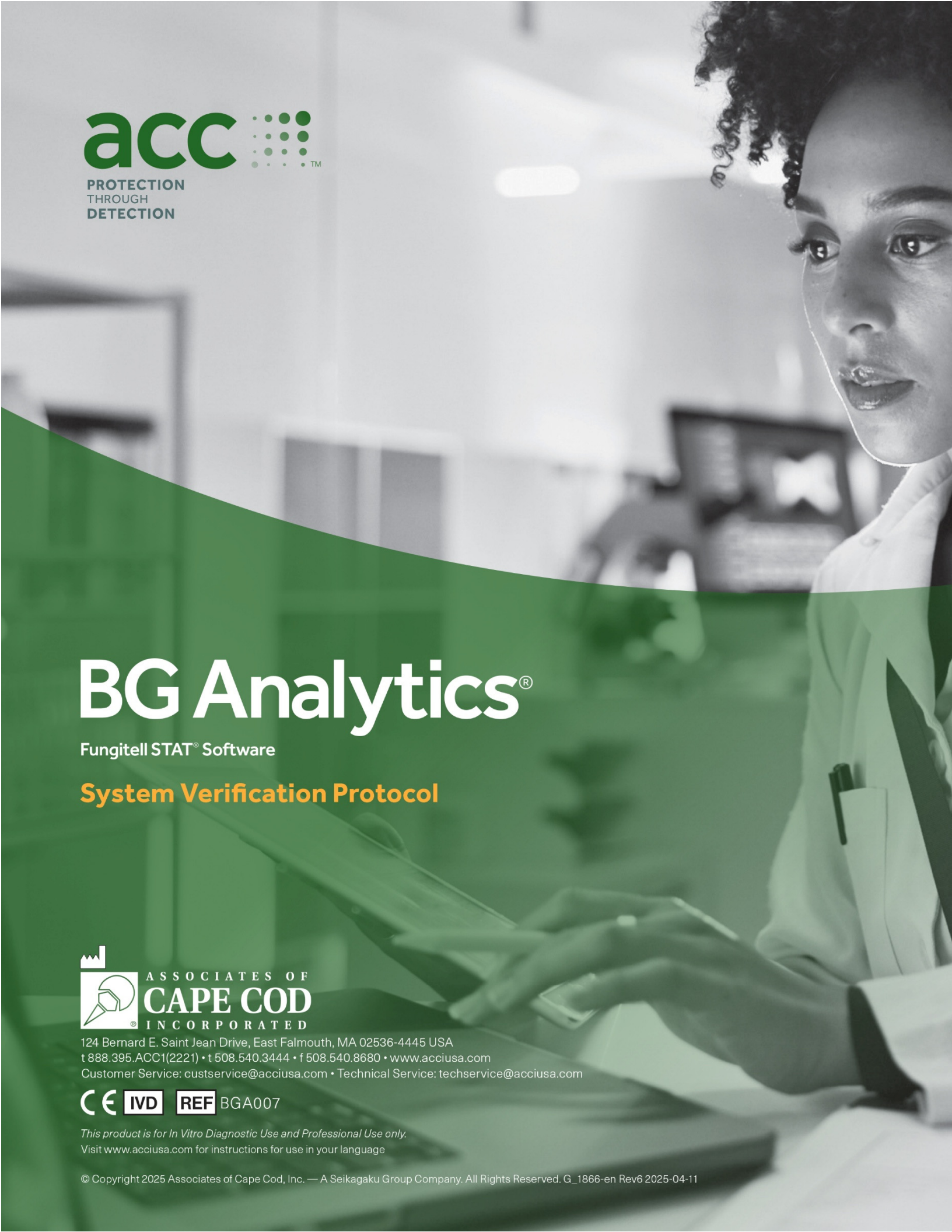

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BG Analytics®

Fungitell STAT® Software

System Verification Protocol

ASSOCIATES OF CAPE COD INCORPORATED
124 Bernard E. Saint Jean Drive, East Falmouth, MA 02536-4445 USA
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Customer Service: custservice@acciusa.com • Technical Service: techservice@acciusa.com

CE IVD REF BGA007

This product is for In Vitro Diagnostic Use and Professional Use only.
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G_1866 Rev6

Contents

1 Overview

1.1 Purpose

This System Verification Protocol is designed to confirm that the system (where the system consists of PKF08 Incubating Kinetic Tube Reader and BG Analytics® software installed on a host computer) performs its required functions accurately and reliably. Specifically, the individual Test Cases (also referred to as TC number) outlined in this System Verification Protocol are designed to demonstrate, document, evaluate and confirm that the system performs as intended.

The following product abbreviations are used throughout this Protocol:

- **The PKF08 instrument** (or **PKF08**) for PKF08 Incubating Kinetic Tube Reader
- **BGA** or **BG Analytics®** for BG Analytics® Software
- **Fungitell STAT®** for Fungitell STAT® (1,3)-B-D-Glucan Detection Assay

Translated versions of this System Verification Protocol are available for download at: www.fungitell.com.

2 System Verification Plan

2.1 Scope

The scope of the System Verification Protocol for PKF08 and BGA defines the process by which the PKF08 instrument and BG Analytics® software will be verified for their intended purpose. The Required Specifications specify the purpose and functions required of the instrument and software as defined in the user needs. This System Verification Protocol specifies that each Required Specification be tested per pre-defined Test Cases included in the Installation Qualification and Operational Qualification Sections. Each executed Test Case includes a formal record of Expected and Observed Results. The Final Verification Report provides an overview of the status of the executed Test Cases and formally documents whether the system conforms to the Required Specifications.

This System Verification Protocol is divided into the following sections:

Section 3 Installation Qualification of PKF08 instrument confirms that the PKF08 instrument is installed according to the manufacturer's specifications and the functional tests have been performed and documented with expected results.

- **Section 4 Installation Qualification of BG Analytics® Software** confirms that the software is installed according to the manufacturer's specifications and the functional tests have been performed and documented with expected results.
- **Section 5 Operational Qualification of PKF08 instrument and BG Analytics® Software** confirms that the system is operating within established limits and tolerances.
- **Section 6 Final Verification Report** provides an overview of applicable Test Cases and their results and the final decision on the status of the system.
- **Section 7 Attachments** is used to file the documentation of tester's training record, objective evidence, additional testing, Discrepancy Report, Problem Resolution Report, and Maintenance documentation.

Associates of Cape Cod, Inc. (ACC) aims to provide guidance, expertise and onsite assistance with the verification of the PKF08 instrument and BG Analytics® software. An Authorized Individual (representing the laboratory) shall identify whether the scope of this System Verification Protocol meets the local requirements, needs and expectations and may further modify this System Verification Plan. Section 2.4 Laboratory's System Verification Plan (Table 4) shall be used to formally document the plan specific for the laboratory where the system is to be permanently placed.

In an event of a discrepancy in Procedure, Expected Results or Observed Results within a certain Test Case, a Discrepancy Report shall be used to document the issue. The Discrepancy Report should include the following: reference to the Test Case, report number, description of the discrepancy, discrepancy investigation, description of resolution and category of resolution.

A failed Test Case may be re-executed following appropriate documentation of the failure on the Discrepancy Report. A pre-approved Problem Resolution Report should be used to document the procedure for re-execution of the Test Case. The Problem Resolution Report should include the following: reference to the Test Case, failure description, corrective actions, expected results and observed results.

Templates for Discrepancy Report, Problem Resolution Report, additional testing and maintenance are available electronically per request.

2.2 Description of the Components to Be Tested

There are three components that will be tested within the scope of this System Verification Protocol.

2.2.1 PKF08 instrument

The PKF08 instrument is an incubating absorbance tube reader equipped with eight (8) wells. Each well is individually read and timed, initiating data collection immediately upon insertion of a reaction tube. The PKF08 instrument is designed to equilibrate at and hold a temperature of 37°C ± 1°C during the 10-minute incubation step and during the assay runtime of 40 minutes. Digital Values are collected at two wavelengths: 405 nm (primary) and 495 nm (secondary) transmitted from the PKF08 instrument to a computer hosting BG Analytics® software. The PKF08 instrument is designed to accept tubes 12 mm in diameter. During incubation, 12x75 mm depyrogenated borosilicate glass may be used for sample preparation and pre-treatment. However, it is critical that the assay is performed in 12x65 mm flat-bottom tubes which are supplied as Fungitell STAT® Reagent.

Environmental requirements for operating PKF08 are described in Table 1. For more information, refer to PKF08 Incubating Kinetic Tube Reader User Manual which is provided as a hard copy with the PKF08 instrument (or is available for download at www.fungitell.com).

Table 1. Environmental Requirements for the PKF08 Instrument

Environmental Requirements for PKF08	Description
Laboratory Conditions	Level and stable surface, away from equipment that may cause excessive vibration or electronic noise Avoid direct sunlight
Ambient Temperature	15°C – 30°C
Ambient Humidity	< 70%
Input Power	100-240 VAC @ 50/60 Hz
Connection to a power outlet	Power conditioner recommended Uninterruptable Power Supply (UPS) (optional)

2.2.2 BG Analytics® Software

The digital values transmitted by PKF08 are received by BG Analytics® software and converted to Optical Density values (OD). Data reduction involves calculation of rate (slope) from the kinetic data set Delta OD (405 – 495 nm) by fitting a linear regression to the range between 1900 and 2400 seconds.

The BG Analytics® software writes the collected data into an unshared local SQLite database referred to as BG Analytics database. The database provides search capabilities based on several criteria. For more information, refer to BG Analytics® User Manual G_1867.

The BG Analytics® software should be installed on a compatible host computer meeting the minimal requirements as described in Table 2:

Table 2: The Minimum System Requirements for the Computer Hosting BG Analytics® Software

System Requirement for Host Computer	Description
Operating System	Microsoft® Windows® 10 x64, version 22H2 or newer Microsoft® Windows® 11 x64, version 22H2 or newer
Physical Memory	Minimum: 4 GB Recommended: 8 GB
Hard Disk Space	Minimum: 10 GB Recommended: 15 GB and more
Communication Ports	At least one free USB port (or two (2) when using barcode scanner)

Additional requirements:

- A Microsoft® Windows user account
  - BG Analytics® software is installed on the host computer with SQLite database installed locally per user account:
    - A shared laboratory Microsoft® Windows user account may be utilized.
    - If multiple Microsoft® Windows user accounts are to be used, BGA has to be individually installed for each one of them.
- Connection to a barcode scanner (optional)
  - BGA is designed to be compatible with any barcode scanner that is configured in USB HID Points of Sale scanner mode. For example, Honeywell healthcare corded barcode scanners (e.g. Honeywell PN 1950HHD, Honeywell 1950HSR). Refer to the barcode scanner's user manual for more information.
- Connection to a printer
- Anti-virus information
  - It is strongly recommended that an antivirus software with the most current update is installed and running on the computer hosting BG Analytics®. ACC recommends following local laboratory security policies.

2.2.3 Fungitell STAT® Assay

Within the BG Analytics® software, the slope of the sample is compared to the slope of the Standard yielding an Index value. Sample Index value is categorically interpreted as a Negative, Indeterminate, or Positive result according to the index value category ranges provided in Table 3. For further information, refer to Fungitell STAT® Instructions for Use (PN002603).

Table 3. Index Ranges as Described in Fungitell STAT® Instructions for Use

Fungitell STAT® Reportable Results	
Result	**Index Value**
Negative	≤ 0.74
Indeterminate	0.75 – 1.1
Positive	≥ 1.2

In addition, BG Analytics® software provides estimated Fungitell pg/mL for specific sample results.

Note: The Fungitell STAT® assay is for in-vitro diagnostic use in the serum of patients. As such, it is recommended to perform the assay within a biological safety cabinet to increase operator's safety while working with clinical samples. This System Verification Protocol does not include the use of clinical samples, however, it is recommended that the Protocol be executed under environmental conditions that match that of intended use, thus within a biological safety cabinet.

2.3 Required Specifications

The required specifications for PKF08 instrument and BG Analytics® software are listed below:

- The PKF08 instrument must be calibrated at ACC prior to installation in the laboratory.
- The PKF08 instrument must be installed according to the manufacturer's requirements and environmental specifications. The PKF08 instrument must be shown to perform as determined based on the following performance data and their specifications:
    - Temperature – reported as a mean of temperatures measured over 5 minutes by the built-in NIST traceable temperature sensor.
    - Signal – mean well intensity (Digital Values, DVs) as measured over 5 minutes
    - Signal to Noise Ratio – Standard deviation of Digital Values over 5 minutes.
- The PKF08 instrument must be able to transmit data over time to BG Analytics® at the specified wavelengths, 405 nm and 495 nm, including incubation temperature.
- BG Analytics® must be installed at the laboratory according to the requirements.
- BG Analytics® must accept Fungitell STAT® Reagent, Fungitell STAT® Standard, LRW, APS, and patient sample identifiers when using a barcode scanner.
- The PKF08 instrument and BG Analytics® must collect, analyze and save test data in the embedded database after assay completion when used with Fungitell STAT® assay as an aid in clinical diagnostics of Invasive Fungal Infection.
- BG Analytics® must display patient test result on the screen at the completion of the test.
- BG Analytics® must display either a categorically negative result or invalid result when LRW is used as a negative control.
- BG Analytics® must display the kinetic trace of the sample when certain invalid Quality Conditions are identified.
- BG Analytics® must provide a printable and exportable report with one sample ID per page.
- BG Analytics® must provide capabilities for searching within the database by Standard lot number, Reagent lot number, Sample ID, and User ID.
- BG Analytics® must provide backup capability of the SQLite database.

2.4 Laboratory's System Verification Plan

This System Verification Protocol may be executed in full as written or, alternatively; an Authorized Individual (as recorded in Section 2.5.3 Personnel Log) may identify and record section(s) of this Protocol as Not Applicable (N/A) and/or define Additional Testing to meet the local requirements, needs and expectations. Table 4 should be used to record which section (if any) is N/A, initialed and dated.

Table 4. Laboratory System Verification Plan

Section No.	Section Description	Component Tested	Not Applicable? Initial/Date
3	**IQ of PKF08**	PKF08 instrument	□ N/A _____
4	**IQ of BGA**	BG Analytics® software	□ N/A _____
5	**OQ of PKF08 and BGA**	PKF08 instrument and BG Analytics® software	□ N/A _____
7.3	**Additional Testing**	_____	□ N/A _____
		_____ _____	

Section(s) recorded as N/A will not be executed and will not be taken into consideration when deliberating whether System Verification Protocol is a PASS in **Section 6 Final Verification Report**.

2.5 Responsibilities

The responsibilities are categorized as:

2.5.1 Vendor

This System Verification Protocol is designed to be executed by a trained individual representing the vendor. Contact information for the vendor supplying the PKF08 instrument, BG Analytics® software and Fungitell STAT® should be filled out in Table 5.

Table 5. Vendor Contact Information

Vendor Information	
Name	**Associates of Cape Cod, Inc.**
Address	124 Bernard E. Saint Jean Drive East Falmouth MA 02536 USA
Phone No.	001-508-540-3444
Technical Services Contact	e-mail: techservice@acciusa.com Phone No.: 001-888-848-3248
Local Authorized Vendor (if not purchasing directly from Associates of Cape Cod, Inc.)	Name: e-mail: Phone No.

2.5.2 Laboratory

This System Verification Protocol is expected to be reviewed and accepted by the Laboratory where the system will be permanently placed. Laboratory information should be filled out in Table 6.

Table 6. Laboratory Information

Laboratory Information	
Laboratory Name	
Company/Hospital Name	
Address	
Phone No.	
Other information	Name: e-mail: Phone No.

2.5.3 Personnel Log

Record the name and title of an Authorized Individual (representing the laboratory above) responsible for overseeing the placement of the PKF08 instrument and BG Analytics® software (including the execution of this Protocol):

Role: Tester	
Name:	Title:
Signature:	Date:

Record the name and title of all personnel involved in the execution of this Protocol:

Role: Authorized individual	
Name:	Title:
Signature:	Date:

Role: Reviewer	
Name:	Title:
Signature:	Date:

Role: _____	
Name:	Title:
Signature:	Date:

2.5.4 Documentation of Training on this System Verification Protocol

Document in **Section 7 Attachments** that individuals listed in Section 2.5.3 Personnel Log as Testers are trained to the content of this Protocol.

2.6 List of Supplies Required to Execute this System Verification Protocol

A list of supplies needed to execute this Protocol in full is provided in Table 7. All materials must be free of interfering glucans. Glassware must be dry-heat depyrogenated for at least 7 hours at a minimum of 235°C (or a validated equivalent) to be considered suitable for use.

Table 7. Required Supplies

Supplies	Vendor	ACC US Catalog Number*	Amount Needed	Storage Conditions
PKF08 instrument and BG Analytics®	ACC	PKF08-PKG	1	Ambient
Fungitell STAT® kit (10 vials of STAT Reagent + 5 vials of STAT Standard)	ACC	FT007	2 kits	2 – 8°C
Alkaline Pretreatment Solution (APS)	ACC	APS51-5	1 vial	2 – 30°C
250 µL pipette tips	ACC*	PPT25	1 pack	Ambient
1000 µL pipette tips	ACC*	PPT10	1 pack	Ambient
Long pipette tips 20 - 200 µL	ACC*	TPT50	1 pack	Ambient
12x75 mm depyrogenated borosilicate glass tubes	ACC	TB240-5	1 pack	Ambient
LAL Reagent Water (LRW)	ACC	W0051-10	1 bottle	2 – 30°C
Tube racks to fit tubes 12 mm in diameter	Any		2	Ambient
Vortex mixer	Any		1	Ambient
Parafilm® M	Any		1	Ambient
Adjustable pipette for volumes 100 - 1000 µL	Any		1	Ambient
Adjustable pipette for volumes 20 - 200 µL	Any		1	Ambient

*Or equivalent as available from regional authorized vendor

2.7 Procedure

Follow the procedure outlined below in the order described. Test Cases within each section are provided to generate objective evidence that the PKF08 instrument and BG Analytics® software meet the Required Specifications.

- Personnel executing or reviewing any section of this Protocol must complete Personnel Log in Section 2.5.3 Personnel Log.
- Personnel executing this Protocol must complete all Sections of this Protocol unless recorded as N/A in Table 4.
- Within each Section, an Authorized Individual may identify, record and appropriately justify if any Test Case(s) is N/A.
- Personnel executing this Protocol must execute all Test Cases within the applicable Section except those recorded as N/A.
- Personnel executing this Protocol must collect the objective evidence as defined in Procedure of each Test Case and document the Observed Results.
- Personnel executing this Protocol must print all objective evidence as defined in Expected Results (screen captures, reports etc.), label with the reference number and file in **Section 7 Attachments**.
- Personnel executing this Protocol must document PASS or FAIL status (except where N/A) for each Test Case.
- Personnel executing this Protocol must record any discrepancy from the Expected Results on Discrepancy

Report and must file the Report in **Section 7 Attachments**.

- Personnel executing this Protocol must follow a pre-approved Problem Resolution Report to resolve a problem and must file the Report in **Section 7 Attachments**.
- An Authorized Individual must review, sign and date each Test Case, including objective evidence, Discrepancy Report and Problem Resolution Report (if any). Discrepancy Report and Problem Resolution Report must be taken into account when making a decision regarding the status of the impacted Test Case.
- An Authorized Individual must identify and prepare a Test Case for additional testing (if any). Test Cases for additional testing must be filed in **Section 7 Attachments**.
- Personnel executing this Protocol must complete, sign and date Section 6.1 Final Verification Report.
- Two Authorized Individuals must review and approve each applicable section of this Protocol.
- Maintenance of the verified system (e.g. re-calibration of PKF08, database cleanup or upgrade of BGA software) may be tracked and filed in **Section 7 Attachments.**
- An Authorized Individual must file the completed System Verification Protocol in a location as indicated in Section 2.9 Location of the Completed System Verification Protocol.

2.8 Acceptance Criteria

- Each applicable Test Case shall PASS in order for the section of this Protocol to be considered conforming. A single Test Case that is recorded as FAIL indicates non-conformance of the entire section unless otherwise justified by an Authorized Individual.
- A Test Case that is recorded as FAIL cannot be re-executed without a documented Discrepancy Report and Problem Resolution Report which must be pre-approved by an Authorized Individual and attached to **Section 7 Attachments**.
- Each applicable Section of this Protocol must conform to the Required Specifications in order for the System Verification Protocol to PASS. The decision should be recorded in **Section 6 Final Verification Report**.

2.9 Location of the Completed System Verification Protocol

Upon completion and review, this System Verification Protocol will be filed in:

2.10 Review and Approval

This completed **Section 2,** identified as **System Verification Plan** of this System Verification Protocol adequately describes how to document that PKF08 instrument and BG Analytics® software meet the intended purpose and function.

Review and Approval
_____ _____ Signature: Authorized Individual Date _____ Title _____ _____ Signature: Reviewer Date _____ Title

3 Installation Qualification of PKF08 Instrument

3.1 Calibration Documentation Test Case

□ *N/A Justification:*_____*Initial/Date:*_____

Purpose:	*The PKF08 instrument must be calibrated at ACC prior to installation in the laboratory.*
Test Procedure:	The PKF08 instrument is supplied with a Certificate of Calibration. This document provides evidence that the PKF08 instrument critical functions are calibrated within manufacturer's specifications.
Expected Results:	A Certificate of Calibration is provided with the PKF08 instrument.
Observed Results:	A Certificate of Calibration is provided: □Yes, Date of Calibration: _____ □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

3.2 Setup of PKF08 instrument Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument must be installed according to the manufacturer's requirements and environmental specifications.*
Prerequisites:	The PKF08 instrument was received. TC 3.1 was successfully executed.
References:	PKF08 Incubating Kinetic Tube Reader User Manual
Test Procedure:	1. Carefully open the PKF08 instrument packaging and transfer the PKF08 instrument to a clean, flat surface. 2. Visually inspect the exterior of the PKF08 instrument for any signs of damage e.g. scratches and record any observations in Observed Results. 3. Remove all the remaining components (power cord, USB communication cable, power conditioner and dust cover) from the box and inspect them for any signs of damage. Record any observations in Observed Results. 4. If any materials are missing or damaged, contact Technical Services at TechnicalServices@acciusa.com.
Expected Results:	• The PKF08 instrument is present and undamaged. • All the remaining components are present and undamaged.
Observed Results:	• The PKF08 instrument is present and undamaged: □Yes □No, _____ • All the remaining components are present and undamaged: □Yes □No, _____
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

3.3 The Installation PKF08 instrument Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument must be installed according to the manufacturer's requirements and environmental specifications.*
Prerequisites:	Hygrometer/thermometer combinationidentification: Model:_____Serial Number:_____Cal Due: _____
References:	PKF08 Incubating Kinetic Tube Reader User Manual
Test Procedure:	1. Record the laboratory environmental conditions in Observed Results. 2. Confirm that the environmental conditions meet the requirements in Observed Results. Electricity is not measured, only recorded based on the type of grid. 3. If the environmental requirements are met, connect the PKF08 instrument to a grounded wall outlet via power conditioner or UPS. 4. Record the PKF08 instrument information in Observed Results.
Expected Results:	• The environmental conditions are documented and meet the requirements. • The PKF08 Instrument information is documented. • The PKF08 instrument is installed.
Observed Results:	• Laboratory environmental conditions: o Ambient temperature:_____°C (required 15 - 30°C) o Ambient humidity:_____% (required < 70%) o Electricity:_____VAC (required 100-240VAC @ 50/60 Hz) • Environmental conditions meet the requirements: □Yes □No,_____
	• PKF08 Instrument information: o Serial Number: _____ o Connection via a power conditioner: □Yes □No o Make/Model: _____ o Connected via UPS (optional): □Yes □No o Make/Model: _____ • The PKF08 Instrument is installed: □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

3.4 Evaluation of PKF08 instrument Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument must be installed according to manufacturer's requirements and environmental specifications.*
Prerequisites:	TC 3.3 was completed. Set up eight 12x75 mm depyrogenated borosilicate glasstubes.
References:	Incubating Kinetic Tube Reader User Manual
Test Procedure:	1. Power on PKF08. 2. Allow PKF08 to go through initialization. 3. Insert 12x75 mm tubes in all eight wells. 4. Observe the performance of the PKF08 instrument as explained in Expected Results. Document in Observed Results.
Expected Results:	• After turning PKF08 on – no tubes inserted: o The LCD screen is on o The LCD screen displays serial number and a wavelength o All empty well LEDs are red • After inserting 12x75 mm tubes in all eight wells: o All tubes can be inserted completely o All the well LEDs turn green
Observed Results:	• After turning PKF08 on – no tubes inserted: o The LCD screen on □Yes □No o The LCD screen displays serial number, wavelength □Yes □No o All empty well LEDs red □Yes □No • After inserting 12x75 mm tubes in all eight wells: o All tubes can be inserted completely □Yes □No o All the well LEDs turn green □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

3.5 Verification of the Performance of PKF08 instrument Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument must be shown to perform as determined based on the following performance data and their specifications:* • *Temperature – reported as a mean of temperatures measured over 5 minutes by the built-in NIST traceable temperature sensor* • *Signal – mean well intensity (Digital Values, DVs) as measured over 5 minutes* • *Signal to Noise Ratio – Standard deviation of Digital Values over 5 minutes*
Prerequisites:	PKF08 has been on for at least 20 minutes. TC 3.4 was completed. All tubes are removed from PKF08. External computer with PKF08 Calibration Tool Version number: _____
Test Procedure:	1. Using the USB communication cable, connect the PKF08 instrument to the external computer hosting PKF08 Calibration Tool. 2. Launch PKF08 Calibration **Tool**. 3. On the home screen, select the PKF08 serial number from the **Instrument** dropdown menu. 4. Click **Auto Calibrate**. 5. Allow the PKF08 Calibration Tool to proceed with the calibration process. 6. Once completed, click Print and label as 3.5_6. 7. Evaluate the As-Found and As-Left data listed under Performance Results per specifications stated in Expected Results. 8. Document in Observed Results. 9. Close the PKF08 Calibration Tool.
Expected Results:	• As shown in TC 3.5_6, under Performance Results: o Active 405nm bank set is identified o Reported Mean Temperature: 37 ± 1°C o Optical Intensity for active 405nm bank for each well number: ≥ 36,000 o Optical Intensity for bank 495nm for each well number: ≥ 36,000 o Signal to Noise Ratio for active 405nm bank: > 261 o Signal to Noise Ratio for 495nm bank: > 261
Observed Results:	• As shown in TC 3.5_6, As Found Performance Results: o Active 405nm bank: _____ o Mean Temperature: 37 ± 1°C: □Yes □No o Optical Intensity for active 405nm bank for each well number ≥ 36,000: □Yes □No o Optical Intensity for bank 495nm for each well number ≥ 36,000: □Yes □No o Signal to Noise Ratio for active 405nm bank > 261: □Yes □No o Signal to Noise Ratio for 495nm bank: > 261: □Yes □No • As shown in TC 3.5_6, As Left Performance Results: o Active 405nm bank: _____ o Mean Temperature: 37 ± 1°C: □Yes □No o Optical Intensity for active 405nm bank for each well number ≥ 36,000: □Yes □No o Optical Intensity for bank 495nm for each well number ≥ 36,000: □Yes □No o Signal to Noise Ratio for active 405nm bank > 261: □Yes □No o Signal to Noise Ratio for 495nm bank: > 261: □Yes □No
Discrepancy Report #:	

Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

3.6 Review and Approval

This completed **Section 3**, identified as **Installation Qualification of PKF08 instrument**, documents that the PKF08 instrument has passed all testing of the specified processes for which it was intended.

Review and Approval
_____ _____ Signature: Authorized Individual Date _____ Title _____ _____ Signature: Reviewer Date _____ Title

4 Installation Qualification of BG Analytics® Software

4.1 Installation of BG Analytics® Software Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*BG Analytics® software must be installed at the laboratory according to the manufacturer's requirements.*
Prerequisites:	Computer meeting minimum system requirements (Win10 64-bit, version 1809 or newer) with at least one available USB port ready for install. A dedicated local Windows® user account. Download BG Analytics® software from ACC software portal https://portal.acciusa.com following instructions within the BG Analytics® User Manual (G_1867) at Section 1.3 for registration steps and Section 2.5 for Installation steps.
References:	BG Analytics® User Manual (G_1867) ACC software portal https://portal.acciusa.com
Test Procedure:	1. In Observed Results, confirm that the computer specifications meet the minimum requirements. 2. In Observed Results, record the computer ID, dedicated User ID and BG Analytics® software version. 3. Install the BG Analytics® software onto the host computer under the dedicated local Windows® user ID. **4.** Upon first-time launch, review and **Accept** the **BG Analytics® Software End User License Agreement** to proceed to the **Home** screen. 5. Take a screenshot of the BG Analytics® **Home** screen. 6. Save the screenshot as TC 4.1_1. 7. Verify that BG Analytics® **Home** page displays **Start Test** and **View Results**. 8. Close BG Analytics®. **9.** On the computer, navigate to **Start** and right-click over BG Analytics®. Click **More**, then **Pin to taskbar** to create an icon on the taskbar.
Expected Results:	• Computer meets minimum system requirements. • BG Analytics® software was successfully installed. • As shown in TC 4.1_1, BG Analytics® **Home** page displays **Start Test** and **View Results**.

Observed Results:	• Computer meets minimum system requirements: □Yes □No
	• Computer and software information:
	  • Computer ID: _____
	  • User ID on the host computer:_____
	  • BG Analytics® software version:_____
	• BG Analytics® software was successfully installed: □Yes □No
	• As shown in TC 4.1_1, BG Analytics® **Home** page displays **Start Test** and **View Results**: □Yes □No

Discrepancy Report #:	

Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

4.2 Installation of Barcode Scanner Test Case

□ *N/A Justification: All information will be entered manually only (keyboard entry)* *Initial/Date:*_____

Purpose:	*BG Analytics® must accept Fungitell STAT® Reagent, Fungitell STAT® Standard, and patient sample identifiers when using a barcode scanner.*
Prerequisites:	A configured a barcode scanner meeting vendor's recommendation. BG Analytics® is installed and closed.
References:	BG Analytics® User Manual (G_1867) Barcode scanner User Manual
Test Procedure:	1. In Observed Results, record the Barcode scanner description. 2. Install a configured scanner on the host computer by following the manufacturer's installation procedure. 3. Launch BG Analytics®. 4. Click **Start Test**. 5. Once on the **Test Setup** screen, scan available barcodes (if any). 6. Take a screenshot of the filled fields on **Test Setup** screen. 7. Save the screenshot as TC 4.2_1. 8. Verify that the information on barcoded items was appropriately filled in BGA.
Expected Results:	• Barcode scanner meets vendor's recommendations. • Barcode scanner was successfully installed. • As shown in TC 4.2_1, BG Analytics® **Test Setup** screen appropriately fills all the barcoded information.
Observed Results:	• Barcode scanner description: _____ • Barcode scanner meets vendor's recommendations: □Yes □No • Barcode scanner was successfully installed: □Yes □No • As shown in TC 4.2_1, BG Analytics® **Test Setup** screen appropriately fills all the barcoded information: □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

4.3 Review and Approval

This completed Section 4, identified as Installation Qualification of BG Analytics" Software, documents that the software is adequately installed and has passed all testing of the specified processes for which it was intended.

Review and Approval	
Signature: Authorized Individual	Date
Title	
Signature: Authorized Individual	Date
Title	

5 Operational Qualification of PKF08 instrument and BG Analytics® Software

5.1 Verification of Data Transmission Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument must be able to transmit data over time to BG Analytics® software at 405 nm and 495 nm, including the incubation temperature.*
Prerequisites:	IQ of PKF08 and IQ of BGA were completed. PKF08 has been on for at least 20 minutes. All tubes are removed from PKF08.
References:	BG Analytics® User Manual (G_1867)
Test Procedure:	1. Launch BG Analytics®. 2. Click on **Start Test**. 3. BGA displays **Verifying Instrument** screen and goes through a minimum of 30-second self-test. 4. Take a screenshot of **Verifying Instrument** screen. 5. Save the screenshot as TC 5.1_1. 6. Verify that BGA displays all the parameters as listed in Expected Results. 7. Upon completion of the self-test, BGA switches to **Test Setup** screen. 8. Take a screenshot of **Test Setup** screen. 9. Save the screenshot as TC 5.1_2. 10. Verify that the transmitted temperature is 37°C ± 1°C.
Expected Results:	• As shown in TC 5.1_1, BG Analytics® **Verifying Instrument** screen displays: o Self-test in progress… o PKF08 serial number o Transmitted temperature o Status: Connected • As shown in TC 5.1_2, following self-test, BGA proceeded to **Test Setup** screen. • As shown in TC 5.1_2, the transmitted temperature is 37°C ± 1°C.
Observed Results:	• As shown in TC 5.1_1, BG Analytics® **Verifying Instrument** screen displays: o Self-test in progress… □Yes □No o PKF08 serial number: □Yes □No o Transmitted temperature: □Yes □No o Status: Connected □Yes □No • As shown in TC 5.1_2, following self-test, BGA proceeded to **Test Setup** screen: □Yes □No • As shown in TC 5.1_2, the transmitted temperature is 37°C ± 1°C: □Yes □No
Discrepancy Report #:	
Pass or Fail:	

Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

5.2 Verification of Collecting, Saving, Analysis and Test Result Delivery Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*The PKF08 instrument and BG Analytics® must collect, analyze and save test data in the embedded database after assay completion when used with Fungitell STAT® assay as an aid in clinical diagnostics of Invasive Fungal Infection.* *BG Analytics® must display patient test results on the screen at the completion of the test.* *BG Analytics® must provide a printable and exportable report with one sample ID (patient result) per page.*
Prerequisites:	IQ of PKF08 and IQ of BGA were completed.
References:	BG Analytics® User Manual (G_1867) Fungitell STAT® Instructions for Use (PN002603)
Test Procedure:	1. Launch BG Analytics®. 2. Click **Start Test**. 3. Wait for **Test Setup** screen. 4. Type in User ID. 5. Use the installed barcode scanner or type in lot number and expiry information for each field (Standard lot, Reagent lot, APS lot, Water lot). 6. Type in Sample ID for all seven (7) samples as “OQ1”, “OQ2” etc. 7. Take a screenshot of **Test Setup** screen. 8. Save the screenshot as TC 5.2_1. 9. Verify that all data entry is correctly displayed on **Test Setup** screen. 10. Click **Start** to proceed to **Incubating** screen. 11. Prepare two (2) Fungitell STAT® STD (STAT STD) tubes: a. Reconstitute each with the specific volume of LRW as per label, vortex for 15 seconds and cover. b. To each tube, add the specific volume of APS as per label, vortex for 15 seconds and cover. 12. On **Incubating** screen, insert both STAT STD tubes in any well of PKF08 for a 10-minute incubation. 13. Take a screenshot of the **Incubating** screen. 14. Save the screenshot as TC 5.2_2. 15. Verify that the status of two wells is “Incubating” and both timers count down from 10:00 minutes. 16. During incubation, reconstitute eight (8) Fungitell STAT® RGT (STAT RGT) tubes with 300 µL of LRW and vortex mix each tube for 1- 2 seconds at no more than 2000 RPM 17. When the well status of both tubes changes to “Done Incubating”, remove both from PKF08 and pool by pipetting the entire volume from one tube to the other. 18. Vortex the pooled STAT STD tube for 15 seconds. 19. Transfer 75 µL from the STAT STD pool to each of the eight STAT RGT.

	20. Vortex each STAT RGT for 1-2 seconds at no more than 2000 RPM and cover. 21. In BGA, when prompted to proceed to data collection, click **Yes**. 22. On **Collecting Data** screen, insert each STAT RGT tube individually into PKF08 to start a 40-minute data collection. 23. Take a screenshot of **Collecting Data** screen. 24. Save the screenshot as TC 5.2_3. 25. Verify that the status of all wells is "Collecting" and all timers count down from 40:00 minutes. 26. Allow the test to run to completion. 27. When BGA displays "The test has finished", click **View Results**. 28. Take a screenshot of the BG Analytics® **Test Result** screen. 29. Save the screenshot as TC 5.2_4. 30. Verify that Test Result screen displays a header containing the test information and test results for samples OQ1 and OQ2. 31. Click **Print** to print the entire report consisting of 7 pages. 32. Label each page from TC 5.2_5 to TC 5.2_11. 33. Verify that each page of the report displays the parameters as defined in Expected Results. 34. Click **Export** to export the report as BG Analytics file. Select a location of the export on the desktop and click **Save**. 35. Take a screenshot of the desktop. 36. Save the screenshot as TC 5.2_12. 37. Verify that the BG Analytics file was successfully exported. 38. Open the exported file and print the exported reports. 39. Label the reports as TC 5.2_13 to TC 5.2_19. 40. Verify that reports TC 5.2_13 to TC 5.2_19 match reports TC 5.2_5 to TC 5.2_11. 41. Close BG Analytics®.
Expected Results:	• As shown on TC 5.2_1, **Test Setup** screen displays all data entry correctly. • As shown on TC 5.2_2, the status of two wells is "Incubating" and both timers count down from 10:00 minutes. • As shown on TC 5.2_3, the status of all wells is "Collecting" and all timers count down from 40:00 minutes. • As shown on TC 5.2_4, the **Test Result** screen displays a header containing the test information and test results for samples OQ1 and OQ2. • As shown on TC 5.2_5 – TC 5.2_11, each page of the report displays the following parameters: o Header with test information o Sample ID o Sample section: ▪ QC Status: Valid – In Range ▪ Index: within the range of 0.75 – 1.2 ▪ Sample category: Indeterminate or Positive • As shown on TC 5.2_12, the report was exported as BG Analytics file. • As shown on TC 5.2_13 to TC 5.2_19, the exported reports match reports TC 5.2_5 to TC 5.2_11.

Observed Results:	• As shown on TC 5.2_1, **Test Setup** screen displays all data entry correctly: □Yes □No • As shown on TC 5.2_2, the status of two wells is "Incubating" and both timers count down from 10:00 minutes: □Yes □No • As shown on TC 5.2_3, the status of all wells is "Collecting" and all timers count down from 40:00 minutes: □Yes □No • As shown on TC 5.2_4, the **Test Result** screen displays a header containing the test information and test results for samples OQ1 and OQ2: □Yes □No • As shown on TC 5.2_5 – TC 5.2_11, each page of the report displays the following parameters: o Header with test information: □Yes □No o Sample ID: □Yes □No o Sample section: ▪ QC Status: Valid – In Range □Yes □No ▪ Index: within the range of 0.75 – 1.2 □Yes □No ▪ Sample category: Indeterminate or Positive □Yes □No ▪ Estimated Fungitell pg/mL □Yes □No • The Report was exported to BG Analytics file as shown in TC 5.2_12: □Yes □No • As shown on TC 5.2_13 to TC 5.2_19, the exported reports match reports TC 5.2_5 to TC 5.2_11. □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

5.3 Verification of BG Analytics® Reporting Test Results Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*BG Analytics® must display either a categorically negative result or invalid result when LRW is used as a negative control.* *BG Analytics® must display kinetic trace of the sample when certain invalid QCs are identified.*
Prerequisites:	IQ of PKF08 and IQ of BG Analytics® were completed.
References:	BG Analytics® User Manual (G_1867) Fungitell STAT® Instructions for Use (PN002603)
Test Procedure:	1. Launch BG Analytics®. 2. Click **Start Test**. 3. Wait for **Test Setup** screen. 4. Type in User ID. 5. Use the installed barcode scanner or type in lot number and expiry information for each field (Standard lot, Reagent lot, APS lot, Water lot). 6. Type in Sample IDs for Sample 1, 2 and 3 as LRW1, LRW2, LRW3. 7. Type in Sample IDs for Sample 4, 5 and 6 as Non recon 1, Non recon 2, Non recon 3. 8. Under Notes, type in the following text: "OQ TC 5.3" 9. Click **Start** to proceed to **Incubating** screen. 10. Prepare one STAT STD tube: • Reconstitute STAT STD with the specific volume of LRW as per label, vortex for 15 seconds and cover. • Add the specific volume of APS as per label, vortex for 15 seconds and cover. 11. Preparation of Sample 1, 2 and 3: • Transfer 50 µL of LRW into three empty 12x75 mm tubes. • Add 200 µL of APS to each. • Vortex mix for 15 seconds and cover. 12. On **Incubating** screen, insert STAT STD and Sample 1, 2 and 3 into the designated wells of PKF08 for a 10-minute incubation. 13. During incubation, reconstitute four (4) STAT RGT tubes with 300 µL of LRW and vortex mix each tube for 1-2 seconds at no more than 2000 RPM. Acquire additional three (3) STAT RGT tubes but do not reconstitute them (for a total of four reconstituted and three non-reconstituted STAT RGT tubes). 14. When the well status changes to "Done Incubating", remove all tubes from PKF08 and vortex each tube for 5 seconds. 15. Transfer 75 µL from the STAT STD to a reconstituted STAT RGT tube. 16. Transfer 75 µL from each of the Sample 1, Sample 2 and Sample 3 tubes to corresponding reconstituted STAT RGT tubes. 17. Transfer 75 µL from the LRW to each of the three non-reconstituted STAT RGT tubes. 18. Vortex the first four (reconstituted) RGT tubes for 1-2 seconds at no more than 2000 RPM and cover. Do not vortex the non-reconstituted RGT tubes, only cover. 19. In BGA, when prompted to proceed to collection data, click **Yes**. 20. On **Collecting Data** screen, insert each STAT RGT tube individually into PKF08 to start a 40-minute data collection. 21. When BGA displays "The test has finished", click **View Results**. 22. Click **Print** to print the generated report. 23. Label the reports as TC 5.3_1 to TC 5.3_6. 24. Verify that the reports for Sample ID: LRW1, LRW2 and LRW3 display parameters as defined in Expected Results.

	25. Verify that the reports for Sample ID: Non recon 1, Non recon 2, Non recon 3 display parameters as defined in Expected Results. 26. Verify that the report displays the entered text in the header under Notes: “OQ TC 5.3”. 27. Close BGA software.
Expected Results:	• As shown in TC 5.3_1 to TC 5.3_6, the reports display the entered text in the header under Notes: “OQ TC 5.3”. • As shown in TC 5.3_1, TC 5.3_2 and TC 5.3_3, the reports for Sample ID: LRW1, LRW2, LRW3 display one of the listed outputs below: o Output 1 o Sample section: ▪ QC Status: Valid – Below Range ▪ Index: Index Not Calculated ▪ Sample Category: Negative ▪ Estimated Fungitell pg/mL: < 31 o Output 2 o Sample section: ▪ QC Status: Invalid – Not Above 0 at 500 ▪ Index: Index Not Calculated ▪ Sample Category: Not Reportable ▪ Estimated Fungitell pg/mL: pg/mL Not Calculated o A plot of sample kinetic plot as (Delta OD (405 – 495 nm) vs. Time (s)) o Y-intercept, slope and R values determined between 1900 and 2400s • As shown in TC 5.3_4, TC 5.3_5 and TC 5.3_6, the reports for Sample ID: Non recon 1, Non recon 2, Non recon 3 display one of the listed outputs below: o Output 1 o Sample section: ▪ QC Status: Valid – Below Range ▪ Index: Index Not Calculated ▪ Sample Category: Negative ▪ Estimated Fungitell pg/mL: < 31 o Output 2 o Sample section: ▪ QC Status: Invalid – Not Above 0 at 500 or Invalid-End OD ▪ Index: Index Not Calculated ▪ Sample Category: Not Reportable ▪ Estimated Fungitell pg/mL: pg/mL Not Calculated

Observed Results	• As shown in TC 5.3_1 to TC 5.3_6, the reports display the entered text in the header under Notes: "OQ TC 5.3": □Yes □No • As shown in TC 5.3_1, TC 5.3_2 and TC 5.3_3, the reports for Sample ID: LRW1, LRW2, LRW3 display one of the listed outputs below: o Output 1 o Sample section: ▪ QC Status: Valid – Below Range □Yes □No ▪ Index: Index Not Calculated □Yes □No ▪ Sample Category: Negative □Yes □No ▪ Estimated Fungitell pg/mL: < 31 □Yes □No o Output 2 o Sample section: ▪ QC Status: Invalid – Not Above 0 at 500 □Yes □No ▪ Index: Index Not Calculated □Yes □No ▪ Sample Category: Not Reportable □Yes □No ▪ Estimated Fungitell pg/mL: pg/mL Not Calculated □Yes □No o A plot of sample kinetic plot as (Delta OD (405 – 495 nm) vs. Time (s)) □Yes □No o Y-intercept, slope and R values determined between 1900 and 2400s □Yes □No • As shown in TC 5.3_4, TC 5.3_5 and TC 5.3_6, the reports for Sample ID: Non recon 1, Non recon 2, Non recon 3 display one of the listed outputs below: o Output 1 o Sample section: ▪ QC Status: Valid – Below Range □Yes □No ▪ Index: Index Not Calculated □Yes □No ▪ Sample Category: Negative □Yes □No ▪ Estimated Fungitell pg/mL: < 31 □Yes □No o Output 2 o Sample section: ▪ QC Status: Invalid – Not Above 0 at 500 or Invalid-End OD □Yes □No ▪ Index: Index Not Calculated □Yes □No ▪ Sample Category: Not Reportable □Yes □No ▪ Estimated Fungitell pg/mL: pg/mL Not Calculated □Yes □No

Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

5.4 Verification of Data Storage and Searching Capabilities Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*BG Analytics® must provide capabilities for searching within the database by Standard lot number, Reagent lot number, Sample ID and User ID.*
Prerequisites:	IQ of PKF08 and IQ of BG Analytics® completed. TC 5.3 was completed.
References:	BG Analytics® User Manual (G_1867)
Test Procedure:	1. Launch BG Analytics®. 2. Click **View Results**. 3. Click into **Search** box to locate the record by Sample ID. Type in "LRW1" which is the Sample ID. 4. Click **Find** to display the search result. 5. Take a screenshot of the **Test History** screen. 6. Label the screenshot as TC 5.4_1. 7. Verify that only result for sample "LRW1" is displayed. 8. Double-click over sample "LRW1" line and click **Print** to print the generated report. 9. Label the report as TC 5.4_2. 10. Verify that the same test report is generated as in TC 5.3_1. 11. Close BG Analytics®.
Expected Results:	• As shown on TC 5.4_1, BGA allows searching by Sample ID. • As shown on TC 5.4_2, after re-opening, the report for Sample "LRW1" is identical to TC 5.3_1.
Observed Results:	• As shown on TC 5.4_1, BGA allows searching by Sample ID: □Yes □No • As shown on TC 5.4_2, after re-opening, the report for Sample "LRW1" is identical to TC 5.3_1: □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

5.5 Verification of Database Backup Capability Test Case

□ *N/A Justification:*_____ *Initial/Date:*_____

Purpose:	*BG Analytics® must provide a capability for a backup of the SQLite database.*
Prerequisites:	IQ of PKF08 and IQ of BG Analytics® were completed.
References:	BG Analytics® User Manual (G_1867)
Test Procedure:	1. Launch BG Analytics®.
	2. Click **Backup**. 3. Select a location on the desktop of the host computer to save the copy of the database. 4. Click **Save** under the default file name in the format bgabackup-YEAR-MONTH-DAY as type: BGA database. 5. Click **OK** to confirm **Backup Complete**. 6. Take a screenshot of the desktop. 7. Save the screenshot as TC 5.5_1. 8. Verify that a file named bgabackup-YEAR-MONTH-DAY is displayed. 9. Close BG Analytics®.
Expected Results:	• As shown on TC 5.5_1, a file named bgabackup-YEAR-MONTH-DAY is displayed.
Observed Results:	• As shown on TC 5.5_1, a file named bgabackup-YEAR-MONTH-DAY is displayed: □Yes □No
Discrepancy Report #:	
Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

5.6 Review and Approval

This completed **Section 5**, identified as **Operational Qualification of PKF08 instrument and BG Analytics® Software** documents that the system has passed all specified testing and will adequately perform when used for the purposes for which it was intended.

Review and Approval
_____ _____ Signature: Authorized Individual Date _____ Title _____ _____ Signature: Authorized Individual Date _____ Title

6 Final Verification Report

6.1 Final Verification Report

Purpose:	To provide an overview of Test Case results
Section 3 Review:	Section N/A □ TC 3.1 Pass □ Fail □ N/A □ TC 3.2 Pass □ Fail □ N/A □ TC 3.3 Pass □ Fail □ N/A □ TC 3.4 Pass □ Fail □ N/A □ TC 3.5 Pass □ Fail □ N/A □ Notes: Section Conforms to Required Specifications: YES □ NO □
Section 4 Review:	Section N/A □ TC 4.1 Pass □ Fail □ N/A □ TC 4.2 Pass □ Fail □ N/A □ Notes: Section Conforms to Required Specifications: YES □ NO □
Section 5 Review:	Section N/A □ TC 5.1 Pass □ Fail □ N/A □ TC 5.2 Pass □ Fail □ N/A □ TC 5.3 Pass □ Fail □ N/A □ TC 5.4 Pass □ Fail □ N/A □ TC 5.5 Pass □ Fail □ N/A □ Notes: Section Conforms to Required Specifications: YES □ NO □
Additional Testing:	N/A □ TC_____Pass □ Fail □ TC_____Pass □ Fail □ TC_____Pass □ Fail □ TC_____Pass □ Fail □ TC_____Pass □ Fail □ Notes: Additional Testing Conforms to Expected Results: YES □ NO □
System Pass or Fail:	
Performed By: (Sign/Date)	
Reviewed By: (Sign/Date)	

6.2 Review and Approval

This completed **Section 6**, identified as **Final Verification Report,** documents that PKF08 instrument and BG Analytics® software passed all specified testing in this System Verification Protocol and will adequately perform when used for the purposes for which it was intended.

Review and Approval	
_____	_____
Signature: Authorized Individual	Date
_____	
Title	
_____	_____
Signature: Reviewer	Date
_____	
Title	

7 Attachments

7.1 Training Records

7.2 Objective Evidence

7.3 Additional Testing

7.4 Discrepancy Report

7.5 Problem Resolution Report

7.6 Maintenance

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Note: serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols Used

CE	Indicates compliance with the requirements of all the applicable EU directives
	Caution – see accompanying documents
IVD	In Vitro Diagnostic Device
REF	Product Model Name
	Manufacturer
EC REP	EU Authorized Representative
	Importer
CH REP	Swiss Authorized Representative

Revision History

Rev 2: Added Downloading procedure, Authorized representative, Revision History and Symbol used sections. Modified Section 5.3. Minor clarifications and formatting. Updated document name within quality system.

Rev 3: Modified sections 2.3, 3.4and 3.5 for use of the new PKF08 Calibration Tool.

Rev 4: Removed Authorized Rep, EC REP name and address.

Rev 5: Updated UK address and removed Germany. Added MedEnvoy for importer for EU and removed ACC Europe GmBh from Contact Information section. Updated symbols used. Added EC-REP, Swiss Importer, and CH-REP name and address. Updated the expected outcome for Test Case 5.3.

Rev 6: Updated logo and reference to the ACC website to www.fungitell.com. Updated the Operating system Microsoft at Table 2 to include Microsoft Version 11. In sections 5.2 and 5.3, updated mixing direction of Fungitell STAT Reagent from “no more than 5 seconds” to “1-2 seconds at no more than 2000 RPM” and added Estimated Fungitell pg/mL to the Observed Results.