SEQUENCE
Quality and Compliance Services

BacT/ALERT 3D™

Microbial Detection System

BacT/ALERT® 3D Signature System (Version B.40)
OBSERVA® Software (Version 4.03)

Installation, Operational, and Performance Qualification Protocol for Asset 001185

VAL-00124

Table of Contents

1. Introduction

1.1. Purpose

The purpose of this document is to verify and document the installation, operational, and performance qualification testing of the BacT/ALERT® 3D System with OBSERVA® data management software. A validation package for the BacT/ALERT® 3D system will be created using test scripts from this IOPQ and any attached supporting documents to validate the system for cGxP use.

1.2. Scope

The scope of this Installation, Operational, and Performance Qualification protocol is limited to the bioMérieux BacT/ALERT® 3D Signature Combination Module System and the OBSERVA® data management software. All supporting documentation will be attached to this protocol. It should be noted that due to the versatility of the system's configuration and use, in certain areas, only the most commonly used aspects of the system are verified.

The verification testing is limited to the following:

- BacT/ALERT® 3D Signature Combination Module system hardware and component verification
- Incubation Module(s) verification (if applicable)
- OBSERVA® Data Management installation and version verification
- Specific default Search and Report configurations in OBSERVA® are verified
- BacT/ALERT® 3D system performance verification (as applicable)
- System functionality (Microbial Detection, Workflow testing, etc.)
- Data Management (Screen verification, audit trails, system backup, etc.)
- Data Security (Secured login, Electronic Signature, etc.)

Note: This protocol assumes that the 21 CFR Part 11 mode is enabled on the BacT/ALERT® 3D that is being qualified.

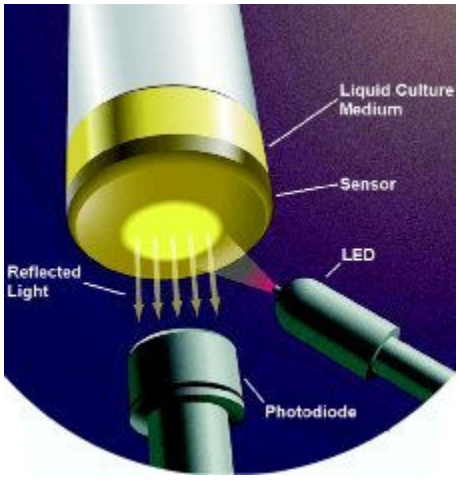
2. System Description

The bioMérieux BacT/ALERT® 3D System is composed of the BacT/ALERT® 3D Signature Combination Module and a bioMérieux workstation with OBSERVA® data management software. The BacT/ALERT® 3D Signature system measures samples, and displays and prints results, while the OBSERVA® software provides data reporting, electronic signatures, and audit trails of the data.

The BacT/ALERT® 3D microbial detection system is a fully automated system built on bioMérieux's patented colorimetric technology that detects microorganisms' growth by tracking CO_2 production. The system incubates, agitates, and with solid-state reflectometers, continuously monitors the status of each culture bottle for microbial growth.

If microorganisms are present in the test sample, CO_2 is produced as the microorganisms metabolize the substrate in the culture medium. When growth of the microorganism produces CO_2, the color of the sensor in the bottom of each culture bottle changes from dark to light. A light-emitting diode (LED) projects light onto the sensor. The light reflected is then measured by a photodetector. As more CO_2 is generated, more light is reflected (refer to Figure 1). This information is compared to the initial sensor reading. If there is high initial CO_2 content, an unusually high rate of CO_2 production, and/or a sustained production of CO_2, the sample is determined to be positive. If the CO_2 level doesn't change significantly after a specified number of days at optimal conditions, the sample is determined to be negative.

Figure 1: Liquid Emulsion Sensor



The BacT/ALERT® 3D Signature System is connected directly to a bioMérieux data management computer where data generated by the BacT/ALERT® 3D Signature is managed by the OBSERVA® data management software. OBSERVA® provides the ability to configure the user interface, data fields and reports to meet specific needs. OBSERVA® provides high levels of security by logging

system activities to ensure that data integrity and change histories are maintained. OBSERVA® can be used to generate reports; graph bottle readings; enter, view, and edit product information and test results; store data; and keep information/data secure using system access levels, user accounts, and user passwords.

3. Documentation Ownership

4. Acronyms and Definitions

Term	Definition
Archive	The process of saving a copy of isolate reports, including all associated audit information from the database to a CD.
CFR	Code of Federal Regulations
CD	Compact Disc
cGxP	A term for Good Practice quality guidelines and regulations where “x” refers to the appropriate process, such as Information Systems, Manufacturing, Clinical, or Laboratory.
HTIM	High Temperature Incubation Module
IOPQ	Installation, Operational, and Performance Qualification
LED	Light Emitting Dioxide
LTIM	Low Temperature Incubation Module
Isolate	A microorganism recovered from a clinical or industrial specimen or sample
IT	Information Technology
NCPF	National Collection of Pathogenic Fungi
NCTC	National Collection of Type Cultures
PM	Preventive Maintenance
QA	Quality Assurance
SOP	Standard Operating Procedure
UPS	Uninterruptible Power Supply (battery power backup, in this case)

5. Responsibilities

Role	Responsibility
System Owner(s)	▪ Ensures the compliant state of the system. ▪ Responsible for the integrity, administration, operation, maintenance, and decommissioning of the system throughout the system's lifecycle. ▪ Assembles a Project Team, if required. ▪ Provides technical guidance to ensure that the development efforts comply with the site's validation practices. ▪ Reviews and approves system validation lifecycle documentation. ▪ Responsible for scheduling instrument maintenance and preventive maintenance. ▪ Performs validation periodic reviews of the operating system in compliance with all site policies and SOPs where applicable.
Sequence, Inc. Laboratory Compliance Consultant(s)	▪ Develops and maintains the BacT/ALERT 3D System's validation documentation. ▪ Reviews and approves system validation lifecycle documentation. ▪ Serves as internal consultants for validation activities. ▪ Provides validation and technical service regarding the system.
Quality Assurance (QA)	▪ Ensures compliance with all company policies, standards, and procedures as well as all regulatory requirements. ▪ Reviews and approves system validation lifecycle documents. ▪ Assists with, or performs, audits of vendors to assess compliance with company policies and SOPs.
Information Technology (IT) Department	▪ Provides instrument's computer workstation, if applicable. ▪ Provides company network connection, if applicable. ▪ Provides network or standalone printer, where applicable. ▪ Maintains company network data according to administrative SOP.

6. Validation Approach

This Installation, Operational, and Performance Qualification validation protocol for the BacT/ALERT® 3D System and the OBSERVA® data management software will be performed by a Sequence, Inc. Validation Consultant. The test scripts within this IOPQ protocol challenge the general installation, operational, and performance requirements of the BacT/ALERT® 3D System and the OBSERVA® data management software. Following the approval of the IOPQ, a Validation Summary Report will be written, summarizing the results from the execution of the IOPQ. Data produced as a result of this PQ testing is only intended for this validation effort and, therefore, will not be used for any release decisions.

6.1. Risk Management

No hazards have been identified to personnel as a result of the operation of this instrument. If any risk is identified during the execution of this protocol, procedural mitigation will be utilized within the instrument SOP(s).

6.2. Material Control and Disposition

During this validation effort, no product will be tested for the purpose of development, release, or stability. Sequence policies will be followed regarding biological use, waste handling, and/or disposal.

7. Prerequisites

7.1. Training Prerequisites

Verify that the training for the following SOPs has been completed by the validation protocol executor(s) prior to commencing.

Table 7-1: Training Verification

SOP No.	Form Title	Version	Effective Date
SOP-001	Document Content and Control (Internal Sequence, Inc. SOP)®		
SOP-003	Good Documentation Practices (Internal Sequence, Inc. SOP)®		
SOP-009	Documenting Validation Deviations (Internal Sequence, Inc. SOP)®		
SOP-017	Operation of the DataTrace System (Internal Sequence, Inc. SOP)®		

®Refer to Attachment ____ pages ____ for training verification from the ZenQMS training system.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

7.2. Preventive Maintenance Verification

Verify that the system has a Preventive Maintenance (PM) established by completing Table 7-2.

Table 7-2: PM Verification

Instrument ID	PM Number	PM Description

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

7.3. Calibration Verification

Verify that the equipment required to perform the validation have been calibrated prior to usage.

Table 7-3: Calibration Verification of Test Equipment

Equipment ID	Description	Calibration Due Date	Initials/Date

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

7.4. System Documentation Verification

Document the Document ID (if applicable), Title, Revision, Revision Date, and Storage Location for all associated equipment/system documentation (e.g., logbooks, manuals, system software, certificates, etc.).

Table 7-4: System Documentation

Document ID	Title	Storage Location	Version / Effective Date

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

8. Installation Qualification

8.1. Test Program 1: Hardware and Software Verification

8.1.1. Objective

The objective of this test program is to verify that the bioMérieux BacT/ALERT® 3D Signature System and the OBSERVA® software meets user requirements and the required hardware components are available. It will ensure that all associated installation of the instrumentation, mechanical components and software are properly installed and meets all installation specifications to show the validity of using this instrument in the laboratory.

8.1.2. Acceptance Criteria

8.1.2.1. The OBSERVA® workstation will have, at minimum, Microsoft Windows XP Operating System, 1.79 GHz processor speed, 512 MB of RAM, 40 GB disk drive, Monitor, Keyboard, Mouse and Barcode scanner.

8.1.2.2. A printer shall be available for the system.

8.1.2.3. The BacT/ALERT® 3D must have the following, power switch, power connector, display switch assembly (if applicable), 2 CPU ports, 2-5 module ports, fan, monitor port, modem port, LIS port, printer port, Comm port, external speaker port.

8.1.2.4. High Temperature Incubation Modules (HTIM) should be available and must have the following: power switch, power connector and controller module port.

8.1.2.5. High Temperature Incubation Module (HTIM) must have the green and yellow indicator lamps.

8.1.2.6. Low Temperature Incubation Module (LTIM) should be available for dual-temperature combination models and must have the following: power switch, power connector and controller module port.

8.1.2.7. Low Temperature Incubation Module (LTIM) for dual-temperature combination models must have the green and yellow indicator lamps.

8.1.2.8. Low Temperature Module Cart for dual-temperature combination models must be available with a Condenser and Evaporator indicator lights.

8.1.2.9. Each incubation module(s) must have the capacity to hold 60 culture bottles per drawer.

8.1.2.10. The Incubation Module(s) racks must be able to agitate samples (if applicable).

8.1.3. Equipment

8.1.3.1. BacT/ALERT® 3D System

8.1.3.2. OBSERVA® workstation

8.1.4. Test Procedure/Results/Data

Complete the tables below as indicated.

Table 8-1: TP 1: Combination Module Software Verification

Parameter	Expected Results	Actual Results	Pass/Fail
Software (Control Module)	B.40		
Software Version (Control Module)	Rel 4	.	
Manufacturer	bioMérieux		

Table 8-2: TP 1: Computer Workstation Software Verification

Parameter	Expected Results	Actual Results	Pass/Fail
Software	OBSERVA		
Software Version	04.03		
Manufacturer	bioMérieux		

Table 8-3: TP 1: Computer/Workstation Verification

Parameter	Expected Results	Actual Results	Pass/Fail
Manufacturer	As Found		
Workstation ID	As Found		
Operating System	Microsoft Windows XP (minimum)		
Processor Speed	1.79 GHz processor speed (minimum)		
RAM	512 MB (minimum)		
Disk Drive	40 GB (minimum)		
Monitor	Available		
Mouse and Keyboard	Available		
Printer	Available		
Scanner	Available		
Acceptance criteria 8.1.2.1 and 8.1.2.2 are successfully challenged.			

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 8-4: TP 1: Combination Module Hardware Verification

Parameter	Expected Results	Actual Results	Pass/Fail
Manufacturer	bioMérieux		
Model	As Found		
Combination Module Serial #	As Found		
System ID #	As Found		
Back-up Drive	Available		
Barcode Reader	Available		
Keyboard Drawer	Available		
Power Switch	Available		
Power Connector	Available		
Display Switch Assembly (if applicable)	Field Verify		
2 CPU Ports	Available		
2-5 Module Ports	Available		
Fan	Available		
Monitor Port	Available		
Modem Port	Available		
LIS Port	Available		
Printer Port	Available		
Comm Port	Available		
External Speaker Port	Available		
Acceptance criterion 8.1.2.3 is successfully challenged.			

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 8-5: TP 1: High Temperature Incubation Module(s) Hardware Verification

	Parameter	Expected Results	Actual Results	Pass/Fail
N/A ☐	Manufacturer	bioMérieux		
	Model	As Found		
	HT Combination Incubation Module 1 Serial #	As Found		
	HT Combination IM 1 ID #	As Found		
	60 bottle capacity drawer(s)	4 Available		
	HTIM green and yellow indicator lamps	Field Verify		
	Incubation Module racks must agitate samples when drawer is closed.	Field Verify		
N/A ☐	Manufacturer	bioMérieux		
	Model	As Found		
	HT Incubation Module 2 Serial #	As Found		
	HT Incubation Module 2 ID #	As Found		
	Incubation Module Power Switch	Available		
	Incubation Module Power Connector	Available		
	Incubation Module Controller Module Port	Available		
	60 bottle capacity drawer(s)	4 Available		
	HTIM green and yellow indicator lamps	Field Verify		
	Incubation Module racks must agitate samples when drawer is closed.	Field Verify		
Acceptance criteria 8.1.2.4, 8.1.2.5, 8.1.2.9 and 8.1.2.10 are successfully challenged.				

Comments: Asset 001185 contains one HTIM and is not a dual-temperature unit at this time. Therefore, 8.1.2.6, 8.1.2.7 and 8.1.2.8 do not apply.

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

8.2. Test Program 2: Field Verification

8.2.1. Objective

The objective of this test program is to verify that the BacT/ALERT® 3D Signature System has been installed according to the manufacturer's recommendations and tagged for identification.

8.2.2. Acceptance Criteria

8.2.2.1. The instrument has been tagged with an instrument ID #.

8.2.2.2. The BacT/ALERT® 3D System shall be located in a laboratory (where applicable).

8.2.2.3. The laboratory is equipped with badge access readers (when applicable) to control access to authorized personnel(s) only.

8.2.3. Test Procedure/Results/Data

Complete the tables below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 8-7: TP 2: Field Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Verify that the system is located in a laboratory (where applicable). Document the building and lab room number (if applicable)	The system is located in a laboratory (where applicable).	The system _____ located in a laboratory (where applicable). Bldg. #: _____ Room #: _____	
2	Verify that the system has been tagged with an ID #.	The system has been tagged with an ID # 001185.	The system has been _____with an ID #. ID # _____	
3	Verify that the laboratory is equipped with access badge readers outside the entrance to the laboratory or building in which the system is located.	The laboratory or building is equipped with access badge readers.	The laboratory _____ building is equipped with access badge readers.	
All acceptance criteria are successfully challenged.				
Test Program 2 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

8.3. Test Program 3: Environmental Conditions and Utility Verification

8.3.1. Objective

The objective of this test program is to verify that the environmental conditions and supplied utilities meet the manufacturer's recommendations.

8.3.2. Acceptance Criteria

8.3.2.1. Laboratory temperature is maintained between 10° C to 30° C for High Temperature Incubation Module (HTIM). For dual-temperature combination units, the temperature is maintained between 15° C to 25° C for Low Temperature Incubation Module (LTIM).

8.3.2.2. Humidity is maintained between 10% - 90% RH, non-condensing for HTIM and for dual-temperature combination units, the humidity is maintained between 20% - 60% RH, non-condensing for LTIM.

8.3.2.3. The supplied utilities shall be between 100 - 240 VAC.

8.3.2.4. The BacT/ALERT® 3D Signature Incubation Modules and computer shall be connected to an UPS backup system in the case of a power failure.

8.3.3. Equipment

8.3.3.1. Temperature and humidity measuring device

8.3.4. Test Setup

8.3.4.1. A temperature and humidity recorder will be placed near the BacT/ALERT® 3D Signature System to capture the ambient laboratory temperature and relative humidity.

8.3.5. Test Procedure/Results/Data

8.3.5.1. Temperature and Relative Humidity Data

- Measure and record the temperature/relative humidity over a **minimum of 4 hours**. Record the data in the Temperature and Relative Humidity table. Verify the results are within specifications. Complete the table(s) below as indicated.

Table 8-8: TP 3: BacT/ALERT® 3D and Incubation Module(s) Temperature and Relative Humidity

Parameter	Expected Results	Actual Results (Average)	Pass/Fail
HTIM Ambient Laboratory Temperature	10° C to 30° C		
LTIM Ambient Laboratory Temperature	15° C to 25° C	N/A – Asset 001185 contains only HTIM at this time.	N/A
HTIM Ambient Laboratory Relative Humidity	10% - 90%, non-condensing		
LTIM Ambient Laboratory Relative Humidity	20% - 60%, non-condensing	N/A – Asset 001185 contains only HTIM at this time.	N/A
Acceptance criteria 8.3.2.1 and 8.3.2.2 are successfully challenged.			
Reference Attachment(s) _____, page(s) _____ for temperature and humidity data.			

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

8.3.5.2. Electrical Verification

- Document the panel number (if applicable) and electrical voltage documented on the panel in the Electrical Verification table. Verify the results are within specifications.
- Complete the table(s) below as indicated.

Table 8-9: TP 3: Control Module Electrical Verification

Parameter	Expected Results	Actual Results	Pass/Fail
Panel ID	Field Verify		
Electrical Supply	100 - 240 VAC		
UPS Backup System	Connected		
Acceptance criteria 8.3.2.3 and 8.3.2.4 and are successfully challenged.			

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 8-10: TP 3: Incubation Module(s) Electrical Verification

	Parameter	Expected Results	Actual Results	Pass/Fail
1	HT Incubation Module 1 Serial #	As Found	Serial #_____	
	Panel ID	Field Verify		
	Electrical Supply	100- 240 VAC		
	UPS Backup System	Connected		
Acceptance criteria 8.3.2.3 and 8.3.2.4 are successfully challenged.				
Test Program 3 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9. Operational Qualification

9.1. Test Program 4: Temperature Optimization

9.1.1. Objective

The objective of this test script is to optimize the temperature set point for each incubator module prior to commencing with formal temperature mapping. The mean of the average values obtained for the DataTrace probes (2 for Combination Module and 9 for Incubation Module) for each incubation module will be used to adjust each individual incubator's set point to the incubator's average temperature of 32.5°C for HTIM and, for dual-temperature units, 22.5°C for LTIM, when applicable.

9.1.2. Acceptance Criteria

9.1.2.1. The minimum, maximum and average values for each DataTrace probe location must be recorded over a minimum of 4 hour(s) time point.

9.1.3. Equipment

9.1.3.1. Computer Workstation with DataTrace Pro Software

9.1.3.2. Micropack III DataLoggers

9.1.3.3. PC Interface Module

9.1.3.4. Empty BacT/ALERT® media bottles

9.1.3.5. Lab Tape and/or silicone

9.1.4. Supplemental Information/Test Rationale

9.1.4.1. Ensure that all data loggers used within the test procedure have been calibrated over the temperature range of testing.

9.1.4.2. Temperature mapping will be conducted on an empty incubator module as it has been determined to be the worst case scenario for temperature fluctuations.

9.1.5. Test Setup

9.1.5.1. Fill 8 empty BacT/ALERT® 3D bottles with deionized (DI) water per incubator and/or 4 for the Combination Module. Seal each bottle with a rubber stopper then seal and crimp each bottle tightly shut (if required).

9.1.5.2. Poke a small hole in the center of the rubber stopper for the insertion of the DataTrace probe (if required).

9.1.5.3. Program the DataTrace probes for each incubator according to SOP 017, Operation *of the DataTrace System*.

9.1.5.4. Place a DataTrace probe into each of the BacT/ALERT® 3D bottles filled with DI water (8 per incubator and/or 4 for the Combination Module). To ensure the top cylinder portion of the DataTrace probe does not come in contact with the incubation module during rocking (if applicable) tape down the DataTrace probes as tight as possible to the rubber stopper with lab tape. Silicone can also be used to securely join the DataTrace probe and the BacT/ALERT® 3D bottles (recommended). Allow silicone to dry prior to placing in the incubator module.

9.1.5.5. Complete data collection Table 9-1.

9.1.5.6. Record “Pass” if the Actual Results match the Expected Results for the line item.

9.1.5.7. Record “Fail” in the table if the Actual Results do not match the Expected Results for the line item.

9.1.5.8. Record any additional information or clarifications in the Comments section provided.

9.1.5.9. Reference any attachments in the Comments section.

9.1.6. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-1: TP 4: Temperature Optimization

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Ensure that each incubator module is set to 32.5°C for HTIM and 22.5°C for LTIM (when applicable).	Each incubator module is set to 32.5°C for HTIM and 22.5 °C for LTIM (when applicable).	Each incubator module is _____ to 32.5°C for HTIM and 22.5 °C for LTIM (when applicable).	
2	Place the BacT/ALERT® 3D bottles with a DataTrace probe into sample bottle positions #12 and # 49 of each drawer for a total of 8 per incubation module and/or 4 for the Combination Module	BacT/ALERT® 3D water bottles with a DataTrace probe are placed into the sample drawer positions # 12 and # 49.	BacT/ALERT® 3D water bottles with a DataTrace probe are _____ into the sample drawer positions # 12 and # 49.	
3 ☐N/A	Place the remaining DataTrace probes that are not within a bottle into the port directly at the center of each incubator module between the 4 drawers (not applicable for Combination Module). Place a tape over the probes to secure in place.	The remaining DataTrace probes are placed into position (not applicable for Combination Module).	The remaining DataTrace probes are _____ into position (not applicable for Combination Module).	
4	Allow the probes to equilibrate for a **minimum of 4 hours** prior to beginning data collection.	A **minimum of 4 hours** is allowed for equilibration of the BacT/ALERT® bottles and DataTrace probes.	A **minimum of 4 hours** is _____ for equilibration of the BacT/ALERT® bottles and DataTrace probes. Time in: _____ Time of data collection: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-1: TP 4: Temperature Optimization

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Following equilibration, collect raw data values for a **minimum of 4 hours**.	A **minimum of 4 hours** is allowed for the collection of raw data temperature values.	A **minimum of 4 hours** is _____ for the collection of raw data temperature values. Data Collection Start Time: _____ Data Collection End Time: _____	
6	Download the DataTrace probes raw data values and calculate the maximum, minimum and average for each temperature probe location.	The average values for each probe position is calculated and recorded. The maximum and minimum value of each probe is calculated and recorded.	The average values for each probe position is calculated and _____. The maximum and minimum value of each probe is calculated and _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-1: TP 4: Temperature Optimization

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
7	Calculate the mean of the average of the 9 probes for each incubation module and/or 4 for the Combination Module.	The mean of the average of the 9 probes and/or 4 for the Combination Module is obtained.	Incubation Module _____ Mean: _____ °C ☐N/A Incubation Module _____ Mean: _____ °C ☐N/A Incubation Module _____ Mean: _____ °C ☐N/A Incubation Module _____ Mean: _____ °C ☐N/A Incubation Module _____ Mean: _____ °C ☐N/A Incubation Module _____ Mean: _____ °C Reference Attachment _____ for calculations.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-1: TP 4: Temperature Optimization

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
8	From the mean average obtained from each incubation module and/or combination module, offset each incubation module to adjust the temperature set point so that the mean value is as close to the target set point as possible (if needed).	Each incubation module and/or combination module is temperature optimized (if needed).	Each incubation module is temperature _____ (if required). Incubation Module _____ Temperature offset utilized: _____ °C ☐N/A Incubation Module _____ Temperature offset utilized: _____ °C ☐N/A Incubation Module _____ Temperature offset utilized: _____ °C ☐N/A Incubation Module _____ Temperature offset utilized: _____ °C ☐N/A Incubation Module _____ Temperature offset utilized: _____ °C ☐N/A Incubation Module _____ Temperature offset utilized: _____ °C	
All acceptance criteria are successfully challenged.				
Test Program 4 is complete.				
Reference Attachment(s) _____ for Test Program 4 raw data, calculations and results.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.2. Test Program 5: OBSERVA® User Password Configuration verification

9.2.1. Objective

The objective of this test program is to verify the system's password protection capabilities when logging in to the OBSERVA® software (while the 21 CFR Part 11 mode is enabled) by conducting the procedure(s) identified within the test scripts of this test program.

9.2.2. Acceptance Criteria

9.2.2.1. The system software must have adequate security controls to ensure that the analyst has a unique ID-password combination to access the system.

9.2.2.2. The BacT/ALERT® 3D must be able to add, delete and configure user passwords in the OBSERVA® software.

9.2.3. Test Setup

9.2.3.1. Ensure OBSERVA 21 CFR Part 11 is enabled.

9.2.3.2. Two user names and passwords must be pre-configured in the system (one with system administrator privileges), and must be used in this section. Each user will need to log-in and change password prior to the executing this test script. Indicate user names and passwords below:

User #1 Name: _____ User #1 Password: _____

***User #2 Name: _____ User #2 Password: _____**

** User with Administrative privileges.*

9.2.4. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-2: TP 5: OBSERVA® User Password Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Start OBSERVA® from the Microsoft Windows® desktop by double clicking the OBSERVA® icon.	The OBSERVA® splash screen appears while the application starts. When program is ready, the System Status screen displays the following: the Log on Pane (bordered in blue) in the Logged-off state the System Status Pane identifying System and Communication Status (with Silence Alarm Button), and General Information Pane identifying the release number of the installed OBSERVA® software (Version 4.03) and the current system date and time. **Take a screenshot.**	The OBSERVA® splash screen _____ while the application starts. When program is ready, the System Status screen _____ the following: the Log on Pane (bordered in blue) in the Logged-off state the System Status Pane identifying System and Communication Status (with Silence Alarm Button), and General Information Pane identifying the release number of the installed OBSERVA® software (Version 4.03) and the current system date and time. Version # of software ID on General Information Pane: _____ **Attachment #_____** **Page___ of _____**	
2	In the User Name and Password boxes, enter the User Name #1 and Password identified for this section. Press the Log On button.	The System Status screen in Logged-on state appears with User #1 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #1 identified as the Current User in the Log on pane.	
3	Press the Change Password button.	The Change Password screen appears.	The Change Password screen _____.	
4	Type the old password in the Password field. Type the new password in the New Password field. Retype the new password in the Confirm Password field. Press the OK button to save the new password.	The System Status screen in Logged-on state appears with User #1 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #1 identified as the Current User in the Log on pane. User #1 new password: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-2: TP 5: OBSERVA® User Password Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Press the Log Off button.	The System Status screen is displayed (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified).	The System Status screen is _____ (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified).	
6	In the User Name and Password boxes, enter the User Name #1 and old password used in step 2. Press the Log On button.	The OBSERVA® Incorrect User Name or password dialog box appears. **Take a screenshot.**	The OBSERVA® Incorrect User Name or password dialog box _____. **Attachment #_____** **Page___ of _____**	
7	Press the OK button.	The System Status screen is displayed (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified). **Take a screenshot.**	The System Status screen is _____ (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified). **Attachment #_____** **Page___ of _____**	
8	In the User Name and Password boxes, enter the User Name #1 and new password identified in step 4. Press the Log On button.	The System Status screen in Logged-on state appears with User #1 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #1 identified as the Current User in the Log on pane.	
9	Press the Log Off button, and attempt to log on 3 times with a password different from the new password identified in step 4.	An OBSERVA® dialog box appears stating: This User name is currently disabled. Please contact the OBSERVA administrator to access the system. **Take a screenshot**.	An OBSERVA® dialog box appears stating: This User name is currently _____. Please contact the OBSERVA administrator to access the system. Password used: _____ **Attachment #_____** **Page___ of _____**	
10	Press the OK button.	The System Status screen is displayed (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified).	The System Status screen is _____ (as described in step 1) and displays the Log on Pane in the Logged-off state (with no Current User identified).	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-2: TP 5: OBSERVA® User Password Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
11	In the User Name and Password boxes, enter the User Name #2 and Password identified for this section. Press the Log On button.	The System Status screen in Logged-on state appears with User #2 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #2 identified as the Current User in the Log on pane.	
12	From the File menu, click Configurations.	The Configure dialog box appears.	The Configure dialog box _____.	
13	Click the Users tab to display the Users screen.	The Users screen appears.	The Users screen _____.	
14	Select User #1's name in the User Name list. Verify that the user is disabled. **Take a screenshot.** Click on the Close button to exit the screen.	The System Status screen in Logged-on state appears with User #2 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #2 identified as the Current User in the Log on pane. **Attachment #_____** **Page___ of _____**	
15	In the User Name and Password boxes, enter the User Name #1 and new password identified in step 4. Press the Log On button.	An OBSERVA® dialog box appears stating: This User name is currently disabled. Please contact the OBSERVA administrator to access the system.	An OBSERVA® dialog box _____ stating: This User name is currently disabled. Please contact the OBSERVA administrator to access the system.	
16	Press the OK button.	The System Status screen is displayed.	The System Status screen is _____.	
17	Press the Log Off button.	The System Status screen is displayed.	The System Status screen is _____.	
18	Log on as User #2 and access the Configuration dialog box and Users screen as described in steps 11-13. Select User #1's name in the User Name list. Click the disable User check box to clear the checkmark. **Take a screenshot**. Click Save button. Click on the Close button to exit the Configuration screen. Press the Log off button on the Log on pane.	The System Status screen is displayed.	The System Status screen is _____. **Attachment #_____** **Page___ of _____**	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-2: TP 5: OBSERVA® User Password Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
19	In the User Name and Password boxes, enter the User Name #1 and new password identified in step 4. Press the Log On button.	The System Status screen in Logged-on state appears with User #1 identified as the Current User in the Log On Pane.	The System Status screen in Logged-on state _____ with User #1 identified as the Current User in the Log On Pane.	
20	Press the Log Off button.	The System Status screen is displayed.	The System Status screen is _____.	
21	Log on as User #2 and access the Configuration dialog box and Users screen as described in steps 11 thru 13. Select User #1's name in the User Name list. In the New Password field, enter a new password. Retype the new password in the Confirm Password field. Click the Save button. Click on the Close button to exit the Configuration screen. Press the Log off button on the Log on pane.	The System Status screen is displayed.	The System Status screen is _____. New Password set by Administrator: _____	
22	In the User Name and Password boxes, enter the User Name #1 and new password identified in step 21. Press the Log On button.	The Change Password dialog box appears.	The Change Password dialog box _____.	
23	Type in Old Password. Type in New Password. Confirm Password by re-typing New Password. Press OK.	The System Status screen in Logged-on state appears with User #1 identified as the Current User in the Log on pane.	The System Status screen in Logged-on state _____ with User #1 identified as the Current User in the Log on pane. New Password Set: _____	
24	Press the Log Off button.	The System Status screen is displayed (as described in step 1) and displays the Log on Pane in the Logged-off state.	The System Status screen is _____ (as described in step 1) and _____ the Log on Pane in the Logged-off state.	
All acceptance criteria are successfully challenged.				
Test Program 5 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.3. Test Program 6: OBSERVA® Screen Verifications

9.3.1. Objective

The objective of this test program is to verify that the first level screens of the OBSERVA® software and its screens aspects are available and functional.

9.3.2. Acceptance Criteria

9.3.2.1. General OBSERVA® software screens and features must be available and functional.

9.3.2.2. Electronic signatures functionality will be enabled within the OSBERVA® software.

9.3.3. Equipment

9.3.3.1. OBSERVA® workstation

9.3.4. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	If necessary, exit the OBSERVA® Software. Start OBSERVA® from the Microsoft Windows desktop by double clicking the OBSERVA® icon.	The OBSERVA® splash screen appears while the application starts. When program is ready, the tab for the System Status screen is the only tab displayed and the screen consists of the following: 1) The Log on Pane (bordered in blue) in the Logged-off state. 2) The System Status Pane identifying System and Communication Status (with Silence Alarm Button) 3) General Information Pane identifying the release number of the installed OBSERVA® software and the current system date and time. The following Main Tabs and menu items are displayed: **Status** **Help** **Take a screenshot.**	The OBSERVA® splash screen _____ while the application starts. When program is ready, the tab for the System Status screen is the only tab _____ and the screen consists of the following: 1) The Log on Pane (bordered in blue) in the Logged-off state. 2) The System Status Pane identifying System and Communication Status (with Silence Alarm Button) 3) General Information Pane identifying the release number of the installed OBSERVA® software and the current system date and time. The following Main Tabs and menu items _____ displayed: **Status** **Help** **Attachment #_____** **Page___ of _____**	
2	In the User Name and Password boxes, enter the User Name #2 and Password identified in the previous section (9.2). Press the Log On button.	The System Status screen in Logged-on state appears with User #2 identified as the Current User in the Log on pane. Favorite buttons are also present on the right (if previously configured).	The System Status screen in Logged-on state _____ with User #2 identified as the Current User in the Log on pane. Favorite buttons _____ also present on the right.	
3	Click on the Culture Data Entry tab.	The Culture Data Entry screen appears.	The Culture Data Entry screen _____.	
4	Click the ▼ button next to the Source field (in the Specimen pane). Click the ▼ button a second time. **NOTE:** Certain field name(s) may be customized with a different name.	Source options are displayed and then are removed.	Source options are _____ and then are removed.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	In the Specimen pane the Date Entered field is available.	In the Specimen pane the Date Entered field is available.	In the Specimen pane the Date Entered field ___ available.	
6	Click on the Data Management tab.	The Data Management screen appears.	The Data Management screen _____.	
7	Click on the Save As button.	The Save Search As dialog box appears.	The Save Search As dialog box _____.	
8	Click on the Cancel button to exit the box.	The Data Management screen appears.	The Data Management screen _____.	
9	Click on the Show Search button.	Lines of search criteria are displayed.	Lines of search criteria are _____.	
10	Click twice on the ▼ buttons next to each of the ▼search criteria fields.	Drop-down choices/lists are displayed and then removed for each of the ▼ search criteria.	Drop-down choices/lists are _____ and then removed for each of the ▼ search criteria.	
11	Click on the System Log tab.	The System Log screen is displayed.	The System Log screen is _____.	
12	Click on the Show Search button.	Additional lines of search criteria are displayed.	Additional lines of search criteria are _____.	
13	Click twice on the ▼ buttons next to each of the ▼ search criteria fields.	Drop-down choices/lists are displayed and then removed for each of the ▼ search criteria.	Drop-down choices/lists are _____ and then removed for each of the ▼ search criteria.	
14	Click on the Add button.	The Edit Pane appears.	The Edit Pane _____.	
15	Click the ▼ button next to the Severity field (in the Edit pane). Click the ▼ button a second time.	Severity options are displayed and then are removed.	Severity options are _____ and then are removed.	
16	Click the ▼ button next to the Occurred field (in the Edit pane). Click the ▼ button a second time.	Calendar options are displayed and then are removed.	Calendar options are _____ and then are removed.	
17	Click on the Cancel button.	The System Log screen is displayed.	The System Log screen is _____.	
18	Click on the Help option on the Menu bar. Click on the Help button a second time.	Drop-down options of Contents and About are displayed and then removed.	Drop-down options of Contents and About are _____ and then removed.	
19	Click on the Searches option on the Menu bar. Click on the Searches	A drop-down list of search options is displayed and then removed.	A drop-down list of search options is _____ and then removed.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
	button a second time.			
20	Click on the Reports option on the Menu bar. Click on the Reports button a second time.	A drop-down list of report options is displayed and then removed.	A drop-down list of report options is _____ and then removed.	
21	Click on the System option on the Menu bar.	A drop-down list consisting of Archive and Delete, Backup Database and Log Temperatures is displayed.	A drop-down list consisting of Archive and Delete, Backup Database and Log Temperatures is _____.	
22	Click on Log Temperatures.	The Log Temperatures dialog box is displayed.	The Log Temperatures dialog box is _____.	
23	Enter a temperature in field next to Incubator 1. Click on the Save button.	The Log Temperatures dialog box is removed.	Date: _____ Time:_____ Temperature Entered*: _____ ***To be referenced in section 9.16.** The Log Temperatures dialog box is _____.	
24	Click on the File option on the Menu bar.	A drop-down list consisting of Configurations and Exit is displayed.	A drop-down list consisting of Configurations and Exit is _____.	
25	Click on the Exit option.	The Confirm Exit dialog box appears.	The Confirm Exit dialog box _____.	
26	Click on the No button.	The dialog box disappears.	The dialog box _____.	
27	Click on the File option on the Menu bar and click on the Configurations option.	The Configure dialog box appears with the Reports screen displayed.	The Configure dialog box appears with the Reports screen _____.	
28	Click twice on the ▼ buttons next to each of the 6 fields with drop-down lists.	Drop-down choices/lists are displayed and then removed for each of the 6 fields.	Drop-down choices/lists are _____ and then removed for each of the 6 fields.	
29	Click the New button.	The Create a New Report dialog box appears.	The Create a New Report dialog box _____.	
30	Press the Cancel button.	The dialog box disappears.	The dialog box _____.	
31	Press the Save As button.	The Create a New Report dialog box appears.	The Create a New Report dialog box _____.	
32	Press the Cancel button.	The dialog box disappears.	The dialog box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
33	Click the Remove button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
34	Press the No button.	The dialog box disappears.	The dialog box _____.	
35	Press the Edit Global Heading Button.	The Edit Global Heading dialog box appears.	The Edit Global Heading dialog box_____.	
36	Press the Cancel button.	The dialog box disappears.	The dialog box _____.	
37	Press the Add button.	The Edit pane is activated (has blue border) and Cancel button is available. Save button is also available (if entry were to be made in fields in the pane).	The Edit pane ____ activated (has blue border) and Cancel button ___ available. Save button ___ also available (if entry were to be made in fields in the pane).	
38	Press the Cancel button.	Blue border on Edit pane is removed, and Cancel and Save buttons are no longer available.	Blue border on Edit pane ___ removed, and Cancel and Save buttons ____ no longer available.	
39	Click the Delete button.	An OBSERVA® dialog box appears stating: "Are you sure you want to delete the selected column from the report"?	An OBSERVA® dialog box _____ stating: "Are you sure you want to delete the selected column from the report"?	
40	Click the No button.	The dialog box disappears.	The dialog box _____.	
41	Click the Move Down button.	Moves the highlighted area down one line.	_____ the highlighted area down one line.	
42	Click the Move Up button.	Moves the highlighted area up one line.	_____ the highlighted area up one line.	
43	Click the Shortcuts tab.	The Shortcuts screen is displayed. **Note:** if a shortcut is not highlighted, the lower, Edit pane will not be present.	The Shortcuts screen is _____.	
44	With one of the Shortcut names highlighted, Click twice on the ▼ buttons next to each of the 2 fields with drop-down lists.	Drop-down choices/lists are displayed and then removed for each of the 2 fields.	Drop-down choices/lists are _____ and then removed for each of the 2 fields.	
45	Press the Add button and choose an entry (from the drop down list) for the first field in the Edit pane.	The Edit pane is activated (has blue border) and Cancel button is available. Save button is also available.	The Edit pane ___ activated (has blue border) and Cancel button ___ available. Save button ____ also available.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
46	Press the Cancel button.	Edit pane disappears.	Edit pane _____.	
47	With one of the Shortcut names highlighted, press the Delete button.	An OBSERVA® dialog box appears stating: "Are you sure you want to delete the selected shortcut?"	An OBSERVA® dialog box _____ stating: "Are you sure you want to delete the selected shortcut?"	
48	Click No.	The dialog box disappears.	The dialog box _____.	
49	Click the Move Down button.	Moves the highlighted area down one line.	_____ the highlighted area down one line.	
50	Click the Move Up button.	Moves the highlighted area up one line.	_____ the highlighted area up one line.	
51	Click the Users tab.	The Users screen appears (without Edit pane).	The Users screen _____ (without Edit pane).	
52	Click the Add button.	The Edit pane appears.	The Edit pane _____.	
53	Click twice on the ▼ button next to the access level field.	Drop-down choices/lists are displayed and then removed for access levels.	Drop-down choices/lists are _____ and then removed for access levels.	
54	Click the Cancel button.	The Edit pane disappears.	The Edit pane _____.	
55	Click the Data Fields tab.	The Data Fields screen appears.	The Data Fields screen _____.	
56	Click on the Add button.	The Edit pane appears, with a blue border.	The Edit pane _____, with a blue border.	
57	Click twice on the ▼ buttons next to each of the 2 fields with drop down lists.	Drop-down choices/lists are displayed and then removed for each of the 2 fields.	Drop-down choices/lists are _____ and then removed for each of the 2 fields.	
58	Click on the Cancel button.	The Edit pane disappears.	The Edit pane _____.	
59	Click on the Screen Views tab.	The Screen Views screen appears.	The Screen Views screen _____.	
60	Click twice on the ▼ buttons next to each of the 2 fields with drop-down lists.	Drop-down choices/lists are displayed and then removed for each of the 2 fields.	Drop-down choices/lists are _____ and then removed for each of the 2 fields.	
61	Click on the Add button.	Select Data Field dialog box appears.	Select Data Field dialog box _____.	
62	Click on the Cancel button.	The dialog box disappears.	The dialog box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
63	Click on the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
64	Click on the No button.	The dialog box disappears.	The dialog box _____.	
65	Click the Move Down button.	Moves the highlighted area down one line.	_____ the highlighted area down one line.	
66	Click the Move Up button.	Moves the highlighted area up one line.	_____ the highlighted area up one line.	
67	Click on the Date/Time Format tab.	The Date/Time Format screen appears.	The Date/Time Format screen_____.	
68	Click twice on the ▼ buttons next to each of the 3 fields with drop-down lists.	Drop-down choices/lists are displayed and then removed for each of the 3 fields.	Drop-down choices/lists are _____ and then removed for each of the 3 fields.	
69	Click on the Groups tab.	The Groups screen appears.	The Groups screen _____.	
70	Click twice on the ▼ buttons next to each of the 2 fields with drop-down lists.	Drop-down choices/lists are displayed and then removed for each of the 2 fields.	Drop-down choices/lists are _____ and then removed for each of the 2 fields.	
71	Highlight a line in the Group hierarchy pane and click on the Add button.	The Add Group dialog box appears.	The Add Group dialog box _____.	
72	Press the Cancel button.	The Add Group dialog box disappears.	The Add Group dialog box _____.	
73	Click on the Electronic Signatures tab	The Electronic Signature screen appears.	The Electronic Signature screen _____.	
74	Click on the "Activated" checkbox to ensure there is a check mark.	The Electronic Signature and Configurations option becomes accessible.	The Electronic Signature and Configurations option _____ accessible.	
75	Click twice on the ▼ button next to the Electronic Signature Configuration field.	The drop-down choices/lists are displayed and then removed for Electronic Signature Configurations.	The drop-down choices/lists are _____ and then removed for Electronic Signature Configurations.	
76	Click on the field next to "Activated" twice: once to deactivate, and then to reactivate by adding the check mark.	The Electronic Signature Configurations option becomes inaccessible, then accessible.	The Electronic Signature Configurations option _____inaccessible, then accessible.	
77	Press the Save and Close buttons.	The Configure screen is exited.	The Configure screen ____ exited.	
All acceptance criteria are successfully challenged.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-3: TP 6: OBSERVA® Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Test Program 6 is complete.				

9.4. Test Program 7: Configuration Verification for Reports, Searches, Shortcuts, Data Fields, Groups, and Global Heading

9.4.1. Objective

The objective of this test program is to verify that the indicated OBSERVA® software system aspects can be configured by conducting the procedure(s) identified within the test scripts of this test program.

9.4.2. Acceptance Criteria

9.4.2.1. The OBSERVA® software features must be configurable.

9.4.2.2. The OBSERVA® software must be able to create reports.

9.4.2.3. The OBSERVA® software can print company name and equipment ID on results printouts.

9.4.3. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Configuring Reports (List Formal) Templates				
1	Go to the Status Tab and, if necessary, log on using User Name #2 and Password identified in section (9.2). Access the File Menu and Configure option. Click the Reports tab.	The user is logged on to the system. The Reports screen is accessed.	The user ____logged on to the system. The Reports screen ____ accessed.	
2	From the Type drop- down list, select the System Log report option. Select List Report from the Style drop-down list. Click the New button.	The Create a New Report dialog box appears.	The Create a New Report dialog box _____.	
3	Type a report name and click the OK button.	The dialog box disappears, and the new report name appears in the Name field.	The dialog box _____, and the new report name appears in the Name field. New Report Name: _____	
4	Click on the Add button.	The Edit pane appears.	The Edit pane _____.	
5	In the Column Heading field, enter a column heading name. From the Data Field drop-down list select a field to report. Enter a number of characters in the Column Width field. Select Ascending or Descending from the Sort drop-down list. Select a break command (Line or Page) from the Break drop-down list. Click Save.	The row information is saved as entered in the Report Table/Parameter pane.	The row information____ saved as entered in the Report Table/Parameter pane. Column Heading: _____ Data Field: _____ # of Characters: _____ Sort Selection: _____ Break command: _____	
6	Click and highlight the row information just entered. Verify row information matches that entered in Step 5. Click on the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
7	Click Yes	The row information is removed from the Report Table/Parameter pane.	The row information ____ removed from the Report Table/Parameter pane.	
8	Click on the Remove button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
9	Click on the Yes button.	The dialog box disappears and the report name is removed from the Name field options.	The dialog box _____ and the report name is removed from the Name field options.	
10	From the Reports screen, select Data Management from the Type drop-down list. Select a style (other than List Report) from the Style drop-down list. Click on the Save As button.	The Create a New Report dialog box appears.	The Create a New Report dialog box _____.	
11	Enter a name for a new instance of the report. Click on the OK button.	The new name is entered in the Name field.	The new name _____ entered in the Name field. New report name: _____	
12	Click on the Remove button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
13	Click on the Yes button.	The dialog box disappears and the report name is removed from the Name field options.	The dialog box _____ and the report name is removed from the Name field options.	
Configuring Shortcuts				
14	Click the Shortcut tab.	The Shortcut screen appears.	The Shortcut screen _____.	
15	Select Reports Menu from the Location box. Press the Add button.	The Edit pane becomes enabled.	The Edit pane becomes _____.	
16	Select a search from the Search field drop-down list. (Do not use a search having a "by" criteria, which would disallow scheduling.) Enter a name for the search in the Name field. Click the field next to "Schedule this Task?" to enable this function. Enter a Start Time and an Interval value. Press the Save button.	The search saved in the Edit pane is now added to the bottom of the Shortcut Table pane.	The search saved in the Edit pane _____ now added to the bottom of the Shortcut Table pane. Search name: _____	
17	Highlight the shortcut just added to the Shortcut Table. Click the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
18	Click the Yes button.	The dialog box disappears and the shortcut added to the table is removed.	The dialog box _____ and the shortcut added to the table is removed.	
19	Select Favorites Buttons from the Location box. Press the Add button.	The Edit pane becomes enabled.	The Edit pane becomes _____.	
20	Select a menu from the Menu drop-down list. Select a menu item from the Item drop-down list. Enter a name in the Name field for the button label. Click on the Save button.	The name saved in the Edit pane is now added to the Shortcut Table pane.	The name saved in the Edit pane _____ now added to the Shortcut Table pane. Name for button label: _____	
21	Click the Close button to exit from the Configure dialog box, and return to the Status screen.	Shortcut button added in step 19 is now added to the other Favorites Buttons on the Status screen. **Take a screenshot.**	Shortcut button added in step 19 ____ now added to the other Favorites Buttons on the Status screen. **Attachment #_____** **Page___ of _____**	
22	Return to the Shortcut screen in the Configure dialog box. Highlight the Shortcut just added and Click on the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
23	Click on the Yes button.	The shortcut name that was previously saved is removed from the Shortcut Table pane.	The shortcut name that was previously saved ____ removed from the Shortcut Table pane.	
24	Click the Close button to exit from the Configure dialog box, and return to the Status screen.	The Shortcut button previously saved on the Status screen is no longer present.	The Shortcut button previously saved on the Status screen ____ no longer present.	
Configuring Data Fields				
25	From the Configure dialog box, click on the Data Fields tab.	Data Fields screen is displayed.	The Data Fields screen _____ displayed.	
26	Select a data category from the Category drop- down list. Click on the Add button.	The Edit pane becomes enabled.	Data Category: _____ The Edit pane becomes _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
27	Enter a new field name in the Name field. Select a data type from the Data Type drop down list. Click the field (to place a check mark) next to both Options list and List Overridable. Enter a Full Name and Abbreviation in the respective fields. Click the field (to place a check mark) next to Validation Pattern. Enter a Validation Pattern in the corresponding field. Select a default option from the Default drop- down list. Press the Save button	The name, data type and default value saved in the Edit pane are now added to the Configuration Table pane.	Name: _____ Data Type: _____ Default Value: _____ Values _____ to the Configuration Table.	
28	Highlight the data field just added and Click on the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
29	Click on the Yes button.	The data field name that was previously saved is removed from the Configuration Table pane.	The data field name that was previously saved ____ removed from the Configuration Table pane.	
Configuring Screens Views				
30	Click on the Screen Views tab. Select the Accession category from the Category drop-down list. Select Culture Data Entry from the View drop-down list. Click the Add button.	The Select Data Field dialog box appears.	The Select Data Field dialog box _____.	
31	Select/highlight an available data field from the dialog box. Click the OK button.	The data field saved in the Edit pane is now added to the Screen View Configuration pane.	Data Field added: _____ Data field _____ to the Screen View Configuration pane.	
32	With the same data category and view option selected (as in step 31), highlight the same data field identified in step 31. Click on the Delete button.	The Confirm Deletion dialog box appears.	The Confirm Deletion dialog box _____.	
33	Click the Yes button.	The dialog box disappears and the data field is removed from the Screen View Configuration Pane.	The dialog box _____ and the data field is removed from the Screen View Configuration Pane.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Configuring the Date/Time Format				
34	Click the Close button to exit the Configure dialog box and access the Status screen. Document the date and time (in the formats they are indicated) from the General Information pane.	Date and Time is displayed on General Pane.	Date:_____ Time:_____ Date and Time ____ displayed on General Pane.	
35	Access the Configure dialog box. Click on the Date/Time Format tab.	The Date/Time Format Screen appears.	The Date/Time Format Screen _____.	
36	Click the ▼of Date Order to select a different format (than what it is currently) for the date. Check the Four Digit Year check box if the year is currently set at two-digit year. Select a date separator from the Separators drop-down list that is different from how the date is currently displayed. Select a time separator from the Time Separators drop-down list that is different from how the time is currently displayed. Check the Twelve Hour Clock check box if the clock is currently set to display a 24-hour clock. Click the Save button.	The Save and Cancel buttons turn gray.	Date Order: _____ # of Year Digits: _____ Date Separator: _____ Time Separator: _____ 12 or 24-hour clock: _____ The Save and Cancel buttons turn _____.	
37	Click the Close button to exit the Configure dialog box and access the Status screen. (User may have to log off and then log back in for changes to display).	The General Information pane indicates the date and time in the newly configured format indicated in step 36. **Take a screenshot.**	**Attachment #_____** **Page___ of _____** Date and Time ____ indicated per step 36 on General Information pane.	
Configuring Groups				
38	From the Configure dialog box, click on the Groups tab.	The Groups screen is displayed.	The Groups screen is _____.	
39	Select a category from the Category drop-down list. Select a data field from the Data Field drop-down list. In the Group Hierarchy pane, click where you would like to make an addition. Click the Add button.	The Add Group dialog box appears.	The Add Group dialog box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
40	Enter a name for the new group and click the OK button.	The new group appears on the hierarchy tree, a list of available options for the new group is displayed in the Available Options pane and the new group name is displayed at the top of the empty pane.	The new group _____ on the hierarchy tree, a list of available options for the new group is displayed in the Available Options pane and the new group name is displayed at the top of the empty pane. Group name: _____	
41	Select/highlight one of the Available Options and click the right-arrow button to move the Option to the empty pane on the right.	The highlighted option is moved to the pane on the right.	Option chosen: _____ The highlighted option __ moved to the pane on the right.	
42	Click the Save button.	The arrows turn gray.	The arrows turn _____.	
43	With the Group name highlighted, press the Rename button.	The Rename Group dialog box appears.	The Rename Group dialog box _____.	
44	Enter a new group name for the group. Click the OK button.	The group name is changed in the Group Hierarchy and at the top of the pane on the right.	The group name _____ changed in the Group Hierarchy and at the top of the pane on the right. New group name: _____	
45	With the group name highlighted, press the Delete button.	The Delete Group dialog box appears.	The Delete Group dialog box _____.	
Configuring Global Report Heading				
46	Click on the Yes button.	The dialog box disappears, the group name is deleted from the Group Hierarchy pane and both the middle and right panes return to their previous state.	The dialog box _____, the group name is deleted from the Group Hierarchy pane and both the middle and right panes return to their previous state.	
47	From the Configure dialog screen, click on the Reports tab. Click on the Edit Global Heading button.	The Edit Global Heading Dialog Box appears.	The Edit Global Heading Dialog Box _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-4: TP 7: OBSERVA® Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
48	Revise/add text by clicking and typing in the white area of the box. Click the Save button.	The dialog box disappears.	The dialog box _____. Revised Heading: _____	
49	Click on the Edit Global Heading button.	The revised/new heading is displayed. **Take a screenshot.**	The revised/new heading is _____. **Attachment #_____** **Page___ of _____**	
50	If the revised heading is not appropriate, revise and save the heading as identified in step 48.	Heading is revised to include preferred information.	Heading _____ revised to include preferred information.	
All acceptance criteria are successfully challenged.				
Test Program 7 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.5. Test Program 8: OBSERVA® User Access Level Verification

9.5.1. Objective

The objective of this test program is to verify that the configured OBSERVA® user access levels by conducting the verifications identified in the corresponding test script.

9.5.2. Acceptance Criteria

9.5.2.1. The OBSERVA® software must allow editing of individual user access to various menus, dialog boxes and settings by an Administrator.

9.5.2.2. For 21 CFR 11 Compliance, the following commands should be available for users with specific privileges for the OBSERVA® software:

A. File/Delete Measurement from database
B. Edit/Cut/Delete
C. View System Log

9.5.2.3. Authority checks are required to ensure that only authorized individual may use the system and perform operation.

9.5.2.4. The OBSERVA® system administrator should have access to all configuration tasks.

9.5.3. Test Setup

9.5.3.1. Prior to conducting the verification procedures, a user with administrator privileges must configure 6 users, each with one of the following access levels: Default, View Only, Data Entry, Editing No Delete, Editing and Administrator. Document the user name and password for each of the users below:

9.5.3.2. Each user should log-in and update passwords prior to executing this test script.

Table 9-5: OSBERVA User Access Levels

Access Level	User Name	Password
Default		
View		
Data Entry		
Editing No Delete		
Editing		
Administrator		

9.5.4. Test Procedure/Results/Data

9.5.4.1. Log into the OBSERVA® software with the user name and password identified in Table 9-5 above for each user. Attempt to access each of the 16 privileges identified in the tables below and verify that the actual results match the stated expected results.

9.5.4.2. Complete the table(s) below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-6:TP 8: Verification of Access Levels for User with Default Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access NOT granted	Access NOT _____.	
6	Perform manual backups	Access NOT granted	Access NOT _____.	
7	Access Reports shortcut items	Access NOT granted	Access NOT _____.	
8	Access the Searches shortcut items	Access NOT granted	Access NOT _____.	
9	View test data on the Data Management screen	Access NOT granted	Access NOT _____.	
10	View system data on the System Log screen	Access NOT granted	Access NOT _____.	
11	Exit OBSERVA	Access NOT granted	Access NOT _____.	
12	Enter new test data on Data Entry screen	Access NOT granted	Access NOT _____.	
13	Edit test data on the Data Management screen	Access NOT granted	Access NOT _____.	
14	Add system log entries to the System Log	Access NOT granted	Access NOT _____.	
15	Delete manual System Log events	Access NOT granted	Access NOT _____.	
16	Access to all configuration tasks	Access NOT granted	Access NOT _____.	
All acceptance criteria are successfully challenged for Default privileges.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-7:TP 8: Verification of Access Levels for User with View Only Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access granted	Access _____.	
6	Perform manual backups	Access granted	Access _____.	
7	Access Reports shortcut items	Access granted	Access _____.	
8	Access the Searches shortcut items	Access granted	Access _____.	
9	View test data on the Data Management screen	Access granted	Access _____.	
10	View system data on the System Log screen	Access granted	Access _____.	
11	Exit OBSERVA	Access granted	Access _____.	
12	Enter new test data on Data Entry screen	Access NOT granted	Access NOT _____.	
13	Edit test data on the Data Management screen	Access NOT granted	Access NOT _____.	
14	Add system log entries to the System Log	Access NOT granted	Access NOT _____.	
15	Delete manual System Log events	Access NOT granted	Access NOT _____.	
16	Access to all configuration tasks	Access NOT granted	Access NOT _____.	
All acceptance criteria are successfully challenged for View Only privileges.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-8:TP 8: Verification of Access Levels for User with Data Entry Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access granted	Access _____.	
6	Perform manual backups	Access granted	Access _____.	
7	Access Reports shortcut items	Access NOT granted	Access NOT _____.	
8	Access the Searches shortcut items	Access NOT granted	Access NOT _____.	
9	View test data on the Data Management screen	Access NOT granted	Access NOT _____.	
10	View system data on the System Log screen	Access NOT granted	Access NOT _____.	
11	Exit OBSERVA	Access granted	Access _____.	
12	Enter new test data on Data Entry screen	Access granted	Access _____.	
13	Edit test data on the Data Management screen	Access NOT granted	Access NOT _____.	
14	Add system log entries to the System Log	Access NOT granted	Access NOT _____.	
15	Delete manual System Log events	Access NOT granted	Access NOT _____.	
16	Access to all configuration tasks	Access NOT granted	Access NOT _____.	
All acceptance criteria are successfully challenged for Data Entry privileges.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-9:TP 8: Verification of Access Levels for User with Editing No Delete Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access granted	Access _____.	
6	Perform manual backups	Access granted	Access _____.	
7	Access Reports shortcut items	Access granted	Access _____.	
8	Access the Searches shortcut items	Access granted	Access _____.	
9	View test data on the Data Management screen	Access granted	Access _____.	
10	View system data on the System Log screen	Access granted	Access _____.	
11	Exit OBSERVA	Access granted	Access _____.	
12	Enter new test data on Data Entry screen	Access granted	Access _____.	
13	Edit test data on the Data Management screen	Access granted	Access _____.	
14	Add system log entries to the System Log	Access granted	Access _____.	
15	Delete manual System Log events	Access NOT granted	Access NOT _____.	
16	Access to all configuration tasks	Access NOT granted	Access NOT _____.	
All acceptance criteria are successfully challenged for Editing No Delete privileges.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-10:TP 8: Verification of Access Levels for User with Editing Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access granted	Access _____.	
6	Perform manual backups	Access granted	Access _____.	
7	Access Reports shortcut items	Access granted	Access _____.	
8	Access the Searches shortcut items	Access granted	Access _____.	
9	View test data on the Data Management screen	Access granted	Access _____.	
10	View system data on the System Log screen	Access granted	Access _____.	
11	Exit OBSERVA	Access granted	Access _____.	
12	Enter new test data on Data Entry screen	Access granted	Access _____.	
13	Edit test data on the Data Management screen	Access granted	Access _____.	
14	Add system log entries to the System Log	Access granted	Access _____.	
15	Delete manual System Log events	Access granted	Access _____.	
16	Access to all configuration tasks	Access NOT granted	Access NOT _____.	
All acceptance criteria are successfully challenged for Editing privileges.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-11:TP 8: Verification of Access Levels for User with Administrator Privileges

Privilege Number	Privilege Description	Expected Results	Actual Result	Pass/Fail
1	View Status screen	Access granted	Access _____.	
2	Silence Alarms	Access granted	Access _____.	
3	Access Help menu (on- line manual)	Access granted	Access _____.	
4	Log on/Log off/Change Password	Access granted	Access _____.	
5	Log Temperatures	Access granted	Access _____.	
6	Perform manual backups	Access granted	Access _____.	
7	Access Reports shortcut items	Access granted	Access _____.	
8	Access the Searches shortcut items	Access granted	Access _____.	
9	View test data on the Data Management screen	Access granted	Access _____.	
10	View system data on the System Log screen	Access granted	Access _____.	
11	Exit OBSERVA	Access granted	Access _____.	
12	Enter new test data on Data Entry screen	Access granted	Access _____.	
13	Edit test data on the Data Management screen	Access granted	Access _____.	
14	Add system log entries to the System Log	Access granted	Access _____.	
15	Delete manual System Log events	Access granted	Access _____.	
16	Access to all configuration tasks	Access granted	Access _____.	
All acceptance criteria are successfully challenged for Administrator privileges.				
Test Program 8 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.6. Test Program 9: Scanner Verification (OBSERVA® Workstation)

9.6.1. Objective

The objective of this test program is to verify the operational functionality of the barcode scanner at the OBERVA workstation to accurately scan bottles ID barcodes by conducting the identified procedure(s) in this test program.

9.6.2. Acceptance Criteria

9.6.2.1. OBSERVA® workstation barcode scanner must be capable of accurately scanning BacT/ALERT® bottle barcodes.

9.6.3. Equipment

9.6.3.1. OBSERVA® workstation

9.6.3.2. Barcode scanner

9.6.3.3. BacT/ALERT® bottles (8)

9.6.4. Test Setup

9.6.4.1. Choose BacT/ALERT® 3D bottles based on incubation module(s) for this test script.

9.6.5. Test Procedure/Results/Data

9.6.5.1. Provide (4) each of (2) different types of bottles if available, for a total of 8 bottles.

9.6.5.2. Using a thick permanent black marker, markup/alter one entire Bottle ID barcode on (1) of each type of bottle. The total will be (6) bottles with unaltered barcodes and (2) bottles with altered barcodes.

9.6.5.3. Number the bottles (1-8 on the bottle necks) with the marker.

9.6.5.4. Document the bottle types and bottle ID numbers by placing bottle barcode tabs on the table below.

Note: For bottles with altered barcodes, document by writing "**unable to scan**" for Bottle ID #s and "**N/A**" for the bottle types.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.6.5.5. From the OBSERVA® status screen, log on with a user name with Administrative privileges. Then click on the Culture Data Entry tab.

9.6.5.6. Type in a different Accession number and choose a Source from the drop-down menu for each of the 8 bottles. Click in the Bottle ID field.

9.6.5.7. Scan the barcode ID for each bottle while making sure that the scanning beam runs across the barcode lines.

9.6.5.8. Document the scanned bottle information in the table below as it appears in the Bottle ID and Bottle Type field on the Culture Data Entry screen.

Table 9-12:TP 9: Scanner Verification at the OBSERVA® Workstation

Bottle #	Barcode Label	Scanned Bottle Type	Scanned Bottle ID#	Does the Scanned information match the Actual information? Y/N	Pass/Fail
1					
2					
3					
4					
5					
6					
7					
8					
All acceptance criteria are successfully challenged.					
Test Program 9 is complete.					

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.7. Test Program 10: BacT/ALERT® 3D User Name and Password Verification (21 CFR Part 11 Mode enabled)

9.7.1. Objective

The objective of this test program is to verify the process for logging in and out of the BacT/ALERT® 3D control module with user names and passwords (while the 21 CFR Part 11 mode is enabled) by conducting the procedures(s) identified in this test program.

9.7.2. Acceptance Criteria

9.7.2.1. The system software must have adequate security controls to ensure that the analyst has a unique ID-password combination to access the system.

9.7.2.2. For 21 CFR Part 11 Compliance, the Signature software must require user login with password.

9.7.2.3. Authority checks are required to ensure that only authorized individuals may use the system and perform operations.

9.7.3. Equipment

9.7.3.1. BacT/ALERT® 3D System

9.7.4. Test Setup

9.7.4.1. Create a user name and password for the BacT/ALERT® 3D system prior to executing this test script. The user name and password of "**setup**" may be used ONCE to access the system so that you may enter a valid user name and password. Indicate the BacT/ALERT® 3D user name and password below:

User Name: _____ Password: _____

9.7.5. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-13:TP 10: BacT/ALERT® 3D User Name and Password Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	From the Main screen while logged out, press the Login button.	The User Login screen appears (screen 1.3)	The User Login screen _____	
2	Touch the login icon and touch the User Name field and enter your user name and password.	The User Name field turns white and your user name and password are entered into the field.	The User Name field turns _____ and your user name and password are entered into the field. User Name entered: _____	
3	From the User Login screen, press the Change Password button.	The New Password and Confirm Password fields appear on the User Login Screen.	The New Password and Confirm Password fields _____ on the User Login Screen.	
4	Enter a new password (6-24 characters) in the New Password field. Re-enter your new password in the Confirm Password field. Press the Check button to change your password.	A new password is entered. The Main screen appears.	A new password ____ entered. The Main screen appears. New password entered: _____	
5	From the Main screen, press the Login button.	The Main screen (while logged out) appears (screen 1.3).	The Main screen (while logged out) _____.	
6	Press buttons on the screen (other than the Login button) to attempt to operate the system without being logged in.	System does not respond.	System does ____respond.	
7	Press the Login button and attempt to log in to the system by entering a name different from the one entered in step 2, and the same password as entered in step 4.	A Wrong User Alert (i.e.: "!" and a stick figure) appears to the right of the User Name field. **Take a screenshot.**	A Wrong User Alert (i.e.: "!" and a stick figure) _____ to the right of the User Name field. **Attachment #_____.** **Page___ of _____**	
8	Press the Cancel button.	The alert is removed and all fields are cleared.	The alert ___ removed and all fields are cleared.	
9	Attempt to log in to the system by entering the same name as the one entered in step 2 and a different password than the one entered in step 4.	A Wrong Password Alert (screen 1.3) appears to the right of the Password field.	A Wrong Password Alert _____ to the right of the Password field.	
10	Press the Cancel (X) button.	The alert is removed and all fields are cleared.	The alert _____ removed and all fields are cleared.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-13:TP 10: BacT/ALERT® 3D User Name and Password Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
11	Attempt to log in to the system by entering the same name as the one entered in step 2 and the same password as the one entered in step 4.	The Main screen (while logged in) appears.	The Main screen (while logged in) _____.	
12	From the Main screen, press the Login button to log out of the instrument.	The Main screen (while logged out) appears (screen 1.3).	The Main screen (while logged out) _____.	
13	From the Main screen press the Login button.	The User Login screen appears (screen 1.3).	The User Login screen _____.	
14	Enter the same name as the one entered in step 2 and the same password as the one entered in step 4. Press the Change Password button.	The New Password and Confirm Password fields appear on the User Login Screen (screen 1.3).	The New Password and Confirm Password fields _____ on the User Login Screen.	
15	Enter a new password in the New Password field, and enter a different password in the Confirm Password field. Press the Check button	A change password error appears on the User Login screen (screen 1.3).	A change password error _____ on the User Login screen. New password entered in the New Password field: _____	
16	Enter the new password indicated in step 15 in the New Password field, and re-enter the same password in the Confirm Password field. Press the Check button.	The Main screen (while logged in) appears (screen 1.0).	The Main screen (while logged in) _____.	
17	From the Main screen, press the Login button to log out of the instrument.	The Main screen (while logged out) appears (screen 1.3).	The Main screen (while logged out) _____.	
18	Attempt to log in to the system by entering the same name as the one entered in step 2 and the new password entered in step 15.	The Main screen (while logged in) appears (screen 1.0).	The Main screen (while logged in) _____.	
19	Leave the Main screen open (while logged in). For approximately 30 minutes, do not 1) press a screen or keyboard button, 2) scan a barcode or 3) load or unload a bottle.	An inactivity timeout occurs and the instrument display reverts back to the Main screen (while logged out).	An inactivity timeout _____ and the instrument display reverts back to the Main screen (while logged out).	
All acceptance criteria are successfully challenged.				
Test Program 10 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.8. Test Program 11: BacT/ALERT® 3D System Password Verification

9.8.1. Objective

The objective of this test program is to verify the process for entering and changing the system password on the BacT/ALERT® 3D by conducting the procedure(s) identified in this test program.

9.8.2. Acceptance Criteria

9.8.2.1. Authority checks are required to ensure that only authorized individuals may use the system and perform operations.

9.8.3. Equipment

9.8.3.1. BacT/ALERT® 3D System

9.8.4. Test Setup

9.8.4.1. Ensure that the BacT/ALERT® 3D system password is available prior to executing this test script. The default password set by the vendor is **1234**.

9.8.5. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-14:TP 11: BacT/ALERT® 3D System Password Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	From the Main screen (while logged in) (screen 1.0), press the Next Screen button.	The Setup screen appears (screen 2.0) and all the function buttons are disabled (gray).	The Setup screen _____ (screen 2.0) and all the function buttons are disabled (gray).	
2	Enter a current valid password on the Password Entry Keypad and press the Key Symbol to accept the password.	The Padlock icon changes to the full open position and the function buttons become enabled blue.	The Padlock icon _____ to the full open position and the function buttons become enabled blue. Password entered: _____	
3	Leave the Setup screen open (while logged in). For approximately 30 minutes, do not 1) press a screen or keyboard button, 2) scan a barcode or 3) load or unload a bottle.	An inactivity timeout occurs and the instrument display reverts back to the Main screen.	An inactivity timeout _____ and the instrument display reverts back to the Main screen.	
4	From the Main screen while logged in (screen 1.0), press the Next Screen button. Using the Password Entry Keypad buttons, enter the password from step 2 and press the Key Symbol button.	The Padlock icon changes to the full open position and the function buttons become enabled blue.	The Padlock icon changes to the full open position and the function buttons _____ enabled blue.	
5	Press the Change Password function button.	The Change Password screen appears.	The Change Password screen _____.	
6	Using the Password Entry Keypad buttons, enter the password from step 2 and press the Key Symbol button.	The Padlock icon changes to a full open position.	The Padlock icon changes to a full _____ position.	
7	Enter a new password using the Password Entry Keypad buttons and press the Key Symbol button.	The Padlock icon changes to a half open position.	The Padlock icon changes to a half _____ position. New Password entered: _____	
8	Re-enter the new password and press the Key Symbol button.	The Padlock icon closes.	The Padlock icon _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-14:TP 11: BacT/ALERT® 3D System Password Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
9	Press the Check button to accept the new password and press the Previous Screen button to return to the Setup screen.	Setup screen (screen 2.0) is displayed with all function buttons enabled blue.	Setup screen _____ displayed with all function buttons enabled blue.	
10	While on the Setup screen press the Previous Screen button.	The Main screen (screen 1.0) is displayed while logged in.	The Main _____ is displayed while logged in.	
11	From the Main screen (screen 1.0), press the Next Screen button. Using the Password Entry Keypad buttons, enter the new password from step 7 and press the Key Symbol button.	The Padlock icon changes to the full open position and the function buttons become enabled blue.	The Padlock icon changes to the full _____ position and the function buttons become enabled blue.	
All acceptance criteria are successfully challenged.				
Test Program 11 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.9. Test Program 12: BacT/ALERT® 3D Control Panel/Screen Verification

9.9.1. Objective

The objective of this test program is to verify the control panel features and screens verifications on the BacT/ALERT® 3D by conducting the procedure(s) identified in this test program.

9.9.2. Acceptance Criteria

9.9.2.1. General BacT/ALERT® 3D control panel features and screens must be available and functional.

9.9.3. Equipment

9.9.3.1. BacT/ALERT® 3D System

9.9.3.2. BacT/ALERT® 3D bottles (3)

9.9.4. Test Setup

9.9.4.1. Load 3 sample bottles (based on incubation module) and set the incubation time period such that they will be ready to unload at the time of the verification testing in this section. Refer to manual as needed for loading bottles into BacT/ALERT® 3D system.

9.9.5. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Using a valid user name and password, as indicated in section 9.7, log on to the system.	The Main screen (screen 1.0) is displayed.	The Main screen is _____.	
2	Press any Unload button on the screen.	Unload mode of Main screen is displayed.	Unload mode of Main screen is _____.	
3	Press the Check button.	Main screen (screen 1.0) while logged in, appears.	Main screen while logged in _____.	
4	From the Main screen, press the Load Bottles button.	Load Mode of Main screen appears.	Load Mode of Main screen _____.	
5	Press the Check button.	Main screen (screen 1.0) while logged in, appears.	Main screen while logged in, _____.	
6	Press the Next Screen (arrow) button. Enter a valid password using the 1-4 buttons and press the Key Symbol button to accept the password (as indicated in section 9.8).	The Setup screen appears (screen 2.0) and function buttons become enabled.	The Setup screen _____ and function buttons become enabled.	
7	Press the Set Date/Time button.	The Set Date/Time screen (screen 2.1) appears and overlays and disables the Setup screen.	The Set Date/Time screen _____ and overlays and disables the Setup screen.	
8	Press the ▼ button to scroll through the time format. Then press the ▲ to scroll through the time format. Set the format to H.	The time format scrolls through AM, PM and H when the▼ and ▲ buttons are pressed.	The time format _____ through AM, PM and H when the▼ and ▲ buttons are pressed.	
9	Press the ▲ buttons to increase both the hour and minutes.	Pressing the ▲ buttons increases both the hour and minutes.	Pressing the ▲ buttons _____ both the hour and minutes.	
10	Press the ▼ buttons to decrease both the hour and minutes.	Pressing the ▼ buttons decreases both the hour and minutes.	Pressing the ▼ buttons _____ both the hour and minutes.	
11	Press the ▲ buttons to increase the month, day and year.	Pressing the ▲ buttons increases the month, day and year.	Pressing the ▲ buttons _____ the month, day and year.	
12	Press the ▼ buttons to decrease the month, day and year.	Pressing the ▼ buttons decreases the month, day and year.	Pressing the ▼ buttons _____ the month, day and year.	
13	With the Date Format slidebar switched to the left.	The date is shown in the "MM/DD/YY" format.	The date ___shown in the "MM/DD/YY" format.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
14	Adjust the Date Format slidebar switch to the right.	The date is shown in the "DD/MM/YY" format.	The date ___ shown in the "DD/MM/YY" format.	
15	Press the Cancel ("X") button.	The original settings are retained and the system returns to the Setup screen.	The original settings ____ retained and the system returns to the Setup screen.	
16	Press the Enable/Disable Module, Drawer, Rack or Cell button.	The Enable/Disable Module, Drawer, Rack or Cell screen (screen 2.2) appears and overlays and disables the Setup screen.	The Enable/Disable Module, Drawer, Rack or Cell screen _____ and overlays and disables the Setup screen.	
17	Press the ▲ buttons to scroll up through the module, drawer, rack or cell options.	Pressing the ▲ buttons scrolls up through the module, drawer, rack or cell options. **Note:** The module option does not scroll if there is only one module.	Pressing the ▲ buttons _____ up through the module, drawer, rack or cell options.	
18	Press the ▼ buttons to scroll down through the module, drawer, rack or cell options.	Pressing the ▼ buttons scrolls down through the module, drawer, rack or cell options. **Note:** The module option does not scroll if there is only one module.	Pressing the ▼ buttons _____ down through the module, drawer, rack or cell options.	
19	Starting with all module, drawer, rack and cell Enable/Disable Slidebar switches set to 1, adjust each from 1 to 0, and from 0 to 1.	Selected module, drawer rack and cell turn gray when slidebar switches are adjusted from 1 to 0 and then back to blue when the switches are adjusted from 0 to 1.	Selected module, drawer rack and cell turn _____when slidebar switches are adjusted from 1 to 0 and then back to blue when the switches are adjusted from 0 to 1.	
20	Press the Cancel ("X") button and the Previous Screen button.	The original settings are retained and the system returns to the Setup screen.	The original settings _____ retained and the system returns to the Setup screen.	
21	Press the Calibrate Module Temperature button.	The Calibrate Module Temperature screen (screen 2.3) appears and overlays and disables the Setup screen.	The Calibrate Module Temperature screen (screen 2.3) _____ and overlays and disables the Setup screen.	
The temperature must be stable (i.e., thermometer icon w/"line through" is not present) prior to executing steps 22-33.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
22	Press the ▲ scroll buttons to increase the Optimal Temp.	Pressing the ▲ buttons increases the Optimal Temp. All other buttons (but the check, cancel and optimal temp) turn gray.	Pressing the ▲ buttons increases the Optimal Temp. All other buttons (but the check, cancel and optimal temp) turn _____.	
23	Press the Cancel ("X") button.	The original setting returns.	The original setting _____.	
24	Press the ▼ buttons to decrease the Optimal Temp.	Pressing the ▼ buttons decreases the Optimal Temp. All other buttons (but the check, cancel and optimal temp) turn gray.	Pressing the ▼ buttons decreases the Optimal Temp. All other buttons (but the check, cancel and optimal temp) turn _____.	
25	Press the Cancel ("X") button.	The original setting returns.	The original setting _____.	
26	Press the ▲ scroll buttons to increase the Actual Temp.	Pressing the ▲ buttons increases the Actual Temp. All other buttons (but the check, cancel and actual temp buttons) turn gray.	Pressing the ▲ buttons increases the Actual Temp. All other buttons (but the check, cancel and actual temp buttons) turn _____.	
27	Press the Cancel ("X") button.	The original setting returns.	The original setting _____.	
28	Press the ▼ buttons to decrease the Actual Temp.	Pressing the ▼ buttons decreases the Actual Temp. All other buttons (but the check, cancel and actual temp buttons) turn gray.	Pressing the ▼ buttons decreases the Actual Temp. All other buttons (but the check, cancel and actual temp buttons) turn _____.	
29	Press the Cancel ("X") button.	The original setting returns. All other buttons (but the check and cancel buttons) turn blue.	The original setting returns. All other buttons (but the check and cancel buttons) turn _____.	
30	Press the ▲ button to scroll up through the Incubation Module selections.	Pressing the ▲ buttons scrolls up through the Incubation Module selections. All other buttons (but the actual temp button) turn gray. **Note:** The Incubation Module selections do not scroll if there is only one module.	Pressing the ▲ buttons scrolls up through the Incubation Module selections. All other buttons (but the actual temp button) turn _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
31	Press the Cancel ("X") button.	The original setting returns.	The original setting _____.	
32	Press the ▼ button to scroll down through the Incubation Module selections.	Pressing the ▼ buttons scrolls down through the Incubation Module selections. All other buttons (but actual temp button) turn gray. The Incubation Module selections do not scroll if there is only one module.	Pressing the ▼ buttons scrolls down through the Incubation Module selections. All other buttons (but actual temp button) turn _____. The Incubation Module selections do _____ scroll if there is only one module.	
33	Press the Previous Screen button and then the Previous Screen button.	The original settings are retained and the system returns to the Setup screen.	The original settings_____ retained and the system returns to the Setup screen.	
34	Press the Calibrate Cell button.	The Calibrate Cell screen (screen 2.4) appears and overlays and disables the Setup screen.	The Calibrate Cell screen _____ and overlays and disables the Setup screen.	
35	Press the ▲ buttons to scroll up through each of the Incubation Module, Cell, and Drawer selections.	Pressing the ▲ buttons scrolls up through each of the Incubation Module, Cell, and Drawer selections. **Note:** The Incubation Module selections do not scroll if there is only one module.	Pressing the ▲ buttons _____ up through each of the Incubation Module, Cell, and Drawer selections.	
36	Press the Check and Cancel ("X") buttons.	The original setting returns.	The original setting _____.	
37	Press the ▼ button to scroll down through each of the Incubation Module, Cell, and Drawer selections.	Pressing the ▼ buttons scrolls down through each of the Incubation Module, Cell, and Drawer selections. **Note:** The Incubation Module selections do not scroll if there is only one module.	Pressing the ▼ buttons _____ down through each of the Incubation Module, Cell, and Drawer selections.	
38	Press the Check and Cancel ("X") buttons and then the Previous Screen button.	The original settings are retained and the system returns to the Setup screen.	The original settings _____ retained and the system returns to the Setup screen.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
39	Press the Set Maximum Test Time button.	The Set Maximum Test Time screen (screen 2.7) appears and overlays and disables the Setup screen.	The Set Maximum Test Time screen _____ and overlays and disables the Setup screen.	
40	Press the ▼ button to scroll through the Media Type. Then press the ▲ to scroll through the Media Type	The Media Type scrolls through media/bottle types when the▼ and ▲ buttons are pressed.	The Media Type _____ through media/bottle types when the▼ and ▲ buttons are pressed.	
41	Press the ▼ buttons to decrease the Incubation Time Period	Pressing the ▼ buttons decreases the Incubation Time Period.	Pressing the ▼ buttons _____ the Incubation Time Period.	
42	Press the ▲ scroll buttons to increase the Incubation Time Period.	Pressing the ▲ buttons increases the Incubation Time Period.	Pressing the ▲ buttons _____ the Incubation Time Period.	
43	Press the Cancel (“X”) button and then the Previous Screen button.	The original settings are retained and the system returns to the Setup screen.	The original settings _____ retained and the system returns to the Setup screen.	
44	Press the Set Audible Alarm Options button.	The Set Audible Alarms Options screen (screen 2.8) appears and overlays and disables the Setup screen.	The Set Audible Alarms Options screen _____ and overlays and disables the Setup screen.	
45*	Starting with all Positive Bottle Alarm, Operator Error Alarm, and Instrument Fault Alarm switches set to 1, adjust each from 1 to 0, and from 0 to 1.	Selected Positive Bottle Alarm, Operator Error Alarm, and Instrument Fault Alarm switches are adjusted from 1 to 0 and from 0 to 1.	Selected Positive Bottle Alarm, Operator Error Alarm, and Instrument Fault Alarm switches are _____ from 1 to 0 and from 0 to 1.	
46	Press the Cancel (“X”) button.	The original settings are retained and the system returns to the Setup screen.	The original settings _____ retained and the system returns to the Setup screen.	
*** NOTE: Repeat Step 45 if necessary based on default settings. (Set Positive Bottle Alarm to ‘1’ for remainder of qualification testing)**				
47	Press the Change Password button.	The Change Password screen appears (screen 2.9) and overlays and disables the Setup screen.	The Change Password screen _____ and overlays and disables the Setup screen.	
48	Press the Previous Screen button.	The system returns to the Setup screen.	The system _____ to the Setup screen.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
49	Press the Select Bottle to Edit/Graph button.	The Select Bottle to Edit/Graph screen (screen 2.11) appears and overlays and disables the Setup screen.	The Select Bottle to Edit/Graph screen _____ and overlays and disables the Setup screen.	
50	Press the ▲ buttons to scroll up through each of the Incubation Module, Cell, and Drawer selections.	Pressing the ▲ buttons scrolls up through each of the Incubation Module, Cell, and Drawer selections. **Note:** The Incubation Module selections do not scroll if there is only one module.	Pressing the ▲ buttons _____ up through each of the Incubation Module, Cell, and Drawer selections.	
51	Press the Cancel ("X") button.	The original setting returns.	The original setting _____.	
52	Press the ▼ button to scroll down each of through the Incubation Module, Cell, and Drawer selections.	Pressing the ▼ buttons scrolls down through each of the Incubation Module, Cell, and Drawer selections. **Note:** The Incubation Module selections do not scroll if there is only one module.	Pressing the ▼ buttons _____ down through each of the Incubation Module, Cell, and Drawer selections.	
53	Scroll through each of the Incubation Module, Cell, and Drawer selections and set to the location of one of the bottles that was loaded prior to starting this verification. Press the Graph Bottle Readings Button.	The Graph Bottle Readings screen appears (screen 2.11.2).	The Graph Bottle Readings screen _____.	
54	Click the Adjust Y Scale button.	The axis re-scales so that the maximum endpoint of the scale is just higher than the maximum value of the range. The arrow on the button changes directions.	The axis re-scales so that the maximum endpoint of the scale is just higher than the maximum value of the range. The arrow on the button _____ directions.	
55	Click the Adjust Y Scale button again.	Returns the axis to the original scale.	Returns the axis to the _____ scale.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
56	Click the Adjust X Scale button.	The axis re-scales so that the maximum endpoint of the scale is just higher than the maximum value of the range. The arrow on the button changes directions.	The axis re-scales so that the maximum endpoint of the scale is just higher than the maximum value of the range. The arrow on the button _____ directions.	
57	Click the Adjust X Scale button again.	Returns the axis to the original scale.	Returns the axis to the _____ scale.	
58	Press the Bottle Readings button.	The Bottle Readings screen (screen 2.11.2.1) appears.	The Bottle Readings screen_____.	
59	Press the Find Text button.	The Find Text screen appears.	The Find Text screen _____.	
60	Press the Cancel (“X”) button.	Search request is cancelled and the system returns to the Bottle Readings screen.	Search request is _____ and the system returns to the Bottle Readings screen.	
61	Press the Save button.	The Save to File screen appears. A default file name and path will also appear in the File Name field.	The Save to File screen _____. A default file name and path will also appear in the File Name field.	
62	Press the Cancel (“X”) button.	Save request is cancelled and the system returns to the Bottle Readings screen.	Save request is _____and the system returns to the Bottle Readings screen.	
63	With the oldest/first data record at the top of the data list, press the Top Anchor Display button.	All other Top buttons go gray.	All other Top buttons go _____.	
64	If not disabled due to lack of data records, press the Line Scroll Down button.	If Line Scroll down button is not disabled, data scrolls down one reading at a time.	If Line Scroll down button is ____ disabled, data scrolls down one reading at a time.	
65	If not disabled due to lack of data records, press the Page Scroll Down button.	Data scrolls down one page at a time, if Page Scroll Down button is not disabled.	Data _____ down one page at a time.	
66	If not disabled due to lack of data records, Press the End Scroll button.	If End Scroll button is not disabled, screen scrolls down to the newest/last data line.	Screen_____ down to the newest/last data line.	
67	With the newest/last data record at the top of the data list, press the Bottom Anchor Display button.	All other Bottom buttons go gray.	All other Bottom buttons go _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
68	If not disabled due to lack of data records, Press the Line Scroll Up button.	If Line Scroll up button is not disabled, data scrolls up one reading at a time.	Data _____ up one reading at a time.	
69	If not disabled due to lack of data records, press the Page Scroll Up button.	Data scrolls up one page at a time, if Page Scroll Up button is not disabled.	Data _____ up one page at a time.	
70	Press the Home Scroll button.	Screen scrolls up to the oldest/first data line.	Screen _____ up to the oldest/first data line.	
71	Press the Previous Screen button.	The Graph Bottle Readings screen (screen 2.11.2) appears.	The Graph Bottle Readings _____.	
72	Press the Previous Screen button.	The Select Bottle to Edit/Graph screen appears.	The Select Bottle to Edit/Graph screen _____.	
73	With a loaded bottle selected, press the Check button.	The Edit Bottle Detail screen appears.	The Edit Bottle Detail screen _____.	
74	Press the ▲ button above the incubation time to increase the incubation time.	The incubation time increases.	The incubation time _____.	
75	Press the ▼ button below the incubation time to decrease the incubation time.	The incubation time decreases.	The incubation time _____.	
76	Press the ▲ button above the bottle type to scroll up through the bottle types.	The bottle types scroll up.	The bottle types _____up.	
77	Press the ▼ button below the bottle type to scroll down through the bottle types.	The bottle types scroll down.	The bottle types _____ down.	
78	Touch Sample ID field	Field turns white.	Field _____ white.	
79	Press the Edit Test Result button.	The Edit Test Result screen (Screen 2.11.1.1) appears and overlays and disables the Edit Bottle screen.	The Edit Test Result screen _____ and overlays and disables the Edit Bottle screen.	
80	Press the Cancel button.	The Edit Bottle Detail screen (Screen 2.11.1) appears. **Note:** Screens 2.12, 2.12.1 and 2.11.1 are the same screen regardless of the screen number indicated in the figure.	The Edit Bottle Detail screen _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
81	Press the Cancel button.	The Select Bottle to Edit/Graph screen (Screen 2.11) appears.	The Select Bottle to Edit/Graph screen _____.	
82	Press the Previous screen button.	The system returns to the Setup screen (Screen 2.0)	The system _____ to the Setup screen.	
83	Press the Edit Cell Contents button.	The Edit Cell Contents screen (Screen 2.12) appears.	The Edit Cell Contents screen _____.	
84	Press any colored cell.	The Edit Bottle Detail screen (Screen 2.12.1) appears. **Note:** Screens 2.12.1 and 2.11.1 are the same screen regardless of the screen number indicated in the figure.	The Edit Bottle Detail screen _____.	
85	Press the Edit Test Result button.	The Edit Test Result screen (Screen 2.11.1.1) appears and overlays and disables the Edit Bottle screen.	The Edit Test Result screen _____ and overlays and disables the Edit Bottle screen.	
85	Press the Cancel button.	The Edit Bottle Detail screen (Screen 2.12.1) appears.	The Edit Bottle Detail screen _____.	
87	Press the Graph Bottle Readings Button.	The Graph Bottle Readings screen appears (Screen 2.11.2).	The Graph Bottle Readings screen _____.	
88	Press the Bottle Readings button.	The Bottle Readings screen (Screen 2.11.2.1) appears.	The Bottle Readings screen _____.	
89	Press the Previous Screen button.	The Graph Bottle Readings screen (Screen 2.11.2) appears.	The Graph Bottle Readings screen _____.	
90	Press the Previous Screen button.	The Select Bottle to Edit/Graph screen appears.	The Select Bottle to Edit/Graph screen _____.	
91	Press the Cancel Screen button.	The -Edit Bottle Screen appears.	The -Edit Bottle Screen _____.	
92	Press the Previous Screen button.	The Setup screen appears.	The Setup screen _____.	
93	Press the View Incubation Module Information button.	The View Incubation Module Information screen (Screen 2.13) replaces the Setup screen.	The View Incubation Module Information screen _____ the Setup screen.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
94	Press the Incubation Module Selection button.	If the system is comprised of more than one Incubator Module, the next module is displayed. If there is not more than one module, the same module is displayed.	The next module _____ displayed (if applicable).	
95	Press the Previous Screen button.	The Setup screen is displayed.	The Setup screen _____ displayed.	
96	Press the Backup Management button.	The Backup Management screen (Screen 2.16) overlays and disables the Setup screen.	The Backup Management screen _____ and disables the Setup screen.	
97	Press the Previous Screen button.	The Setup screen appears.	The Setup screen _____.	
98	Press the Edit Data Relationships button.	The Edit Bottle ID to Sample ID screen (Screen 2.17) appears. **Note:** The Sample ID Selection button will only appear if the system is set to allow reuse of Sample Ids / Accession numbers.	The Edit Bottle ID to Sample ID screen _____.	
99	Press the Previous Screen button.	The Setup screen appears.	The Setup screen _____.	
100	Press the Configure Users button.	The User Configuration screen (Screen 2.23) appears.	The User Configuration screen_____.	
101	Press the Add User button.	The Add User screen (Screen 2.23.1) appears.	The Add User screen _____.	
102	Press the Previous Screen button.	The User Configuration screen appears.	The User Configuration screen _____.	
103	Press the Delete User button.	The Delete User screen (Screen 2.23.2) appears.	The Delete User screen _____.	
104	Press the Previous Screen button.	The User Configuration screen appears.	The User Configuration screen _____.	
105	Press the Clear Password button.	The Clear Password screen (Screen 2.23.3) appears.	The Clear Password screen _____.	
106	Press the Previous Screen button.	The User Configuration screen appears.	The User Configuration screen _____.	
107	Press the Previous Screen button.	The Setup screen appears.	The Setup screen _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-15:TP 12: BacT/ALERT® 3D Control Panel/Screen Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
108	Press the Previous Screen button.	The Main screen appears.	The Main screen _____.	
109	Touch an Incubation Module on the Instrument icon.	The View Cell Status screen (Screen 1.1) appears.	The View Cell Status screen _____.	
110	Press the Incubation Module Selection button.	If the system is comprised of more than one Incubator Module, the next module is displayed. If there is not more than one module, the same module is displayed.	The next module _____ displayed (if applicable).	
111	Press the Drawer Selection button.	The next drawer is displayed.	The next drawer _____ displayed.	
112	Press the Previous Screen button.	The Main screen appears.	The Main screen _____.	
All acceptance criteria are successfully challenged.				
Test Program 12 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.10. Test Program 13: BacT/ALERT® 3D User Configuration Verification- 21 CFR Part 11 Mode enabled

9.10.1. Objective

The objective of this test program is to verify the process for adding and deleting users, and for clearing user passwords on the BacT/ALERT® 3D system by conducting the procedures identified in this test program.

9.10.2. Acceptance Criteria

9.10.2.1. The BacT/ALERT® 3D must be able to add, delete and configure user passwords in the Signature firmware.

9.10.3. Equipment

9.10.3.1. BacT/ALERT® 3D system

9.10.4. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-16:TP 13: BacT/ALERT® 3D User Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Access the Setup Screen (Screen 2.0) and enter the valid password from step 7 in Section 9.8.	The Padlock icon changes to the full open position and the function buttons become enabled.	The Padlock icon _____ to the full open position and the function buttons become enabled.	
2	Press the Configure Users button.	The User Configuration screen (Screen 2.23) appears.	The User Configuration screen _____.	
3	Press the Add User button.	The Add User screen (Screen 2.23.1) appears.	The Add User screen _____.	
4	Touch the User Name field and enter the user name "New User". Press the Add User button.	The field turns white when accessed. "New User" is added to the User list. **Take a screenshot.**	The field turns _____ when accessed. "New User" is added to the User list. **Attachment #_____** **Page___ of _____**	
5	Press the Check button.	The User Configuration (Screen 2.23) screen appears.	The User Configuration screen _____.	
6	Press the Delete User button.	The Delete User screen (Screen 2.23.2) appears.	The Delete User screen _____.	
7	Press the Scroll Up or Scroll Down button to locate the user name to be deleted. Highlight "New User" and press the Delete User button to delete the selected user from the User list.	The highlight bar scrolls until user name "New User" is highlighted. "New User" is deleted from the User list after the Delete User button is pressed.	The highlight bar scrolls until user name "New User" is highlighted. "New User" is _____ from the User list after the Delete User button is pressed.	
8	Press the Check button.	The User Configuration screen (Screen 2.23) appears.	The User Configuration screen _____.	
9	Continue to back out of the menus until the Main menu appears. Press the Logout button.	The Main screen (Screen 1.0) while logged out appears.	The Main screen while logged out _____.	
10	Press the Login button and attempt to login with the User name indicated in step 4.	A Wrong User Alert appears to the right of the User Name field.	A Wrong User Alert _____ to the right of the User Name field.	
11	Press the Cancel button and re-enter the User name from section 9.7 Step #2, and press the Change Password button to enter a new password.	The User Login screen with Change Password fields appears.	The User Login screen with Change Password fields _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-16:TP 13: BacT/ALERT® 3D User Configuration Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
12	Enter a new password in the New Password field, re-enter the new password in the Confirm Password field, and press the Check button.	The Main screen appears (while logged in).	The Main screen _____ (while logged in). New Password entered: _____	
All acceptance criteria are successfully challenged.				
Test Program 13 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.11. Test Program 14: Calibrating an Instrument cell

9.11.1. Objective

The objective of this test program is to verify the functionality of performing a cell calibration on the BacT/ALERT® 3D system by conducting the procedure(s) identified in this test program.

9.11.2. Acceptance Criteria

9.11.2.1. The BacT/ALERT® 3D system must be able to perform cell calibrations.

9.11.3. Equipment

9.11.3.1. BacT/ALERT® 3D Signature system

9.11.3.2. BioMérieux BacT/ALERT® Reflectance Standard Kit (P/N 206543)

9.11.4. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-17:TP 14: Calibrating an Instrument Cell

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Find a cell that does not contain a bottle. From the Setup screen, press the Calibrate Cell button.	The Calibrate Cell screen (Screen 2.4) appears and overlays and disables the Setup screen. An **X** is at the base of the Staircase icon.	The Calibrate Cell screen _____ and overlays and disables the Setup screen. An **X** is at the base of the Staircase icon.	
2	Choose the appropriate Incubation Module, Drawer and Cell for the cell to be calibrated.	The chosen cell's readings will be below the cell scroll buttons.	The chosen cell's readings _____ below the cell scroll buttons. Cell to be calibrated: _____	
3	Press the Check button.	If enabled, the alarm beeps twice. The drawer LED lights up to indicate which drawer to open. The cell light of the cell selected for calibration is now illuminated and #1 appears above the first step of the Calibration Staircase icon.	If enabled, the alarm _____ twice. The drawer LED lights up to indicate which drawer to open. The cell light of the cell selected for calibration is now illuminated and #1 appears above the first step of the Calibration Staircase icon.	
4	Insert Calibration **Standard #1** into the selected cell without touching the ends of the calibration standard. (A single ring around the end of the reflectance standard identifies Standard #1). Press the Check button.	If enabled, the alarm beeps once. A #2 appears above the second step of the Calibration Staircase icon.	If enabled, the alarm beeps _____. A #2 appears above the second step of the Calibration Staircase icon. Calibration Standard ID #: _____	
5	Insert **Standard #2** into the selected cell. (Two rings around the end of the reflectance standard identifies Standard #2). Press the Check button.	If enabled, the alarm beeps once. A #3 appears above the third step of the Calibration Staircase icon.	If enabled, the alarm beeps _____. A #3 appears above the third step of the Calibration Staircase icon.	
6	Insert **Standard #3** into the selected cell. (Three rings around the end of the reflectance standard identifies Standard #3). Press the Check button.	If enabled, the alarm beeps once. A #4 appears above the fourth step of the Calibration Staircase icon.	If enabled, the alarm beeps _____. A #4 appears above the fourth step of the Calibration Staircase icon.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-17:TP 14: Calibrating an Instrument Cell

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
7	Insert **Standard #4** into the selected cell. (Four rings around the end of the reflectance standard identifies Standard #4). Press the Check button.	If enabled, the alarm beeps twice. A check mark appears at the top of the Calibration icon, indicating that the calibration was successful.	If enabled, the alarm beeps _____. A check mark appears at the top of the Calibration icon, indicating that the calibration was successful.	
8	Press the Check button to save the calibration data. Press the Previous Screen button.	If enabled, the alarm beeps twice. The Setup screen appears.	If enabled, the alarm beeps _____. The Setup screen appears.	
All acceptance criteria are successfully challenged.				
Test Program 14 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.12. Test Program 15: Enabling and Disabling Modules, Drawers, Rack and Cells

9.12.1. Objective

The objective of this test program is the ability to conduct the procedure(s) identified in the test script below to verify the functionality of enabling and disabling modules, drawers, racks and cells on the BacT/ALERT® 3D system.

9.12.2. Acceptance Criteria

9.12.2.1. The BacT/ALERT® 3D system must be capable of enabling and disabling incubation modules, drawers, racks and cells.

9.12.3. Equipment

9.12.3.1. BacT/ALERT® 3D system

9.12.4. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-18:TP 15: Enabling and Disabling Modules, Drawing, Racks and Cells

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Access the Setup screen and enter a valid password. Enter the Enable/Disable Module, Drawer, Rack or Cell button.	The Enable/Disable Module, Drawer, Rack or Cell screen appears (Screen 2.2).	The Enable/Disable Module, Drawer, Rack or Cell screen _____.	
2	Select a module with the Incubation Module scroll button. Set the Enable/Disable slidebar switch under the Module Icon to disable (0). Press the Check button.	The chosen module, including its drawers, racks, and cells turn gray.	The chosen module, including its drawers, racks, and cells turn _____. Module disabled: _____	
3	Access the Main screen and touch the module disabled in step 2.	All drawers, racks and cells in the module are displayed with gray diagonal stripes.	All drawers, racks and cells in the module are displayed with _____ diagonal stripes.	
4	Access the Setup screen and enter a valid password. Enter the Enable/Disable Module, Drawer, Rack or Cell button. Select the disabled module and set the Enable/Disable slidebar switch under the Module icon to enable (1). Press the Check button.	The chosen module, including its drawers, racks, and cells are no longer gray.	The chosen module, including its drawers, racks, and cells are no longer _____. Module enabled: _____	
5	Access the Main screen and touch the module disabled in step 2.	The gray diagonal stripes are removed from the chosen module as well as from the module's drawers, racks and cells.	The gray diagonal stripes are _____ from the chosen module as well as from the module's drawers, racks and cells.	
6	Access the Setup screen and enter a valid password. Enter the Enable/Disable Module, Drawer, Rack or Cell button. Select a module, and then, with the Drawer scroll button, select a drawer within the module. Set the Enable/Disable slidebar switch below the Drawer icon to disable (0). Press the Check button.	The toggle switches turns gray.	The toggle switches turns _____. Module: _____ Drawer disabled: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-18:TP 15: Enabling and Disabling Modules, Drawing, Racks and Cells

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
7	Select a module, a drawer, and then, with the Rack scroll button, select a rack within the drawer. Set the Enable/Disable slidebar switch below the Rack icon to disable (0). Press the Check button.	The toggle switches turns gray.	The toggle switches turns _____. Module: _____ Drawer: _____ Rack disabled: _____	
8	Select a module, a drawer, a rack, and then, with the Cell scroll button, select a cell within the rack. Set the Enable/Disable slidebar switch below the Cell icon to disable (0). Press the Check button.	The toggle switches turns gray.	The toggle switches turns _____. Module: _____ Drawer: Rack: _____ Cell disabled: _____	
9	Access the Main screen and touch the module that has the drawer that was disabled in step 6. Access the drawer via the Drawer Selection button.	The appropriate disabled location on the Incubator Module on the Main Screen displays gray diagonal stripes. The disabled drawer is displayed with gray diagonal stripes within its borders.	The appropriate disabled location on the Incubator Module on the Main Screen displays gray diagonal stripes. The disabled drawer ____ displayed with gray diagonal stripes within its borders.	
10	Access the Main screen. Touch the module and access the drawer that has the rack that was disabled in step 7.	The disabled rack is displayed with gray diagonal stripes within its borders.	The disabled rack _____ displayed with gray diagonal stripes within its borders.	
11	Access the Main screen. Touch the module and access the drawer that has the cell that was disabled in step 8.	The disabled cell is displayed with gray diagonal stripes within its borders.	The disabled cell _____ displayed with gray diagonal stripes within its borders.	
Note: Execute Step 12 through 18 below AFTER section 9.18 has been completed.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-18:TP 15: Enabling and Disabling Modules, Drawing, Racks and Cells

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
12	Access the Setup screen and enter a valid password. Enter the Enable/Disable Module, Drawer, Rack or Cell button. Access the disabled drawer (from step 6) and set the Enable/Disable slidebar switch under the Drawer icon to enable (1). Press the Check button.	The drawer, including its racks, and cells turns back to blue (no longer gray).	The drawer, including its racks, and cells _____ back to blue (no longer gray).	
13	Access the disabled rack (from step 7) and set the Enable/Disable slidebar switch under the Rack icon to enable (1). Press the Check button.	The rack, including its cells turns back to blue (no longer gray).	The rack, including its cells _____ back to blue (no longer gray).	
14	Access the disabled cell (from step 8) and set the Enable/Disable slidebar switch under the Cell icon to enable (1). Press the Check button.	The cell turns back to blue (no longer gray).	The cell _____ back to blue (no longer gray).	
15	Access the Main screen and touch the module where the drawer (disabled in step 6) is located.	There are no gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the drawer.	There are _____ gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the drawer.	
16	Access the Main screen and touch the module and access the drawer where the rack (disabled in step 7) is located.	There are no gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the rack.	There are _____ gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the rack.	
17	Access the Main screen and touch the module and access the drawer where the cell (disabled in step 8) is located.	There are no gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the cell.	There are _____ gray diagonal stripes displayed on the Incubator Module icon. The gray diagonal stripes are removed from the cell.	
18	Press the Left Arrow Button. To return to the Main Screen. Press the Logout button.	The Main screen (while logged out) appears.	The Main screen (while logged out) _____.	
All acceptance criteria are successfully challenged.				
Test Program 15 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.13. Test Program 16: Scanner Verification (BacT/ALERT® 3D)

9.13.1. Objective

The objective of this test program is to verify the operational functionality of the barcode scanner at the BacT/ALERT® 3D system to accurately scan bottle ID barcodes by conducting the procedure(s) identified in this test program.

9.13.2. Acceptance Criteria

9.13.2.1. The BacT/ALERT® 3D system barcode scanner must be capable of accurately scanning BacT/ALERT® bottle barcodes.

9.13.3. Equipment

9.13.3.1. BacT/ALERT® 3D System

9.13.3.2. Barcode scanner

9.13.3.3. BacT/ALERT® bottles (8)

9.13.4. Test Setup

9.13.4.1. Choose bottles type based on incubation module(s) for this test script.

9.13.5. Test Procedure/Results/Data

9.13.5.1. Provide (4) each of (2) different types of bottles if available, for a total of 8 bottles.

9.13.5.2. Using a thick permanent black marker, markup/alter one entire Bottle ID barcode on (1) of each type of bottle. The total will be (6) bottles with unaltered barcodes and (2) bottles with altered barcodes.

9.13.5.3. Number the bottles (1-8 on the bottle necks) with the marker.

9.13.5.4. Document the bottle types and bottle ID numbers by placing bottle barcode tabs on the table below.

Note: For bottles with altered barcodes, document by writing "**unable to scan**" for Bottle ID #s and "**N/A**" for the bottle types.

9.13.5.5. From the BacT/ALERT® 3D main screen, log on with a valid user name and password. Then press the Load Buttons button.

9.13.5.6. In the Load Mode screen, ensure that the Bottle ID field is white.

9.13.5.7. Scan the barcode ID using the scanner on the BacT/ALERT® 3D for each bottle while making sure that the scanning beam runs across the barcode lines.

9.13.5.8. Document the scanned bottle information in the table below as it appears in the Bottle ID and Bottle Type field on the Load Mode screen.

9.13.5.9. After scanning each bottle, touch the Bottle ID field and manually (with the keyboard) erase the ID number.

9.13.5.10. Repeat the scanning and ID verification steps above for the remaining bottles and document the scans in the table below.

Table 9-19:TP 16: Scanner Verification at the BacT/ALERT® 3D System

Bottle #	Barcode Label	Scanned Bottle Type	Scanned Bottle ID#	Does the Scanned information match the Actual information? Y/N	Pass/Fail
1					
2					
3					
4					
5					
6					
7					
8					
All acceptance criteria are successfully challenged.					
Test Program 16 is complete.					

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.14. Test Program 17: OBSERVA® and BacT/ALERT® 3D Operational Verification Workflows

9.14.1. Objective

The objective of this test program is to verify the operational functionality that applies to both the OBSERVA® software and the BacT/ALERT® 3D System. Two verification workflows will be tested along with general system features and functionality.

9.14.2. Acceptance Criteria

9.14.2.1. The BacT/ALERT® 3D system must communicate with the OBSERVA® software and the Signature firmware.

9.14.2.2. The BacT/ALERT® 3D control panel must be operational with the Signature firmware.

9.14.2.3. The BacT/ALERT® 3D Signature system must alert operators when positive microbial growth is detected.

9.14.2.4. The BacT/ALERT® 3D Signature system must accommodate simultaneous sample analysis.

9.14.2.5. The OBSERVA® software must provide functionality to print reports.

9.14.2.6. The OBSERVA® software prints the raw data using a local/network printer.

9.14.3. Equipment

9.14.3.1. BacT/ALERT® 3D System

9.14.3.2. OBSERVA® workstation

9.14.3.3. BacT/ALERT® bottles (as needed)

9.14.4. Test Setup

9.14.4.1. Ensure that the BacT/ALERT® 3D system is empty. Use login credentials created in section 9.2 for accessing the OBSERVA® workstation and section 9.7 for accessing the BacT/ALERT® 3D control panel.

9.14.5. Test Procedure/Results/Data

Complete the table below as indicated.

9.14.6. Verification Workflow #1

Workflow Option # 1 is a common way to enter bottle data into the OBSERVA® software and then load bottles into the BacT/ALERT® 3D System. This workflow demonstrates the communication between the two interfaces.

Note: Different accession number can be assigned if specified accession number is not available.

Note: Certain field names may be different due to customization based on usage, options such a calendar view, manual accession number assignment may not be available. In some cases auto assignment of accession number and date and time may be customized.

Workflow #1 is defined as follows:

- The accession number, date and time collected, (and other bottle information) and bottle ID information is entered (when applicable) at the OBSERVA® Culture Data Entry screen.
- The Bottle ID is scanned at the BacT/ALERT® 3D Combination Module (the accession number will “friendly fill”).
- The bottle is loaded into the incubator module.

The procedure in the table below will verify this approach, as well as verify basic system functionality when utilizing simulated product in the process.

Prior to executing the following verification, the following must be completed:

- Acquire 4 bottles based on incubation module(s). If available, use 2 types of bottles, 2 for each type (2 aerobic, 2 anaerobic, if available) for a total of 4 bottles.
- Number the bottles on their labels (with a marker) 1 through 4.
- Document the required bottle information in the table below prior to executing the verification within this workflow.

Table 9-20:TP 17: Workflow #1 Bottle Information

Bottle #	Bottle Barcode Label	Initial/Date
1		
2		
3		
4		

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Log on to the OBSERVA® software as a user with Administrator privileges. Verify that the information in the General information pane is correct.	The indicated date is correct. The indicated time is within ~5 minutes of the actual time. The indicated version of the software is Version 4.03. **Take a screenshot.**	Current User: _____ Actual date: _____ Date displayed:_____ Actual time:_____ Time displayed:_____ Software Version displayed:_____ **Attachment #_____** **Page___ of _____**	
2	Verify that the OBSERVA Status is indicated in the System Status pane.	OBSERVA Status is indicated in the System Status pane.	OBSERVA Status ____ indicated in the System Status pane.	
3	Verify the BacT/ALERT® communication status in the System Status pane.	The BacT/ALERT® communication status is identified as OK in the System Status screen.	The BacT/ALERT® communication status ____ identified as OK in the System Status screen.	
4	Access the Culture Data Entry screen and manually enter the following when applicable: --"1" for the bottle Accession number, --"1" for the Alt Org. ID or Patient ID, --"1" for the Org. ID or Patient ID --The Date Collected and Time (if manual, enter today's date/time or else auto assigned). --Choose Source Scan the Bottle ID barcode for bottle #1 with the scanner at the OBSERVA® workstation. Click the Save button.	The required information is manually entered. The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #1 in the table above.	Date Collected and Time: _____ Source:_____ Accession #:_____ Alt ID #:_ Org./Pat. ID:_____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Log into the BacT/ALERT® 3D and access the Load Bottle Mode screen of the Main screen. Touch the Bottle ID field and scan the bottle ID barcode for bottle #1 with the scanner at the BacT/ALERT®. Change the Maximum test time to 0.1.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #1 in the table above. The Accession number "friendly fills" and matches the Accession # entered at the OBSERVA® workstation in step 4. The exterior indicators for the Drawers with empty cells are lit.	User Name: _____ Bottle ID displayed: _____ Bottle Type displayed: _____ Accession # displayed: _____ All entries matched corresponding fields, accession number friendly filled and indicator light is lit.	
6	Slowly open a drawer with an illuminated indicator light.	All empty cells (that have not been disabled) have an illuminated cell indicator light.	All empty cells (that have not been disabled) _____ an illuminated cell indicator light.	
7	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® screen have cleared.	**Bottle #1 Location info:** Module:_____ Drawer: _____ Rack: _____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® screen is cleared.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
8	While in the OBSERVA® software, access the Culture Data Entry screen and manually enter the following when applicable: --"2" for the bottle Accession number, --"2" for the Alt Org. ID or Patient ID, --"2" for the Org. ID or Patient ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). -- Choose Source Scan the bottle ID barcode for bottle #2 with the scanner at the OBSERVA® workstation. Click on the Save button.	The required information is manually entered. The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #2 in the table above.	Date Collected and Time: _____ Source:_____ Accession #:_____ Alt. ID #:_____ Org./Pat. ID:_____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields.	
9	At the BacT/ALERT® 3D, access the Load Mode screen of the Main screen. Touch the Bottle ID field and scan the bottle ID barcode for bottle #2 with the scanner at the BacT/ALERT®. Change the Maximum test time to 0.1.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #2 in the table above. The Accession number "friendly fills" and matches the Accession # entered at the OBSERVA® workstation in step 8. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID displayed: _____ Bottle Type displayed: _____ Accession # displayed: _____ All entries matched corresponding fields, accession number friendly filled and indicator light is lit.	
10	Slowly open a drawer with an illuminated indicator light.	All empty cells (that have not been disabled) have an illuminated cell indicator light.	All empty cells (that have not been disabled) _____ an illuminated cell indicator light.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
11	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® screen have cleared.	**Bottle #2 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® screen is cleared.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
12	While in the OBSERVA® software, access the Culture Data Entry screen and manually enter the following when applicable: --"3" for the bottle Accession number, --"3" for the Alt Org. ID or Patient ID, --"3" for the Org. ID or Patient ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). -- Choose Source Scan the bottle ID barcode for bottle #3 with the scanner at the OBSERVA® workstation. Click the Save button.	The required information is manually entered. The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #3 in the table above.	Date Collected and Time: _____ Source:_____ Accession #:_____ Alt. ID #:_____ Org./Pat. ID:_____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields.	
13	At the BacT/ALERT® 3D, access the Load Mode screen of the Main screen. Touch the Bottle ID field and scan the bottle ID barcode for bottle #3 with the scanner at the BacT/ALERT®. Change the Maximum test time to 0.1.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #3 in the table above. The Accession number "friendly fills" and matches the Accession # entered at the OBSERVA® in step 12. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID displayed: _____ Bottle Type displayed: _____ Accession # displayed: _____ All entries matched corresponding fields, accession number friendly filled and indicator light is lit.	
14	Slowly open a drawer with an illuminated indicator light.	All empty cells (that have not been disabled) have an illuminated cell indicator light.	All empty cells (that have not been disabled) _____ an illuminated cell indicator light.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
15	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® screen have cleared.	**Bottle #3 Location info:** Module:_____ Drawer: _____ Rack: _____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® screen is cleared.	
16	While in the OBSERVA® software, access the Culture Data Entry screen and manually enter the following when applicable: --"4" for the bottle Accession number, --"4" for the Alt Org. ID or Patient ID, --"4" for the Org. ID or Patient ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). -- Choose Source Scan the bottle ID barcode for bottle #4 with the scanner at the OBSERVA® workstation. Click the Save button.	The required information is manually entered. The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #4 in the table above.	Date Collected and Time: _____ Source:_____ Accession #:_____ Alt. ID #:_____ Org./Pat. ID:_____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-20:TP 17: Workflow #1 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
17	From the BacT/ALERT® 3D, access the Load Mode screen of the Main screen. Touch the Bottle ID field and scan the bottle ID barcode for bottle #4 with the scanner at the BacT/ALERT®. Change the Maximum test time to 0.1.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #4 in the table above. The Accession number "friendly fills" and matches the Accession # entered at the OBSERVA® in step 16. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID displayed: _____ Bottle Type displayed: _____ Accession # displayed: _____ All entries matched corresponding fields, accession number friendly filled and indicator light is lit.	
18	Slowly open a drawer with an illuminated indicator light.	All empty cells (that have not been disabled) have an illuminated cell indicator light.	All empty cells (that have not been disabled _____ an illuminated cell indicator light.	
19	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® screen have cleared.	**Bottle #4 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® screen is cleared.	
20	Press the Check button on the Load Bottles Mode screen.	The Main screen is displayed.	The Main screen _____ displayed.	
21	Using the Edit Bottle Detail screen, change the status of each recently loaded bottle so that two are Negative and two are Positive.	Two negative and two positive bottles are present.	Two negative and two positive bottles _____ present.	
Workflow #1 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.14.7. Verification Workflow #2

Workflow Option # 2 is a common way to load bottles into the BacT/ALERT® 3D System and then enter the required bottle data into the OBSERVA® software. This workflow demonstrates the communication between the two interfaces.

Note: Different accession number can be assigned if specified accession number is not available.

Workflow #2 is defined as follows:

- Scan or enter Bottle ID at the BacT/ALERT® 3D Combination Module (the accession number will not “friendly fill”).
- Scan or enter the accession number and load bottle into the incubator module. Load the bottle.
- Enter the accession number at the OBSERVA® Culture Data Entry screen and press Tab. The Bottle ID will “friendly fill”.
- Enter the Date and Time (and other indicated information if applicable) information.

The procedure in the table below will verify this approach, as well as verify basic system functionality when utilizing simulated product in the process.

Prior to executing the following verification, the following must be completed:

- Acquire 4 bottles based on incubation module(s). If available, use 2 types of bottles, 2 of each type (2 aerobic, 2 anaerobic, if available) for a total of 4 bottles.
- Number the bottles on the label (with a marker) 5 through 8.
- Document the required bottle information in the table below prior to executing the verification within this workflow.

Table 9-21:TP 17: Workflow #2 Bottle Information

Bottle #	Bottle Barcode Label	Initial/Date
5		
6		
7		
8		

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	With the same user logged in at the BacT/ALERT® 3D as was for the previous workflow, Access the Load Mode screen of the Main screen. Touch the Bottle ID field and scan the bottle ID barcode for bottle #5 with the scanner at the BacT/ALERT®. Change the Maximum test time to 0.1.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #5 in the table above. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID entered: _____ Bottle Type displayed: _____ All entries matched corresponding fields, and indicator light is lit.	
2	Manually enter the Accession number "5" in the appropriate field on the screen.	The accession number is entered as required.	Accession Number entered: _____	
3	Insert the bottle, sensor first into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® 3D screen have cleared.	**Bottle #5 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® 3D screen is cleared.	
4 **Note:** Step 4 and 5 may be executed con-currently	Log into the OBSERVA® software as the same user as in the previous section, access the Culture Data Entry screen. Click on the Accession number field and manually enter the accession number from step 2.	The bottle ID and bottle type will "friendly fill" after source is chosen from Step 5. Match the bottle ID and bottle type initially documented for bottle #5 in the table above.	Accession number entered: _____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields, bottle ID and bottle type friendly filled.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Choose a Source from the drop down list, and enter the following additional information when applicable: --Enter "5" for the Alt. Org. ID or Pat. ID. --Enter "5" for the Org. ID or Pat. ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). Click the Save button.	The information for Source, Alt Org./Pat. ID, Org./Pat. ID, and Date Collected/Time, is entered as required.	Source: _____ Alt. ID entered: _____ Org./Pat. ID:_____ Date Collected & Time: _____	
6	Access the Load Bottle Mode screen of the Main screen at the BacT/ALERT® 3D. Change the Maximum test time to 0.1. Touch the Bottle ID field and scan the bottle ID barcode for bottle #6 with the scanner at the BacT/ALERT®.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #6 in the table above. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID entered: _____ Bottle Type displayed: _____ All entries matched corresponding fields, and indicator light is lit.	
7	Manually enter the Accession number "6" in the appropriate field on the screen.	The accession number is entered as required.	Accession Number entered: _____	
8	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® 3D screen have cleared.	**Bottle #6 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® 3D screen is cleared.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
9 **Note:** Step 9 and 10 may be executed con-currently	Access the Culture Data Entry screen from the OBSERVA® software. Click on the Accession number field and manually enter the accession number from step 7.	The bottle ID and bottle type will "friendly fill" after source is chosen from Step 10. Match the bottle ID and bottle type initially documented for bottle #6 in the table above.	Accession Number entered: _____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields, bottle ID and bottle type friendly filled.	
10	Choose a Source from the drop down list, and enter the following additional information when applicable: Enter "6" for the Alt. Org. ID or Pat. ID. --Enter "6" for the Org. ID or Pat. ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). Click the Save button.	The information for Source, Alt Org./Pat. ID, Org./Pat. ID, and Date Collected/Time, is entered as required.	Source: _____ Alt. ID entered: _____ Org./Pat. ID:_____ Date Collected & Time: _____	
11	Access the Load Bottle Mode screen of the Main screen at the BacT/ALERT® 3D. Change the Maximum test time to 0.1. Touch the Bottle ID field and scan the bottle ID barcode for bottle #7 with the scanner at the BacT/ALERT®.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #7 in the table above. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID entered: _____ Bottle Type displayed: _____ All entries matched corresponding fields, and indicator light is lit.	
12	Manually enter the Accession number "7" in the appropriate field on the screen.	The accession number is entered as required.	Accession Number entered: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
13	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® 3D screen have cleared.	**Bottle #7 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® 3D screen is cleared.	
14 **Note:** Steps 14 and 15 may be executed con-currently	Access the Culture Data Entry screen from the OBSERVA® software. Click on the Accession number field and manually enter the accession number from step 12.	The bottle ID and bottle type will "friendly fill" after source is chosen from Step 15. Match the bottle ID and bottle type initially documented for bottle #7 in the table above.	Accession Number entered: _____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields, bottle ID and bottle type friendly filled.	
15	Choose a Source from the drop down list, and enter the following additional information when applicable: Enter "7" for the Alt. Org. ID or Pat. ID. --Enter "7" for the Org. ID or Pat. ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). Click the Save button.	The information for Source, Alt Org./Pat. ID, Org./Pat. ID, and Date Collected/Time, is entered as required.	Source: _____ Alt. ID entered: _____ Org./Pat. ID:_____ Date Collected & Time: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
16	Access the Load Bottle Mode screen of the Main screen at the BacT/ALERT® 3D. Change the Maximum test time to 0.1. Touch the Bottle ID field and scan the bottle ID barcode for bottle #8 with the scanner at the BacT/ALERT®.	The bottle ID and bottle type appear in the correct corresponding fields and both match the bottle ID and bottle type initially documented for bottle #8 in the table above. The exterior indicators for the Drawers with empty cells are lit.	Bottle ID entered: _____ Bottle Type displayed: _____ All entries matched corresponding fields, and indicator light is lit.	
17	Manually enter the Accession number "8" in the appropriate field on the screen.	The accession number is entered as required.	Accession Number entered: _____	
18	Insert the bottle, sensor first, into a cell with an illuminated cell indicator light. Close the drawer.	The cell indicator blinks slowly to acknowledge the bottle is loaded. The texts fields on the BacT/ALERT® 3D screen have cleared.	**Bottle #8 Location info:** Module:_____ Drawer:_____ Rack:_____ Cell #:_____ Cell indicator blinks and text field on BacT/ALERT® 3D screen is cleared.	
19	Access the Culture Data Entry screen from the OBSERVA® software. Click on the Accession number field and manually enter the accession number from step 17.	The bottle ID and bottle type will "friendly fill" after source is chosen from Step 20. Match the bottle ID and bottle type initially documented for bottle #8 in the table above.	Accession Number entered: _____ Bottle ID displayed: _____ Bottle Type displayed: _____ All entries matched corresponding fields, bottle ID and bottle type friendly filled.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-21:TP 17: Workflow #2 Bottle Load

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
20	Choose a Source from the drop down list, and enter the following additional information when applicable: Enter "8" for the Alt. Org. ID or Pat. ID. --Enter "8" for the Org. ID or Pat. ID --The Date Collected and Time (if manual enter today's date/time or else auto assigned). Click the Save button.	The information for Source, Alt Org./Pat. ID, Org./Pat. ID, and Date Collected/Time, is entered as required.	Source: _____ Alt. ID entered: _____ Org./Pat. ID:_____ Date Collected & Time: _____	
21	Press the Check button on the Load Mode screen.	The Main screen is displayed.	The Main screen _____ displayed.	
22	Using the Edit Bottle Detail screen, change the status of each recently loaded bottle so that two are Negative and two are Positive.	Two negative and two positive bottles are present.	Two negative and two positive bottles _____ present.	
Workflow #2 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.14.8. Workflow #1 and Workflow #2 Bottle ID/Status/Location Summary

Summarize and document the required information for the bottles loaded into the BacT/ALERT® 3D system in sections 9.14.6 and 9.14.7 in the tables below.

Table 9-22:TP 17: Workflow #1 Bottle Information

Bottle #	Bottle ID	Status	Location			Initial/Date
			Module	Drawer	Cell #	
1						
2						
3						
4						
5						
6						
7						
8						
Workflow #1 and Workflow #2 Summary is complete.						

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-23:TP 17: Workflow #1 and #2 Bottle Status

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Access the Main screen at the BacT/ALERT® 3D and document the screen background color.	The background color is **yellow**. An audible alarm (intermittent beeping) is also heard.	Screen Color: _____. An audible alarm is also heard.	
2	Document the total number of bottles and number of positive and negative bottles indicated on the Main screen.	The Main screen indicates that there are a total of 8 bottles loaded, with (4) positive bottles and (4) negative bottles.	The Main screen indicates that there are a total of ____ bottles loaded, with (4) positive bottles and (4) negative bottles.	
3 **Note:** Step 3 and 4 may be executed con-currently	Access the Edit Cell Contents screen (2.12) for each bottle. Verify that the bottle status for each specific location is displayed on the Edit Cell screens as indicated in the Summary Table 9-12 (9.14.8) above. (Bottle information is further verified in step 4. Steps 3 and 4 may be conducted concurrently) ****Note:** The color of the circle outlining the cell indicates the status of the bottle in the cell. The colors indicate the following: Hollow (no color)-- Empty cell (no bottle) Black— Negative-to-date bottle Green—Negative bottle Yellow—Positive bottle White—Cell is pending QC check	The bottle location and status indicated for each of the 8 bottles on the Edit Cell Contents screens match the location and status documented for each bottle in the Summary Table 9-22 (9.14.8) above.	As displayed in the Edit Cell Contents screens: # Loc* Cell Color** 1. _____ _____ 2. _____ _____ 3. _____ _____ 4. _____ _____ 5. _____ _____ 6. _____ _____ 7. _____ _____ 8. _____ _____ Bottle location and status match as indicated. * Location is indicated by 3 components as follows: Incubation Module #, Drawer Letter, Cell # (e.g.: 1A01) ** See Note in procedure column.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-23:TP 17: Workflow #1 and #2 Bottle Status

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
4	Access the relevant Edit Bottle Detail screen (2.12.1) for each bottle by touching the specific cell on the Edit Cell Contents screen to verify the bottle ID, status and locations of all of the bottles. Verify that the bottle ID, location and status of the bottles is displayed on the Edit Bottle Detail screens as indicated in the Summary Table 9-22 (9.14.8) above.	The bottle location and status indicated for each of the 8 bottles on their respective Edit Bottle Detail screens match the bottle ID, location and status documented for each bottle in the Summary Table 9-22 (9.14.8) above.	As displayed in the Edit Bottle Detail screens: # Bottle ID Loc* Status 1._____ _____ _____ 2._____ _____ _____ 3._____ _____ _____ 4._____ _____ _____ 5._____ _____ _____ 6._____ _____ _____ 7._____ _____ _____ 8._____ _____ _____ Bottle location and status match as indicated. *Location is indicated by 3 components as follows: Incubation Module #, Drawer Letter, Cell # (e.g.: 1A01)	
Workflow #1 and #2 Bottle Status is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.14.9. Viewing Bottle Data and Graphs

Verify that bottle data entered in Section 9.14 can be viewed and edited by executing the procedures in the table below.

Table 9-24:TP 17: Viewing Bottle Data and Graphs

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	From the Setup Screen, press the Select Bottle to Edit / Graph button.	The Select Bottle to Edit screen appears, overlaid on the disabled Setup screen.	The Select Bottle to Edit screen _____, overlaid on the disabled Setup screen.	
2	Enter the Bottle ID of bottle # 1 as noted in Section 9.14.6, Step 4. Press the Check button.	The Edit Bottle Detail screen appears.	The Edit Bottle Detail screen _____.	
3	View bottle #1 Edit Bottle Detail data: **Take a screenshot**	Edit Bottle Detail data should match that entered in Section 9.14.6; Steps 4-7: Bottle ID: Accession #: 1 Date Loaded: Last Unloaded: (blank) Time of last bottle reading: View Test Time: date/time blank if bottle is NTD. Test Result Icon: * (NTD) Load Status: 1 Maximum Test Time: 0.1 Bottle Type: Bottle Status: Cell Location: Algorithm/Polynomial How Determined/Positivity Index	Edit Bottle Detail data does _____ that entered in Section 9.14.6 **Attachment #_____** **Page___ of _____**	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-24:TP 17: Viewing Bottle Data and Graphs

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
4	Press Edit Test Result button. Check **"+"** checkbox to manually change Bottle Status to Positive. Change back to **"-"** for Bottle Status. Press Check button to accept the change.	Changed status to Positive and then back to Negative.	Changed status to _____ and then back to _____.	
5	Press the Graph Bottle Readings button	Displays the bottle graph on the Graph Bottle Readings Screen.	_____ the bottle graph on the Graph Bottle Readings Screen.	
Viewing Bottle Data and Graphs is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.14.10. Unloading Bottles, Unload Negative Report and Report Recent Positives Report Verification

Follow the procedures in the table below to verify that the bottles loaded in sections 9.14.6 and 9.14.7 can be accurately unloaded from the BacT/ALERT® 3D System using the OBSERVA® software. This section also verifies two reports: *Unload Negatives Report and Report Recent Positives*.

Table 9-25:TP 17: Verification of Unloading Bottles and Report Generation

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Unload Negative Bottles				
1	Log on to OBSERVA® using a password with Administrator access. Click on the OBSERVA Reports option on the Menu bar.	A drop-down list of report options is displayed.	A drop-down list of report options ____ displayed.	
2	Click on Report Negatives to Unload. **Note:** Choose MB only report for MB module.	Report generated and printed which includes all Negative bottles yet to be unloaded.	Report generated and printed which _____ all Negative bottles yet to be unloaded. **Attachment #_____** **Page___ of _____**	
3	On the Main screen of the BacT/ALERT® 3D Controller Module, verify that (4) bottles are Negative	The Negative Bottle button is 'blue' and the number (4) appears in the BC cell (MB cell for MB modules) directly above the Negative Bottle button.	The Negative Bottle button _____ 'blue' and the number (4) appears in the BC cell (MB cell for MB modules) directly above the Negative Bottle button.	
4	Press the Unload Negative Bottles button.	The Unload Mode screen appears. Green indicators illuminate on drawers containing negative bottles	The Unload Mode screen _____. Green indicators illuminate on drawers containing negative bottles	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-25:TP 17: Verification of Unloading Bottles and Report Generation

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Slowly open a drawer with an illuminated indicator light.	Cells with negative bottles have an illuminated cell indicator light. Compare to cell IDs listed in section 9.14.8 Summary Table 9-22 and listed on Report generated in Step 2 above.	**Cell IDs from section 9.14.8:** _____ _____ _____ _____ **Cell IDS from generated report:** _____ _____ _____ _____ Cells with negative bottles _____ an illuminated cell indicator light.	.
6	Remove bottles, one at a time.	Bottle ID and accession number appear on the Unload Mode screen.	Bottle ID and accession number _____ on the Unload Mode screen.	
7	Verify that each cell light blinks slowly as each bottle is removed.	Cell light blinks slowly to acknowledge bottle removal.	Cell light _____ slowly to acknowledge bottle removal.	
8	When all negative bottles are unloaded, close the drawer, and press the Check button on the Unload Negative Bottles screen.	The Main screen is displayed.	The Main screen _____ displayed.	
Unload Positive Bottles				
9	Click on the Reports option on the Menu bar.	A drop-down list of report options is displayed.	A drop-down list of report options _____ displayed.	
10	Click on Report Recent Positives. **Note:** Choose MB only report for MB module.	Report generated and printed that includes all bottles determined Positive.	Report generated and printed that includes _____ bottles determined Positive. **Attachment #_____** **Page___ of _____**	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-25:TP 17: Verification of Unloading Bottles and Report Generation

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
11	On the Main screen of the BacT/ALERT® 3D Controller Module, verify that four (4) bottles are Positive, and that the screen is 'yellow'	The Positive Bottle button is '**blue'** and the number (4) appears in the BC cell (MB cell for MB modules) directly above the Positive Bottle button. Screen is '**yellow'**.	The Positive Bottle button is 'blue' and the number (4) appears in the BC cell (MB cell for MB modules) directly above the Positive Bottle button. Screen is _____.	
12	Press the Unload Positive Bottles button.	The Unload Mode screen appears. Green indicators illuminate on drawers containing positive bottles.	The Unload Mode screen _____. Green indicators illuminate on drawers containing positive bottles.	
13	Slowly open a drawer with an illuminated indicator light.	Cells with positive bottles have an illuminated cell indicator light. Compare to cell IDs listed in section 9.14.8 Summary Table 9-22 and listed on Report generated in Step 10 above.	**Cell IDs from 10.14.8:** _____ _____ _____ _____ **Cell IDS from generated report:** _____ _____ _____ _____ Cells with positive bottles _____ an illuminated cell indicator light.	
14	Remove bottles, one at a time.	Bottle ID and accession number appear on the Unload Mode screen.	Bottle ID and accession number _____ on the Unload Mode screen.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-25:TP 17: Verification of Unloading Bottles and Report Generation

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
15	Verify that each cell lights blinks slowly as each bottle is removed.	Cell light blinks slowly to acknowledge bottle removal.	Cell light _____ slowly to acknowledge bottle removal.	
16	When all positive bottles are unloaded, press the Check button on the Unload Positive Bottles screen.	The Main screen is displayed.	The Main screen _____ displayed.	
All acceptance criteria are successfully challenged.				
Test Program 17 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.15. Test Program 18: Faults and Operator Error Codes/Alarms Verification

9.15.1. Objective

The objective of this test program is to verify the faults and error codes described within this test script. Only the most commonly occurring faults and error conditions, and those that can be triggered without harming the system or the program will be verified. Error codes alarms are audible when the feature is enabled from the BacT/ALERT® 3D control module.

9.15.2. Acceptance Criteria

9.15.2.1. The system must be set to sound audible and visual alarm when various events occurs (e.g. when positive bottle is identified or when the drawer is open).

9.15.3. Equipment

9.15.3.1. BacT/ALERT® 3D System

9.15.4. Test Setup

9.15.4.1. Ensure that the BacT/ALERT® 3D system is empty.

9.15.5. Test Procedure/Results/Data

Complete the table below as indicated. Note, the control module is part of the Combination Module.

Table 9-26:TP 18: Faults and Operator Error Codes/Alarms Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Error Code 1 & 710 Verification				
1	Turn off main power switch to the Incubator.	Error Code 1 displays on the main screen.	Error Code ____ displays on the main screen.	
2	Turn on main power switch to the Incubator.	Error Code 710 is displayed and Error Code 1 is gone.	Error Code _____ is displayed and Error Code 1 is gone.	
Error Code 4, 20, 39 Verification (Do not perform on system with samples under test)				
3	Open a drawer on an incubator and leave open.	Error Code 20 will appear on Main Screen, and subsequently, Error Codes 39 and 4.	Error Code ____ will appear on Main Screen, and subsequently, Error Codes 39 and 4.	
4	Close drawer to incubator.	Error codes will disappear after temperature is equilibrated.	Error codes will disappear after temperature ____ equilibrated.	
Error Code 10 Verification				
5	Remove Controller Module AC power by unplugging the cord.	Note Error Code 10 on Main Screen.	Note Error Code ___ on Main Screen.	
6	Restore Controller Module AC power by plugging cord back in.	Error Code 10 goes away.	Error Code ___ goes away.	
Error Code 60 Verification				
7	Select one empty cell and perform Cell Calibration substituting Standard #1 for #4.	Error Code 60 appears above the stair steps.	Error Code ____ appears above the stair steps.	
8	Press the 'X' check mark button.	Error 60 is removed from the screen.	Error _____ is removed from the screen.	
9	Re-calibrate the cell using correct Standards #1 - #4.	Error Codes disappear	Error Codes _____.	
Error Code 81 Verification				
10	Load a bottle via the Load Bottle function on the Main Screen.			
11	Remove bottle from incubator.	Acknowledge the Error Code 911 by pressing the check mark button.	Acknowledge the Error Code _____ by pressing the check mark button.	
12	Load a new bottle into the same cell location.	Acknowledge the Error Code 909 by pressing the check mark button.	Acknowledge the Error Code_____ by pressing the check mark button.	
13	View the Cell Status screen for the bottle loaded.	Note that Error Code 81 is displayed.	Note that Error Code _____ is displayed.	
Error Code 99 Verification				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-26:TP 18: Faults and Operator Error Codes/Alarms Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
14	Access the Setup screen and disable an empty cell.	Cell is disabled.	Cell disabled: _____	
15	Load a bottle via the Load Bottle function on the Main Screen into the disabled cell.	Acknowledge the Error Code 910 by pressing the check mark button.	Acknowledge the Error Code 910 by _____ the check mark button.	
16	View the Cell Status screen for the bottle loaded.	Note that Error Code 99 is displayed.	Note that Error Code ____ is displayed.	
17	Remove bottle.	Acknowledge the Error Code 911 by pressing the check mark button.	Acknowledge the Error Code ____ by pressing the check mark button.	
Error Code 800 Verification (Note: Can only be performed if a printer is connected to the system). ☐ N/A				
18	Disconnect printer cable from the Controller Module.			
19	Attempt to print a document (i.e. Cell Calibration Report)	Note Error Code 800 on the Main Screen.	Note Error Code _____ on the Main Screen.	
20	Reconnect printer cable.			
Error Code 810 Verification				
21	Remove the USB flash drive from the USB port (if applicable).			
22	Initiate a manual backup from the Setup screen.	Note Error Code 810.	Note Error Code _____.	
Operator Error Codes appear in a separate window on the Main Screen and are identified by a "99" in the top left corner of the window.				
23	Using the Load Bottle function, load a bottle into the disabled cell identified in step 14 above.	(If activated for Operator errors, alarm beeps.) Screen turns red and window appears with Operator Error Code 909 displayed in upper right corner. (910 is a valid error code if the cell was undergoing QC at the time this step was performed.) The Cell ID will be displayed in the error window.	Cell loaded: _____ Cell ID displayed in window: _____ Screen turns red and window appears with Operator Error Code 909 displayed in upper right corner. The Cell ID _____ displayed in the error window.	
24	Remove bottle from cell.	Operator Error screen disappears.	Operator Error screen _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-26:TP 18: Faults and Operator Error Codes/Alarms Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
25	Press the Check button.	Main Screen appears.	Main Screen _____.	
26	Using the Load Bottle function, scan and load a bottle into any available cell.	Bottle scanned and loaded.	Bottles scanned and loaded. Cell Loaded: _____	
27	Referring to step 26 above, open drawer and remove the bottle. (without using an Unload function).	Alarm beeps if activated. Window appears with Operator Error Code 911 displayed in upper right corner. The Cell ID will be displayed in the error window; cell indicator light flashes rapidly.	Alarm beeps if activated. Window appears with Operator Error Code 911 displayed in upper right corner. The Cell ID ____ displayed in the error window; cell indicator light flashes rapidly.	
28	Replace the bottle into the cell from which it was just removed.	The Operator Error screen disappears. Main Screen appears.	Cell loaded: _____ The Operator Error screen disappears. Main Screen _____.	
29	At the Main screen, scan an unused, uninoculated bottle barcode label.	Alarm beeps, if activated. Window appears with Operator Error Code 921 displayed in upper right corner. Error screen disappears within 5 seconds.	Bottle ID: _____ Alarm beeps, if activated. Window appears with Operator Error Code _____ displayed in upper right corner. Error screen disappears within 5 seconds.	
30	In Load Bottles mode, manually type above bottle's barcode label ID in the Bottle ID field, replacing the last character of the label ID with an asterisk (*).	Alarm beeps, if activated. Window appears with Operator Error Code 923 displayed in upper right corner.	Alarm beeps, if activated. Window appears with Operator Error Code _____ displayed in upper right corner.	
31	Press the Check (X) button.	Error acknowledged and error screen disappears.	Error acknowledged and error screen _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-26:TP 18: Faults and Operator Error Codes/Alarms Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
32	Remove bottle from cell noted in Step 26 above.	Alarm beeps if activated. Window appears with Operator Error Code 911 displayed in upper right corner. Cell ID is displayed in the error window.	Bottle ID: _____ Alarm beeps if activated. Window appears with Operator Error Code _____ displayed in upper right corner. Cell ID is displayed in the error window.	
33	Press the Check button. Do not reload bottle. Retain bottle.	Error acknowledged and error screen disappears within 5 seconds. Load Bottle screen appears.	Error acknowledged and error screen disappears within 5 seconds. Load Bottle screen _____.	
34	Press the Check button.	Main screen appears.	Main screen _____.	
All acceptance criteria are successfully challenged.				
Test Program 18 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.16. Test Program 19: Verification of Default Search/Report and Electronic Signature

9.16.1. Objective

The objective of this test program is to verify the operational functionality of the OBSERVA® software by verifying a Default Search along with its electronically signed report and one additional electronically signed Default Report that comes pre-configured with the software. The searches and reports will be generated in order to verify that the activities performed in sections 9.3 (step 23), 9.14.6 and 9.14.7 along with the data acquired from these activities are accurately captured.

Note: Due to the extensive number of default searches and reports, only commonly used search and reports are verified in this section.

9.16.2. Acceptance Criteria

9.16.2.1. The BacT/ALERT® 3D Signature system must capture descriptive data for the sample including analyst, analysis date/time, and sample number.

9.16.2.2. The OBSERVA® software must provide functionality to print reports.

9.16.2.3. The system must be able to generate accurate and complete copies of records in both human readable and electronic from suitable for copying by government agencies.

9.16.2.4. The OBSERVA® software will facilitate results review and approval through electronic signatures.

9.16.3. Equipment

9.16.3.1. BacT/ALERT® 3D System

9.16.3.2. OBSERVA® workstation

9.16.4. Test Setup

9.16.4.1. Prior to beginning this section, you must log on to OBSERVA® with privileges that are Editing No Delete or higher. Also, configure Electronic Signatures with "Review/Sign and Approve/Sign" within the software.

9.16.5. Test Procedure/Results/Data

Complete the table below as indicated.

Table 9-27:TP 19: Verification of Default Search/Report and Electronic Signature

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
Search for Bottle by Bottle ID				
1	Click on the Searches option on the Menu bar.	A drop-down list of search options is displayed.	A drop-down list of search options _____ displayed.	
2	Click on Search for Bottle by Bottle ID.	The Run Search window appears.	The Run Search window _____.	
3	Enter Bottle ID for Bottle #1 documented in section 9.14.6, Table 9-20, (choose Source if necessary) and click the OK button.	Data Management screen appears. Bottle ID for Bottle #1 appears on a tree node.	Data Management screen appears. Bottle ID for Bottle #1 _____ on a tree node.	
4	Click on the Run Report button to product an Accession Report.	Select Report to Run window appears.	Select Report to Run window _____.	
5	At the Report Field, press the ▼ button to choose the Accession Report.	"Accession Report" appears in Report field.	"Accession Report" _____ in Report field.	
6	Click on the Review and Sign button.	The Enter Electronic Signature dialog box appears.	The Enter Electronic Signature dialog box _____.	
7	Enter the User Name and Password of the user with 'Editing' access level as noted in Table 9-5 in section 9.5. Click the OK button. Refer to step 48, section 9.4 for Global Heading (enter Global Heading if applicable to display on report).	"Report is Being Generated, please wait" message appears (if applicable). Verify the following from the Accession Report: Global Heading: Reviewed by: Approved by: Org. ID or Patient ID Alt. Org. ID or Patient ID Source Date Collected/Time Accession Number Note: This default clinical accession report will consist of other general information and field names may be different based on usage.	Accession Report _____ the following information: Global Heading: Reviewed by: Approved by: Org./Pat. ID Alt. Org./Pat. ID Source Date Collected/Time Accession Number	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-27:TP 19: Verification of Default Search/Report and Electronic Signature

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
8	Click the Sign button.	An electronic signature is applied and the Data Management screen displays.	An electronic signature ____ applied and the Data Management screen displays.	
9	Click on the Status tab on the Main screen.	"1 Report to Approve and Sign" appears in red type in the 'Approve and Sign' pane of the Status screen.	"1 Report to Approve and Sign" _____ in red type in the 'Approve and Sign' pane of the Status screen.	
10	Click on the Approve and Sign button	The Enter Electronic Signature dialog box appears.	The Enter Electronic Signature dialog box _____.	
11	Enter the User Name and Password of the user with 'Administrator' access. Click the OK button.	The Select Reports to Approve dialog box appears.	The Select Reports to Approve dialog box _____.	
12	Click to highlight the Accession Report field.	Field turns 'blue'. User Name of user with Editing access appears in "Reviewed By" cell. "Date/Time Archived" = current date and current time (+/- 15 minutes)	Field _____ 'blue'. User Name of user with Editing access appears in "Reviewed By" cell. "Date/Time Archived" = current date and current time (+/- 15 minutes)	
13	Click the OK button.	The Accession Report appears. Reviewed by: User Name of user with Editing access, current date, current time +/-15 minutes. Data are the same as listed in step 7 above.	The Accession Report _____. Data fields are as indicated.	
14	Click the Sign and Print button.	The Accession Report prints.	The Accession Report _____. **Attachment #_____** **Page___ of _____**	
15	Click the Status tab on the Main screen.	"0 Reports to Approve and Sign" appears in black type in the 'Approve and Sign' pane of the Status screen, and the Approve and Sign button is disabled (gray).	"0 Reports to Approve and Sign" appears in black type in the 'Approve and Sign' pane of the Status screen, and the Approve and Sign button ____ disabled (gray).	
Logged Temperature Report				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-27:TP 19: Verification of Default Search/Report and Electronic Signature

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
16	Click the Reports option on the Menu bar.	A drop-down list of report options is displayed.	A drop-down list of report options _____ displayed.	
17	Click Report Logged Temperatures	The Run Search dialog box appears.	The Run Search dialog box _____.	
18	Click the ▼at the "Occurred is after…" cell.	Calendar for current month appears.	Calendar for current month _____.	
19	Click date when OQ temperatures were recorded.	Date when OQ temperatures were recorded appears in uppermost cell.	Date when OQ temperatures were recorded _____ in uppermost cell.	
20	Click the ▼at the "Occurred is before…" cell.	Calendar for current month appears.	Calendar for current month _____.	
21	Click today's date.	Today's date appears in bottom cell.	Today's date _____ in bottom cell.	
22	Click the OK button.	The Temperature Report prints.	The Temperature Report _____. **Attachment #_____** **Page___ of _____**	
23	Compare data on report to that entered in section 9.3 step 23.	Report Title = Temperature Report Incubation Module: 1 Occurred: Current date, time: same as listed in 9.3 step 23 Temperature: same as listed in 9.3 step 23 User: same as listed in section 9.3.	Report Title: _____ Incubation Module: _____ Occurred: _____ Temperature: _____ User: _____	
All acceptance criteria are successfully challenged.				
Test Program 19 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.17. Test Program 20: Archived Report Verification

9.17.1. Objective

The objective of this test program is to verify that an archived report cannot be edited by executing the procedures in the test script below.

9.17.2. Acceptance Criteria

9.17.2.1. The OBSERVA® software must be able to archive the data produced by the BacT/ALERT® 3D system.

9.17.2.2. Entries in the archived report may not be deleted or modified.

9.17.3. Test Procedure/Results/Data

Note: You may have two Archived Reports folders. If so, refer to the folder without a space between the words 'Archived' and 'Reports'.

Complete the table below as indicated.

Table 9-28:TP 20: Archived Report verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Access the following directory: D:\ProgramFiles\bioMérieux\OBSER VAII\ArchivedReports	Directory with reports listed appears.	Directory with reports listed _____.	
2	Open the Accession Reports directory.	Directory with Accession reports appears.	Directory with Accession reports _____.	
3	Open an Accession Report folder and attempt to edit the selected file.	The selected file opens. File cannot be edited. **Take a screenshot.**	File selected _____ be edited. **Attachment #_____** **Page___ of _____**	
All acceptance criteria are successfully challenged.				
Test Program 20 is complete.				

9.18. Test Program 21: BacT/ALERT® 3D and OBSERVA® Audit Trail Verification

9.18.1. Objective

The objective of this test program is to verify that the Audit Trail from the BacT/ALERT® 3D and the OBSERVA® software accurately represents the activities indicated in the table below.

9.18.2. Acceptance Criteria

9.18.2.1. The OBSERVA® software provides an audit trail of all user operations.

9.18.2.2. The BacT/ALERT® 3D Signature firmware provides an audit trail of all user operations.

9.18.2.3. The audit trail can be viewed and printed using the OBSERVA® software.

9.18.2.4. The System log can be viewed and printed with appropriate access level using the OBSERVA software.

9.18.2.5. The BacT and OBSERVA audit trail cannot be altered or deleted.

9.18.3. Equipment

9.18.3.1. BacT/ALERT® 3D System

9.18.3.2. OBSERVA® workstation

9.18.4. Test Procedure/Results/Data

Complete the table below as indicated. Note, the control module is part of the Combination Module.

Table 9-29:TP 21: BacT/ALERT® 3D and OBSERVA® Audit Trail Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
BacT/ALERT® 3D Audit Trail				
1	Log on to the instrument using your valid ID and password. Access the BacT/ALERT® 3D Controller Module Setup screen.	Setup screen appears and padlock icon is closed.	Setup screen _____ and padlock icon is closed.	
2	Enter a valid password and press the key symbol button.	Padlock icon changes to open position and function buttons become enabled.	Padlock icon _____ to open position and function buttons become enabled.	
3	Press Ctrl + D on the keyboard.	The software test screen appears (2.18).	The software test screen _____.	
4	Press the 7 key on the keyboard. Attempt to alter and/or delete the BacT/ALERT 3D audit trail.	Audit trail appears and cannot be altered or deleted. **Take a screen shot.**	Audit trail appears and _____ be altered or deleted. **Attachment #_____** **Page___ of _____**	
5	Verify that the valid user is (step 1) logged in.	"'X' (User ID) Login" with expected date and time appears.	"'X' (User ID) Login" with expected date and time _____.	
6	Verify the instrument temperature had been set.	"Temp Set Mod 'x'…" appears.	"Temp Set Mod 'x'…" _____.	
7	Verify cells had been calibrated.	"Cell Cal Loc 'xxxx' …" with expected date and time appears.	"Cell Cal Loc 'xxxx' …" with expected date and time _____.	
8	Press the Left Arrow button.	The Setup Screen appears	The Setup Screen _____.	
9	Press the Left Arrow button.	The Main Screen appears.	The Main Screen _____.	
10	Press the Log Out Button.	The Main Screen, with the Log In icon appears.	The Main Screen, with the Log In icon _____.	
OBSERVA® Audit Trail				
11	Log on to OBSERVA® using an Administrator User Name and password.	The System Status screen in Logged-on state appears.	The System Status screen in Logged-on state _____.	
12	Go to the System Log and click on the ▼to choose "Search for User Activity by Date". Click the Show Search button.	Four lines of search criteria appear.	Four lines of search criteria _____.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-29:TP 21: BacT/ALERT® 3D and OBSERVA® Audit Trail Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
13	Use the ▲and ▼at the cells to enter the following data: Display = System Log Event Sorted by = Occurred Date/Time In = Ascending (order) User is equal to = User #1 or User #2 in section 9.2 AND Occurred – Date Only is after or equal to = date section 9.2 verified AND Occurred – Date Only is before or equal to = Today's date. Press the Run button. Attempt to alter and/or delete the OBSERVA audit trail.	Screen appears with Occurred date matching that entered, Type = System, Description = Logged on User: xxx (same as User #1 or User #2 from section 9.2), Severity = None, Comment cell is blank, Summary = USER: (same as User #1 or User #2 from section 9.2). The audit trail cannot be altered or deleted. **Take a screen shot.**	Screen _____ with data matching as indicated. The audit trail _____ be altered or deleted. **Attachment #_____** **Page___ of _____**	
All acceptance criteria are successfully challenged.				
Test Program 21 is complete.				

ATTENTION: COMPLETE STEPS 12-18 OF SECTION 9.12 NOW.

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.19. Test Program 22: BacT/ALERT® 3D Backup Verification

9.19.1. Objective

The objective of this test program is to verify the operational functionality of the backup function on the BacT/ALERT® 3D using a USB back-up media.

9.19.2. Acceptance Criteria

9.19.2.1. Data shall be saved to an electronic back-up media and then downloaded to a company networked workstation to transmit data onto the network for archival (if applicable).

9.19.2.2. Back-up media will be downloaded to company workstation for data transmission to the network (if applicable).

9.19.2.3. Data will be transferred from the instrument to a back-up media for data storage and archival (if applicable).

9.19.3. Equipment

9.19.3.1. BacT/ALERT® 3D System

9.19.3.2. USB flash drive (bioMérieux)

9.19.4. Test Procedure/Results/Data

Complete the table below as indicated.

Table 9-30:TP 22: BacT/ALERT® 3D Backup Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Insert a USB flash drive into the BacT/ALERT® 3D USB port (near the scanner area).	USB flash drive is inserted into BacT/ALERT® 3D module.	USB flash drive is _____ into BacT/ALERT® 3D module.	
2	Access the Setup screen and enter a valid password. Press the Backup Management button.	The Backup Management screen (2.16) overlays and disables the Setup screen.	The Backup Management _____ and disables the Setup screen.	
3	Press the Manual Backup button.	Manual backup is initiated.	Manual backup ____ initiated.	
4	Press the Previous Screen button to return to the main screen.	The Backup in Progress icon appears in the upper left corner of the Main Screen. **Take a screen shot.**	The Backup in Progress icon _____ in the upper left corner of the Main Screen **Attachment #_____** **Page___ of _____**	
5	When backup is complete, verify that the backup occurred by accessing the USB flash drive information and verifying the file is present. **Take a screen shot** of backup files from the USB flash drive.	The Backup In Progress icon no longer appears on the Backup Management and Main screens. USB flash drive contains the correct the backup files.	The Backup In Progress icon _____ longer appears on the Backup Management and Main screens. **Attachment #_____** **Page___ of _____**	
6 ☐ **N/A**	Log ON to a company networked workstation using a valid company account.	Logon is successful.	Logon is _____.	
7 ☐ **N/A**	Insert the backup media device into the workstation.	Workstation successfully reads the backup media device.	Workstation _____ reads the backup media device.	
8 ☐ **N/A**	From the **Start** menu on the desktop select **My Computer** and navigate to the media drive and then double click. Capture and **attach a screen shot** of the files.	Backup files are located on media drive.	Backup files_____ located on media drive. **Attachment #_____** **Page___ of _____**	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-30:TP 22: BacT/ALERT® 3D Backup Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
9 ☐ **N/A**	Cut the backup files from the current folder and navigate to network path. Paste the backup files into the network folder on the networked drive. Capture and **attach a screen shot** of the backup files on the networked drive.	Backup files are saved to the networked drive.	Backup files _____ saved to the networked drive. **Attachment #_____** **Page___ of _____** Network Path: _____ _____.	
All acceptance criteria are successfully challenged.				
Test Program 22 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.20. Test Program 23: OBSERVA® Backup Verification

9.20.1. Objective

The objective of this test program is to conduct the procedure(s) identified in the table below to verify that the backup function using a DVD media disc for the OBSERVA® data management software.

9.20.2. Acceptance Criteria

9.20.2.1. The OBSERVA® software is installed on a workstation regulating user access to the system.

9.20.2.2. Data shall be saved to an electronic back-up media and then downloaded to a networked company workstation to transmit data onto the network for archival (if applicable).

9.20.2.3. Back-up media will be downloaded to company workstation for data transmission to the network (if applicable).

9.20.2.4. Data will be transferred from the instrument to a back-up media for data storage and archival (if applicable).

9.20.3. Equipment

9.20.3.1. OBSERVA® workstation

9.20.3.2. DVD+R or DVD+RW (if applicable)

9.20.3.3. Company networked workstation (if applicable)

9.20.4. Test Setup

Note: If the computer uses a USB flash drive, a DVD+R disc will be required for the backup process. The USB must be properly installed and functional prior to performing this test script.

9.20.5. Test Procedure/Results/Data

Complete the tables below as indicated.

Table 9-31: TP 23: OBSERVA® Backup Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Log ON to the OBSERVA® workstation using a valid account.	Successful login occurs.	Successful login _____.	
2	Open the OBSERVA® software.	The OBSERVA® software window opens successfully.	The OBSERVA® software window opens _____.	
3	Enter a valid administrator login ID and password.	Admin logon is successful.	Admin logon is _____.	
4	From the Main menu, click **System→ Backup Database**	The Backup process begins.	The Backup process _____.	
5	Verify the Backup process is complete.	OBSERVA software message appears "Backup completed on <date><time>.	OBSERVA software message _____ "Backup completed on <date><time>.	
6	Minimize OBSERVA to display Windows desktop. Insert a blank DVD disc in the DVD drive and double click the **Burn Backup** icon located on the desktop.	The Burn backup dialog is displayed while the files from the USB drive are copied to the DVD disc.	The Burn backup dialog is _____ while the files from the USB drive are copied to the DVD disc.	
7	Verify the Backup is burned on the DVD.	A dialog box appears indicating the backup was successful.	A dialog box _____ indicating the backup was successful.	
8	Click **OK** on OBSERVA® dialog box.	Burn Backup successful dialog box disappears.	Burn Backup successful dialog box _____.	
9	Obtain the backup media device and label accordingly.	Backup media obtained and labeled.	Backup media obtained and _____.	
10 ☐ **N/A**	Log ON to a company networked workstation using a valid company account.	Logon is successful.	Logon is _____.	
11 ☐ **N/A**	Insert the backup DVD disc into the DVD drive.	Workstation successfully reads the backup DVD disc.	Workstation _____ reads the backup DVD disc.	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-31: TP 23: OBSERVA® Backup Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
12 ☐ **N/A**	From the **Start** menu on the desktop select **My Computer** and navigate to the media drive and then double click. Capture and **attach a screenshot** of the files.	Backup files are located on media drive.	Backup files_____ located on media drive. **Attachment #_____** **Page___ of _____**	
13 ☐ **N/A**	Cut the backup files from the current folder and navigate to network path. Paste the backup files into the network folder on the networked drive. Capture and **attach a screenshot** of the backup files on the networked drive.	Backup files are saved to the networked drive.	Backup files _____ saved to the networked drive. **Attachment #_____** **Page___ of _____** Network Path:_____ _____ _____	
All acceptance criteria are successfully challenged.				
Test Program 23 is complete.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

9.21. Test Program 24: Temperature Distribution Verification

9.21.1. Objective

The objective of this test script is to verify the temperature distribution present within each incubator module on the BacT/ALERT® 3D for a minimum of 4 hours. The mean of the average values obtained from the DataTrace probes (2 for the Combination Module and 9 for the Incubation Module) will be used to determine the overall temperature distribution.

9.21.2. Acceptance Criteria

9.21.2.1. The BacT/ALERT® 3D Signature system must have an empty chamber temperature distribution mapped at the target set points (32.5°C ± 1°C for HTIM and 22.5°C ± 1°C for LTIM, when applicable) .

9.21.2.2. The BacT/ALERT® 3D system must contain incubator(s) to provide a controlled environment for samples being monitored for microbial growth.

9.21.3. Equipment

9.21.3.1. Computer Workstation with DataTrace Pro Software

9.21.3.2. Micropack III DataLoggers

9.21.3.3. PC Interface Module

9.21.3.4. Empty BacT/ALERT® media bottles

9.21.3.5. Lab Tape

9.21.3.6. Silicone (if applicable)

9.21.4. Supplemental Information/Test Rationale

9.21.4.1. Ensure that all data loggers used within the test procedure have been calibrated over the temperature range of testing.

9.21.4.2. Temperature mapping will be conducted on an empty incubator module as it has been determined to be the worst case scenario for temperature fluctuations.

9.21.5. Test Setup

9.21.5.1. Fill 8 empty BacT/ALERT® 3D bottles with deionized (DI) water per incubator and/or 4 for the Combination Module. Seal each bottle with a rubber stopper then seal and crimp each bottle tightly shut (if applicable).

9.21.5.2. Poke a small hole in the center of the rubber stopper for the insertion of the DataTrace probe (if applicable).

9.21.5.3. Program the DataTrace probes for each incubator according to SOP 017, Operation of the DataTrace System.

9.21.5.4. Place a DataTrace probe into each of the BacT/ALERT® 3D bottles filled with DI water (8 per incubator and/or 4 for the Combination Module). To ensure the top cylinder portion of the DataTrace probe does not come in contact with the incubation module during rocking (if applicable) tape down the DataTrace probes as tight as possible to the rubber stopper with lab tape. Silicone can also be used to securely join the DataTrace probe to the BacT/ALERT® 3D bottles.

9.21.5.5. Complete data collection Table 9-32 below.

9.21.5.6. Record “Pass” if the Actual Results match the Expected Results for the line item. Record “Fail” in the table if the Actual Results do not match the Expected Results for the line item.

9.21.5.7. Record any additional information or clarifications in the Comments section provided.

9.21.5.8. Reference any attachments in the Comments section.

9.21.6. Test Procedure/Results/Data

Complete the table(s) below as indicated.

Table 9-32: TP 24: Temperature Distribution Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
1	Ensure that each incubator module is set to 32.5°C for HTIM and 22.5°C for LTIM (when applicable).	Each incubator module is set to 32.5°C for HTIM and 22.5°C for LTIM (when applicable).	Each incubator module is _____ to 32.5°C for HTIM and 22.5°C LTIM (when applicable).	
2	Place the BacT/ALERT® 3D bottles with a DataTrace probe into sample bottle positions #12 and # 49 of each drawer for a total of 8 per incubation module and/or 4 for the Combination Module.	BacT/ALERT® 3D water bottles with a DataTrace probe are placed into the sample drawer positions # 12 and # 49.	BacT/ALERT® 3D water bottles with a DataTrace probe are _____ into the sample drawer positions # 12 and # 49.	
3 ☐ N/A	Place the remaining DataTrace probes that are not within a bottle into the port directly at the center of each incubator module between the 4 (not applicable for Combination Module) drawers. Place a tape over the probes to secure in place.	The remaining DataTrace probes are placed into position (not applicable for Combination Module).	The remaining DataTrace probes are _____ into position (not applicable for Combination Module).	
4	Allow the probes to equilibrate for a **minimum of 4 hours** prior to beginning data collection.	A **minimum of 4 hours** is allowed for equilibration of the BacT/ALERT® bottles and DataTrace probes.	A **minimum of 4 hours** is _____ for equilibration of the BacT/ALERT® bottles and DataTrace probes. Time in: _____ Time of data collection: _____	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-32: TP 24: Temperature Distribution Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
5	Following equilibration, collect raw data values for a **minimum of 4 hours**.	A **minimum of 4 hours** is allowed for the collection of raw data temperature values.	A **minimum of 4 hours** is _____ for the collection of raw data temperature values. Data Collection Start Time: _____ Data Collection End Time: _____	
6	Download the DataTrace probes raw data values and calculate the maximum, minimum and average for each temperature probe location.	The average values obtained for each probe position is within 32.5°C ± 1°C for HTIM and 22.5°C ± 1°C for LTIM (when applicable). The maximum value of each probe is less than 33.54 °C for HTIM. The minimum value of each probe is greater than 31.45 °C for HTIM The maximum value of each probe is less than 23.54 °C for LTIM. The minimum value of each probe is greater than 21.45 °C for LTIM	The average values obtained for each probe position is _____ 32.5°C ± 1°C for HTIM and 22.5°C ± 1°C for LTIM (when applicable). The maximum value of each probe is _____ 33.54 °C for HTIM. The minimum value of each probe is _____ 31.45 °C for HTIM. The maximum value of each probe is _____ 23.54 °C for LTIM. ☐ **N/A** The minimum value of each probe is _____ 21.45 °C for LTIM. ☐ **N/A**	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 9-32: TP 24: Temperature Distribution Verification

Step	Test Procedure	Expected Result	Actual Result	Pass/Fail
7	Calculate the mean of the average of the 9 probes for each incubation module and/or 4 for the Combination Module.	The mean of the average of the 9 probes and/or 4 for the Combination Module is obtained.	Incubation Module _____ Mean: _____ °C ☐ **N/A** Incubation Module _____ Mean: _____ °C ☐ **N/A** Incubation Module _____ Mean: _____ °C ☐ **N/A** Incubation Module _____ Mean: _____ °C	
8	Record the Highest and Lowest temperature per incubation module.	The Highest and Lowest temperature per incubation module is obtained.	Incubation Module _____ Min: _____ °C Max: _____ °C ☐ **N/A** Incubation Module _____ Min: _____ °C Max: _____ °C ☐ **N/A** Incubation Module _____ Min: _____ °C Max: _____ °C ☐ **N/A** Incubation Module _____ Min: _____ °C Max: _____ °C	
All acceptance criteria are successfully challenged.				
Test Program 24 is complete.				
Comments: Reference Attachment(s) _____ for Test Program 24 raw data and results.				

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

10. Performance Qualification

10.1. Test Program 25: Performance Qualification (PQ)

10.1.1. Objective

The objective of this test program is to verify and document that the BacT/ALERT® 3D system can reliably and consistently detect low levels of microorganisms using the BacT/ALERT culture bottles. This test script will test the instrument's performance for detection of microorganisms using sample(s) of product(s) seeded with microorganisms along with a negative control per bottle type. The execution of this performance qualification will validate the instrument and the bottles types for its intended use.

10.1.2. Acceptance Criteria

10.1.2.1. The BacT/ALERT® 3D system must detect microbial growth at or below 100 CFU within 7 days or less.

10.1.2.2. The BacT/ALERT® 3D system must be able to incubate sample(s) at the specified target temperature(s).

10.1.2.3. Each challenged sample must be positive and the negative controls (unchallenged product) must be negative.

10.1.3. Validation Strategy

The test procedure for growth performance will be validated in order to ensure the growth promoting and detecting capabilities in the SA (aerobic testing) and SN (anaerobic testing) BacT/ALERT® culture bottles. To demonstrate this, the challenge organisms listed in Table 10-1 will be used. Each organism will be inoculated into its respective BacT/ALERT® culture bottles per Table 10-2. The BacT/ALERT bottles will be inoculated with each organism as listed in Table 10-2 per the test procedure outlined in the test program. The bottles will then be loaded into the BacT/ALERT® 3D incubator and left in the instrument until the test results for the inoculated bottles are complete. Plate counts verification for the BioBalls microorganism suspensions will be performed to confirm inoculum concentration of not more than 100 CFU.

Acceptable results from this test program will confirm the ability to detect the microbial growth using BacT/ALERT® SA and SN culture bottles.

All inoculated bottles must have growth detected by the instrument within the incubation time recommended by the product's Instructions for Use (IFU). Meeting the IFU guidance indicates that the method is able to detect growth within the intended use parameters of the BacT/ALERT® culture bottles, the bottles are incubated for "five to seven days, or until designated positive". For the purpose of this validation protocol, growth must be detected within 7 days of less since it represents a more stringent challenge of the culture bottles.

10.1.4. Materials/Equipment

10.1.4.1. SA BacT/ALERT® Culture Bottles- aerobic (bioMérieux Product # 259789)

10.1.4.2. SN BacT/ALERT® Culture Bottles-anaerobic (bioMérieux Product # 259790)

10.1.4.3. BacT/ALERT® 3D Microbial Detection System

10.1.4.4. BioBall® MultiShot 550 Aspergillus brasiliensis (bioMérieux Product # 412540 or equivalent; NCPF 2275)

10.1.4.5. BioBall® MultiShot 550 Bacillus subtilis (bioMérieux Product # 412540 or equivalent; NCTC 10400)

10.1.4.6. BioBall® MultiShot 550 Pseudomonas aeruginosa (bioMérieux Product # 412540 or equivalent; NCTC 12924)

10.1.4.7. BioBall® MultiShot 550 Staphylococcus aureus (bioMérieux Product # 412540 or equivalent; NCTC 10788)

10.1.4.8. BioBall® MultiShot 550 Candida albicans (bioMérieux Product # 412540 or equivalent; NCPF 3179)

10.1.4.9. BioBall® MultiShot 550 Clostridium sporogenes (bioMérieux Product # 56004 or equivalent; NCTC 12935)

10.1.4.10. BioBall® Rehydration fluid (bioMérieux Product # 56021)

10.1.4.11. Tryptic Soy Agar with 5% Sheep's Blood Media Plates or equivalent

10.1.4.12. Sterile sleeves and gloves

10.1.4.13. 27G Sterile syringe needles

10.1.4.14. 1-3mL sterile syringe

10.1.4.15. Vortexer

10.1.4.16. Calibrated Pipettes (if necessary) and tips

10.1.4.17. Calibrated 30-35°C Incubator

10.1.4.18. Calibrated Timer

10.1.4.19. Anaerobic System (packs/containers to incubate media plates)

10.1.4.20. 70% Isopropyl Alcohol Spray or equivalent

10.1.4.21. BTA Bottle Rack

10.1.4.22. Alcohol pads

10.1.4.23. Personal Protective Equipment (when necessary)

10.1.4.24. Appropriate biohazard waste containers for materials potentially contaminated with infectious agents.

10.1.5. Test Setup

Note: Sample(s) must be collected aseptically, and maintained under sterile conditions prior to testing.

10.1.6. Challenge Microorganisms:

The following challenge microorganisms are chosen to verify the performance qualification using the SA and SN BacT/ALERT® culture bottles.

Table 10-1: Challenged Microorganisms

Bottle Type	Challenged Microorganism	Source	BioBall® Multishot-550 Product # or equivalent
SA	*Bacillus subtilis*	NCTC 10400	412540 (Mixed Kit)
	Staphylococcus aureus	NCTC 10788	412540 (Mixed Kit)
	Pseudomonas aeruginosa	NCTC 12924	412540 (Mixed Kit)
	Aspergillus brasiliensis	NCPF 2275	412540 (Mixed Kit)
	Candida albicans	NCPF 3179	412540 (Mixed Kit)
SN	*Bacillus subtilis*	NCTC 10400	412540 (Mixed Kit)
	Clostridium sporogenes	NCTC 12935	56004

10.1.7. Supplemental Information

NCPF (National Collection of Pathogenic Fungi)

NCTC (National Collection of Type Cultures)

Copies of Table 10-4, 10-5, 10-6 and 10-7 can be made as needed to document results.

10.1.8. Test Procedure

10.1.8.1. General Guidelines:

A. Aseptic technique is critical throughout this procedure and shall be used throughout testing.

B. Analyst must wear required PPE during the procedure as well as sterile sleeve covers and second pair of sterile gloves during the testing procedure.

C. Record all necessary procedural material and result information on the corresponding tables (10-4, 10-5, 10-6 and 10-7).

D. Verify the BacT/ALERT® 3D instrument preventive maintenance due date by checking the preventive maintenance sticker. Do not use the instrument if it is past the preventive maintenance due date and notify area management.

E. All procedural materials and equipment must be sanitized with 70% IPA (or equivalent) before placement into the BSC.

F. Sequence representative will be executing the testing described in this protocol.

G. Only one (1) BacT/ALERT® 3D system will be utilized during testing.

H. Label all bottles accordingly prior to incubation.

10.1.9. Sample Preparation:

10.1.9.1. Refer to Table 10-1 for organism utilized in this validation procedure. Each organism will be prepared using BioBalls.

10.1.9.2. BioBall® Multi-Shot 550 Preparation:

A. Obtain the appropriate BioBall® based on the BacT/ALERT® culture bottles to be tested.

B. Tip the BioBall® into the Rehydration Fluid (**1.1 mL**), replace the cap and wait for **30 seconds**.

C. Vortex for **5 seconds**. BioBall® suspension (**0.1 mL contains ~50 CFU**) is ready for inoculation.

10.1.9.3. Bottle Preparation

A. Each challenged microorganism will be tested individually according to Table 10-2 using the two (2) BacT/ALERT bottle types.

B. Negative control bottles will be tested per Table 10-3.

10.1.9.4. Bottle Testing

A. Inoculate 2 (two) BacT/ALERT® bottle with 100 µL (~50 CFU) of the challenged microorganism BioBall® suspension as specified in Table 10-2 using a proper needle gauge and aseptic techniques. Invert the inoculated bottles to mix. Label the bottles accordingly.

B. Negative Control: Obtain one (1) BacT/ALERT® bottles for each bottle type. Label the bottles accordingly. Do NOT inoculate the negative control with organism.

C. Load the bottles into the BacT/ALERT® 3D system as soon as possible following inoculation to optimize detection times. Refer to user manual for loading and unloading bottles into the BacT/ALERT® 3D system and/or site SOPs.

D. The inoculated bottles should remain in the instrument until they become positive within seven (7) days or less.

E. The negative control bottles should remain in the instrument until seven (7) days or after the last positive bottle is off-tested.

10.1.9.5. Plate Counts

A. Obtain the BioBall microorganism suspensions used during bottle inoculation. Each microorganism will be plated in duplicates for plate counts.

B. Draw **100 µL** aliquot and pipette onto the media plate (Tryptic Soy Agar with 5% Sheep's Blood). Spread and incubate at 30-35°C for 2 to 3 days. Prepare the second media plate in the same manner. For anaerobic organism(s), incubate media plates in an anaerobic system.

C. After incubation, count the colonies and record the results in Table 10-6.

10.1.10. Assay Validity Criteria

10.1.10.1. In the event any assay validity criteria are not met, initiate a deviation report.

A. The BacT/ALERT® 3D system must detect microbial growth at or below 100 CFU.

B. Each of the negative controls (unchallenged product) must be negative.

C. The quantitation plates must contain pure culture.

Table 10-2: Inoculation and Incubation Parameters

Bottle Type	Challenge Microorganism	Microorganism		Needle Gauge	BacT/ALERT® Incubation Temperature
		Final Conc.	Inoc. Vol.		
SA	*Bacillus subtilis*	~50 CFU	100 µL	27G	32.5 ± 1°C
	Staphylococcus aureus				
	Pseudomonas aeruginosa				
	Aspergillus brasiliensis				
	Candida albicans				
SN	*Bacillus subtilis*				
	Clostridium sporogenes				

Table 10-3: Negative Control Incubation Parameters

BacT/ALERT® Bottle Type	BacT/ALERT® Incubation Temperature
SA- one uninoculated bottle	32.5 ± 1°C (HTIM)
SN- one uninoculated bottle	

Table 10-4: Performance Qualification Results

Bottle Type:			Lot No.:			BacT/ALERT® System ID:		
	No.	Bottle Barcode (Place label here)	Challenge Microorganism	Organism Volume Inoculated into BacT bottles (µL)	Time to Detection (Days)	BacT/ALERT® Incubation Temperature	Bottle Results	Pass/Fail
Challenged Product	1					☐ 32.5 ± 1°C	☐ Positive ☐ Negative	
	2					☐ 32.5 ± 1°C	☐ Positive ☐ Negative	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 10-5: Negative Control Results

BacT/ALERT® System ID:							
	No.	**Bottle Barcode ID**	**Bottle Type and Lot Number**	**Time to Detection (Days)**	**BacT/ALERT® Incubation Temperature**	**Bottle Results**	**Pass/Fail**
Negative Control	1				☐ 32.5 ± 1°C	☐ Positive ☐ Negative	
	2				☐ 32.5 ± 1°C	☐ Positive ☐ Negative	

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 10-6: Plate Counts

Organisms	Media Plate[1,2] #	Colony Count per Plate (CFU)	Average (CFU)	Incubation Info.
Bacillus subtilis	1			
	2			
Staphylococcus aureus	1			
	2			
Pseudomonas aeruginosa	1			
	2			
Aspergillus brasiliensis	1			
	2			
Candida albicans	1			
	2			
Clostridium sporogenes	1			
	2			
	2			

Incubation Start Date: _____
Incubation End Date:_____

Comments: ☐ **N/A**

[1] *Growth Medium: Tryptic Soy Agar with 5% Sheep's Blood or equivalent*
[2] *Incubation Conditions: 30-35°C for 2 to 3 days, anaerobic conditions where applicable.*

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

Table 10-7: Materials Log

Reagent/Equipment	Manufacturer	Lot Number	Expiration Date	Comments

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

11. References

Table 11-1: References

Identifier	Title/Description
VAL-00123	Validation Plan for the bioMérieux BacT/ALERT® 3D Signature System
REQ-00010	User Requirement Specification for the bioMérieux BacT/ALERT® 3D Signature System
24340 (05/2010)	OBSERVA User Manual for Software Version 4.01[1]
21 CFR Part 11	Electronic Records; Electronic Signatures code of federal regulations for food and drug
GAMP 5 Guide	A Risk-Based Approach to Compliant GxP Computerized Systems

[1] *OBSERVA version 4.03 references software user manual version 4.01.*

12. Signature Log

All personnel who participate in the execution of this protocol must write their signature, print their name and print their initials in the form below.

Note: Non-Client Site personnel must also document their company name next to their printed name.

Table 12-1: Signature Log

Printed Name	Signature	Initials

Comments: ☐ N/A

Reviewed By: _____ Date: _____

13. Deviation Log

List all deviations generated during the execution of this protocol per applicable procedure. Copy this form as necessary to accommodate all deviations generated during execution. If necessary, refer to **SOP-009**, *Documenting Validation Deviations.*

Note: Complete this section to track the number of pages utilized for this log:

Deviation Log Page _____ of _____

Table 13-1: Deviation Log

Deviation Number	Test Section and Step Number	Recorded By	Date Recorded

Comments: ☐ N/A

Reviewed By: _____ Date: _____

14. Attachments

List all attachments collected during the execution of this protocol. Copy this form as necessary to accommodate all attachments generated during execution. Number the attachment pages upon completion of protocol execution and attach to the protocol.

Page _____ of _____

Table 14-1: Attachments

Attachment Number	Description	Section Number and Page Number

Comments: ☐ N/A

Entered By: _____ Date: _____

Reviewed By: _____ Date: _____

REVISION HISTORY

Version 01 Effective on 02-Nov-2016 by Mary Connor-Reynolds
Refer to the version history.

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Mary Connor-Reynolds	I am the author of this document. *Signed 3:23:22 PM UTC 02-Nov-2016*

Required Workflow Steps for this Category

Eric Borries *Sequence, Inc. / System Owner*	I have reviewed and approve this document. *Signed 3:31:35 PM UTC 02-Nov-2016*
Jill Schmitt *Sequence, Inc. / Validation/Quality Assurance*	I have reviewed and approve this document. *Signed 3:33:52 PM UTC 02-Nov-2016*