reference to a text that appears on screen.
- Type like this (see *Introduction*) is a reference to text elsewhere in this manual.

There are three notice types used in this reference: a warning, a caution and a note. These notices highlight important information or warn the operator of potentially dangerous situations. The appearance and usage of each type is detailed below:

#### **WARNING**

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

#### **CAUTION**

Indicates the possibility of equipment damage or invalid results if instructions are not followed.

#### NOTE

Gives helpful information about the BD PrepStain™ system.

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# **Chapter 1 System Overview**

#### **Intended Use**

The BD PrepStain™ system (formerly the AutoCyte® PREP System) is a liquid based thin layer cell preparation process. The BD PrepStain™ system produces BD SurePath™ Liquid-based Pap Test slides that are 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

BD SurePath<sup>™</sup> Preservative Fluid is an appropriate collection and transportation medium for gynecologic specimens tested with BD ProbeTec<sup>™</sup> *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays.

Refer to the assay package inserts for instructions on using BD SurePath™ Preservative Fluid to prepare specimens for use with these assays.

1. Solomon D, Nayar R (editors): The Bethesda System for Reporting Cervical Cytology. New York, Springer Verlag, 2004.

#### Installation

Installation and initial verification of performance can be performed only by BD authorized service personnel.

The BD PrepStain™ system arrives in one or more shipping cartons. The remainder of this chapter details the content of these cartons.

The instrument must be unpacked by a qualified BD representative or termination of the warranty may result.

If the BD PrepStain<sup>™</sup> instrument must be moved after it is installed by BD personnel, note the weight in the Specifications section and take the appropriate steps to move it safely.

#### Introduction

This chapter introduces the BD PrepStain™ Slide Processor and system components. The components of the system and their functions are described, as are the various consumable items used in processing a BD SurePath™ Pap test.

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

#### 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.

#### BD PrepStain™ components

The following illustrations and descriptions describe the primary components that make up the BD PrepStain™ system.

## Vortexer descriptions

Figure 1 illustrates the single and multi-vial vortexers that are used to mix the specimen so that there is a homogeneous distribution of cells for processing on the BD PrepStain<sup>™</sup> instrument.

- The single-vial vortexer processes a single specimen vial at a time. It is also used to vortex the centrifuge bucket after the second centrifuge cycle. (This item is not supplied by BD.)
- The multi-vial vortexer allows you to process up to 25 specimen vials at a time. (This item is provided by BD.)

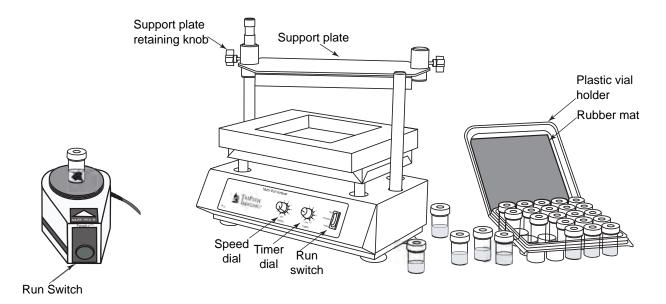


Figure 1 - Single and multi-vial vortexers

#### **CAUTION**

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

#### NOTE

Confirm the rubber mat is placed inside the lid of the clamshell in order to secure the vial in place during vortexing.

## BD PrepMate<sup>™</sup> description

Figure 2 illustrates the BD PrepMate<sup>™</sup> Automated Accessory (BD PrepMate<sup>™</sup>), the specimen processing rack, and the centrifuge bucket. The BD PrepMate<sup>™</sup> is designed to transfer the cell solution from the BD SurePath<sup>™</sup> Collection Vial to a BD Centrifuge Tube that contains the BD Density Reagent.

The specimen rack holds the centrifuge bucket, and up to 12 sets of specimen vials, BD Centrifuge Tubes, and BD Syringing Pipettes. The specimen vials contain the detached head of the sampling device, in BD SurePath™ Preservative Fluid. The centrifuge tubes contain 4 mL of BD Density Reagent (aliquoted into each tube by the user). The BD Syringing Pipettes are used to mix and then transfer the specimen solution from the BD SurePath™ Collection Vials to the centrifuge tubes. After the transfer, the centrifuge tubes are placed in the centrifuge rack.

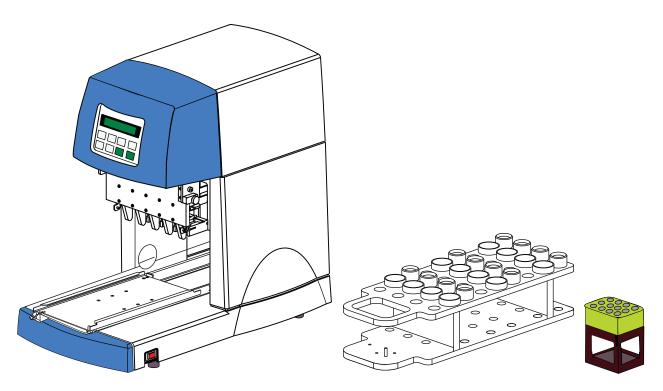


Figure 2 - PrepMate, plastic specimen rack, and centrifuge bucket

## BD PrepMate™ specimen rack

Figure 3 illustrates a BD PrepMate<sup>™</sup> specimen rack fully loaded with a centrifuge bucket, BD Centrifuge Tubes, specimen vials, and syringing pipettes.

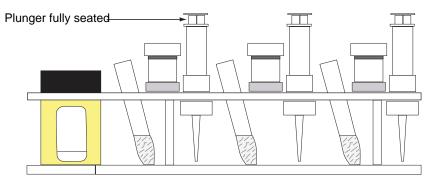


Figure 3 – Loaded specimen rack

## **BD Syringing Pipettes**

The BD Syringing Pipettes (illustrated in Figure 3) are plastic syringes that transfer the sample from the specimen vial to the centrifuge tube.

## Centrifuge bucket

Figure 4 illustrates the centrifuge bucket. As illustrated in Figure 3, Figure 5, and Figure 13, this component fits into the BD PrepMate™ tray, the centrifuge, and the waste station of the BD PrepStain™. It holds the BD Centrifuge Tubes that contain the cell solution and BD Density Reagent. The bucket holds up to 12 centrifuge tubes at a time through both centrifugation cycles and during processing on the BD PrepStain™ instrument.

#### **Slides**

BD SurePath<sup>™</sup> PreCoat Slides are standard 25 by 75 mm microscope slides that have been coated and prepared for use in the BD PrepStain<sup>™</sup> System by the manufacturer.

#### Specimen vials

The BD SurePath<sup>™</sup> Collection Vial (illustrated in Figure 1 and Figure 3) is used to transport the patient sample.

## Centrifuge tubes

The BD Centrifuge Tubes (illustrated in Figure 4 and Figure 29) are 12 mL plastic test tubes that contain the sample throughout the cell enrichment process.

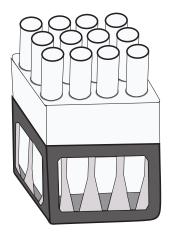


Figure 4 - Centrifuge bucket

#### Centrifuge

The centrifuge is used to prepare the concentrated cell pellet that is processed on the BD PrepStain™ instrument. This centrifuge provided with the BD PrepStain™ system is programmable and includes a variety of safety features. All programs necessary to process specimens on the BD PrepStain™ instrument have been pre-programmed at the manufacturer for your convenience. These programs occupy positions numbered 1 through 4 on the centrifuge.

Figure 5 illustrates the centrifuge racks being loaded into the centrifuge. The model of centrifuge may vary.



Figure 5 - Centrifuging the cell samples

#### **CAUTION**

The centrifuge Operator's Manual is separate from this manual. Please read the centrifuge Operator's Manual before operating the centrifuge.

## Fluid aspiration system

Figure 6 illustrates the Easy Aspirator (aspirator) block with the tips installed. The aspirator block connects to the vacuum pump by way of a waste bottle that collects the aspirated fluids.

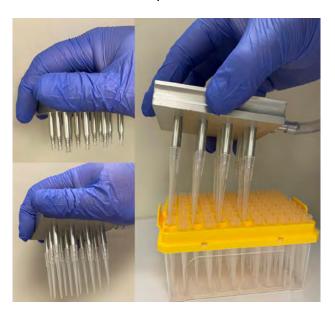


Figure 6 - Aspirator with tips

Figure 7 illustrates the vacuum waste bottle with its lid and tubing connections properly secured.



Figure 7 – Waste bottle for aspirated fluids

The vacuum pumps pictured in Figure 8 and Figure 9 are used to aspirate excess fluids. There are two of these pumps in a typical BD PrepStain™ system installation. (Either model may be present.)

- One pump is connected to the aspirator block. The tips insert into the BD Centrifuge Tubes, and are used to remove the excess fluids that have been isolated from the cell sample in the first centrifuge cycle.
- The second pump connects to the BD PrepStain<sup>™</sup> instrument's quad arm. Its function is to aspirate fluids from the BD Settling Chambers.



Figure 8 – Vacuum pump (international models may vary)



Figure 9 - KNF pump

#### WARNING

A POTENTIALLY SAFETY HAZARD HAS BEEN IDENTIFIED CONCERNING ALCOHOL VAPORS THAT ARE EXHAUSTED FROM THE BD PREPSTAIN™ VACCUUM PUMP (ALL SCHUCO AND KNF-NEUBERGER MODELS). THE VACCUUM PUMP EXHAUSTS ALCOHOL VAPORS DURING NORMAL OPERATION THAT COULD CAUSE INFLAMMABLE ATMOSPHERE IF THE PUMP IS KEPT IN AN ENCLOSED SPACE, e.g. CABINET. REMOVE THE VACCUUM PUMP FROM ANY ENCLOSED SPAVES THAT ARE NOT VENTILATED. THE VACCUUM PUMP SHOULD BE USED IN A WELL-VENTILATED SPACE THAT IS FREE OF IGNITION SOURCES CLOSE TO THE EXHAUST.

## BD PrepStain™ instrument

Figure 10 illustrates the BD PrepStain™ Slide Processor. The BD PrepStain™ instrument transfers cell samples from the BD Centrifuge Tube to a settling chamber mounted on a microscope slide. The BD PrepStain™ instrument then automatically stains and rinses each slide.

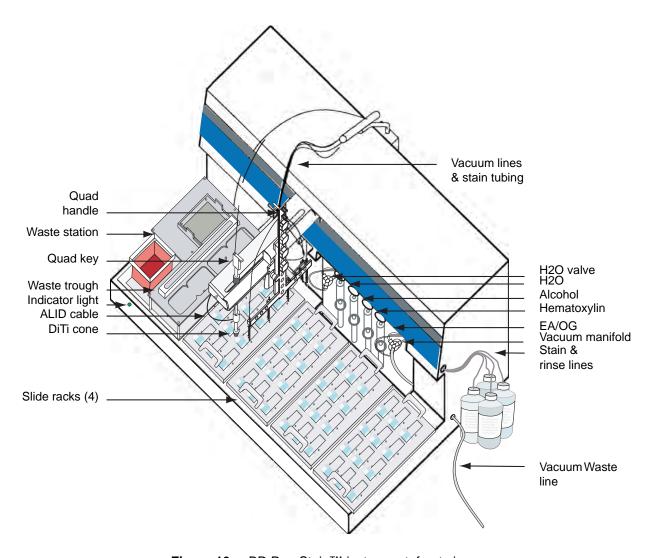


Figure 10 - BD PrepStain™ instrument, front view

#### **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 INSTRUMENT IS IN OPERATION. THE INSTRUMENT IS DESIGNED FOR AUTOMATIC "HANDS-OFF" OPERATION ONLY. NEVER REACH INTO THE INSTRUMENT WORK SPACE WHEN THE UNIT IS IN AN OPERATING MODE. A SAFETY GUARD IS PROVIDED WITH THE INSTRUMENT TO PREVENT ACCIDENTAL CONTACT WITH ANY MOVING COMPONENTS.
- BUMPING THE ROBOTIC DEVICE (QUAD ARM OR DITI ASSEMBLY) MAY RESULT IN INSTRUMENT ERROR.
- IF IT IS NECESSARY TO INTERRUPT OPERATION OF THE INSTRUMENT, CHECK THE SCREEN DISPLAY FOR THE "USER BREAK" COMMAND (THE <F-10> KEY ON THE COMPUTER KEYBOARD). THE SYSTEM WILL STOP AFTER COMPLETION OF THE CURRENT COMMAND AND AN OPTION MENU WILL APPEAR ON SCREEN.

#### WARNING

THIS EQUIPMENT GENERATES, USES AND CAN RADIATE RADIO FREQUENCY ENERGY, AND IF NOT INSTALLED AND USED IN ACCORDANCE WITH THE INSTRUCTIONS IN THIS MANUAL, MAY CAUSE INTERFERENCE TO RADIO COMMUNICATIONS.

The primary components of the BD PrepStain™ instrument are listed below:

- Robotic processor
- Waste station
- Quad arm
- Disposable Tip (DiTi) Assembly
- Rinsing and staining syringes
- Slide racks

Figure 11 illustrates the layout of a typical BD PrepStain™ instrument back panel. Refer to this illustration for help locating connections, switches, or fuses.

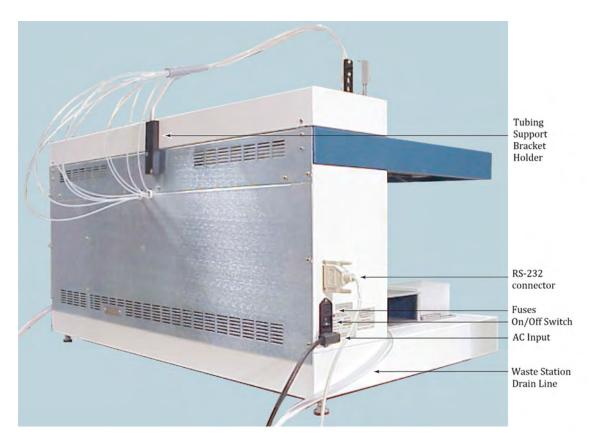


Figure 11 - BD PrepStain™ instrument, back panel

Figure 12 illustrates the connection layout of the inputs and outputs to the BD PrepStain™ instrument, the PC workstation and monitor, the vacuum pump, the vacuum waste bottle and waste bottle. Refer to this illustration and the following discussion for help in determining if all connections are setup properly.

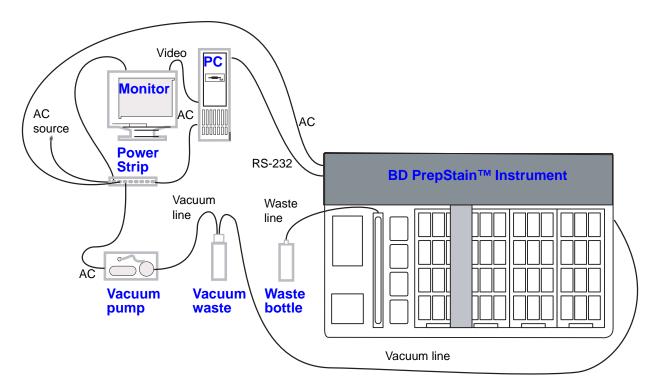


Figure 12 - BD PrepStain™ system connections

#### WARNING

THE BD PREPSTAIN™ INSTRUMENT MUST BE ELECTRICALLY CONNECTED TO EARTH-GROUND AT ALL TIMES.

TO ENSURE THAT THE POWER CORD AND OUTLET STRIP HAVE THE REQUIRED ELECTRICAL CURRENT RATINGS, ONLY USE THE CORD AND POWER STRIP SUPPLIED WITH THE UNIT, OR AS PROVIDED BY BD.

#### BD PrepStain™ instrument connections

There are two electrical inputs: AC power comes from the power strip and an RS-232 connection provides communication with the PC workstation.

#### PC workstation connections

Both the workstation and monitor get AC from the power strip. The workstation connects to the BD PrepStain™ instrument via an RS-232 cable. The monitor and workstation connect via a standard VGA cable.

#### Vacuum pump and waste bottle connections

The vacuum pump gets AC from the power strip. A vacuum line connects the pump to the vacuum waste bottle. The other line from the vacuum waste bottle connects to the vacuum manifold on the rear of the BD PrepStain<sup>™</sup> instrument (refer to Figure 11). The waste bottle connects to the waste trough via the waste line tubing.

Figure 13 illustrates the primary elements of the waste station. This component slides onto the slide processor as pictured in Figure 10.

- The waste container holds discarded tips.
- The tip holder stores unused tips in position for the DiTi arm to pick them up.
- The four centrifuge bucket holders position the BD Centrifuge Tubes so that the pelletized cell samples can be transferred to the BD Settling Chambers.
- The waste trough is used to drain the excess solution that is primed through the DiTi Assembly and reagent pipette bundles.
- The waste tubing drains the waste trough.

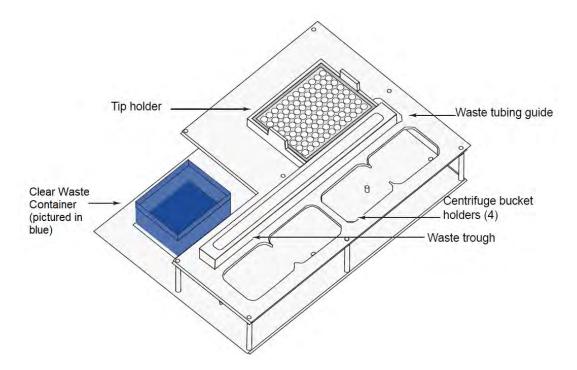


Figure 13 - Waste Station

Figure 14 illustrates the quad arm assembly. This assembly mounts to the chassis under the cover plate.

The arm is positioned perpendicular to the work platform and aligns with the slide racks in parallel with the Y axis. The arm's movement is in parallel to the X axis.

#### NOTE

The four manifolds correspond to the four reagents used, not to the four bundled sets of pipette tips and aspirator tips. Tubing from each manifold is routed to each bundle.

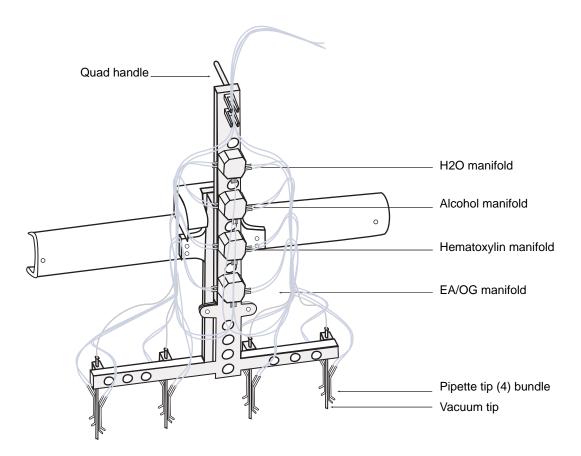


Figure 14 - Quad arm with pipette bundles, stain, and vacuum lines

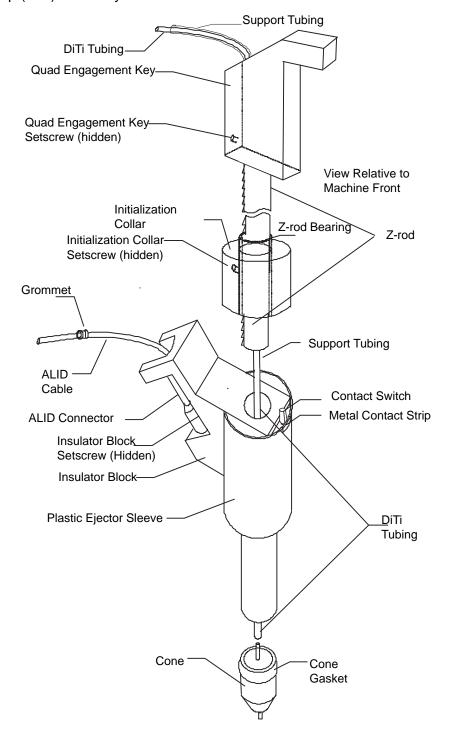


Figure 15 illustrates the key components that make up the disposable tip (DiTi) assembly

Figure 15 - Disposable tip (DiTi) assembly detail

Figure 16 illustrates the 5 mL syringes that are used to pump the rinsing and staining solutions to the quad arm pipette bundles.

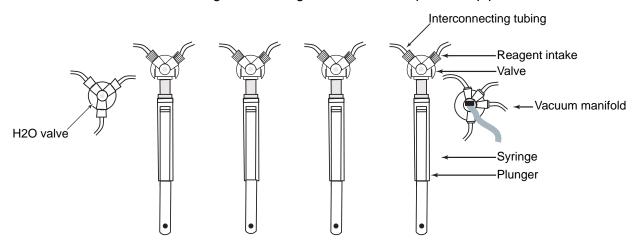


Figure 16 - Rinsing and staining syringes

Figure 17 illustrates one of four slide racks. The BD Settling Chambers insert into cutouts and then lock into place with a clockwise twist. Each chamber has a settling chamber seal. This seal keeps the liquid cell solution from seeping out from the settling chamber during processing.

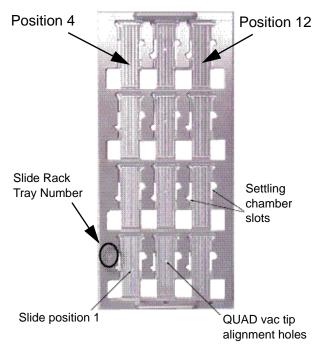


Figure 17 - Slide rack with settling chamber slots

Settling chamber

Rack alignment pins (keys)

The slide racks insert onto the work platform as illustrated in Figure 18. The work platform mounts to the right of the waste station.

Figure 18 - BD PrepStain™ slide racks

# **Chapter 2 System Specifications**

#### **BD PrepStain™ Slide Processor components**

BD PrepStain™ instrument specifications

| Weight:    | 147 lb (67 kg)         |
|------------|------------------------|
| Height:    | 34 inches (86 cm)      |
| Width:     | 40 inches (102 cm)     |
| Clearance: | 44 inches (112 cm)     |
| Depth:     | 25 inches (64 cm)      |
| Waste:     | 408 mL/48 sample       |
|            | run-Transfer and Stain |

#### **Operating conditions**

| Temperature       | 18-30 °C (64-86 °F)             |
|-------------------|---------------------------------|
| Relative Humidity | 20-80% non-condensing           |
| Altitude          | evaluated for safety to 2,000 m |
|                   | (6,562 ft.)                     |

#### Storage conditions

| Temperature       | 0-50 °C (32-122 °F)             |
|-------------------|---------------------------------|
| Relative Humidity | 30-85% at 40 °C or below        |
| ·                 | non-condensing                  |
| Altitude          | evaluated for safety to 2,000 m |
|                   | (6.562 ft.)                     |

#### **Power Requirements**

| Voltage   |   | 100–240  | VAC |
|-----------|---|----------|-----|
| Frequency | · | 50/60 Hz |     |

#### Computer

PC 386 or higher or any 100% compatible
At least 4 MB RAM
Serial Asynchronous Interface Adapter (RS 232)
Hard Disk with at least 10 MB of free space
3.5 inch floppy
VGA (640x480) or SVGA display adapter and monitor
MS DOS 6.0 and higher
Voltage: 120 V / 50–60 Hz

Power: 350 W

#### **Monitor**

Voltage: 100-240 V~ / 6A 50-60 Hz

Power: 25 watts

Height: approx. 24 inches

## Multi-vial vortexer (optional)

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

|           | 490406           | 490125           |
|-----------|------------------|------------------|
| VOLTAGE   | 100 to 120 Volts | 220 to 240 Volts |
| FREQUENCY | 50 to 60 Hertz   | 50 to 60 Hertz   |
| Power     | 100 Watts        | 100 Watts        |

Fuse 5 Amp quick acting (F) 1 Amp quick acting (F)

5x20 mm 5x20 mm

#### **Non-Operating Storage**

Ambient Temperature: -20-65 °C, -4-149 °F

Ambient Humidity: 20-85% RH, non-condensing

#### Operating conditions

Indoor Use only

Ambient Temperature: 18-33 °C, 64-91 °F

Ambient Humidity: 20–85% RH, non-condensing Altitude: 0 to 6,562 ft. (2,000 m) above sea level

Installation Category II and Pollution Degree 2 in accordance with IEC 664

General Weight: 36 lb (16.3 kg)
Width: 15 inches Depth: 12 inches

### Single vial vortexer

Required, but not provided, the single vial vortexer must be capable of developing 3,000 RPM.

100 to 120 Volts, 50 to 60 Hertz, 40 Watts

For BD PrepMate<sup>™</sup> specifications, please refer to BD PrepMate<sup>™</sup> User's Manual.

#### Centrifuge

Centrifuge specifications vary depending on the model shipped with your system. Values listed below are typical.

 Voltage:
 120 Volts

 Power:
 400 Watts

 Height:
 17 inches

 Clearance:
 38 inches (full open)

Width: ..... 24 inches

#### 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 INSTRUMENT IS IN OPERATION. THE INSTRUMENT IS DESIGNED FOR AUTOMATIC "HANDS-OFF" OPERATION ONLY. NEVER REACH INTO THE INSTRUMENT WORK SPACE WHEN THE UNIT IS IN AN OPERATING MODE. A SAFETY GUARD IS PROVIDED WITH THE INSTRUMENT TO PREVENT ACCIDENTAL CONTACT WITH ANY MOVING COMPONENTS.
- BUMPING THE ROBOTIC DEVICE (QUAD ARM OR DITI ASSEMBLY) MAY RESULT IN INSTRUMENT ERROR.
- IF IT IS NECESSARY TO INTERRUPT OPERATION OF THE INSTRUMENT, CHECK THE SCREEN DISPLAY FOR THE "USER BREAK" COMMAND (THE F-10 KEY ON THE COMPUTER KEYBOARD). THE SYSTEM WILL STOP AFTER COMPLETION OF THE CURRENT COMMAND AND AN OPTION MENU WILL APPEAR ON SCREEN.

## PREP system component layout

The following table describes the physical layout of a BD PrepStain™ system. How you situate each component in relation to the others depends on your space constraints and workflow.

| COMPONENT<br>NAME | COMPONENT<br>ILLUSTRATION | CLEARANCE   |
|-------------------|---------------------------|---|
| CENTRIFUGE        | 24" —                     | Overhead clearance: 38 inches for lid to open fully. However the lid's stabilizers allow partial opening in tight spaces. |

Table 2-1 BD PrepStain™ slide processor counter top space

| COMPONENT<br>NAME                   | COMPONENT<br>ILLUSTRATION | CLEARANCE  |
|-------------------------------------|---------------------------|--|
| MONITOR & KEYBOARD                  | 18'                       | Overhead clearance: 24 inches Although the monitor and keyboard do not need to be on the counter, they must be in close proximity to the instrument. (Model may vary.)   |
| MULTI-VIAL<br>VORTEXER              | 17.5"                     | Note: to reduce the effects of vibration, consider locating automated components on a counter top that is separate from the one that supports the BD PrepStain™ instrument.  |
| PREPSTAIN INSTRUMENT AND STAIN RACK | 25", 12"                  | Rear clearance: 4 inches Overhead clearance: 34 inches Note: to reduce the effects of vibration, consider locating automated components on a counter top that is separate from the one that supports the BD PrepStain™ instrument. |
| PREPMATE                            | → 13" →  26"              | Note: to reduce the effects of vibration, consider locating automated components on a counter top that is separate from the one that supports the BD PrepStain™ instrument.  |
| WORKSTATION<br>CPU                  | _6.5"<br>17"<br>          | Although the CPU does not need to be on the counter, it must be in close proximity to the instrument.  |

Table 2-1 BD PrepStain™ slide processor counter top space

Although there is no clearance specification for the components listed below, make sure there is either floor space below or space above the counter nearby, and that the instrument is operating in a well-ventilated area.

| COMPONENT                             | FOOTPRINT (length x depth) |
|---------------------------------------|----------------------------|
| BD PrepStain™ instrument Vacuum Pump  | 12 x 18 inches             |
| BD PrepStain™ instrument Waste bottle | 7 x 10 inches              |

Table 2-2 BD PrepStain™ Slide Processor floor or under counter space

In addition, backside clearance is essential for the power cords, vacuum pumps, and the CPU air intake grills.

#### **CAUTION**

Do not store in closed, non-ventilated areas as vacuum pump exhausts alcohol vapors that could cause a flammable atmosphere if the pump is kept in an enclosed space, e.g., cabinet.

#### NOTE

Check the Use By date on carton labels of consumables for expiration dated material.

# Materials required (available from BD)

BD PrepStain™ Slide Processor and accessories

- BD SurePath<sup>™</sup> Collection Vials
- Cervical sampling device(s) with detachable head(s)
- BD Density Reagent
- BD Syringing Pipettes
- BD Settling Chambers
- BD Cytology Stain Kit
- BD SurePath™ PreCoat slides
- BD PrepStain™ Transfer Tips
- BD Centrifuge Tubes
- BD PrepMate<sup>™</sup> Automated Accessory
- BD Aspirator Tips
- BD PrepMate<sup>™</sup> Installation Kit
- BD PrepStain™ System Install Kit
- BD Alcohol Blend Rinse
- BD SurePath™ Preservative Fluid
- Tris Buffered Saline Pack pH 8.0

## Materials required but not provided

- Deionized Water
- Isopropanol and Reagent Grade Alcohol (alternative to BD Alcohol Blend Rinse)
- Clearing Agent, Mounting Media and Glass Coverslips
- Contrad 70, Decon 90, or bleach

#### Installation

BD PrepStain™ Slide Processor installation must be performed only by BD authorized personnel. A service representative will work with key operators and provide verification documentation of correct system installation.

# **Chapter 3 Principles of Operation**

This chapter describes the process used by the BD PrepStain<sup>™</sup> system in the preparation of BD SurePath<sup>™</sup> slides. The sequence of tasks and the operating principles used by each component in the process are described as well.

#### **Process overview**

The BD PrepStain<sup>™</sup> system is based on a semi-automated procedure for the preparation of liquid based cervical cell samples.

There are three main phases in the BD SurePath<sup>™</sup> slide preparation process. These phases are listed below:

- Specimen collection
- Cell enrichment
- Slide preparation and staining

#### **Specimen collection**

Using the collection device, the specimen is collected at the doctor's office. The device head containing the cervical sample is placed into a vial of BD SurePath™ Preservative Fluid and sent to the laboratory.

Specimen Vial

Specimen Vial

Specimen Vial

Specimen Vial

Figure 19 - Specimen collection device and collection vial

### Collection vial and devices

The BD SurePath<sup>™</sup> Collection Vial contains a buffered 24% ethanol solution that is similar to other cytologic preservative fluids. The preservative fluid fixes diagnostic cells and is bactericidal for gram-negative enterics, gram-positive cocci, and fungi.

#### Detachable head collection devices

A broom-type device and a combination brush/plastic spatula are the two recommended sampling devices for the collection of cervical specimens for the BD SurePath<sup>™</sup> Pap Test. These devices are pictured in Figure 20.



Figure 20 – Detachable head collection devices

#### **Broom-type device**

A broom-type device (e.g., Rovers<sup>®</sup> Cervex-Brush, Rovers Medical Devices B,V., Oss - The Netherlands) is one of two recommended sampling devices for the collection of cervical specimens for the BD SurePath™ system. The central bristles of the device are inserted far enough into the cervical os to obtain cells from the endocervix. The device is rotated 360 degrees in a clockwise direction five times. The side bristles sweep cells from the ectocervix and transformation zone.

#### Combination brush/plastic spatula device-type device

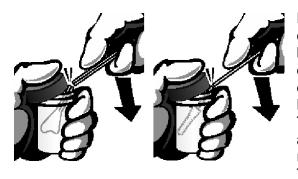
The Pap Perfect® (CooperSurgical Inc., Trumbull, CT) spatula and Cytobrush® Plus GT devices combine to make up the other recommended sampling method for the collection of cervical specimens for the BD SurePath™ Pap Test.

First, the contoured end of the plastic spatula is inserted into the cervical os and then rotated 360° around the entire exocervix. Next the brush is inserted into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ½ to ½ turn in one direction.

Once the cervical cells have been obtained, the sampling device is placed in a vial of preservative fluid and the handle of the device is removed, leaving the head(s) of the device in the collection vial. The labeled vial is capped tightly and transported to the clinical laboratory for testing.



Figure 21 - BD SurePath™ Collection Vial



Drop or snap off the device heads from their handles and drop the detachable heads of the device into the BD SurePath™ vial. There are several approved methods for removing these heads. The cap-assisted method is pictured here. See product insert for instructions.

Figure 22 – BD SurePath™ Collection Vial and combination devices

#### Specimen handling and cell enrichment

During this phase of the BD SurePath™ slide preparation process, the cervical samples are homogenized (blended) and the cellular material is evenly distributed throughout the vial (randomized). In the process, the sample is prepared in a series of manual steps that include vortexing to mix and disaggregate the sample, mixing, layering onto BD Density Reagent, and centrifugation. This process is called cell enrichment and removes a significant amount of obscuring material such as mucus, blood and white blood cells leaving the diagnostically relevant cells available for evaluation.

## Sample randomization

To start the cell enrichment process, the BD SurePath<sup>™</sup> collection vials are vortexed for 15 ± 5 seconds at 3,000 rpm. Shearing forces of the vortex free cells and cell clusters from the specimen collection device and partially disaggregate cell clusters.

#### NOTE

Place rubber mat inside the clamshell lid to secure the vials during vortexing. Failure to do so will prohibit the vortexing action that must occur within the vial.



Figure 23 – Preparing specimen vials for transfer

#### NOTE

Figure 23 and Figure 24 illustrate some of the components used to perform these particular tasks.

#### NOTE

An aliquot of the specimen (up to 0.5 mL) may be removed from the vial for ancillary testing prior to the BD SurePath<sup>™</sup> Pap test process.

See Chapter 11, *Ancillary Testing from the BD SurePath*<sup>™</sup> *Collection Vial* for more information.

# BD Density Reagent

BD Density Reagent is a polysaccharide solution with sodium azide added as a preservative. The cell suspension is layered on top of the density reagent and is then centrifuged through the density reagent for 2 minutes  $\pm$  15 seconds at 200 rcf  $\pm$  25 (soft spin). Small particulates and debris become trapped above the interface between the supernatant preservative fluid and the density reagent, and are removed, using the easy aspirator, enriching the remaining clinical materials in the sample.

A second centrifugation, at 800 rcf  $\pm$  50 for 10  $\pm$  1 minute (hard spin), concentrates the diagnostic cellular material in the bottom of the tube. The remaining density reagent is decanted, leaving the resulting enriched pellet of cellular material in the BD Centrifuge Tube, which is vortexed and placed on the BD PrepStain<sup>TM</sup> instrument for further processing.

#### NOTE

Vortexing is a critical step to ensure the cellular material in the centrifuge tube is mixed and evenly distributed throughout the centrifuge tube enabling access to the cells for testing.

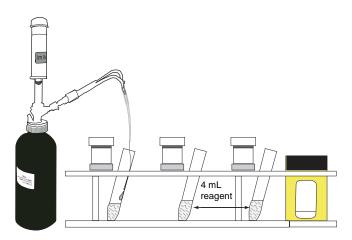


Figure 24 – Preparing centrifuge tube for transfer

# Mixing and layering

Samples are mixed and then gradually transferred to a BD Centrifuge Tube that contains BD Density Reagent. This transfer is referred to as layering. This part of the process is accomplished automatically, using the BD PrepMate<sup>™</sup> Automated Accessory. This method is summarized below.

The BD PrepMate<sup>™</sup> is an automated accessory to the BD PrepStain<sup>™</sup> system. The BD PrepMate<sup>™</sup> automates the initial enrichment process of mixing and dispensing the specimen over the density reagent.

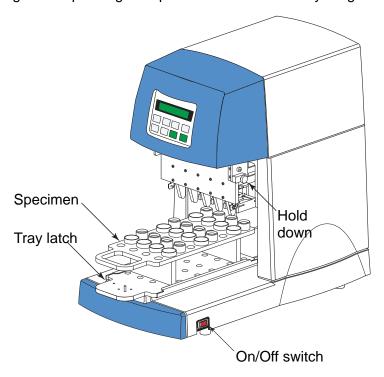


Figure 25 - BD PrepMate™ front view

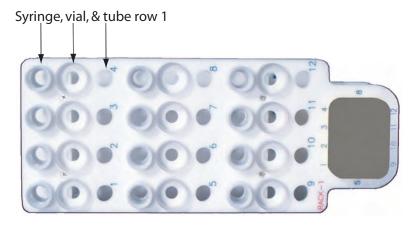


Figure 26 – BD PrepMate<sup>™</sup> processing rack

The BD PrepMate<sup>™</sup> Automated Accessory mixes and removes a portion of the specimen from the preservative vial. It then layers the specimen onto the density reagent in the BD Centrifuge Tube. The BD PrepMate<sup>™</sup> automated process handles from one to twelve specimens per cycle.

To reduce the possibility of specimen contamination, the tops of vials are not removed during the process. The BD PrepMate<sup>™</sup> provides a unique, puncture-top process that mixes and dispenses with the top on. Vials, syringes, and tubes are disposable. To eliminate the possibility of specimen contamination, they are not reused.

## Centrifugation

Centrifugation consists of three steps:

- a "soft spin" pulls cell solution through density reagent
- the Easy Aspirator removes the supernate
- a "hard spin" concentrates diagnostic cellular materials in the bottom of the tube

## Specimen processing with the BD PrepStain™ system

The BD PrepStain™ system performs the automated slide preparation and staining steps for the thin-layer preparation of cytologic materials on a BD SurePath™ PreCoat Slide.

The BD SurePath<sup>™</sup> PreCoat Slide has been coated with a high molecular weight cationic solution. The resulting positive charge allows adhesion of the negatively charged diagnostic cytological material to the slide throughout the slide preparation process.

# BD Settling Chamber

The BD Settling Chamber serves as a vessel to contain the resuspended cellular materials while they settle onto the coated microscope slide. The resulting thin-layer preparation is stained discretely in the same settling chamber.

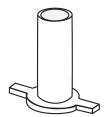


Figure 27 – BD Settling Chamber

# Computer workstation

The BD PrepStain™ instrument is linked to a DOS-based computer. The software that runs the sample processor is started by typing a command at the DOS prompt, and then controlled using a series of menus.

#### NOTE

Refer to *Chapter 10 Non-GYN Slide Processing* for instructions on using the BD PrepStain<sup>™</sup> instrument for NonGYN applications.

# BD PrepStain™ instrument

The BD PrepStain<sup>™</sup> instrument performs the automated sample transfer and staining steps that create a thin-layer preparation of cytologic material on a coated microscope slide.

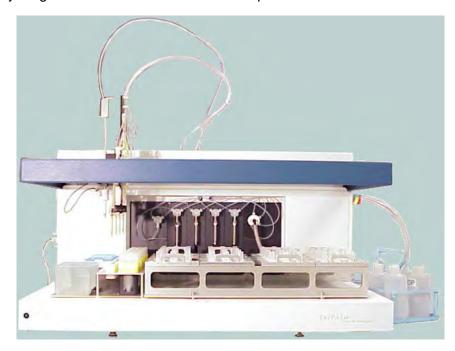


Figure 28 - BD PrepStain™ instrument

#### Robotic sample processor

The Tecan robotic sample processor illustrated in Figure 28 is a fully automated sample processor. It is the base instrument of the BD PrepStain™ system. The BD PrepStain™ instrument is a system of microprocessor-controlled liquid handling components controlled by system software that resides on the hard disk of a computer. An operator controls the mechanical components from the computer keyboard. Special preparation methods, supplied by BD are used for each application.

The BD PrepStain™ instrument resuspends the pelleted cell samples in buffered deionized (DI) water, and transfers aliquots of the cell suspensions to BD Settling Chambers mounted on BD SurePath™ PreCoat slides. An incubation period allows the cells to settle onto the microscope slide surface, and then the processor performs a sequence of washes and staining steps to stain the slide by the Papanicolaou method. The sequences, volumes, times, and orientation of the transfer and staining steps are controlled by the computer workstation.

The BD PrepStain™ instrument hardware is based on a modular design concept in which each of the major processor functions are performed by an independent component of the instrument. The principle components of the processor are listed below:

- Syringe Pump
- X/Y/Z Movement Mechanism (Arm)
- Disposable Tip (DiTi) Assembly
- Quad Arm
- External Water Valve
- Waste Station
- Slide Racks and Work Platform

#### **BD Syringe Pump**

The BD Syringe Pump is a microprocessor-controlled syringe with a pump and two-way valve that connects to the quad tubing and a reagent container via tubing. All parts that come into contact with liquid are made of inert materials such as glass, Teflon, or Fluoroethylpropylene (FEP). A stepper motor drives the syringe plunger. Both the valve and the stepper motor are operated by a built-in microprocessor. The BD PrepStain™ instrument has 4 syringe pumps to control aspiration and dispensing of programmed volumes of reagents and samples with high accuracy and at variable speeds.

#### X/Y/Z movement mechanism (robotic arm)

The robotic arm moves in the X (left-right), Y (forward-backward) and Z (up-down) directions. It has a Z-rod that moves up and down. The DiTi (Disposable Tip) assembly is mounted on the Z-rod, which is raised or lowered (Z-direction) by the Z-stepper motor. The quad arm is mounted on the robotic arm and attached to the safety bar. The arm moves left and right (X-direction), and is driven by the X-stepper motor. The robotic arm must be free of impediments in order to operate correctly. The X, Y, and Z stepper motors are powered and controlled by electronics located inside the board cage of the instrument.

#### Disposable tip (DiTi) assembly

The BD PrepStain<sup>™</sup> instrument uses a disposable tip assembly for aspirating and pipetting samples. Figure 15 illustrates the principle components that make up this assembly.

The instrument uses a fresh BD PrepStain™ Transfer Tip to mix, aspirate, and transfer each sample. This assures that transfers are free of contamination. Tips are picked up by driving the DiTi cone down into the tip with sufficient force to form an airtight seal about the tip hub. This secures the tip to the cone for pickup and displaces a contact spring. The BD PrepStain™ instrument uses this displacement to detect the presence and proper pickup of a tip. The sample is then transferred (from tube to slide), the tip is discarded and a new tip is picked up for the next transfer.

#### **Quad Arm**

The quad arm illustrated in Figure 14 is a system of BD Syringing Pipettes, tubing, and manifolds that is mounted on the arm of the BD PrepStain™ instrument. The device is self-retracting and remains clear of DiTi operations when not in use. The Z-rod and quad key of the DiTi assembly engage the quad handle so that the arm moves in parallel with the DiTi when it is lowered. This positions the four pipette bundles into four BD Settling Chambers simultaneously.

Each pipette bundle has four dispensing tips mounted about a larger vacuum tip. When lowered to just above the surface of the slide, the vacuum tip empties out the chamber. The dispensing tips can then apply one of four reagents to the chambers. Bundling the dispensing and vacuuming tips in this manner allows simultaneous staining operations to be performed on four samples.

#### **Waste Station**

The waste station, which is located on the left side of the instrument is illustrated in Figure 13.

During priming or cleaning of the system tubing, excess liquids are dispensed to the waste trough, which drains into a large waste container for safe and easy disposal. After use, BD PrepStain™ Transfer Tips are discarded into a waste container.

The waste station also includes the BD PrepStain<sup>™</sup> Transfer Tip holder which positions 96 disposable tips for pickup by the DiTi cone. Along the right side of the waste station, four slots hold the centrifuge buckets in position. To help ensure chain of custody, the bucket holders are numbered 1–4 and are uniquely pinned at the base so that each centrifuge bucket can fit into only a single position and orientation.

For example: tube bucket number 1 will fit only into tube holder position 1, and must face the front of the station.

#### Slide Racks and Work Platform

The work platform illustrated in Figure 18 holds the slide racks, and mounts to the right of the waste station.

Each slide rack has a four row by three column array of glass slide positions. The work platform and slide racks are numbered 1–4 and pinned so that each slide rack will fit only into its correspondingly numbered position.

Each slide is mounted on the rack under a settling chamber that locks into place with a clockwise twist. The settling chamber seal and the slide form a barrier 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 in the settling chamber. After staining, the settling chamber is removed and discarded. The slide is cleared and coverslipped to prepare it for screening.

### Slide Preparation and staining

The slide preparation, staining, and rinsing process is performed by the BD PrepStain™ instrument. The steps in this process are outlined below:

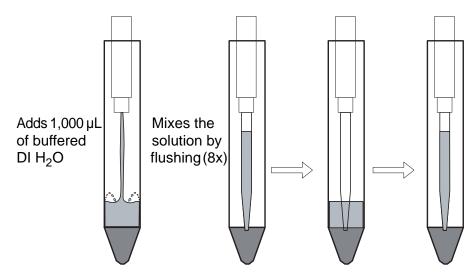


Figure 29 – Preparing to transfer the cell pellet

- First the instrument adds buffered DI water to the Settling Chamber by the Quad arm pipette bundle.
- Next, the instrument adds 1,000 µL of buffered DI water to the cell pellet via the DiTi.
- It then picks up a BD PrepStain<sup>™</sup> Transfer Tip and mixes the resulting solution by flushing it in and out of the disposable Pipette Tip eight times.

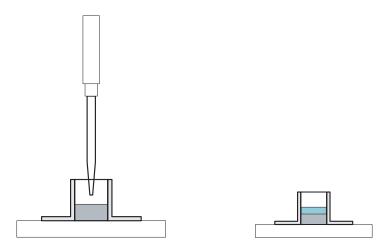


Figure 30 – Transferring the sample to the settling chamber

 Next, the BD PrepStain<sup>™</sup> instrument aspirates 200 µL of the sample from the BD Centrifuge Tube and dispenses 200 µL of specimen into the settling chamber. The laboratory determines when the tube and remaining specimen can be discarded, or retained for reprocessing a BD SurePath<sup>™</sup> slide, or for adjunctive testing.

#### NOTE

If retaining the tube containing specimen, add 2 mL of BD SurePath™ Preservative Fluid to the tube to preserve the cell pellet.

 The sample is allowed to settle onto the slide for a minimum of 10 minutes. During this time, cells bonding with the BD SurePath™ PreCoat slide coating form a thin layer of cells.

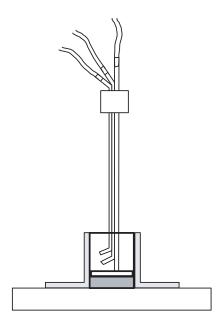


Figure 31 - Washing the cell sample

- The BD PrepStain™ instrument adds a 600 µL alcohol wash to the sample and evacuates all remaining fluids.
- The sample is then allowed to dry for approximately 60 seconds.
- The last part of the automated processing is a sequence of stain and rinse cycles. Stain and rinse cycles are essentially the same: all that varies from cycle to cycle is the reagent used and the duration of the pause.

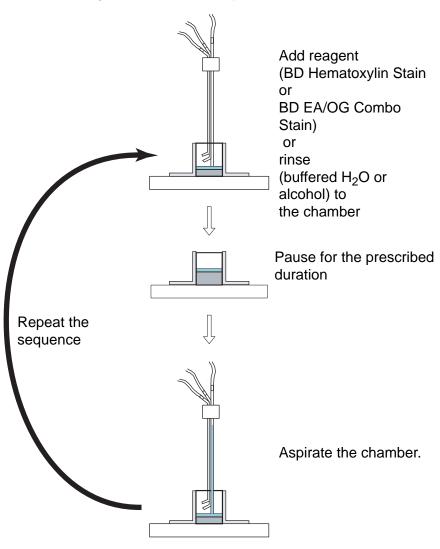


Figure 32 illustrates a typical stain and rinse sequence.

Figure 32 – Typical stain or rinse cycle

### Screening BD SurePath™ thin-layer preparations

The BD PrepStain™ system produces a uniform layer of stained cells in a 13 mm diameter circle. The sample layer contains single cells, or sheets and groups of cells. 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 33 – Serpentine, double screening method

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

# **Chapter 4 Preprocessing Steps**

This chapter provides the procedures used to prepare cervicovaginal specimens for processing by the BD PrepStain<sup>™</sup> instrument. These procedures are listed below.

### Preparation of buffered water

# Required materials

- One liter volumetric flask
- Deionized (DI) or distilled water
- Tris Buffered Saline packet, pH 8.0
- Measuring device, 200 mL
- One (1) 4 L bottle

#### **CAUTION**

Read this procedure carefully. The stock buffer solution must be prepared before the working solution can be made.

# Procedure to make Stock Buffer

- 1. Fill the 1 liter flask approximately half full with de-ionized (DI) or distilled water.
- 2. Empty 1 pack of Tris Buffered Saline packet, pH 8.0 into flask and swirl until dissolved.
- 3. Fill flask to the 1 liter mark and seal the flask with Parafilm.
- 4. Invert the flask several times to ensure complete mixing.
- 5. Transfer stock solution to the 1 liter bottle provided during installation.
- 6. Label bottle with date prepared and expiration date.
- 7. The stock solution is stable for 4 weeks refrigerated (2–10 °C). Discard after four weeks. Clean or replace container before making a new batch of stock solution.

# Procedure to make Working Solution of Buffered Water

- 1. Measure 200 mL of Stock Buffer and pour into a 4L bottle labeled with BD Tris Buffered Water Working Solution.
- 2. Add 3,400 mL of de-ionized (DI) or distilled water.
- 3. Cap and invert to mix well.
  - Label gallon container with date prepared and expiration date.

The Working Solution is stable for two (2) weeks at room temperature (15–30 °C). Clean or replace container before making a new batch of working solution.

#### **NOTE**

Wash containers using appropriate labware cleaner (do not use bleach). Rinse container thoroughly with de-ionized (DI) or distilled water after cleaning or before using a new container.

## **Setup for specimen transfer**

#### **CAUTION**

Cytologic specimens may contain infectious agents. Wear gloves and follow appropriate biohazard precautions when handling sample vials.

This chapter discusses the BD PrepMate<sup>™</sup> automated transfer method.

## **Chain of custody**

In order to maintain chain of custody of test samples, all specimen vials, BD Centrifuge Tubes, and glass slides are loaded in their respective racks **front to back** and **left to right**. The correspondence between rows and columns in the BD PrepMate<sup>™</sup> rack, centrifuge tube rack, and slide rack is illustrated in Figure 34. The illustration identifies the location of Position 1 (row 1, column 1) in three places: on the BD PrepMate<sup>™</sup> rack, the centrifuge tube rack, and the slide rack.

#### WARNING

TUBES IN CENTRIFUGE RACKS MUST BE CAREFULLY ORIENTED WITH MATCHING SLIDE RACKS. CORRECT PLACEMENT OF LABELED TUBES WITH CORRESPONDINGLY LABELED SLIDES IS ESSENTIAL AND MUST BE VERIFIED BY THE OPERATOR IN ORDER TO PREVENT SAMPLE MIX-UPS.

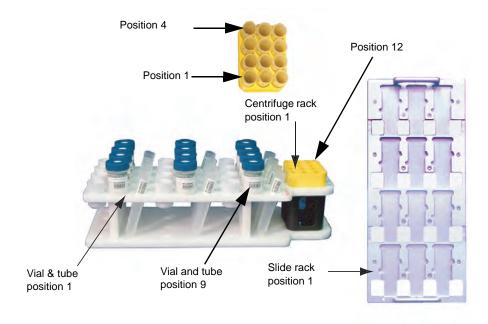


Figure 34 – BD PrepMate<sup>™</sup> rack, centrifuge tube rack, and slide rack row and column correspondence

#### NOTE

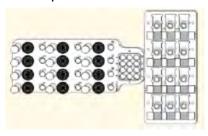
Positioning pins on the BD PrepMate<sup>™</sup> rack and BD PrepStain<sup>™</sup> instrument help to ensure proper alignment. This ensures the sample from position 1 in the BD PrepMate<sup>™</sup> rack is deposited on the slide in position 1 on the slide rack.

## Prepare slides on slide rack

#### Slide rack



 Place BD SurePath<sup>™</sup> PreCoat slides on the slide racks in the same position as the tubes in the centrifuge tube rack. Be careful not to touch the surface of the slide. Place labeled slides into slide racks ensuring proper orientation with its corresponding BD PrepMate<sup>™</sup> rack. Attach settling chambers.



#### **CAUTION**

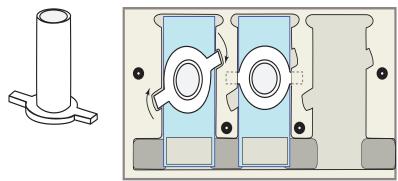
Slide Coat can be removed from the surface of the slide if it is scratched or touched during the application of the settling chamber which can impact the quality of the slide preparation.



Figure 35 – Frosted tab of slide up and toward front of slide tray.

2. Lock the chamber into place over each slide on the slide rack as shown in Figure 36.

3. If there are less than four specimens in a column, place blank slides and BD Settling Chambers in the corresponding spaces.



Twist settling chamber to lock onto slide rack

Figure 36 – Lock BD Settling Chambers over each slide

## BD PrepStain<sup>™</sup> process procedure

1. For each sample to be tested, label the test requisition, specimen vial, BD Centrifuge Tube, and a BD SurePath™ PreCoat Slide with a uniquely identifying label. Use a solvent resistant marker to write on the frosted end of the glass slide or apply a printed label with sample identification.

#### **CAUTION**

Recheck labels on collection vials, BD SurePath™ PreCoat slides, and centrifuge tubes in specific preparation rack positions to ensure that each sample set matches the correct sample.

#### Vortexer



2. Vortex sample vials for a minimum of 15 ± 5 seconds. The vortex speed must be sufficient to cause a funnel in the collection vial (approximately 3,000 rpm). If using the Multi-vial Vortexer, place a rubber liner on top of the vials inside the clamshell to secure the vials and prevent the vials from spinning which would decrease effectiveness of the vortexing.

#### 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 properly may impact the quality of the diagnostic test results.

#### BD PrepMate™ Rack



3. Place labeled specimen vials and centrifuge tubes into the BD PrepMate<sup>™</sup> rack in ascending order (proper orientation of the BD PrepMate<sup>™</sup> rack is with the centrifuge tube rack facing to the front as shown in the image). Reconfirm that each centrifuge tube is labeled the same as its corresponding specimen vial.

**Density Reagent** 



- 4. Dispense  $4 \pm 0.1$  mL of BD Density Reagent into each BD Centrifuge Tube.
- 5. Place a BD Syringing Pipette into the rack adjacent to each specimen vial. Make sure the plunger of each syringe is fully seated. The BD PrepMate<sup>™</sup> Automated Accessory will not operate if a plunger is too high. Figure 37 illustrates this point.

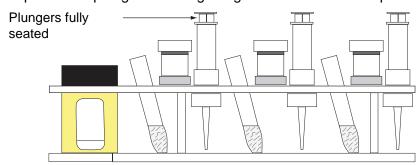


Figure 37 - Centrifuge tubes fully seated

#### BD PrepMate™



- 6. Run the BD PrepMate<sup>™</sup>. (For detailed operation instructions, please consult the BD PrepMate<sup>™</sup> user's manual.
  - a. Make sure the BD PrepMate™ is connected to an AC power source and the side panel power switch is in the On position. Follow on-screen prompts prior to loading specimen rack. Do not load the specimen rack until the display reads PREPMATE READY, (V X.X)LOAD SPECIMEN RACK.
  - b. Make sure the vial hold-down door is in the vertical, latched position.
  - c. Place a loaded specimen rack into the instrument's tray. Slide the rack in from the front until the tray latch at the front left corner of the tray engages. Do not manually move the metal tray, as this may cause instrument malfunction.
  - d. If you are processing fewer than three rows, press DEC to decrease the number of specimen rows to the correct setting before you press START. The number of rows to be processed appears in parentheses as part of the start message. When you press DEC or INC, the display is updated accordingly. If any problems occur, follow the instructions that appear on the display.
  - e. When a specimen rack processing cycle completes, an audible tone sounds. Replace the finished rack with the next rack to be processed, reset the number of rows if necessary, and press START.
  - f. Inspect the centrifuge tubes to verify that the correct amount of sample has been transferred. The correct amount of sample in the tube is 12 ± 1 mL (4 mL of density reagent and 8 mL of sample).
- 7. After the specimen rack has been processed, carefully unload the rack from the BD PrepMate<sup>™</sup> Automated Accessory.

#### NOTE

The BD PrepMate<sup>™</sup> specimen racks should be cleaned between runs to prevent cross-contamination. See BD PrepMate<sup>™</sup> User's Manual for more information.

8. Place the tubes containing the cell suspension and density reagent into the centrifuge tube racks in the same order as they were in the PrepMate rack.

Remove the syringes and discard.
 Allow the specimen vials to remain in the BD PrepMate™ rack (this can be used as a labeling template for the slide rack).

#### NOTE

For each residual specimen vial to be retained, the existing cap should be replaced. (Replacement caps can be ordered from BD). Handle the punctured caps and open specimen vials with care to avoid cross-contamination. Dispose of the punctured caps properly into a biohazard material container.

#### **CAUTION**

- To obtain optimum results, after the specimen sample has been layered onto the density reagent, samples should be centrifuged and the supernatant aspirated within 30 minutes.
- To maintain chain of custody, take care to properly position the BD Centrifuge Tubes and specimen vials when loading the BD PrepMate™ rack, and when transferring the centrifuge tubes to the tube rack.

#### Centrifuge Program 1



- 10. Ensure centrifuge tubes racks are properly balanced.
  - a. If the tube count between the two racks is not matched, add blank tubes and balance with DI water.
  - b. Do not reposition tubes to balance the tube racks as this will compromise chain of custody.
- 11. Centrifuge the tubes at 200 rcf ± 25 for 2 minutes ± 15 seconds using Program #1.

#### Tube Vac



- 12. Remove supernatant using the Tube Vac and Easy Aspirator.
  - a. Turn on the Tube Vac vacuum pump, adjust vacuum pressure to 8–10 in. Hg (Schuco) or 5–6 in. Hg / 180–220 mBar (KNF). Always allow pump come to equilibrium vacuum pressure before beginning aspiration.
  - b. Attach a set of Tips with Easy Aspirator Head. With only very moderate pressure, press head downward, squarely and evenly, to attach tips.

#### NOTE

Do not bury the post seal so deeply into Tip hub that hub is flush with metal post.

- c. Observe that the twelve BD Aspirator Tips (aspirator tips) are securely attached to the posts on the Easy Aspirator Head.
- d. Slowly lower aspirator tips into supernatant, staying just below the dropping fluid level, until the aspirator head rests evenly across the tops of the BD Centrifuge Tubes. At this point you should hear the tips drawing air.

#### NOTE

At this position, the level of the interface fraction at the density reagent should have been penetrated and the majority of supernatant fraction and interface fraction removed.

e. Carefully withdraw the aspirator head with loaded tips from the tube set.

#### NOTE

Discard EZ aspirator tips after aspiration of each centrifuge tube rack.

f. Hold aspirator head of tip ejector in front of and at same plane as the white Delrin wedge in top of tip ejector. Slide the aspirator head along top of wedge so that posts align into slots.

#### NOTE

The tip ejector slots may seem to be a little tight at first. This tightness loosens over time as the white Delrin wedge material wears and adjusts with use.

g. Sliding the aspirator head should eject all of the tips into the disposal tray (see the note below). Withdraw the head by pulling up and out. If no further specimens are to be aspirated, turn OFF vacuum pump.

#### NOTE

To prevent clogs, it is important to run water through the aspirator posts before shutting off the vacuum pump. Perform this rinse after the last tube bucket is aspirated and the tips are still seated on the aspirator posts.

- h. Dispose of used tips, as required by local procedures for disposal of hazardous wastes, collected in tip waste container when it becomes half full.
- i. After the supernatant has been aspirated, rebalance the tube racks as described in step 10.

#### Centrifuge Program 2



13. Centrifuge the remaining fluid at 800 rcf ± 50 for 10 minutes ± 1 minute using Program #2. This centrifugation concentrates the diagnostic components into a cell pellet.

**Decant Tubes** 



14. Remove the tube racks from the centrifuge. In a single, rapid motion, decant the supernatant by inverting each tube rack 180° so as not disturb the cell pellet. While inverted, carefully blot the mouth of all tubes in the rack with absorbent paper. Turn the rack upright after 3–5 seconds.

Hand Vortexer



15. Holding a gloved hand on top of the tubes, vortex the centrifuge tube racks thoroughly for 15 ± 5 seconds. The absorbent material used to blot after decanting may be held in place during hand vortexing.

#### **CAUTION**

Failure to re-suspend the cellular material by vortexing may impact the quality of the sample.

#### BD PrepStain™



#### Reagent containers



#### 16. Run the BD PrepStain™ Slide Processor:

- a. Place the tube racks and slide racks on the BD PrepStain™ instrument. Confirm that the position of each labeled slide on the slide rack corresponds to the position of its matching labeled tube in the tube rack. Confirm that all tube racks and slide racks are seated properly on the instrument.
- b. Place each labeled intake tubing into its corresponding reagent container (the intake tubing must go all the way to the bottom of the reagent bottle). Confirm there is adequate reagent in each bottle to complete the run.
- c. Place 96 pre-loaded BD PrepStain™ Transfer Tips onto the DiTi station. Press down firmly on the plastic tip holder so that the front and back tabs snap into place on the station securely.

#### **CAUTION**

The pipetting instrument is a robotic device that operates under computer control. As with most robotic devices, there is potential for injury and bodily harm from moving mechanical components whenever the BD PrepStain™ is in operation. BD PrepStain™ is designed for automatic "hands-off" operation only. If the robotic movement is impeded, this generates an error. To avoid aborting the run, do not obstruct operation of the robotic arm.

- d. Turn on the BD PrepStain<sup>™</sup> system. The computer automatically runs the GYN software application.
- e. To process and stain slides, select slide Preparation and Staining from the Main Menu and follow the instrument prompts. Refer to *Chapter 5*, *Gynecologic (GYN) Slide Processing* in this manual for instructions on operating the software.
- f. An alarm sounds as each slide rack has completed the staining process.
- 17. As each slide rack is completed, remove it from the BD PrepStain™ instrument.
- 18. Invert the slide rack to decant the residual alcohol. Before returning to an upright position, blot excess alcohol from the BD Settling Chambers. Turn the slide rack right side up.
- 19. Taking one slide at a time, remove and discard the settling chamber and then coverslip the slide.

- a. Direct a stream of reagent alcohol or 2-propanol above the preparation area on the slide or dip the slide in a container of reagent alcohol or 2-propanol.
- b. Clear each slide in 100% dehydrant (e.g. absolute alcohol) before moving to xylene or xylene substitute by dipping the slide or streaming the reagent over the preparation area.
- c. Clear each slide by directing a stream of xylene or xylene substitute above the preparation area on the slide.
- d. Using a 24 mm x 30 mm cover glass, coverslip the slide as usual, using a polymer-based mounting medium.

#### **CAUTION**

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain
- 20. Remove the tube racks from the BD PrepStain<sup>™</sup> instrument. Add 2 mL of BD SurePath<sup>™</sup> preservative fluid to each tube. Cap each tube or cover with Parafilm. From the date of collection, cell pellets with preservative can be stored for up to 4 weeks at room temperature (15–30 °C), or 6 months refrigerated (2–10 °C).
- 21. System clean-up and quit:
  - a. Select Clean Up System, and follow the directions displayed on the monitor.
  - b. After the clean-up procedure is complete, the screen will return to the Main Menu.
  - c. Select ouit.
  - d. Turn off the power.

## Reprocessing BD SurePath™ cell pellets

The reprocessing procedure begins with the cell pellet that remains after the initial slide Preparation and Staining run.

- 1. If refrigerated, allow specimen(s) to come to room temperature.
- 2. Proceed with steps 13–19 of the BD PrepStain<sup>™</sup> process procedure.

# Chapter 5 Gynecologic (GYN) Slide Processing

This chapter provides both instructions and overview information for processing gynecologic specimen slides on the BD PrepStain™ instrument. To jump right to the procedure for processing specimen slides, turn to page 64. To familiarize yourself with the screens and controls used to perform this procedure refer to the following discussion.

## BD PrepStain™ GYN program

# Program overview

The GYN program operating principles and its sequence of events are discussed in *Chapter 3*, *Principles of Operation*. To summarize this sequence, the slide processor transfers the samples and then performs a series of stain and rinse cycles that create a thin-layer preparation of cytologic materials on a BD SurePath™ PreCoat slide.

Each stain and rinse cycle follows the same pattern: what varies from cycle to cycle is the reagent used and the duration of the pause.

The BD PrepStain™ instrument's functions are controlled using a computer workstation. Three DOS based, menu-driven applications provide access to the programs that run the BD PrepStain™ instrument.

Using the workstation menus, you communicate with the instrument and monitor the progress of slide processing.

To access the gynecologic (GYN) slide processing functions, you just turn the workstation on. If the workstation is already running, you can access this and other functions by typing the appropriate command from the DOS prompt and pressing **Enter**. Table 5-1 lists the commands and their corresponding function.

| COMMAND | FUNCTION   |
|---------|--|
| GYN     | Access the Slide Preparation and Staining, BD Slide Preparation, and Slide Staining procedures for gynecologic specimens |
| NONGYN  | Access the Slide Preparation and Staining and Slide Staining procedures for non-gynecologic specimens                    |
| UTIL    | Flush stain and DiTi lines   |

Table 5-1 BD PrepStain™ workstation commands

Figure 38 illustrates the welcome and version check screen that displays when you open the GYN program. (Program run version may differ.)



Figure 38 - GYN Version Check menu

The screens in the GYN application are divided into three sections as illustrated in Figure 38.

- a. The top (banner) section displays text messages on several lines. These messages tell you what action the system is performing or about to perform.
- b. The middle (menu) section displays menu prompts you use to control the system.
- c. The bottom (prompt) section displays text messages on a single line. These messages tell you what's happening and what to do next.

#### NOTE

Screens pictured are for illustration purposes only. Current display may differ in appearance.

#### Main Menu screen

After you verify the version, the GYN Main Menu screen is displayed. Figure 39 illustrates this screen.



Figure 39 - GYN Main Menu

This chapter discusses the slide Preparation and Staining, slide Preparation, and slide Staining Options. The Clean Up System option is discussed in *Chapter 6*. The System setup and Diagnostics options are discussed in *Chapter 9*. These last two options should only be accessed by (or with the help of) a BD-authorized technician unless specified as part of routine maintenance.

# Step in Progress screen details

While processing is underway, the monitor displays the current status of the process using the Step in Progress screen. Figure 40 illustrates this screen.

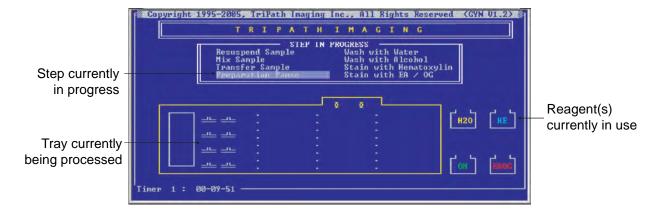


Figure 40 – Step in Progress screen

As pictured in Figure 40, the steps in the Sample and Stain process are listed at the top of the screen. The step that the BD PrepStain™ instrument is currently performing is highlighted and blinking.

The lower portion of the screen displays a settling chamber icon for each sample being processed (8 in this example). The sample currently being processed blinks.

The lower right corner displays icons for the reagent syringe pumps. Blinking arrows indicate the reagent(s) in use.

Definitions for each of the steps are listed below:

**Resuspend Sample:** Buffered water is added to re-suspend the cell pellet in the BD Centrifuge Tube.

**Mix Sample:** The cell pellet is repeatedly aspirated and dispensed to mix the cell material.

**Transfer Sample:** The mixed cell suspension is aspirated and dispensed into the Settling Chamber of the corresponding slide position.

**Preparation Pause:** The BD PrepStain™ system pauses for sedimentation of cells, drying, dehydration, rehydration and incubation of stains.

**Wash with Water:** The BD Settling Chamber is emptied and then rinsed with deionized water.

**Wash with Alcohol:** The BD Settling Chamber is emptied and then rinsed with BD Alcohol Blend Rinse.

**Stain with Hematoxylin:** The BD Hematoxylin Stain (hematoxylin) is applied, aspirated and reapplied to stain. BD Hematoxylin is the first stain used in the staining process.

**Stain with EA/OG:** The BD EA/OG Combo Stain (EA/OG) is applied, aspirated, and reapplied to stain. EA/OG is the second stain used in the staining process.

Processing gynecologic (GYN) specimens

Before you can perform this procedure you must first complete the preparation procedures in Chapter 4, *Preprocessing Steps*.

- The GYN application runs automatically when starting the BD PrepStain™ instrument workstation. If the workstation is already running, but the GYN application is not: from the DOS prompt, type in GYN and then press Enter. The GYN Version Check screen is displayed.
- 2. Select Run Version 1.3.0.3 from the menu, and then press Enter. This brings up the GYN Main Menu. The main menu (Figure 39) provides access to all functions of the program.
- Select Slide Preparation and Staining, and then press Enter.
   The BD PrepStain™ Run Information screen (illustrated in Figure 41) is displayed.

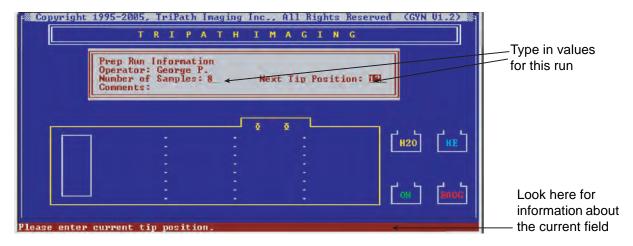


Figure 41 - PrepStain Run Information screen

#### NOTE

You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on BD PrepStain<sup>™</sup> system screens.

4. Navigate to the second field (skip the operator field), type in the number of samples to be processed and then press **Enter**. The number of samples must be a multiple of four.

#### NOTE

If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add blank slides,

BD Settling Chambers, and tubes to the tube rack to make up the difference.

- 5. Navigate to the next field, and either press **Enter** to confirm that the Next Tip Position is correct; or type in the correct tip position, and then press **Enter** (skip the comments field).
- 6. The Reenter Run Information prompt is displayed.



Figure 42 - Reenter Run Information menu

- To change the number of samples or the next tip position, select **Yes**, press **Enter**, and repeat the last two steps.
- To confirm your entries and proceed, select No and then press Enter.
- 7. The Change Sample/Stain Parameters prompt is displayed.



Figure 43 – Change Sample/Stain Parameters prompt

- To change the sample or stain settings, select Yes and then press Enter. Refer to Change sample/stain parameters on page 76 for details on how to make these adjustments.
- To use the existing settings and proceed, select No and then press Enter.
- 8. The Scan barcodes? menu is displayed.



Figure 44 - Scan Barcodes menu

- To use a barcode scanner, select Yes and then press Enter.
   Refer to Scan Barcodes (optional feature) on page 79 for details on using this feature.
- To bypass the barcode program and proceed, select No and then press Enter.
- 9. The vacuum prompt is displayed and the alarm sounds. Press any key to silence the alarm.



Figure 45 - Vacuum Pump Prompt screen

- 10. Turn on the vacuum pump, wait a few minutes for it to warm up.
- If using the Schuco pump, adjust pressure to 8–10 inHg, and then press any key to continue.
- If using the KNF pump, adjust the pressure to 5–6 inHg, and then press any key to continue.

#### NOTE

The pump pressure setting at the bottom of the screen (8–10) is only for the blue Schuco pump. Use 5–6 inHg if using the KNF pump with pressure gauges in units of inHg. Use 180–220 mBar if using the KNF pump with pressure gauges in units of mBar.

11. The Prime ALL Tubing? prompt is displayed.



Figure 46 - Prime All Tubing menu

- If this is the first run of the day, select Yes and then press Enter
  to prime the system tubing. The system initializes and the
  syringe pumps pump two full syringe volumes through the quad
  arm tubing and into the waste station.
- For subsequent runs during the next eight hours, select **No** and then press **Enter** to skip the full priming function.
- Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.

While the system is priming, the BD PrepStain™ System Priming screen is displayed.

#### NOTE

The elapsed time of the sequence displays in the lower left corner. This display is present for each task the BD PrepStain™ instrument performs.

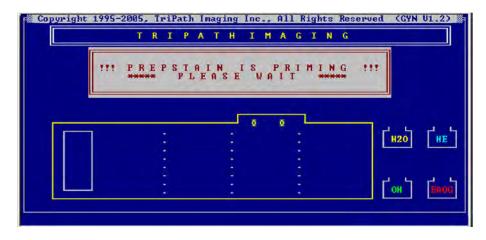


Figure 47 – BD PrepStain™ is Priming screen

12. When the priming cycle is complete, The screen displays the **Is** the **PrepStain tubing primed?** prompt.



**Figure 48** – Is the tubing primed?

- To repeat the priming sequence, select **No**, **repeat priming** and then press **Enter**.
- To proceed with slide preparation and staining, select **Yes**, **start preparation run** and then press **Enter**.

#### NOTE

Steps 13–17 describe the Sample Preparation and Staining process. During this sequence, the Step in Progress screen is displayed. For a description of this screen, refer to Figure 40.

- 13. The DiTi dispenses buffered water into each BD Centrifuge Tube to re-suspend the cell pellet. Next, the DiTi picks up a disposable tip, and then a sample of the cell suspension is aspirated, carried to its corresponding slide, and deposited into the settling chamber.
- 14. After samples have been transferred to all racks, the instrument pauses for at least ten minutes while the cells sediment onto the slide.
- 15. When the sedimentation pause is complete, an alarm alerts the operator that the arm is about to move.
  - Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG Combo Stain) and then stained. Each settling chamber is completely emptied between stains and washes. After the staining is complete, the slide is washed with alcohol.
- 16. When all of the slides on a rack have been stained, the BD PrepStain™ system sounds an alarm, and then continues to stain the next slide rack.
  - a. As each slide rack is completed, remove it from the BD PrepStain™ instrument and decant the alcohol from the BD Settling Chambers into a proper receptacle.

#### **CAUTION**

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.
- 17. When the BD PrepStain™ instrument finishes processing, the sample Preparation Complete prompt appears and an alarm sounds. Press any key to silence the alarm and continue.
- 18. When you complete a Slide Preparation and Staining run, you can either run another batch, exit to DOS, clean the instrument, or simply turn the PC and BD PrepStain™ instrument off.

#### NOTE

If for any reason it becomes necessary to pause the instrument, press the **F10** key. The BD PrepStain™ instrument suspends processing. Follow the screen prompts to resume processing.

#### Prep only

Before you can perform this procedure you must first complete the preparation procedures in *Chapter 4*, *Preprocessing Steps*. Access to the Slide Preparation process is via the GYN Version Check and GYN Main menu screens. These screens are illustrated in Figure 38 and Figure 39.

- The GYN application runs automatically when you start the BD PrepStain™ instrument workstation. If the workstation is already running, but the GYN application is not: from the DOS prompt, type in GYN and then press Enter. The GYN Version Check screen is displayed.
- 2. Select **Run Version 1.3.0.3** from the menu, and then press **Enter**. This brings up the GYN Version Main Menu. The main menu (Figure 39) provides access to all functions of the program.
- 3. Select **Slide Preparation**, and then press **Enter**. The PrepStain Run Information screen will be displayed.

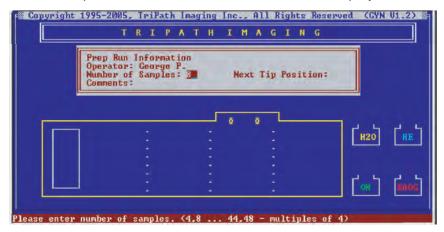


Figure 49 - BD PrepStain™ Run Information screen

#### NOTE

You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on BD PrepStain™ system screens.

- 4. Load samples, slides, and BD Settling Chambers, and then check the reagent levels. (Note that it is not necessary to place tubing in the hematoxylin and EA/OG reagent containers)
- 5. Follow instructions as prompted on the screen.
- 6. The BD PrepStain™ instrument will automatically transfer samples to the appropriate slides.

- 7. The BD PrepStain™ instrument sounds an alarm after each rack is finished processing.
- 8. Remove the finished slide rack from the instrument.
- 9. Invert the rack to decant the liquid. With the rack still inverted, lightly tap the slide rack on absorbent material to blot excess alcohol from the BD Settling Chambers. Leave the rack inverted for up to a minute to drain any residual rinse agent.
- 10. Return the rack to an upright position, and then carefully remove the BD Settling Chambers one at a time. Immediately place the slides into a rack submerged in 95–100% Ethanol.
- 11. Repeat steps 8–10 for the remaining slide racks.
- 12. Begin the staining procedure.

### **Slide Staining**

Access to the **Slide Staining** process is via the GYN Version Check and GYN Main menu screens. These screens are illustrated in Figure 38 and Figure 39.

- The GYN application runs automatically when you start the BD PrepStain™ instrument workstation.
   If the workstation is already running, but the GYN application is not:
   from the DOS prompt, type in GYN and then press Enter.
   The GYN Version Check screen is displayed.
- 2. Select Run Version 1.3.0.3 from the menu, and then press Enter. This brings up the GYN Version Main Menu. The main menu (Figure 39) provides access to all functions of the program.
- Select Slide Staining, and then press Enter.
   The BD PrepStain™ Run Information screen will be displayed.

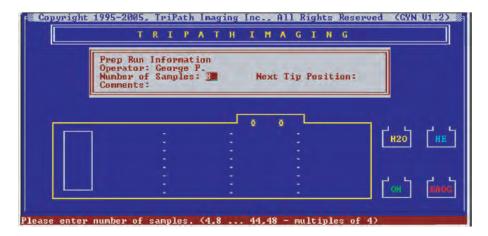


Figure 50 - BD PrepStain™ Run Information screen

### NOTE

You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on BD PrepStain™ system screens

4. Navigate to the second field (you can skip the operator field), type in the number of samples to be processed and then press **Enter**. The number of samples must be a multiple of four.

### NOTE

If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add an equal number of blank slides and BD Settling Chambers.

- 5. Press **Enter** again (you can skip the comments field), to complete the BD PrepStain<sup>™</sup> Run Information screen.
- 6. The Reenter Run Information prompt is displayed.
  - To change the number of samples, select **Yes**, press **Enter**, and repeat step 4.
  - To confirm your entries and proceed, select No and then press Enter.
- 7. The Change Sample/Stain Parameters prompt is displayed.



Figure 51 - Change Sample/Stain Parameters menu

- To change the sample or stain settings, select Yes and then press Enter.
  - Refer to Change sample/stain parameters on page 76 for details on how to make these adjustments.
- To use the existing settings and proceed, select No and then press Enter.
- 8. The scan Bar Codes? prompt is displayed.
  - To use a barcode scanner, select Yes and then press Enter.
     Refer to Scan Barcodes (optional feature) on page 79 for details on using this feature.
  - To bypass the barcode program and proceed, select **No** and then press **Enter**.
- 9. The vacuum prompt is displayed and the alarm sounds. Press any key to silence the alarm.
- 10. Turn on the vacuum pump, adjust the pressure to 8–10 inHg for Schuco pump or 5–6 inHg (180–220 mBar) for KNF pump, and then press any key to continue.
- 11. The Prime ALL Tubing? prompt appears.
  - If this is the first run of the day, select Yes and then press Enter
    to prime the system tubing. The system initializes and the
    syringe pumps pump two full syringe volumes through the quad
    arm tubing and into the waste station.
  - For subsequent runs during the next eight hours, select No and then press Enter to skip the full priming function.
  - Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.
- 12. When the priming cycle is complete, the Is the tubing primed? prompt is displayed.

- To repeat the priming sequence, Select No and then press Enter.
- To proceed with slide staining, select Yes and then press Enter.
   The Step in Progress screen is displayed.

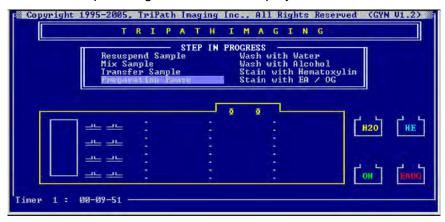


Figure 52 – Step in Progress screen

#### NOTE

Steps 13–15 describe the Slide Staining process. During this sequence, the Step in Progress screen is displayed. For details on this screen, refer to Step in Progress screen details on page 63. Note that the first three elements in the list (Resuspend Sample, Mix Sample, and Transfer Sample) do not occur in the Slide Staining sequence.

#### NOTE

You can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next on BD PrepStain™ system screens

- 13. Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG) and then stained. Each settling chamber is completely emptied between stains and washes. After the staining is complete, the slide is washed with alcohol.
- 14. When all of the slides on a rack have been stained, the BD PrepStain™ system sounds an alarm, and then continues to stain the next slide rack.

 a. As each slide rack is completed, remove it from the BD PrepStain™ instrument and decant the alcohol from the BD Settling Chambers into a proper receptacle.

#### CAUTION

- When removing the settling chamber, avoid scraping cell circle from slide with the extended tips of the settling chamber.
- Do not allow the slides to dry prior to coverslipping.
- Each slide must be coverslipped one at a time to avoid air drying associated artifacts.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.
- 15. When the BD PrepStain™ instrument finishes processing, the sample Preparation Complete prompt appears and an alarm sounds. Press any key to silence the alarm and continue.
- 16. When you complete a Slide Staining run, you can either run another, exit to DOS, clean the instrument, or simply turn the PC and BD PrepStain™ instrument off.

### Change sample/ stain parameters

The Change Sample/Stain Parameters function provides the means of adjusting the sampling volumes, staining times and cell sedimentation times. You have the opportunity to access this function when you run a Slide Preparation and Staining, Slide Preparation, or Slide Staining cycle and the Change Sample/Stain Parameters prompt is displayed. Note, that access to this function is protected by password.

### **CAUTION**

Password access should be limited to authorized individuals only.



Figure 53 - Change Sample/Stain Parameters menu

This procedure is detailed below:

- During the BD PrepStain<sup>™</sup> process, after you specify the number of samples and the next tip position, you have the opportunity to change the stain parameters. To change the parameters that control the staining process, select Yes when prompted. The Password prompt is displayed.
- 2. Type in the password.
- 3. The Sample/Stain Parameters screen (as illustrated in Figure 54) is displayed so that you can change the parameter settings.



Figure 54 - Sample/Stain Parameters screen

4. The currently active field is highlighted and marked with a flashing cursor. The prompt line at the bottom of the screen displays the range of acceptable values as you move from field to field. Use either the **Tab** or **Enter** keys to navigate to the field you wish to change, and then type in the new values. Table 5-2 details the parameters you can set using this screen.

| PARAMETER<br>NAME | ACCEPTABLE<br>VALUES | DEFINITION AND DEFAULT VALUES  |
|-------------------|----------------------|--|
| RESUSPENSION      | <b>0–1,000</b> μL    | The Resuspension volume is the amount of buffered deionized water added to the cell pellet. The default amount is 1,000 $\mu\text{L}.$                                       |
| Mix               | <b>100–500</b> μL    | The Mix volume is the amount of water pumped in and out of the disposable tip during the re-suspension of the pellet. The default amount is 500 $\mu$ L.                     |
| SAMPLE            | <b>100–500</b> μL    | The Sample volume is the amount of sample transferred to the settling chamber. The default amount is 200 $\mu\text{L}.$  |
| DILUTION          | <b>0–1,000</b> μL    | The Dilution volume is the amount of buffered deionized water pH (7.5–8.5) added to the sample volume after it is dispensed on the slide. The default amount is 600 $\mu$ L. |
| SEDIMENTATION     | 0-1,200 SEC.         | The Sedimentation pause is the amount of time allowed for the cells to settle onto the BD SurePath™ PreCoat slide. The default amount is 600 sec.                            |
| DRYING            | 55-300 SEC.          | The Drying pause is the amount of time allowed for the cells to dry onto the BD SurePath™ PreCoat slide. The default amount is 60 sec.                                       |
| HEMATOXYLIN       | 55-180 SEC.          | The Hematoxylin incubation is the amount of time allowed for the cells to absorb the stain. The default amount is 85 sec.  |
| EA/OG             | 55-180 SEC.          | The EA/OG incubation is the amount of time allowed for the cells to absorb the stain. The default amount is 75 sec.  |
| Mix               | 1–15                 | The Mix cycles is the number of times that the diluted sample is pumped in and out of the disposable tip to re-suspend the cell pellet. The default number is 8.             |
| WATER WASH        | 1–9                  | The Water washes is the number of water cycles used to wash the slide after hematoxylin staining is complete. The default number is 2 cycles.                                |
| ALCOHOL WASH      | 1–9                  | The Alcohol washes is the number of alcohol cycles used to wash the slide after EA/OG staining is complete. The default number is 3 cycles.                                  |

Table 5-2 Sample and Stain parameter values

### NOTE

Entries of ten (10) or more are rejected as invalid for the number of rinse cycles of both water and alcohol, but there is no audible alarm or onscreen warning to alert you that your entry was rejected. Further, an attempt to enter an invalid value results in only the first digit being accepted. For instance, if you enter 10 the instrument accepts that as 1, or if you enter 80 the instrument accepts that as 8.

Restrict entries to the recommended range, and always confirm changed parameters before running and/or saving modified preparation parameters.

5. When the cursor has been to each field, you are presented with 4 options as shown in Figure 55.



Figure 55 - Select a save option

- Choose the appropriate option, and then press Enter.
- When you choose one of the first three options, the change parameters procedure is complete, and the scan Barcodes prompt is displayed.
- If you choose option four, return to the previous step.

### Scan Barcodes (optional feature)

If barcode labels are in use to accession the centrifuge tubes, specimen vials, and slides, use this procedure to enter the barcode label numbers. This option provides a means of including an additional identity confirmation step to the sample preparation process.

 To initiate the Scan Barcodes procedure, choose Yes at the scan Barcodes prompt.
 The Scan Barcodes screen is displayed. As illustrated in

The Scan Barcodes screen is displayed. As illustrated in Figure 56, the screen has 24 blank fields; 12 for the active slide rack and 12 for the active tube rack.

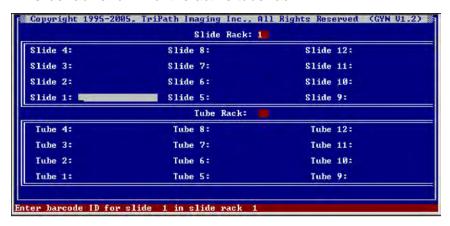


Figure 56 – Scan Barcodes screen

#### NOTE

If you are processing less than a full rack of slides, the screen still displays 24 fields (12 positions), but only fields that correspond to the number you are processing are active. That is, the cursor does not go to inactive fields.

- Use the barcode scanner to scan the label on each slide in the first slide rack. As you scan each label, the cursor moves automatically to the next field.
- 3. When the labels have been scanned for the slide rack, the cursor moves down to the tube rack. Use the barcode scanner to scan the label on each tube in the first tube rack.

#### NOTE

The numbers on the labels for corresponding slides and centrifuge tubes must match. If there is a discrepancy between the numbers, reposition the tubes to correct the correspondence and then re-scan the label(s) to resolve the mismatch. The process cannot continue until you have scanned a correctly oriented tube rack.

4. When you finish scanning the labels in the first tube rack, the screen displays blank fields for the second slide rack and its corresponding tube rack. Repeat steps 2 and 3 for as many additional racks as required. When you finish scanning all racks, return to the BD PrepStain™ processing procedure.

# **Chapter 6 Maintenance Procedures**

This chapter details the procedures you need to follow in order to properly maintain the BD PrepStain™ system. Proper maintenance is necessary for the BD PrepStain™ Slide Processor system to consistently produce quality slides. If neglected, the instrument's performance will deteriorate over time. BD is not responsible, under warranty or otherwise, for damage due to abuse or neglect.

Once every 12 months, preventive maintenance is required to be performed by BD authorized service personnel.

### **Daily maintenance**

Perform daily maintenance at the end of each day or after every eight hours of BD PrepStain<sup>™</sup> system operation, whichever comes first.

### **Materials Required**

- Shallow (approximately 100 mL) container/beaker
- Deionized (DI) water
- DI water clean-up container
- Alcohol
- Alcohol clean-up container
- · Lint free cloth
- Cleaning solution

### Perform system clean-up

Access to the system clean-up procedure is via either the GYN or NonGYN applications.

- As directed in the list of materials required, have prepared cleaning water and alcohol in the appropriate bottles. Do not remove any of the tubing from the reagent bottles until instructed by the on-screen prompts.
- 2. The GYN application runs automatically when you start the BD PrepStain™ instrument workstation. If the workstation is already running, but the GYN application is not: from the DOS prompt, type in GYN and then press Enter. The GYN Version Check screen is displayed.
- 3. If it's not already running, turn the vacuum pump on. Select Run Version 1.3.0.3 from the menu, and then press Enter.

  The GYN Version Main Menu is displayed. This menu (illustrated in Figure 39) provides access to all functions of the program.
- 4. Select Clean Up System, and then press Enter.
  The PrepStain instrument initializes and then back flushes all reagent lines into their reagent containers.

The prompt line displays:

Please wait for back flushing to complete.

The PC workstation sounds an alarm when this step is complete.

5. Press any key to silence the alarm.

The prompt line displays:

Back flushing complete. Press any key to continue clean up.

6. Put the hematoxylin line in the cleaning water and the EA/OG line into the cleaning alcohol, and then press any key to continue. The prompt line displays:

Please wait for stain line cleaning to complete.

- 7. The BD PrepStain™ instrument flushes each stain line with the appropriate solvent, and then sounds an alarm.
- 8. Press any key to silence the alarm.

The prompt line displays:

Rinsing complete, press any key to continue clean up.

Put both the EA/OG and alcohol lines into the DI water. Press any key to continue.

The prompt line displays:

Please wait for lines to fill with DI water.

- The BD PrepStain<sup>™</sup> instrument flushes the tubing and associated syringes with water. When rinsing is complete, all tubing is filled with deionized water.
- 10. The PC workstation sounds an alarm and prompts you to hold a container of DI water under each pipette bundle on the Quad arm to flush out the vacuum lines. Press any key to silence the alarm, and then use a small container (approximately a 100 mL) to flush out the vacuum lines for approximately 10 seconds.

The prompt line displays:

Press any key to return to the Main Menu.

11. When you finish rinsing the pipette bundles, press any key to return to the Main Menu.

This completes the system clean-up procedure.

### Additional daily tasks

After system clean-up, these additional tasks must be performed daily.

- 1. Turn off the BD PrepStain™ system and vacuum pump.
- 2. If the instrument is not to be used for more than eight hours, leave the system filled with the deionized water. Place all intake tubing in deionized water. Other solutions can form precipitates, which can shorten the life of the tubing, valves, and syringes and can affect the precision and accuracy of the instrument.
- 3. Empty tip disposal container into an approved biohazard container.
- 4. Check all syringes and tubing for leaks.
- 5. Empty Vacuum Waste container if needed.
- 6. Wipe pipette bundles with a lint-free cloth.
- 7. Clean the DiTi cone and Grip Tip with a lint-free cloth.
  - Raise the plastic sleeve to expose the DiTi cone and Grip Tip.
  - Using a lint-free cloth, carefully clean the DiTi cone and Grip Tip using a downward motion only.
- 8. Remove racks from the instrument surface. Carefully clean and dry the work surface with a soft cloth using cleaning solution.

### Weekly maintenance

Weekly maintenance is comprised of the following procedures:

- Flush stain and vacuum lines with a 5% cleaning solution
- Check tubing connectors and syringes for tightness
- Clean Quad Bundles
- Clean the Z-rod
- XYZ Test
- Slide Rack Inspection
- Empty gravity and waste containers

Perform weekly maintenance at the end of each week or after forty hours of operation, whichever comes first.

### **Materials Required**

- DI water (at least 1 L)
- 5% cleaning solution (at least 1 L)
- 4 L container with cap
- Stylus
- Lint free wipes

### Slide rack inspection

Remove all slide racks from the instrument and carefully evaluate the racks to ensure that the screws are not loose and the pin-holes are completely intact and undeformed. Additionally, evaluate all slide racks that are in current use, or will be used in the future.

#### **CAUTION**

If the slide racks do not sit perfectly flat on the deck, please discard the slide racks immediately and contact BD customer support.

## Preparation of 5% cleaning solution

- 1. Add 180 mL of Contrad 70, Decon 90, or bleach to a 1-gallon container.
- 2. Fill 4 L container to 3,600 mL with DI or distilled water.
- 3. Cap and invert gently to mix.

#### **CAUTION**

Use of bleach at a concentration greater than 5% may be harmful to the system.

### Flush stain and vacuum lines

This procedure flushes the stain and vacuum lines with a 5% cleaning solution followed by a water rinse. The BD PrepStain™ instrument's Utilities program automates this process.

- 1. Prepare bottles with cleaning solution and fresh DI water for the rinse.
- The GYN application runs automatically when you start the BD PrepStain™ instrument workstation. Exit this application to access a DOS prompt so that you can display the BD PrepStain™ Utilities Version Check screen (Figure 57). This screen provides access to the cleaning process.
  - If the workstation is running the GYN application, select Quit to display the DOS prompt, type in UTIL, and then press Enter.
     The BD PrepStain™ Utilities Version Check screen is displayed.

• If the workstation is already displaying the DOS prompt, type in UTIL and then press **Enter**.

The BD PrepStain™ Utilities menu is displayed.



Figure 57 - Utilities menu

3. If it's not already running, turn the vacuum pump on. From the PrepStain Utilities menu, select **Run Utility Version 1.1** and press **Enter** 

The Utilities menu will be displayed.

- 4. Select Flush Tubing With Cleaning Solution, and then press Enter.
  The PrepStain instrument initializes; then the prompt line displays:
  Place ALL Reagent Intake tubing into cleaning solution.
  Press any key to begin flushing PREP.
- 5. Move all four lines into the cleaning solution container, and then press any key to continue.

The PrepStain instrument initializes, and then flushes the intake tubing with cleaning solution.

The prompt line displays:

Please wait for cleaning solution flush to finish.

- 6. When the flush is complete, the PC workstation sounds an alarm and prompts you to press any key to silence it.
- 7. Press any key to silence the alarm.

The prompt line displays:

Place All Reagent Intake tubing into fresh, clean DI water. Press any key to begin.

8. Move all four lines into the DI water container, and then press any key to continue.

The BD PrepStain™ instrument flushes all lines with DI water, and displays the prompt:

Please wait for DI water flush to finish.

- 9. When the flush is complete, the PC workstation sounds an alarm and the prompt line displays:
  - Clean up complete, press any key to silence alarm.
- 10. Press any key to silence the alarm, and then hold a small container of cleaning solution under each vacuum tip for approximately10 seconds to flush the vacuum lines with cleaning solution.
- 11. Rinse each vacuum line by holding a small container of DI water under each vacuum tip for 10 seconds.
  - The prompt line displays:
  - Clean up complete, press any key to return to the Utility Menu.
- 12. When you finish rinsing the pipette bundles, wipe off the pipette bundles with a clean, lint free cloth, and then press any key to return to the Main Menu.
- 13. Turn off the vacuum pump. This completes the flush stain and vacuum lines procedure.

### Clean the Z-rod

Clean the Z-rod with a lint-free tissue. Do not use oil or solvents to clean the Z-rod.

### Clean Quad Bundles Using Stylus

Ensure that the reagent lines are removed from the reagent bottles containing any fluids. To clean the Quad Bundles, perform the following steps:

1. From the Main Menu, select 4 Clean Up System.



Figure 58 – Main Menu with option 4 Clean Up System selected.

2. Turn off the instrument.

3. After you have placed the Quad Bundles over the waste trough, carefully remove the aspiration line (plastic tube) from the top of the aspiration tip on the Quad Bundle.



Figure 59 – Aspiration Line being removed.

4. Carefully insert the stylus into the top if the aspiration tip. Without losing grip over the stylus, extend it as far as it will go.

#### NOTE

If the stylus passes through the aspiration tip it will fall into the waste trough and be easily retrieved.



Figure 60 – Stylus being inserted to the top of the aspiration tip

5. Once the Quad Bundles are cleaned, carefully replace the tubing over the top of the aspiration bundle tip.

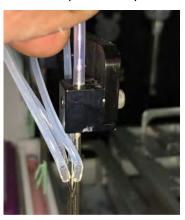


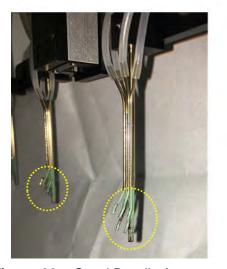
Figure 61 - Tube being re-attached.

#### NOTE

Cleaning the Quad Bundle is a preventive measure to mitigate clogs and manage any possible buildup of material in the lines.

### **Quad Bundle Assessment**

- 1. Ensure that the BD PrepStain™ is turned off.
- 2. Carefully assess each Quad Bundle to ensure that the Teflon coating is clean and not compromised.
- 3. Verify that the Quad Bundles are not bent or damaged.



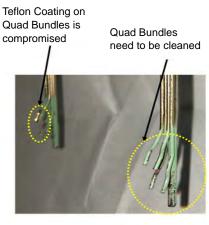


Figure 62 – Quad Bundle Assessment

### **Quad Bundle Alignment**

1. Ensure that the system is turned off and at least one Slide Tray (with Alignment holes) is present.

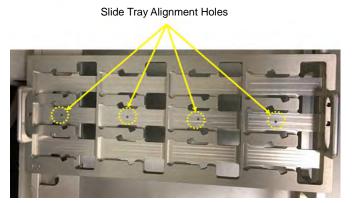


Figure 63 – Slide Trays with Alignment holes

2. Gently move the arm to position the Quad Bundles on the Slide Tray with the Alignment holes.

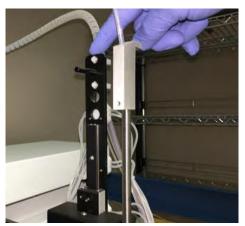


Figure 64 – Positioning Quad Bundles on Slide Trays with Alignment holes

3. Carefully lower the Quad Bundles and position them over the alignment holes.

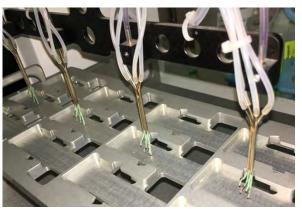


Figure 65 – Placing Quad Bundles over Alignment holes

## Empty gravity and waste containers

Depending on your lab volume, this task may be required daily.

Empty the vacuum and gravity waste containers into an approved biohazard container.

#### NOTE

When re-attaching waste bottle, make sure the vacuum hoses are properly connected and the cap is tightened.

### XYZ test

Running the random X, Y, Z test is required every week. Refer to Chapter 9, Setup and Diagnostics for details.

The BD PrepStain™ Slide Processor should not be used to prepare patient specimens if more than a week has passed since the last successful random XYZ test. Failure to confirm proper motion control function with this test may result in misdelivery of patient specimen.

### **Monthly maintenance**

Perform the following maintenance routine once a month.

## Replace Schuco vacuum pump felt silencer

#### NOTE

This section only applies to the blue Schuco pump.

To replace the felt silencer on the vacuum pump:

- 1. On the vacuum pump, locate the chrome air exhaust fitting.
- 2. Unscrew the exhaust fitting.
- 3. Replace the felt silencer pad.
- 4. Replace the exhaust fitting

# Clean all water bottles and tubing

Using a 5% bleach or Contrad 70 or Decon 90 solution, clean all water bottles thoroughly. Rinse all bottles until all cleaning solution is gone with warm tap water and then rinse with DI water. Using ~100 mL straight bleach, clean vacuum bottle; add water and let stand until clean. Rinse with tap water.

### **Syringe Pump Lubrication**

1. Use Lubriplate DS-ES to lubricate the Syringe Pump lead screw.

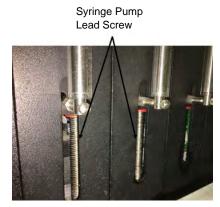


Figure 66 - Syringe pump lead screw

2. Apply 3 small dabs of Lubriplate DS-ES. Each dab should be approximately 1" (25 mm) apart when applied to the Syringe Pump Lead Screw.



Figure 67 – Lubricating the syringe pump lead screw

| Department | Month |
|------------|-------|
|            |       |

Serial # \_\_\_\_\_

Please initial each space. If a problem is found take appropriate steps to resolve. For further assistance, contact BD Technical Service and Support at 1.800.638.8663 or bd.com.

**BD PrepStain™ Slide Processor Maintenance Log** 

| 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 |
|--|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Perform system clean up                                  |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Empty tip disposal and waste containers                  |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Check syringes and tubing for leaks                      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Clean pipette bundles and DiTi cone                      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Wipe racks and work table surface with cleaning solution |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Check vacuum and gravity waste containers                |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Leave tubing in DI water overnight                       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |

Steps for each of these procedures are provided earlier in this chapter.

| WEEKLY  | WEEK 1 ( / / ) | WEEK 2 ( / / ) | WEEK 3 ( / / ) | WEEK 4 ( / / ) | WEEK 5 ( / / ) |
|---|----------------|----------------|----------------|----------------|----------------|
| Run the Utility program flush procedure   |                |                |                |                |                |
| Clean the Z-rod with a lint-free tissue   |                |                |                |                |                |
| Run the Random X, Y, Z test   |                |                |                |                |                |
| Empty vacuum and gravity waste containers (as needed, may be required daily, depending on lab volume) |                |                |                |                |                |
| Check tubing connectors and syringes for tightness.   |                |                |                |                |                |
| Use stylus to clean inside of vacuum tips   |                |                |                |                |                |
| Slide rack inspections  |                |                |                |                |                |

| MONTHLY   | ( / / ) |
|---|---------|
| Replace the felt silencer and filter (if applicable) on the vacuum pump |         |
| Replace water bottles or clean with disinfecting solution               |         |
| Clean tubing with the disinfecting solution using Utilities software    |         |
| Quad Bundle Assessment  |         |
| Quad Bundle Alignment   |         |
| Syringe Pump Lubrication  |         |

8

# Chapter 7 Troubleshooting

This chapter provides procedures you can use to isolate and resolve problems with the BD PrepStain™ Slide Processor system.

Using the information in this chapter, many of the operating problems that can occur with the BD PrepStain™ system can be corrected by the operator. By taking note of the error codes and messages that appear on the computer screen and working with the Problems and Solutions table you can often resolve the problem on your own. When calling BD Technical Support, please have a precise description of the problem available, including error code information and attempted corrective action.

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

### Error codes and messages

There are a number of errors that the BD PrepStain<sup>™</sup> instrument can detect. When one of these errors is detected, the PC monitor displays an error message as illustrated in Figure 68.

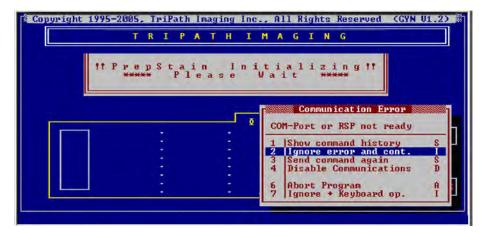


Figure 68 – Error message display screen

The following tables list the error codes that can be displayed. If one of these codes is displayed, note the code, call BD Technical Support.

### **Device ID Numbers**

Error messages include device number and error code number. Table 7-1 lists the device number that will appear in the error code and the corresponding device name.

| DEVICE No. | DEVICE DESCRIPTION       |
|------------|--------------------------|
| 11         | Water Syringe Pump       |
| 12         | Alcohol Syringe Pump     |
| 13         | Hematoxylin Syringe Pump |
| 14         | EA/OG Syringe Pump       |
| 18         | Arm                      |
| 21         | SmartValve               |

Table 7-1 Device ID numbers

### General error message codes

| CODE # | MESSAGE                             |
|--------|-------------------------------------|
| 1      | Initialization Error                |
| 2      | Invalid Command                     |
| 3      | Invalid Operand                     |
| 4      | Invalid Command Sequence            |
| 5      | Device Not Implemented              |
| 6      | Time-out Error                      |
| 7      | Device Not Initialized              |
| 8      | Command Overflow                    |
| 9      | Plunger Overload/No Liquid Detected |
| 10     | Valve Blocked/Z-position Overrun    |
| 11     | Not Enough For Liquid Sampling      |
| 12     | No Liquid Detected                  |
| 13     | Not Enough Liquid Detected          |
| 17     | Arm Collision Avoided               |
| 20     | Step loss detected on X-axis        |
| 21     | Step loss detected on Y-axis        |
| 22     | Step loss detected on Z-axis        |
| 24     | ALIDUM pulse time out               |
|        |                                     |

Table 7-2 General error message codes

### Syringe pump error keys

The following error codes can be triggered by the syringe pumps. If one of these codes is displayed, note the code, call BD Technical Support.

| ERROR | POSSIBLE CAUSES   |
|-------|---|
| 1     | Defective diluter valve Defective syringe Valve drive faulty Plunger faulty       |
| 2     | Software problem<br>Wrong string command  |
| 3     | Wrong setup<br>Program problem<br>Wrong operand in string command                 |
| 4     | Software problem  |
| 5     | Diluter is faulty<br>CPU87 is faulty  |
| 6     | Valve is worn out<br>Diluter is faulty  |
| 7     | Device is not initialized<br>Diluter is faulty                                    |
| 8     | Too many commands used on one line  |
| 9     | Syringe is too tight Valve is blocked Diluter speed is too fast Diluter is faulty |
| 10    | Initialization Error  |

Table 7-3 Syringe pump error keys

### Robot arm error codes

The following error codes can be triggered by problems with the robot arm. If one of these codes is displayed, see **Keyboard initialization for arm errors**. For more information, note the code and call BD Technical Support.

| ERROR | POSSIBLE CAUSES                        |
|-------|--|
| 1     | Setup is not correct<br>Arm is blocked |
| 2     | Software problem                       |
| 3     | Wrong setup<br>Software problem        |
| 4     | Software problem                       |

Table 7-4 Robot arm error codes

| ERROR | POSSIBLE CAUSES   |  |  |  |
|-------|---|--|--|--|
| 7     | Device is not initialized   |  |  |  |
| 8     | Too many commands used on one line  |  |  |  |
| 9     | Syringe is too tight Valve is blocked Diluter speed is too fast Diluter is faulty |  |  |  |
| 17    | Arm collision avoided   |  |  |  |
| 20    | X step loss detected  |  |  |  |
| 21    | Y step loss detected  |  |  |  |
| 22    | Z step loss detected  |  |  |  |
| 24    | ALIDUM connection or ADRI board failure   |  |  |  |

Table 7-4 Robot arm error codes

## Keyboard initialization for arm errors

If the arm is bumped, or in response to a Device 18 Error message, it is necessary to reset the arm.

- 1. Select option Ignore + Keyboard op. See Figure 68 for example, where it is option 7 in the list. (May not always be option 7.)
- 2. A new window will open. At the Command prompt, type LOAD and press Enter twice.
- 3. At the next Command prompt, type SETUP and press Enter.
- 4. At the next Command prompt, press the F8 button and type PI. (Screen will read #18PI.) Hit Enter to reset the arm. The arm will move up, back, and to the left to home.

### NOTE

Place paper towels under the DiTi or under staining bundles if these functions were in operation when arm error occurred.

5. Press Esc key to continue operation from where the error occurred.

### **Problems and solutions**

The following table describes situations that can occur during processing with the BD PrepStain<sup>™</sup> instrument. If one of these problems should occur, trying the suggested solutions before calling BD Technical Support will help more quickly resolve the problem.

| SYMPTOM  | LIKELY CAUSE(S)                              | CORRECTIVE ACTION SEQUENCE  |  |  |  |  |  |
|--|--|---|--|--|--|--|--|
| ALL BD SETTLING CHAMBERS DO                                      | The vacuum pump is not on.                   | Turn on the vacuum pump.  |  |  |  |  |  |
| NOT EMPTY  | The cap on the vacuum waste bottle is loose. | 1.If you just changed the vacuum waste bottle, check that the lid is on securely.     2.Check that all tubing connections are secure.   |  |  |  |  |  |
|  | The vacuum pressure is too low.              | 1.Check all connections from the vacuum manifold. Adjust the vacuum pressure to 8–10 inHg for Schuco pump or 5–6 inHg (180–220 mBar) for KNF pump. 2.Call BD Technical Support for assistance.              |  |  |  |  |  |
|  | The vacuum line is clogged.                  | 1. Isolate the vacuum line that is causing the obstruction.     2. Use a stylus to unclog the vacuum line.     3. If the clog is not cleared, call BD Technical Support.                                    |  |  |  |  |  |
|  | The waste manifold is clogged.               | Call BD Technical Support for assistance.   |  |  |  |  |  |
| <b>DOUGHNUTTING</b> Macroscopically                              | Vacuum bundle<br>touching slide<br>surface.  | Call BD Technical Support.  |  |  |  |  |  |
| visible holes on slide.  | Vacuum pressure is too high.                 | Adjust pressure to between 8–10 inHg for Schuco pump or 5–6 inHg (180–220 mBar) for KNF pump.   |  |  |  |  |  |
| DROPS FORM AT THE END OF THE DITI TIP OR PIPETTE STAINING BUNDLE |  | <ol> <li>Tighten all liquid connections.</li> <li>If air is observed in the tubing, tighten the tubing connections.</li> <li>Tighten the syringe connection.</li> <li>Call BD Technical Support.</li> </ol> |  |  |  |  |  |
| FAILURE TO PICK<br>UP A TIP                                      |  | Call BD Technical Support.  |  |  |  |  |  |

Table 7-5 Troubleshooting suggestions

| SYMPTOM                                   | LIKELY CAUSE(S)   | CORRECTIVE ACTION SEQUENCE   |
|---|---|--|
| HYPOCELLULARITY<br>(TOO FEW CELLS)        | The Tris buffered water is out of date                            | Make up a new batch of Tris buffered water.  |
|   | BD SurePath™<br>PreCoat slides were<br>not used.                  | Use only BD SurePath™ PreCoat slides for optimal results.  |
|   | An inappropriate fixative was used to fix the specimen.           | For optimal results, use BD SurePath™ Preservative Fluid.  |
|   | The vacuum pressure is too high.                                  | Adjust to 8–10 inches Hg for Schuco pump or 5–6 inHg (180–220 mBar) for KNF pump.  |
|   | The BD SurePath™ PreCoat slides are out of date.                  | Discard out of date BD SurePath™ PreCoat slides. Use only BD SurePath™ PreCoat slides that are within expiration date limits.  |
| NUCLEUS IS TOO<br>DARK                    | An inappropriate fixative was used to fix the specimen.           | For optimal results, use BD SurePath™ Preservative Fluid.  |
|   | The hematoxylin staining time was too long.                       | Decrease the number of seconds for staining.   |
|   | Drying artifact   | The settling chamber was removed and the cell surface dried before the mounting media and cover glass was added.   |
| OBSTRUCTION                               | One of the vacuum tips is clogged.                                | <ol> <li>1. Isolate the vacuum tip that is causing the obstruction.</li> <li>2. Use a stylus to unclog the vacuum tip.</li> <li>3. Clean the outside of the tip with an alcohol wipe.</li> <li>4. If the clog is not cleared, call BD Technical Support.</li> </ol>            |
| ONE SETTLING<br>CHAMBER DOES<br>NOT EMPTY | Vacuum line pops off of the stain bundle.                         | Replace the line and then call BD Technical Support.   |
|   | This usually is caused by a clog in the vacuum pipette.           | <ol> <li>1. Isolate the vacuum pipette that is causing the obstruction.</li> <li>2. Use a stylus to unclog the vacuum pipette.</li> <li>3. Clean the outside of the pipette with an alcohol wipe.</li> <li>4. If the clog is not cleared, call BD Technical Support</li> </ol> |
| ONE SETTLING<br>CHAMBER DOES<br>NOT FILL  | This is caused by a clog in the manifold or a dispensing pipette. | <ol> <li>Isolate the manifold or pipette that is causing the obstruction.</li> <li>Use a stylus to unclog it.</li> <li>Clean the outside of the manifold or pipette with an alcohol wipe.</li> <li>If the clog is not cleared, call BD Technical Support.</li> </ol>           |

Table 7-5 Troubleshooting suggestions

| SYMPTOM   | LIKELY CAUSE(S)  | CORRECTIVE ACTION SEQUENCE  |
|---|--|---|
| PINK SPOTS  | Z-max of the Slide<br>Quad is too high.                      | Call BD Technical Support for adjustment.   |
|   | The dispense tips are dripping.                              | Check all tubing connections.   |
| PIPETTE TIP<br>MISSES TARGET  |  | <ol> <li>Check that the slide rack is properly seated on the worktable and adjust, if necessary.</li> <li>Call BD Technical Support.</li> <li>Perform Slide Preparation and Staining or Slide Preparation and confirm that pipette tip is picked up.</li> </ol> |
| RIMMING<br>(SIMILAR TO<br>DOUGHNUTTING)                             | An inappropriate fixative was used. Only for NonGYN.         | For optimal results, use BD SurePath™ Preservative Fluid.   |
| Most of the cells are located on the outer edge of the 13mm circle. | The settling chambers are not sealed on the slide.           | Use only BD SurePath <sup>™</sup> PreCoat slides and do not re-use the settling chambers.   |
|   | BD SurePath <sup>™</sup><br>PreCoat slides were<br>not used. | Use only BD SurePath™ PreCoat slides.   |
|   | The Z dispense setting is incorrect.                         | Call BD Technical Support.  |
|   | The pipette bundle position is incorrect.                    | Call BD Technical Support.  |
| STAIN QUALITY IS<br>INCONSISTENT                                    | One of the pipettes in the pipette bundle is clogged.        | <ol> <li>Isolate the pipette that is clogged.</li> <li>Use a stylus to unclog it.</li> <li>Clean the outside of the pipette with an alcohol wipe.</li> <li>If the clog is not cleared, call BD Technical Support.</li> </ol>                                    |
|   | One or more of the<br>Reagent bottles is too<br>low          | Check the levels of all reagent bottles prior to slide processing.  |
| STAINING<br>INTERRUPTIONS   |  | Remove the partially stained rack. Since the system stains one rack at a time, there should be only one such rack.  |
| TIP IS NOT EJECTED  |  | Call BD Technical Support.  |
| TIP FALLS OFF<br>DURING<br>TRANSPORT                                |  | Call BD Technical Support.  |

Table 7-5 Troubleshooting suggestions

| SYMPTOM                                  | LIKELY CAUSE(S) | CORRECTIVE ACTION SEQUENCE  |
|--|-----------------|---|
| TRANSFER<br>INTERRUPTION                 |                 | <ol> <li>1. Remove the centrifuge tubes that contain the samples that have not been transferred.</li> <li>2. Replace "odd" slides (slides in excess of the next highest multiple of four).</li> <li>3. Wait ten minutes for all the cells to settle onto the slide.</li> <li>4. Select Slide Staining and process the transferred specimens.</li> <li>5. Replace the specimens not transferred onto the BD PrepStain trays.</li> <li>6. Change the resuspension volume to 10 μL. Refer to Change sample/stain parameters on page 5-76 for details.</li> <li>7. Run Slide Preparation and Staining for these specimens. placing blank slides and BD Settling Chambers in the "odd" slide locations.</li> </ol> |
| VOLUME OF<br>DISPENSED<br>REAGENT VARIES |                 | <ul><li>1.If you can see air bubbles in the tubing, tighten the tubing connections.</li><li>2.Check the levels in the reagent containers.</li><li>3.Call BD Technical Support.</li></ul>  |

Table 7-5 Troubleshooting suggestions

# **Chapter 8 Glossary of terms**

Refer to the following descriptions as a guide to the mechanical components that make up the BD PrepStain™ Slide Processor and the terms used in the process.

| Term                               | Description / function   |  |
|------------------------------------|--|--|
| Barcode Reader                     | <ul> <li>An option only.</li> <li>Scans and reads labels with barcodes.</li> <li>Used to verify slide and tube position; that is, it does not enter patient information.</li> </ul>  |  |
| Base Unit                          | <ul> <li>Robotic sample processor</li> <li>A system of microprocessor-controlled liquid handling components.</li> </ul>  |  |
| BD EA/OG                           | <ul> <li>One component of the cytoplasmic Papanicolaou stain.</li> <li>The mixture contains a modified Eosin-50 and Orange G.</li> </ul>   |  |
| BD Hematoxylin Stain               | <ul> <li>Designed specifically for use on the BD PrepStain™ instrument</li> <li>Compatible for use with slides to be processed on the BD FocalPoint™ slide profiler.</li> <li>Water based, nuclear stain used as part of the Papanicolaou staining process.</li> </ul> |  |
| BD Settling Chambers               | <ul> <li>Fastens onto the slide in the slide rack.</li> <li>Holds samples and other liquids during processing.</li> </ul>  |  |
| BD SurePath™<br>Preservative Fluid | A proprietary fluid used to collect and preserve gynecologic samples.  |  |
| Centrifugation                     | A process to separate fluid(s) and solid(s) using centrifugal force.   |  |
| Centrifuge                         | The BD PrepStain™ waste station and the BD PrepMate™ specimen rack are designed to fit the shape of the centrifuge buckets.  |  |
| 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.   |  |

| Term  | Description / function  |  |
|---|---|--|
| Computer (CPU)                                  | Hardware component that stores software applications (programs) and data.   |  |
| Computer Monitor                                | Monitor that displays program screens that guide the user through the application.  |  |
| Decant  | Pouring off supernatant (liquid).   |  |
| DiTi ( <b>Di</b> sposable <b>Ti</b> p) assembly | A plastic pipette that is used to mix and distribute the cell solution onto the glass slide.  |  |
| Easy Aspirator                                  | <ul> <li>A 12-position block connected to a vacuum pump used to aspirate fluid from the centrifuge tubes.</li> <li>Disposable pipette tips are used.</li> </ul>   |  |
| Microscope Slides                               | <ul> <li>Clear glass slides of a prescribed size and precoated with a high molecular weight cationic film. Uses brand name known as BD SurePath™ PreCoat slides.</li> <li>Cell samples are deposited onto the slide's surface.</li> </ul>   |  |
| Mounting Media                                  | Toluene or xylene based solution used to adhere the coverglass to the microscope slide.   |  |
| Pipette Bundle                                  | <ul> <li>Located on the quad arm.</li> <li>Consists of four dispensing tips mounted around a larger vacuum tip.</li> <li>Dispenses stains, alcohol, and water.</li> </ul>   |  |
| Quad Arm  | <ul> <li>A system of pipette bundles, tubing and manifolds mounted on the arm of the BD PrepStain™ Slide Processor.</li> <li>Allows staining operations to be performed on four samples at once.</li> <li>Reagents are dispensed through four pipettes, and waste is removed through a vacuum pipette.</li> <li>Engaged to move by the quad engagement key on the Z-rod handle. See Figure 14 –.</li> </ul> |  |
| Quad Engagement Key                             | Engages the quad handle.  |  |
| Quad Manifold                                   | <ul> <li>Four plastic housings mounted on the quad arm.</li> <li>Tubing from syringes to pipette bundles.</li> </ul>  |  |

| Term                        | Description / function   |  |
|-----------------------------|--|--|
| Slide Rack                  | <ul> <li>A metal rack fabricated with twelve rectangular cut-outs designed specifically to hold microscope slides.</li> <li>Each cut-out has a slotted track used to hold a settling chamber on top of the slide surface.</li> <li>Four racks fit on the work platform of the BD PrepStain™ Slide Processor.</li> <li>Holds up to 12 glass slides in a 4 x 3 array.</li> </ul> |  |
| Solvent Resistant<br>Marker | A pen/marker with ink that will not dissolve in alcohol, water or xylene/xylene substitutes.   |  |
| Syringe Pump                | A microprocessor-controlled pump with syringe and 2-way valve.   |  |
| Syringes                    | <ul> <li>A device used to aspirate and then expel a liquid solution.</li> <li>On the BD PrepStain™ instrument, 4 syringes are used to move water, alcohol, hematoxylin, and EA/OG (Eosin-50 and Orange G).</li> <li>The BD PrepMate™ Automated Accessory uses twelve syringes to first mix and then deposit cell sample solution onto a BD Density Reagent.</li> </ul>         |  |
| Tube Bucket                 | A centrifuge bucket capable of holding either: 2, 50 mL centrifuge tubes or 12, 12 mL centrifuge tubes in a 3 x 4 format.  |  |
| Vacuum Pump                 | <ul> <li>An electric pump that must be turned on for aspiration to occur.</li> <li>PVC tubing lines must be securely attached for proper use.</li> </ul>   |  |
| Vortexer                    | An electric vibrating device used to agitate the cell pellets in the test tubes and centrifuge tube racks.   |  |
| Waste Containers            | Bottles used to collect waste liquids used during sample processing.   |  |
| Waste Station               | <ul> <li>Consists of the waste trough, waste tip container, tip holder, and centrifuge bucket holder. See Figure 13.</li> <li>When priming or cleaning, any excess liquid is dispensed to the trough.</li> <li>Trough is emptied to a waste container via drain tubing.</li> </ul>   |  |
| Work Platform               | <ul> <li>An adjustable rectangular metal plate on the deck of the<br/>BD PrepStain™ slide processor.</li> <li>Holds the slide racks.</li> </ul>  |  |

| Term  | Description / function  |
|-------|---|
| Z-Rod | <ul> <li>A vertical toothed rack that is raised or lowered by the Z-stepper motor.</li> <li>Holds the DiTi assembly components.</li> <li>Z movement mechanism.</li> </ul> |

# **Chapter 9 Setup and Diagnostics**

This section describes how to access and perform the BD PrepStain™ instrument's setup and diagnostic tests.

#### **CAUTION**

Only use the BD PrepStain™ System as directed. Passwords may be required for certain functions. This section will only be used when directed by service personnel or as indicated for routine use and maintenance.

### System setup

Access to the System Setup functions, is via the System Setup option on the GYN Main menu.

1. Select **System Setup** from the GYN Main Menu as shown in Figure 69.



Figure 69 - Main Menu screen

2. When you choose System Setup, the Enter Password screen is displayed.



Figure 70 - Enter Password screen

3. Type in your password and then press **Enter**. The System Setup screen is displayed.



Figure 71 – System Setup screen

4. From the System Setup screen, you have access to the Machine Setup, Implement Racks, Computer Setup, and Password Setup functions. All but the last option should be used only under the guidance of a BD service representative.

## Machine setup

Sets the robotic parameters of the BD PrepStain<sup>™</sup> instrument. These parameters are set by a BD service representative prior to or during installation.

#### NOTE

Incorrect parameter settings will cause instrument error if there is improper contact between the Quad arm or DiTi assembly and the DiTi Tips, Centrifuge tubes, or Settling Chambers.

# Implement racks

Sets the robotic parameters of the BD PrepStain<sup>™</sup> instrument. These parameters are set by a BD service representative prior to or during installation.

#### NOTE

Incorrect parameter settings will cause instrument error if there is improper contact between the Quad arm or DiTi assembly and the DiTi Tips, Centrifuge tubes, or Settling Chambers.

## **Computer setup**

Sets up the PC workstation, monitor, and printer and assigns a subdirectory location for stored data. These parameters are set by a BD service representative prior to or during installation.

## **Password setup**

This screen allows you to change the password. The password is required to change parameters and enter the System Setup menu. Before you can create a new password, you must provide the current password. Please contact a BD service representative if assistance is required.

1. Select **Password Setup** and press **Enter**. The Password Setup screen will be displayed.



Figure 72 - Password Setup screen

- In the Current Password field, type in the current password for the BD PrepStain™ system, and then press Enter. Characters you type appear as asterisks.
- 3. The screen prompts you to provide the new password. In the New Password field, type in the new password. The BD PrepStain™ system password must be precisely 8 keystrokes long and must be comprised entirely of numbers. No letters or other characters are allowed.
- 4. In the **Confirm New Password** field, type in the new password again to verify that you typed in what you intended.
  - If you mistype, the screen prompts to type in the password again.
  - When you correctly confirm the new password, the Confirm password change menu is displayed.



**Figure 73** – Confirm Password change menu

- 5. Choose the appropriate option:
  - To replace the existing password with the just-specified password, select **Change to new password**, and then press **Enter**.
  - To specify a different password to replace the existing password, select **Enter another password**, and then press **Enter**.
  - To keep the existing password and discard the just-specified password, select **Keep old password**, and then press **Enter**.

This completes the change password procedure.

# **Diagnostics**

The Diagnostic menu provides access to the Keyboard Operation, Random XYZ Test, and DiTi Tests.

To access the Diagnostics menu, from the GYN Main menu, choose **Diagnostics** and then press **Enter**. The Diagnostics menu is displayed.



Figure 74 - Diagnostics menu

# Keyboard operation

This utility should be used only under the guidance of a BD representative or authorized personnel, unless otherwise directed by this User's Manual.

# Random XYZ test

The Random XYZ Test automatically drives the robotic arm to random locations within the instrument worktable, simultaneously recording information about errors, skipped steps, and the parameters of the current test cycle.

Additionally, this test is used during weekly maintenance. See Chapter 6 for details.

1. From the Diagnostics menu, select Random XYZ Test and press Enter. The Random XYZ test screen will appear.



Figure 75 - Random XYZ: Number of Moves screen

2. The screen prompts you to enter the number of moves for the test. 540 moves is the recommended number for a significant test. Type in the desired number of moves, and then press **Enter**. The select test speed menu is displayed.



Figure 76 – Random XYZ: Select test speed screen

3. Select **Normal** and then press **Enter**. The system sounds an alarm and prompts you to check the DiTi for a disposable tip. Remove if present, and then press **Enter** to start the test.

Random XYZ Test Moves in Test 540
Speed Normal
Inits Done: 0
Init Errors 0 0 0
Init Errors 0 0 0 0

4. The system runs the Random XYZ Test and then displays the results on screen.

Figure 77 - Random XYZ: Results screen

5. Figure 77 illustrates a typical Results screen. Listed below are the acceptable test values for each parameter.

| PARAMETER       | ACCEPTABLE RESULTS  |
|-----------------|---|
| Moves Done      | The total number of moves completed by the arm. At least 540 moves should be completed in a random test.                            |
| INITS DONE      | The total 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 maximum number of steps lost during the entire test. This number must not exceed three.   |
| INIT ERRORS     | The number of errors occurring during an initialization cycle. This number must be zero.  |

6. The BD PrepStain™ Slide Processor should not be used to prepare patient specimens if there are any initialization errors. Contact BD Technical Support to resolve the failed test. Only after a successful test of at least 540 moves should the device be used for a period of one week. At that point and every week thereafter, the test should be run again to assure continued function of the three motion drives. Failure to confirm proper motion control function with this test may result in misdelivery of patient specimen.

This completes the Random XYZ Test.

## **DiTi Tests**

The DiTi tests are used to evaluate the performance of the DiTi and its components. There are three tests: Tip handling, Z-rod recovery, and Contact Spring Recovery. To display the DiTi Test menu, select **DiTi Test** from the Diagnostics menu.

## Tip handling test

The Tip Handling test records the step losses associated with tip pickups and drop-offs.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.



Figure 78 – DiTi Test Options

2. From the DiTi Tests menu, select **Tip Handling** and then press **Enter**. The Tip Handling Test screen is displayed.



Figure 79 – DiTi Tip Handling Test

- 3. The cursor starts in the **Tips Tested** field. Type in the number of tip pickups for this test, and then press **Enter**. The cursor moves to the **First Test Tip** field.
- 4. Type in the position number of the first tip for pickup, and then press Enter to start the test.

  The system picks up a disposable tip, starting with the first test tip, and then drops it in the Tip Waste container. The DiTi performs a test to detect step losses after each drop off. Step
- 5. When the test is complete, the repeat Test option menu is displayed with the test results. You can either repeat the test or quit and return to the DiTi Tests menu.

## **Z-Rod recovery**

loss should be 8 or less.

The Z-Rod Recovery test checks the recovery of the Z-rod spring after extension.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.



Figure 80 - DiTi Test Options

2. From the DiTi Tests menu. select **Z** Rod Recovery and then press **Enter**. The Z Rod Recovery screen is displayed.



Figure 81 – Z Rod Recovery Test Start

- 3. Type in the number of Test Trials for this test, and then press **Enter** to start the test.
- 4. The system performs the test, and then displays the test results and the Repeat Test Option Menu.



Figure 82 – Z Rod Recovery Test Start

5. Maximum change should be 5 or less. This completes the Z Rod Recovery test.

## **Contact spring recovery**

The Contact Spring Recovery test checks that the contact spring on the DiTi recovers its position after compression.

1. From the Diagnostics menu, select **DiTi Tests** and press **Enter**. The DiTi Test screen will display the DiTi Test Options menu.



Figure 83 - DiTi Test Options

From the DiTi Tests menu. select Contact Spring Recovery and then press Enter. The Contact Spring Recovery screen is displayed.



Figure 84 – Contact Spring Recovery Test Start

3. Press **Enter** to start the test. The screen prompts you to manually raise the DiTi plastic sleeve and allow it to freely drop to its original position five times.



Figure 85 – Manually Compress Spring prompt

After you have done the five drops, press Enter to continue the test. The DiTi will re-initialize the Z-axis to check for step losses.

4. When the test is complete, the results and the Repeat Test Option menu will be displayed.



Figure 86 - Repeat Test Option menu

 Select Repeat Trial to test the contact spring again. Select Quit to exit to the DiTi Tests Menu. This completes the Contact Spring Recovery test.

When you select the **Quit** option from one of the DiTi test results screens, the DiTi Tests Menu is displayed. To exit this screen, press the **Esc** key. The Diagnostics Menu is displayed. To exit back to the Main Menu, press the **Esc** key again. To exit back to the DOS prompt, either select **Quit** and press **Enter** or press the **Esc** key again.

## Parts Replacement

Some parts are field replaceable and can be replaced by the user. The decisions to replace a part is made after the root cause of the issue is determined thereby troubleshooting the issue with BD Technical Support. BD Technical Support will provide the user with detailed instructions on how to replace the following parts:

- Syringes
- Valves
- Waste trough
- Quad Manifold
- Quad Manifold Flexible tubing
- Reagent Intake Tubing

# **BD PrepStain™ Parts Replacement**

This section will provide step by step instructions on how to replace some parts. Before performing any part replacements, contact your regional technical phone support group for appropriate troubleshooting and guidance.

Replaceable parts include:

- Syringes, Syringe Valves and Smart Valve
- Waste trough and tubing
- Reagent intake tubing
- Quad tubing
- Quad Manifold

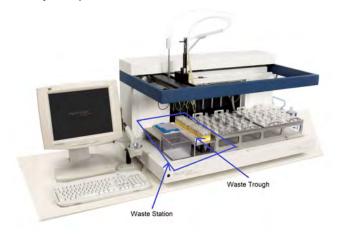
# Performance Outcomes

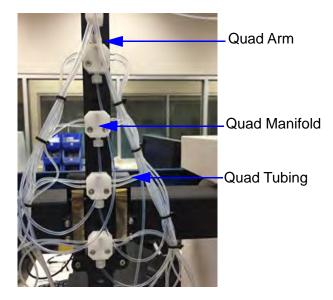
After confirming the root cause of the issue with technical support and using these instructions to replace the required part, the intended performance outcomes are as follows:

- Contacts BD Technical Support to troubleshoot issue.
- Confirms correct parts are ordered and received e.g., US Tecan I vs. II
- Prepares instrument for part replacement e.g., empty system of fluids, turn power off
- Follows appropriate instructions.
- Verifies system operates successfully after part is replaced
- Returns any parts, if required, as per BD Technical Support
- Documents activity in laboratory maintenance log

# Parts Identification

Before starting out, it is important to ensure that all parts referenced are clearly identified and located on the instrument. Follow the images below to identify the parts.





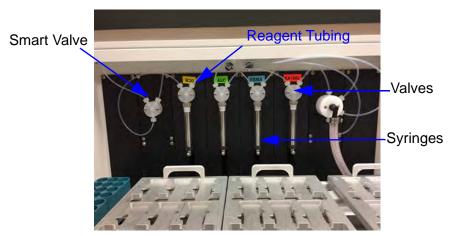


Figure 87 - BD PrepStain™ Parts Identification

#### **Tools**

The following tools will be required to remove and replace various parts. These tools come in many sizes. Therefore look at the parts as described in *Parts Identification*, identify the screws to remove and select the appropriate sized tool for the job. Once you have these tools, keep them close at hand for easy retrieval in the future. You will need the following tools:

- Phillips Head Screwdriver
- Flat Head Screwdriver
- Allen wrench
- Cutting tool (scissors)
- Small plastic tie wraps

# **Customer Replaceable Parts Instructions**

Syringes, Syringe Valves & Smart Valve When replacing syringes and valves, do the following:

- 1. Empty all fluid from the system.
  - a Exit the GYN main menu, and type UTIL at the command prompt. Press Enter.
  - **b** Select **Run Utilities Version 1.2.0.1** and then press Enter.
  - c Next select option 1 Flush Tubing with Cleaning Solution and then press Enter.
  - **d** Remove the reagent lines from any of the reagents or cleaning fluids and place them into an empty container. Press any key to begin fluid removal.
  - **e** After the fluid is removed from the system, press **F10** to stop the program from flushing.
  - f Select option 4 Abort Program.
  - g Press Enter to Move arms to Waste position.
  - h Turn off the system.

2. Use your fingers to remove the thumb screw from the bottom of the syringe and set aside for later use (see Figure 88). Turn it counterclockwise to loosen the screw.

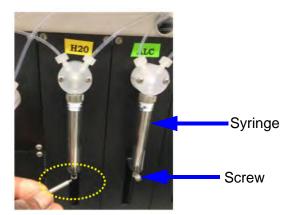


Figure 88 - Removing thumb screw from the bottom of the syringe

 Remove the clear tubing connected to the left side of the syringe valve that is further connected to the syringe to be replaced. In Figure 89, the tubing connected to the H20 reagent is being removed.



Figure 89 - Removing clear tubing connected to syringe valve

4. Remove the clear tubing from the right side of the syringe valve connected to the syringe to be removed. Figure 90 shows both the left and right side tubing removed.



Figure 90 - Both left and right side tubing removed

5. Using a Phillips-head screwdriver remove both the left and right screws from the syringe valve and set aside for later use.



Figure 91 – Screws removal from the syringe valve using Phillips-head screwdriver

6. Remove the syringe and syringe valve from the syringe pump by pulling towards yourself and discard.



Figure 92 - Syringe and syringe valve removal from syringe pump

7. Install the new syringe and/or valve by threading the syringe into the valve until you feel a slight resistance. Continue to thread no more than a ¼ turn to ensure a complete seal.

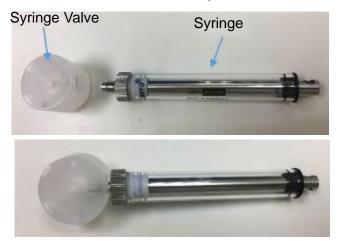


Figure 93 – Installing new syringe

8. Attach the syringe and valve to the correct syringe pump, and ensure the flat surfaces are aligned.



Figure 94 - Syringe alignment

9. Once aligned and attached to the syringe pump, re-install the screws to the syringe valve that were previously removed.



Figure 95 - Re-installing previously removed screws

10. Now re-install the thumb screw through the syringe and to the syringe pump plunger. Be sure to completely tighten the thumb screw.



Figure 96 - Re-installing thumbscrew

11. Finally attach the tubing to their correct locations. The tubing from the reagents attach to the right of the valve. The tubing to the left goes to the Quad Manifold to be distributed to the Quad Bundles.



Figure 97 - Final tubing attachments

# **Test System Operation**

After replacing any part on the BD PrepStain™ system it is important to perform a sample run to ensure that the system is functioning properly. In this situation set up a 4-sample run using water to verify that the valves, syringes and tubing are installed correctly. Place distilled water in the c-tubes to simulate a patient sample. Re-connect all other reagents according to manufacturer's recommendations. Begin the test run and check for the following:

| QUAD BUNDLES DURING PRIMING   |   |  |
|---|---|--|
| Are they leaking?   | If yes, Re-check the syringes for proper fit  |  |
| Do they require tightening?   | Only tighten ¼ turn at a time.  |  |
| QUAD MANIFOLDS  |   |  |
| Are they leaking?   | If yes, check tubing connections for tightness and Check Syringes for proper fit, tighten a ¼ turn at a time. |  |
| CORRECT REAGENT DISPENSED   |   |  |
| Is the correct tube going to the correct location?  | Watch what is being dispensed and when during the processing cycle.   |  |
| REAGENT NOT BEING DISPENSED   |   |  |
| You notice that some or all reagents are not dispensing as                                | Are the tie wraps on the Quad Tubing too tight?   |  |
| appropriate. Check the following:   | Is the Quad Tubing not in the correct location?   |  |
|   | Is the Reagent tubing not connected to the correct bottle?  |  |
|   | Did the thumb screw get replaced on the Syringe during replacement?   |  |
| DITI TIP PICKUP FAILURE   |   |  |
| Check to ensure that the tubing from the Syringes to the Quad Manifold are not too tight. |   |  |

#### NOTE

It is not necessary to use live patient samples to test system operation.

## Replacing Waste Trough and Tubing

- 1. For better access to the waste tubing, remove the DiTi tips and the DiTi waste container. The tie wrap securing the waste tubing will be visible through the DiTi tip holding area.
- 2. Cut the tie-wrap that is securing the tubing to the Waste trough as shown in Figure 98.



Figure 98 - Cutting tie-wrap

- 3. Remove the tubing from the waste trough. Discard the waste tubing and/or the waste trough.
- 4. Route the waste tubing through the back of the Waste Station and then up through the location where the Waste Trough resides as demonstrated in the figures above.



Figure 99 - Routing Waste Tubing

5. Connect the waste tubing to the barbed fitting on the waste trough and secure with a tie-wrap.

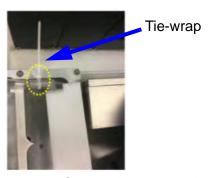


Figure 100 - Connecting waste tube using tie-wrap

6. Trim off excess material from the tie-wrap and then carefully return the waste trough to its location on the waste station.



Figure 101 – Returning waste trough to its location on the waste station

7. Route the other end of the waste tubing to the Waste Bottle under the machine. Be sure there are no kinks, as this is a gravity flow system.



Figure 102 – Routing other end of waste tubing under the machine

- 8. You have now completed the installation of the waste trough.
- 9. Perform a 4-sample test run. For more information see **Test System Operation**.

## Replacing Reagent Intake Tubing

The intake tubing is located to the right of the syringe valve as you are looking at the instrument. Note the arrows in Figure 103. These tubes bring reagent from the reagent bottles in the reagent station to the valve to be re-distributed to the Quad Manifolds and Bundles.

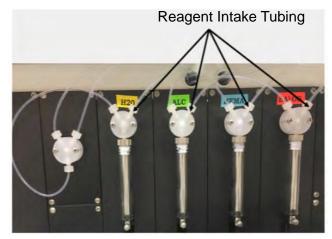


Figure 103 - Reagent Intake Tubing

1. Remove the Reagent tubing from the right side of its syringe valve. For this example the EA/OG tubing is demonstrated in Figure 104.



Figure 104 – Removing reagent tubing from right side of its syringe valve

2. Carefully remove the white panel to the right of the instrument, and continue to pull the tubing through to the exterior (far right side) of the instrument.



Figure 105 - Accessing reagent tubing

- 3. Disconnect the reagent tubing from its reagent bottle and discard.
- Connect the replacement reagent tubing to the Hose Barb Coupling and then connect the Hose Barb Coupling to its Bottle Cap Connector.



Figure 106 - Hose Barb Coupling

- 5. Take the other end of the intake tubing and follow it through the side panel and line it back up with the corresponding valve to reconnect.
- 6. Replace the white panel.
- 7. Perform a 4-sample test run. For more information see **Test System Operation**.

# Replacing Quad Tubing

The following section is provided to orient you on the tubing system. Figure 107 indicates the reagents with the associated Quad Manifolds.

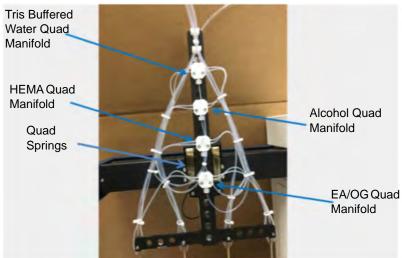


Figure 107 - Replacing Quad Tubing

1. To replace the tubing, disconnect the Quad tubing from the Quad Manifold as shown in Figure 108.

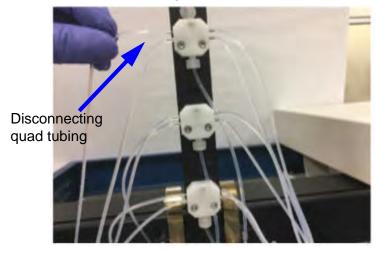


Figure 108 – Disconnecting Quad tubing from Quad Manifold

2. Follow the tube down to the Quad Bundle and disconnect the quad tubing from the Quad Bundle. Discard this tubing.

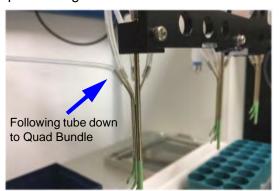


Figure 109 - Following tube down to Quad Bundle

3. Install the new Quad tubing to the Quad Bundle and then to the Quad manifold.

### NOTE

It is recommended to replace one quad tube at a time to maintain orientation. Failure to align appropriately will have an impact on slide staining.

4. Perform a 4-sample test run. For more information see *Test System Operation*.

# Replacing Quad Manifold

To confirm the location of the Quad Manifold see Parts Identification.

1. Remove the quad tubing from the Quad Manifold to be replaced as shown in the Figure 110.



Figure 110 - Removing Quad Tubing

2. Remove the Quad Reagent Tubing from the bottom of the Quad Manifold using your fingers.



Figure 111 - Removing quad reagent tubing

3. With an Allen wrench, remove the screws that secure the Quad Manifold and set aside for later use.

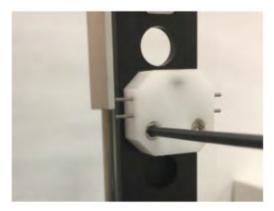


Figure 112 - Removing screws using Allen wrench

4. Remove the manifold by pulling it towards you and then discard the Quad Manifold.

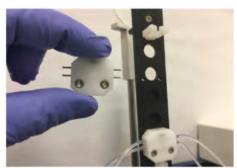


Figure 113 - Removing and discarding manifold

- 5. Install replacement Quad Manifold using the screws that were previously set aside.
- 6. Finally reconnect the quad tubing and the quad reagent tubing to the new Quad Manifold. Note the tubing from the Quad Manifold are still connected to the Quad Bundles.

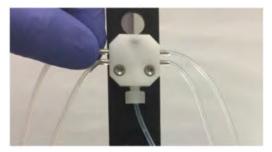


Figure 114 - Reconnecting the quad tubing

7. Perform a 4-sample test run. For more information see **Test System Operation**.

# Centrifuge

If you are experiencing issues with the centrifuge, contact your local BD customer service phone support to report the issue. If it is determined that the centrifuge requires replacement, BD will authorize an RMA (Return Materials) and dispatch a new unit to the laboratory. A BD associate is not required to be present to set up the new centrifuge and return the old one unless specifically requested by the customer. The following information will prepare the laboratory for the replacement and return of the centrifuges respectively when a BD associate is not present.

The equipment will arrive at the laboratory by a local carrier similar to UPS. The laboratory should make arrangements to transport the crate to the laboratory from the shipping dock (if necessary) and to secure at least two individuals to unload and lift the instrument to the laboratory bench space.

#### NOTE

- The unit weighs approximately 70 lb.
- Be sure to preserve the box and all packing materials as the old instrument will be placed in the same box using the same materials for the return.
- A return shipping label with instructions will be sent with the new centrifuge.
- In some regions Team Worldwide, which is a BD contracted service, will deliver and remove the old centrifuge and place the new centrifuge on the counter.

The new centrifuge is pre-programmed from the BD manufacturer for use with the BD PrepStain™ or BD SlidePrep systems. Use the Operating instructions provided with the instrument to set up the centrifuge e.g., connect the electrical cord, check rotor operation etc.

#### NOTE

If the laboratory is not comfortable with setting up the new centrifuge, a field service engineer will be dispatched to unlock the new centrifuge and prepare the old for shipping.

Prior to removing the old centrifuge it is recommended to decontaminate and clean the centrifuge using standard reagents such as 5% bleach prior to shipping. Wipe down all interior surfaces and clean the centrifuge buckets. Secure internal components using existing packing materials from the new centrifuge and then transfer the unit to the crate. Secure with packing tape and return to BD using the return shipping labels provided.

# Chapter 10 Non-GYN Slide Processing

All of the BD PrepStain™ instrument's functions are controlled using a computer workstation. Access to the programs that run the BD PrepStain™ instrument is via three DOS based, menu-driven applications.

Using the workstation menus, you communicate with the instrument, and monitor the progress of slide processing. This chapter describes how to use the Non-GYN application to process Non-GYN specimen slides.

# BD PrepStain™ Non-GYN program

# Program overview

Figure 115 illustrates the initial welcome and version check screen that displays when you open the Non-GYN program.

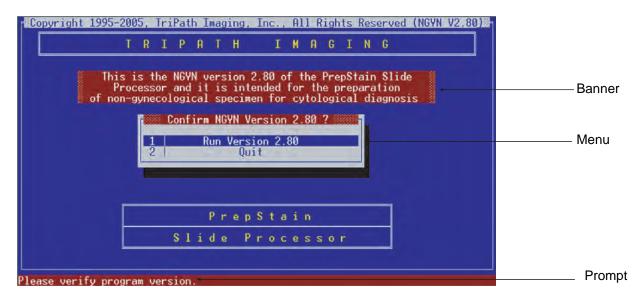


Figure 115 - BD PrepStain™ System Non-GYN Version Menu

The screens in the Non-GYN application are divided into three sections as illustrated in Figure 115.

- The top (banner) section displays text messages on several lines. These messages tell you what action the system is performing or about to perform.
- The middle (menu) section displays menu prompts you use to control the system.

 The bottom (prompt) section displays text messages on a single line. These messages tell you what's happening and what to do next.

## Non-Gyn Main Menu

When you choose the first option in the Non-GYN Version menu, the Non-GYN Main Menu is displayed. This screen is illustrated in Figure 116.

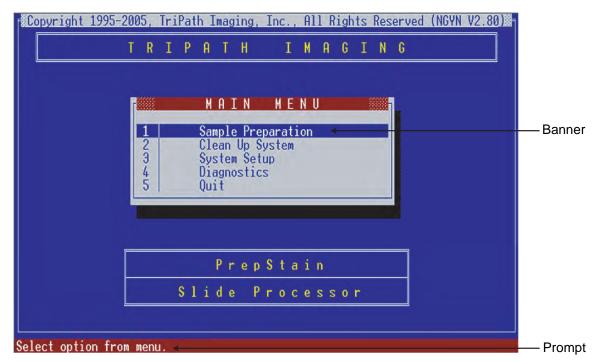


Figure 116 - Non-GYN Main Menu

This section provides details on how to use the sample Preparation option. For details on how to use the Clean Up System option, refer to *Maintenance Procedures* in Chapter 6. For details on how to use the System Setup and Diagnostics options, refer to *Setup and Diagnostics* in Chapter 9.

# Processing non gynecologic (Non-GYN) specimens

- The GYN application runs automatically when you start the BD PrepStain™ instrument workstation. Exit this application to access a DOS prompt so that you can display the Non-GYN Version Check menu (Figure 115). This screen provides access to all functions of the program.
  - If the workstation is running the GYN application, select Quit to display the DOS prompt, type in NONGYN, and then press Enter.
     The Non-GYN Version Check menu (Figure 116) is displayed.
  - If the workstation is already displaying the DOS prompt, type in NONGYN and then press Enter.
     The Non-GYN Version Check menu is displayed.
- Select Run Version 2.80 from the menu, and then press Enter.
   This brings up the Non-GYN Version 2.80 Main Menu. The main menu (Figure 116) provides access to all functions of the program.
- 3. Select **Sample Preparation**, and then press **Enter**. The Number of Samples screen (Figure 117) is displayed.



Figure 117 - Number of Samples screen

#### NOTE

On this and all other BD PrepStain™ system screens, you can use either the **Tab** or **Enter** keys to move the cursor (navigate) from one field to the next.

 In the first field, type in the number of samples to be processed, and then press Enter. The number of samples must be a multiple of four.

#### NOTE

If the number of slides to be processed is not divisible by four, type in the next higher multiple of four, and then add blank slides, settling chambers, and tubes to the slide tray to make up the difference.

- 5. Go to the next field and type in the number of slides you want created for each sample. For example, you might want to create three slides from each sample centrifuge tube.
- 6. Navigate to the next field and type in the number of slides that you want stained for each sample. For example, if you were creating three slides for each sample, you might only want one of them stained using the current sample and stain settings.
- 7. Navigate to the next field, and either press **Enter** to confirm that the **Next Tip Position** is correct; or type in the correct tip number, and then press **Enter**.
- 8. The Reenter Run Information prompt is displayed.
  - To change any of your entries: select **Yes**, press **Enter**, and then repeat the last three steps.
  - To confirm your entries and proceed: select No and then press Enter.
- 9. The Change Sample/Stain Parameters prompt is displayed.
  - To change the sample or stain settings, select **Yes** and then press **Enter**.
    - Refer to **Change sample/stain parameters** on page 76 for details on how to make these adjustments.
  - To use the existing settings and proceed, select **No** and then press **Enter**.
- 10. The Turn on Vacuum screen (Figure 118) is displayed.

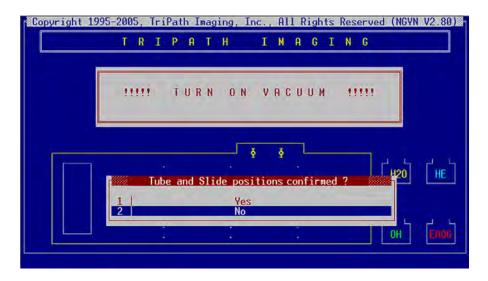


Figure 118 - Turn on Vacuum screen

- Confirm that the position of the sample tubes and their corresponding slides match.
- Select **Yes** and then press **Enter**.
- 11. The vacuum prompt is displayed and the alarm will sound. Press any key to silence the alarm.
- 12. Turn on the vacuum pump, wait a few minutes for it to warm up, adjust pressure to 8–10 inHg for Shuco pump or 5–6 inHg (180–220 mBar) for KNF pump, and then press any key to continue.
- 13. The Prime ALL Tubing? prompt will appear.
  - If this is the first run of the day, select Yes and then press Enter
    to prime the system tubing. The system initializes and the
    pumps dispense reagents through the quad arm tubing and into
    the waste station.
  - For subsequent runs during the next eight hours, select **No** and then press **Enter** to skip the full priming function.
  - Before each run, a single syringe volume is automatically pumped through the tubing to ensure that the system is filled.
- 14. When the priming cycle is complete, the is the tubing primed? prompt is displayed.
  - To repeat the priming sequence, select No and then press Enter.
  - To proceed with slide preparation and staining, select **Yes** and then press **Enter**.
- 15. The DiTi dispenses buffered water into each BD Centrifuge Tube to re-suspend the cell pellet. Next, the DiTi picks up a disposable tip, and then a sample of the cell suspension is aspirated, carried to its corresponding slide, and deposited into the settling chamber.

- 16. After a sample is transferred, the BD PrepStain™ instrument dispenses an additional amount of buffered water. When samples have been transferred to all racks, the instrument pauses for ten minutes while the cells sediment onto the slide.
- 17. When the sedimentation pause is complete, an alarm alerts the operator that the arm is about to move.
  - Staining is performed one slide rack at a time. During each staining cycle, each slide is pre-washed in the appropriate reagent (buffered water for hematoxylin, alcohol for EA/OG) and then stained. After the staining is complete, the slide is washed with alcohol. Each settling chamber is completely emptied between stains and washes.
- 18. When all of the slides on a rack have been stained, the BD PrepStain™ system sounds an alarm, and then continues to stain the next slide rack.
  - As each slide rack is completed, remove it from the BD PrepStain™ instrument and decant the alcohol from the BD Settling Chambers into an appropriate receptacle.

#### **CAUTION**

- When removing the settling chamber, avoid scraping cell circle from slide.
- Do not allow the slides to dry prior to coverslipping. Each slide must be coverslipped one at a time.
- Leaving samples in alcohol for an extended length of time can cause the cells to destain.
- 19. When the BD PrepStain™ instrument finishes processing, the sample Preparation Complete prompt is displayed and an alarm sounds. Press any key to silence alarm and continue.
- 20. When you complete a Sample and Stain run, you can either run another batch, clean up the instrument, or exit to DOS so you can start one of the other BD PrepStain<sup>™</sup> applications.

## Slide arrangements for multiple slides

When you process multiple slides for each sample (just as when you process a single slide for each tube), the first sample from each tube is delivered to the corresponding slide on the first available rack, beginning at the front left corner of that rack and moving toward the back. Subsequent samples created from that tube are delivered to the corresponding slide in the next available rack. Some examples are shown in Figure 119, Figure 120, and Figure 121.

### Two slides from eight samples

To process 8 samples, making 2 slides for each sample, the Steps in Progress screen looks like Figure 119. As an example, a sample from tube 6 would be transferred to two places: slide position 6 on Rack 1, and slide position 6 on Rack 2.



Figure 119 – Two slides from eight samples

### Three slides from eight samples

To process 8 samples, making 3 slides for each sample, the Steps in Progress screen looks like Figure 120. As an example, a sample from tube 6 would be transferred to three places: slide position 6 on Rack 1, slide position 6 on Rack 2, and slide position 6 on Rack 3.



Figure 120 – Three slides from eight samples

## Two slides from sixteen samples

To process 16 samples, making 2 slides for each sample, the Steps in Progress screen looks like Figure 121. In this case there are too many samples being made from each tube to transfer the second copy to rack 2, so the second set of slides is created beginning in the next available rack. In this case that is rack 3.



Figure 121 – Two slides from sixteen samples

You can make 2 slides per sample for up to 24 samples per run. You can make up to 4 slides per sample for 12 samples or less.

# Chapter 11 Ancillary Testing from the BD SurePath™ Collection Vial

An aliquot of the specimen (up to 0.5 mL) may be removed from the BD SurePath<sup>™</sup> Collection Vial for ancillary testing *prior* to the BD SurePath<sup>™</sup> Pap test process.

In order to perform *Chlamydia trachomatis (CT)* and/or *Neisseria gonorrhoeae (GC)* testing using BD ProbeTec<sup>™</sup> *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays out of the BD SurePath<sup>™</sup> Collection Vial, specific processing steps must be followed as detailed in this section.

## **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 a Pap test using the BD PrepStain™ system (requires 8.0 ± 0.5 mL).

#### NOTE

A maximum of 0.5 mL aliquot may be removed prior to processing the BD SurePath™ Pap test. Only one aliquot may be removed from the BD SurePath™ Collection Vial prior to performing the Pap test, regardless of the volume of the aliquot.

1 In order to ensure a homogenous mixture, the BD SurePath™ Collection Vial must be vortexed for 10–20 seconds and the 0.5 mL aliquot must be removed within one minute of vortexing.

- appropriately for the volume being withdrawn must be used for aliquot removal. *Note:* Serological pipettes should not be used. Good laboratory practices must be followed to avoid introducing contaminants into the BD SurePath™ Collection Vial or the aliquot. Aliquot removal should be performed in an appropriate location outside an area where amplification is performed.
- 3 Visually check the aliquot material in the pipette for evidence of large gross particulates or semi-solids. Evidence of such material encountered while withdrawing the aliquot material should prompt return of all the material to the specimen vial and disqualify the specimen for ancillary testing prior to performing the Pap test.
- **4** For instructions on processing the aliquot using the BD ProbeTec<sup>™</sup> *Chlamydia trachomatis* (CT) Q<sup>x</sup> and *Neisseria gonorrhoeae* (GC) Q<sup>x</sup> Amplified DNA Assays, refer to the Package Inserts provided by the assay manufacturer.

# Limitations of Procedure

A volume of  $8.0 \pm 0.5$  mL of the gynecologic specimen collected in the BD SurePath<sup>TM</sup> Collection Vial is required for processing the BD SurePath<sup>TM</sup> Pap test in the laboratory.

General precautions on ancillary testing from BD SurePath™ Collection Vial

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™ Pap test.

# **Chapter 12 Symbol Glossary**

|                     | Manufacturer   |
|---------------------|--|
| EC REP              | Authorized Representative in the European Community  |
| REF                 | Catalogue number   |
| IVD                 | In vitro diagnostic medical device   |
| R <sub>X</sub> Only | This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." |
| 88                  | Biological Risks   |
| $\triangle$         | Caution  |
| 1                   | Temperature limit  |
| [i]                 | Consult instructions for use or consult electronic instructions for use  |
| $\subseteq$         | Use-by date  |
| LOT                 | Batch code   |
| SN                  | Serial number  |
| <b>®</b>            | Do not use if package is damaged and consult instructions for use  |
| Σ                   | Contains sufficient for <n> tests</n>  |
| 2                   | Do not re-use  |
| ?                   | For IVD performance evaluation only  |
| 1                   | Lower limit of temperature   |
|                     | Upper limit of temperature   |
| **                  | Keep dry   |

| 0              | Collection time                 |
|----------------|---------------------------------|
| (A)            | Peel here                       |
| ?!!            | Perforation                     |
| 촣              | Keep away from sunlight         |
| <b>ور</b>      | Cut                             |
| 12             | Collection date                 |
| H <sub>2</sub> | Hydrogen gas is generated       |
|                | Keep away from light            |
| <b>•</b> #     | Patient ID number               |
| Ţ              | Fragile, Handle with Care       |
| CONTROL -      | Negative control                |
| CONTROL +      | Positive control                |
| STERILEEO      | Sterilized using ethylene oxide |
| STERILE R      | Sterilized using irradiation    |

# **Chapter 13 Ordering Information**

Below is a list of components and kits for use with the BD PrepStain™ System. For product availability, refer to the product catalog or contact your local distributor or BD representative.

| Catalog Number | Product Description   |
|----------------|---|
| 490100         | BD PrepStain™ Slide Processor   |
| 490510         | BD Aspirator™ Tips, 96  |
| 490513         | BD PrepStain™ Transfer Tips, 96   |
| 490515         | BD Centrifuge Tubes, 480  |
| 490516         | BD Dispenser, 4 mL  |
| 490518         | Tris Buffered Saline Packet   |
| 490625         | BD Clamshell, 88  |
| 491103         | BD PrepMate <sup>™</sup> Automated Accessory  |
| 491248         | BD SurePath™ PreCoat Slides, 96   |
| 491267         | BD PrepStain™ Slide Library Kit  Contains:  BD SurePath™ PreCoat Slides, 96  BD Settling Chambers, 96  BD PrepStain™ Transfer Tips, 96                |
| 491331         | BD Syringing Pipettes, 240  |
| 491332         | BD Density Reagent, 480 mL  |
| 491337         | BD SurePath™ Preservative Fluid, 3600 mL  |
| 491454         | BD PrepStain™ Consumables Kit  Contains:  BD SurePath™ PreCoat Slides, 480  BD Settling Chambers, 480  BD PrepStain™ Transfer Tips, 480               |
| 491455         | BD PrepMate™ Consumables Kit  Contains:  BD Density Reagent, 4 x 480 mL  BD Centrifuge Tubes, 480  BD Syringing Pipettes, 480  BD Aspirator Tips, 480 |

| Catalog Number | Product Description  |
|----------------|--|
| 491457         | BD Alcohol Blend Rinse, 1700 mL  |
| 491458         | BD Cytology™ Stain Kit  Contains:  BD Hematoxylin Stain 0.75, 480 mL  BD EA/OG Combo Stain, 480 mL |

Additional components or kits for Non-Gynecological use with the BD PrepStain™ System.

| Catalog Number | Product Description   |
|----------------|---|
| 490719         | BD CytoRich™ Clear Preservative, 3600 mL  |
| 491303         | BD PrepStain™ Non-GYN Test Kit  Contains:  BD Centrifuge™ Tubes, 192  BD SurePath™ PreCoat Slides, 192  BD Settling Chambers, 192  BD PrepStain™ Transfer Tips, 192 |
| 491335         | BD CytoRich™ Blue Preservative, 3600 mL   |
| 491336         | BD CytoRich™ Red Preservative, 3600 mL  |
| 491459         | BD Non-GYN Stain Kit  Contains:  BD Hematoxylin Stain 0.5, 480 mL  BD EA/OG Combo Stain, 480 mL   |