PROTECTION
THROUGH
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BG Analytics®

Fungitell STAT® Software

User Manual

ASSOCIATES OF
CAPE COD
INCORPORATED

124 Bernard E. Saint Jean Drive, East Falmouth, MA 02536-4445 USA
t 888.395.ACC1(2221) • t 508.540.3444 • f 508.540.8680 • www.acciusa.com
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.
Visit www.acciusa.com for instructions for use in your language

G_1867 Rev.5

Contents

1 About BG Analytics® User Manual

Before setting up and using the BG Analytics® β-Glucan Analysis Software (referred to as BG Analytics® or BGA throughout this Manual), read this User Manual including **Section 2 Setting up BG Analytics® Software** and **Section 3 Setting up the System.**

1.1 Intended Use

BG Analytics® is intended for use with the *in vitro* diagnostic Fungitell STAT® assay which provides a qualitative measurement of (1-3)-β-D-glucan in the serum of patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infection (Associates of Cape Cod Inc.'s (ACC) catalog No. FT007). The serum concentration of (1⟶3)- β -D-glucan, a major cell-wall component of various medically important fungi, can be used as an aid in the diagnosis of deep-seated mycoses and fungemias. The assay is based upon a modification of the *Limulus* Amebocyte Lysate (LAL) pathway. For more information, please refer to the Fungitell STAT® Instructions for Use (PN002603).

The software collects and processes data from Lab Kinetics Incubating 8-well Tube Reader (referred to as PKF08 instrument or PKF08 throughout this Manual), stores the information in a database, and produces reports of sample results. This product is for In Vitro Diagnostic Use and Professional Use only.

The use of Fungitell STAT® Assay with the PKF08 instrument and BG Analytics® software:

- Fungitell STAT® Assay comes with ten (10) STAT Reagent vials (referred to as STAT RGT) and five (5) STAT Standard vials (referred to as STAT STD).
- PKF08 instrument has a total of eight (8) wells: the first well on the instrument is labeled as **Standard** and is designated specifically for STAT STD; the seven remaining wells, numbered 1 to 7, are dedicated to patient samples.
- It is required that each assay run includes one STAT STD, based on the Instructions for Use for Fungitell STAT®.

The following materials supplied with each product are sufficient for a total of 10 reactions (based on the 10 tubes of Fungitell STAT® Reagent). Each product also contains 5 Fungitell STAT® Standard tubes.

A single Fungitell STAT® kit can support testing of five (5) to eight (8) patient samples depending on the configuration of the assay runs:

- 5 patient samples over 5 runs
- Up to 8 patient samples over two runs (leaving three STAT STD vials unused).

1.2 Principle of the Procedure

(1→3)-β-D-glucan activates Factor G, a serine protease zymogen. The activated Factor G converts the inactive pro-clotting enzyme to the active clotting enzyme, which in turn cleaves the para-nitroanilide substrate Boc-Leu-Gly-Arg-pNA, creating a chromophore, para-nitroaniline that absorbs at 405 nm. The Fungitell STAT® kinetic assay, described below, is based upon the determination of the rate of optical density increase produced by a patient's sample.

This rate is compared to the rate of optical density increase of the Fungitell STAT® Standard to produce an Index value. The patient sample Index value is categorically interpreted as a Negative, Indeterminate, or Positive result according to the ranges provided in Table 1.

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

Table 1. Index Ranges as Described in Fungitell STAT® Instructions for Use

Note: The qualitative categorical results are further provided along with estimated Fungitell® pg/mL values (for reference only).

1.3 Material supplied with the Software

- The BG Analytics® software together with the PKF08 instrument are available from Associates of Cape Cod, Inc. (Cat. No. PKF08-PKG).
- The BG Analytics® software is available for download through the ACC software portal at: https://portal.acciusa.com.
    - Select the BG Analytics® Software option
    - Follow the software registration steps
    - You will need the serial # of your PKF08 Instrument
        - Your PKF08 instrument serial number is located on the rear panel label of the instrument (beginning with PKF).
    - A valid email address will be required for confirmation and to complete registration process
- BG Analytics® software manual (G_1867) and the BG Analytics® System Verification Protocol (G_1866) are available in multiple languages on *ACC website: www.fungitell.com*.

1.4 Materials Required For Use with Fungitell STAT® assay but not Supplied

1. Fungitell STAT® assay (catalog # FT007)
2. LAL Reagent Water* (5.5 mL vial, catalog # W0051-10)
3. Alkaline Pretreatment Solution 0.125 M KOH and 0.6 M KCl* (2.5 mL vial, catalog # APS51-5)
4. Pipettes capable of delivering 20-200 µL and 100-1000 µL volumes
5. Pipette tips* (250 µL catalog # PPT25 and 1000 µL catalog # PPT10)
- Long Pipette tips* (20-200 µL, catalog # TPT50)
- Test tubes* for patient sample preparation and combining serum pretreatment solution. (12 x 75 mm, catalog # TB240-5)
6. Compatible Incubating (37°C) tube reader capable of reading at 405 nm and 495 nm with a range of at least 0 – 1.0 Absorbance Units. The PKF08 instrument (as supplied by Associates of Cape Cod, Inc. under catalog no. PKF08-PKG) and BGA007 software have been validated for use with the Fungitell STAT® test (see below for more details)

** These products, supplied by Associates of Cape Cod, Inc., are certified free of interfering glucans*.

1.5 Compatible Instrumentation

BGA is compatible with an automated the PKF08 instrument (as supplied by Associates of Cape Cod, Inc. under catalog no. PKF08-PKG). The PKF08 instrument is an incubating absorbance tube reader equipped with eight (8) wells. Each well is individually timed, initiating both incubation and data collection immediately upon insertion of a tube into a well. The PKF08 instrument is designed to be used together with 12x65 mm flat-bottom borosilicate glass tubes.

Figure 1. PKF08 instrument

The PKF08 instrument can equilibrate and hold a temperature of 37 C ± 1°C during a 10-minute incubation as well as while collecting data. Together with BG Analytics® software, the PKF08 instrument reads optical density over time (kinetic) at two wavelengths: 405 nm (primary) and 495 nm (secondary). The kinetic runtime is 40 minutes (2400 seconds). The first read is initiated upon tube insertion within the read interval of 5 seconds.

Associates of Cape Cod, Inc. developed a BG Analytics® System Verification Protocol (G_1866) which can be used to confirm that the system consisting of the PKF08 instrument and BG Analytics® software was calibrated and performs the required functions accurately and reliably.

1.6 User Proficiency

Each user of the test should establish a quality control program to assure proficiency in the performance of the test in accordance with the regulations applicable to their location.

2 Setup of BG Analytics® Software

2.1 Requirements for the Computer Hosting BG Analytics®

The minimum system requirements are described in Table 2.

System Requirement	Value
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 or more
Communication Ports	At least one (1) free USB port (or two (2) when using barcode scanner)

Table 2. Minimum System Requirements for Computer Hosting BG Analytics®

Note: ACC strongly recommends that Microsoft® Windows updates are performed on a regular basis to ensure the latest security fixes and critical updates.

Additional requirements:

- A general laboratory Microsoft® Windows user account
  - BG Analytics® is installed locally per user account. If multiple Microsoft® Windows user accounts are to be used, BGA has to be individually installed for all them.
- Connection to a printer

2.2 Requirements for Barcode Scanners

BGA is designed to be compatible with any barcode scanner that is configured in USB HID Points of Sale scanner mode (in both linear and QR code). For example, Honeywell healthcare corded barcode scanners (e.g. Honeywell PN 1950HHD, Honeywell 1950HSR) are compatible. Refer to the barcode scanner's user manual for more information on installation, configuration and appropriate scanning technique.

2.3 Anti-Virus Information

It is strongly recommended that antivirus software with the most current update is installed and running on the computer hosting BG Analytics®. ACC recommends following your local laboratory security policies.

2.4 Preventing Unintended Access to Resources

To prevent access to the SQLite local database, ACC recommends following local laboratory security policies. BG Analytics® does not contain any configurable security settings. BG Analytics® does not expose any network services.

2.5 Installation and Update Procedure

BGA is available for download and installation via digital distribution portal: https://portal.acciusa.com.

BGA is typically installed under a dedicated Microsoft® Windows user account. It can be also installed under a dedicated group Microsoft® Windows account in order to collect all results into a single database.

Upon installation, BGA will automatically install and configure a local SQLite database.

BGA is packaged using Microsoft's MSIX packaging format. The default installation method uses AppInstaller to provide an easy-to-use graphical install sequence that installs per-user. For more advanced environments, the software can be installed / updated using deployment tools including PowerShell, Microsoft Intune and Microsoft Endpoint Configuration Manager.

Note: The BG Analytics software is signed with a digital certificate to verify code integrity and the publisher identity. Please verify the signature and that the publisher is Associates of Cape Cod, Inc. (CN="Associates of Cape Cod, Inc.", O="Associates of Cape Cod, Inc.", L=East Falmouth, S=Massachusetts, C=US US or CN = Associates of Cape Cod, Inc. O = Associates of Cape Cod, Inc. L = East Falmouth S = Massachusetts C = US SERIALNUMBER = 042541505 2.5.4.15 = Private Organization 1.3.6.1.4.1.311.60.2.1.2 = Massachusetts 1.3.6.1.4.1.311.60.2.1.3 = US) before installing the BGA software.

Note: Starting with BGA version 1.1.21, BGA is signed with an Extended Validation (EV) certificate. This changes the publisher ID from an 7jsm1jwze3c to 398cxz97z3hx0. On Microsoft(R) Windows 10, this requires that users upgrading BGA from versions below 1.1.21 first remove BGA followed up installing the newer version. On Microsoft(R) Windows 11, later versions will be installed side by side. A database import can be used to migrate data to the new version.

To install the software, follow the steps described below:

- Before installing any software take a backup of the system, including any BGA databases.

1. Double-click the BG Analytics® installer (.MSIX file).

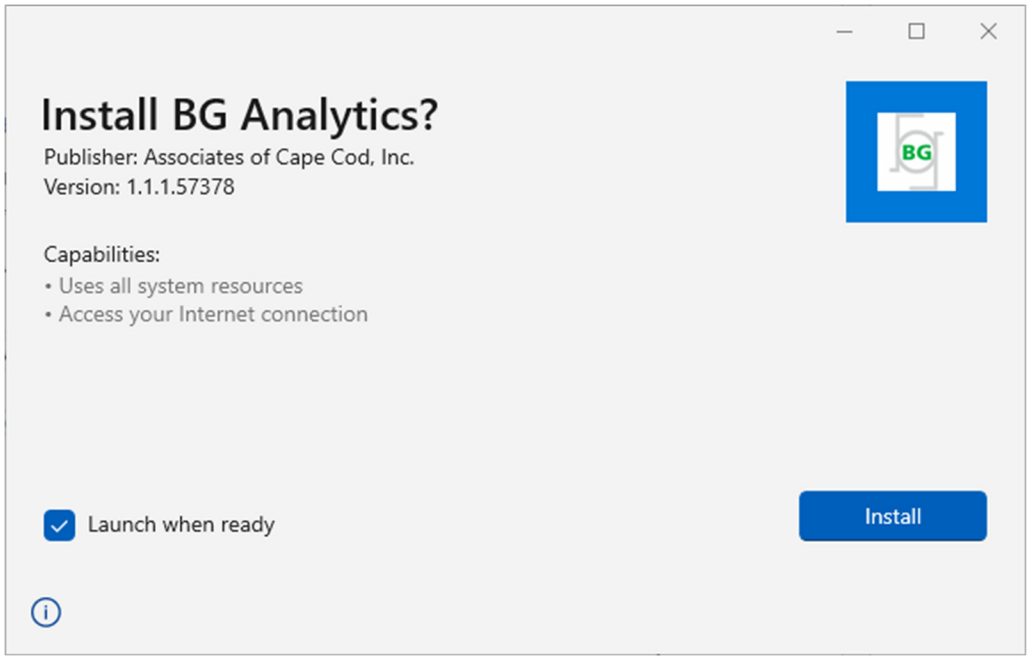


Figure 2. BG Analytics® Installation Screen

2. Verify that the Publisher is Associates of Cape Cod, Inc.
3. Click **Install** or **Update** to install or update the software.

4. Once the installation is complete, BG Analytics® is automatically launched.

- Upon first-time launch, **BG Analytics® Software End User License Agreement** appears. Review and click **Accept** to proceed to the **Home** screen.

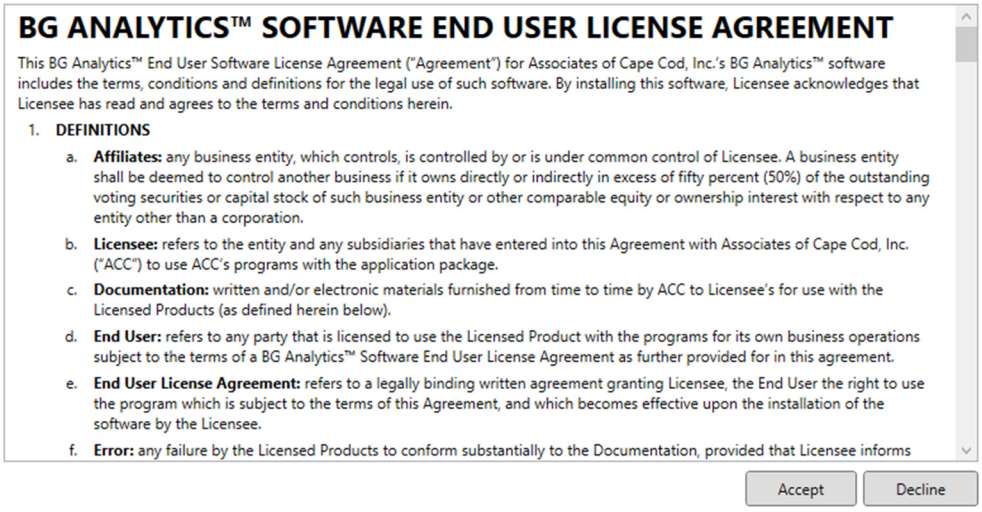


Figure 3. BG Analytics® Software End User License Agreement Screen

Note: The installation and configuration of BG Analytics® software does not require administrative privileges.

2.6 Routine Launch of BG Analytics®

Following first-time launch, BGA can be routinely accessed as follows:

1. Navigate to **Start** on the computer screen (bottom left-hand corner of the computer screen).
2. BG Analytics® can be accessed under **Recently added** as well as under alphabetical order of applications (under **B**).

- To create an icon for easier access, on the computer, navigate to **Start** and right-click over BG Analytics®. Click **More**, and **Pin to taskbar**.
- The **Home** screen appears as shown in Figure 4.

Figure 4. BG Analytics® Home Screen

2.7 Home Screen

The top bar of the **Home** screen displays logo, software name and the installed version.

The **Home** screen offers three icons that describe the basic functions of the software as described in Table 3.

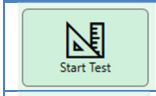
Icon	Function
	**Start Test** – To run a new assay
	**View Results** – To access results stored in the database
	**Backup** – To create a backup of the database

Table 3. BG Analytics® Icons and their Functions

⚠ **WARNING: Before continuing to Section 2.7.1 Start Test, the entire system (the PKF08 instrument and barcode reader (optional)) must be installed and configured. Refer to Section 3 Setting up the System.**

2.7.1 Start Test

After clicking **Start Test**, with the PKF08 instrument connected and on, the software will automatically show the status as **Verifying Instrument** as shown in Figure 5.

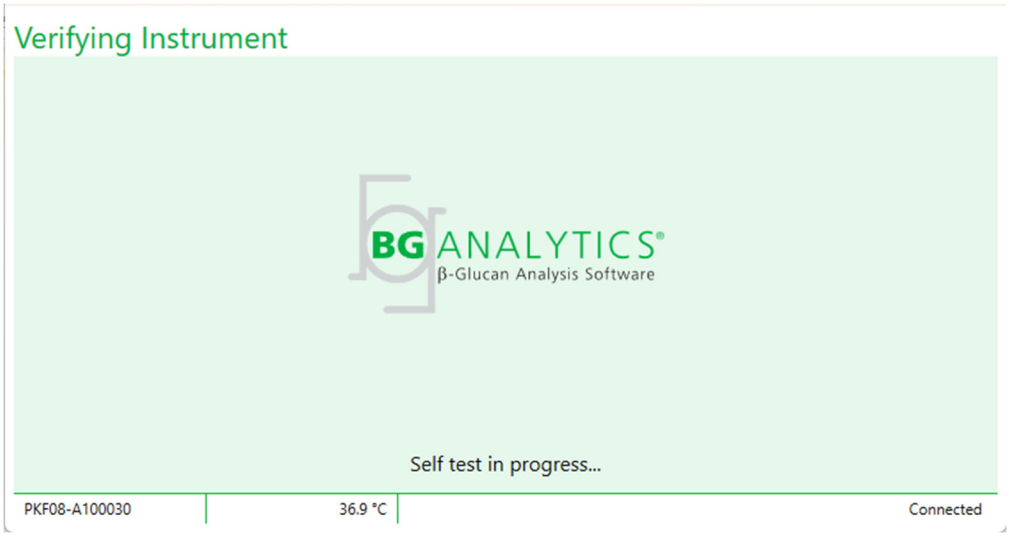


Figure 5. BG Analytics® Verifying Instrument Screen

Verifying Instrument screen confirms the connectivity to the PKF08 instrument and immediately proceeds to instrument self-test.

If the connectivity to the PKF08 instrument is not confirmed, the instrument self-test cannot be initiated. Scenarios that may occur on **Verifying Instrument** screen and their resolutions are summarized in Table 4.

BGA Footer Information			BGA Notification	Resolution
PKF S/N	Temperature	Status		
Blank	**Blank**	**None**	Make sure PKF08 is connected and turned on.	Connect and turn on PKF08
Shown	**Blank**	**Disconnected**	Make sure PKF08 is connected and turned on.	Turn on PKF08 (already connected)
Shown	**Shown**	**Connected**	Remove all tubes.	Remove all tubes before proceeding to self-test
Shown	**Shown**	**Connected**	Self-test in progress…	No action needed; takes at least 30 seconds

Table 4. BG Analytics® Verifying Instrument Screen Scenarios

While in self-test, BGA collects the following data for at least 30 seconds:

- Digital Intensity Values (DV) reading at 405 nm
- DV readings at 495 nm
- Temperature

BGA evaluates the obtained data against required specifications:

- If the data meets the specs, BGA proceeds to **Test Setup** screen.
- If the data does not meet the specs, BGA does not proceed to **Test Setup** screen. BGA remains on the **Verifying Instrument** screen and displays notifications that may indicate the reason for the failure.

A list of self-test outcomes and BGA notifications is summarized in Table 5.

BGA Self-Test Notification	Comment
PKF08 DV readings high	Refer to Section 8 Troubleshooting
PKF08 DV readings low	Refer to Section 8 Troubleshooting
PKF08 DV readings unstable	Refer to Section 8 Troubleshooting
PKF08 Temperature is low	Allow additional time to equilibrate PKF08
PKF08 Temperature is high	Refer to Section 8 Troubleshooting
PKF08 Temperature is unstable	Allow additional time to equilibrate PKF08

Table 5. BG Analytics® System Self-Test Output Scenarios

Following a successful instrument self-test, BGA automatically transitions to **Test Setup** screen.

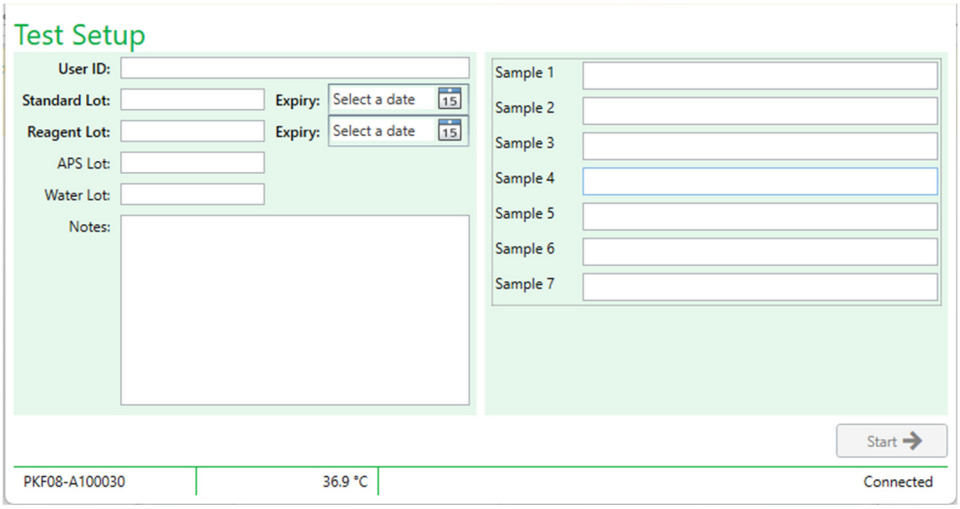


Figure 6. BG Analytics® Test Setup Screen

For a step-by-step description on how to run an assay proceed to **Section 4 Running a Fungitell STAT® Assay** of this User Manual.

2.7.2 View Results

After clicking **View Results**, the software will display the **Test History** screen as shown in Figure 7. For information on how to use this functionality, refer to **Section 5 Data Analysis.**

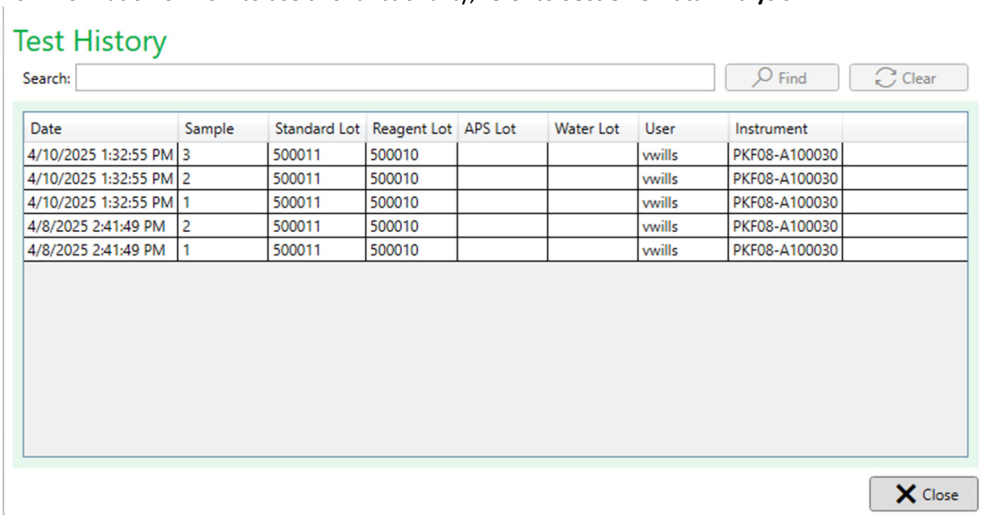


Figure 7. BG Analytics® Test History Screen

2.8 Backup and Restore of Database Provided with BG Analytics® Software

The backup and restore instructions below should be reviewed and tested for compliance with local requirements and policies.

2.8.1 Backup of BGA Database

1. Launch BG Analytics®.
2. From the **Home** screen, click **Backup**.
3. Navigate to the designated remote storage device.
4. **Save** under the default file name (i.e. bgabackup-YEAR-MONTH-DAY) as type: BGA database.
5. Click **OK** to confirm **Backup Complete**.

2.8.2 Restore of BGA Database

⚠**WARNING: Restoration of a database should be done on a separate host computer in order to prevent any data loss. The description below should be used only under an extreme situation when no other host computer is available. This procedure will replace the live data with backed up data.**

1. Close BG Analytics®.

- Navigate to a folder where BGA database is saved on the host computer (usually as local application data). For example: %LocalAppData%\Packages\BGAnalytics.Package_398cxz97z3hx0 \LocalCache\Local.

2. Save a copy of the backed-up database in the local folder.
3. Delete the current database named bganalytics.db.:
4. Rename the backed-up database from i.e. bgabackup-YEAR-MONTH-DAY to bganalytics.db.
5. Launch BG Analytics® and click **View Results**.
6. The database will now show the restored data from the backup file.

3 Setting up the System

This section describes the installation of the PKF08 instrument and barcode scanner. Both should be completed before running any assays.

3.1 Installation of the PKF08 Instrument

BG Analytics® is intended to be used with the PKF08 instrument which allows running kinetic assays. For information on detailed requirements and safe use of the PKF08 instrument, refer to PKF08 Instrument User Manual included with the instrument. An electronic copy of the PKF08 Instrument User Manual in English and other languages can be found on fungitell.com.

Set up the instrument as follows:

1. Unpack the instrument.
2. Place PKF08 on a level and stable surface away from equipment that might cause excessive vibration or electronic noise (e.g. refrigerators or centrifuges). Avoid placing PKF08 in direct sunlight or in an area with excessively bright lights.
3. Plug the power cable into a grounded wall outlet via the provided power conditioner and connect to PKF08. Optionally, PKF08 can be connected to Uninterruptable Power Supply (UPS).
4. Connect the PKF08 to the host computer using the USB communication cable provided.
5. Press the power button located on the side of PKF08. The USB communication driver is installed automatically.
6. Allow the instrument to equilibrate to 37°C ± 1°C for at least 20 minutes before use.
7. Operational use of PKF08:
    - Keep the cover on at all times while not in use.
    - Take caution not to introduce any debris or particles into the wells.
    - Keep the instrument on in between use (during a work week). Power down the instrument for the weekends.

3.2 Installation of Barcode Scanner (Optional)

BG Analytics® is designed to be compatible with barcode scanners configured in USB HID Points of Sale scanner mode. For detailed information on installation and use, refer to the barcode scanner's user manual.

3.2.1 Requirements for Barcode Formats

Any barcode that can be scanned by the chosen scanner is supported.

3.2.2 Setup of Barcode Scanner

The scanner should be set up as follows:

1. Ensure that BG Analytics® software is closed.
2. Follow installation instructions provided by the manufacturer of the barcode scanner when installing for use with BG Analytics®.
3. Once the scanner is properly installed, launch BG Analytics®.
4. Click **Start Test.**
5. Once on the **Test Setup** screen, scan the available barcodes.
6. **Important**: **Ensure that all the scanned information is displayed in BG Analytics® correctly**.

Note: ACC strongly recommends that the use of all barcode scanners (as third-party instrumentation) should be validated according to local quality control program and applicable regulations.

Once the entire system is installed and verified (e.g. using the BG Analytics® System Verification Protocol (G_1866)), the Fungitell STAT® Assay can be performed to test patient samples.

4 Running a Fungitell STAT® Assay

This section describes in detail how to use BG Analytics® software to perform Fungitell STAT® Assay.

4.1 Test Setup

Refer to Fungitell STAT® Instructions for Use (PN002603) and Fungitell STAT® Quick Visual Guide (PN002617) for detailed procedure on the preparation of patient samples, STAT STD and STAT RGT.

1. Turn on PKF08 and allow equilibrating at 37°C ± 1°C for at least 20 minutes
2. Launch BG Analytics®.
3. Click **Start Test**.
4. On **Test Setup** screen, use the barcode scanner or manually fill in the minimum required information (see Figure 8) and optional information (if any):

   Minimum required information:

   - User ID (no user configuration needed)
   - Standard (STAT STD) lot number and expiry
   - Reagent (STAT RGT) lot number and expiry

- Sample ID: at least one (and up to seven (7)) samples can be included per test (each sample tested in a single replicate) meeting the following requirements:
- Sample IDs must be unique and cannot be identical within the same assay
  I. Sample IDs must not be entered as “Standard”

   Optional information:

   - Alkaline pretreatment solution (APS) lot number and expiry
   - Water lot number and expiry
   - Notes

5. Confirm the accuracy of the entries before proceeding to the next step.

Note: BG Analytics® displays a notification if any entered material is past due its expiry date (i.e. “Warning: Standard Lot Has Expired.”).

- Click **Start** to begin the 10-minute incubation step.

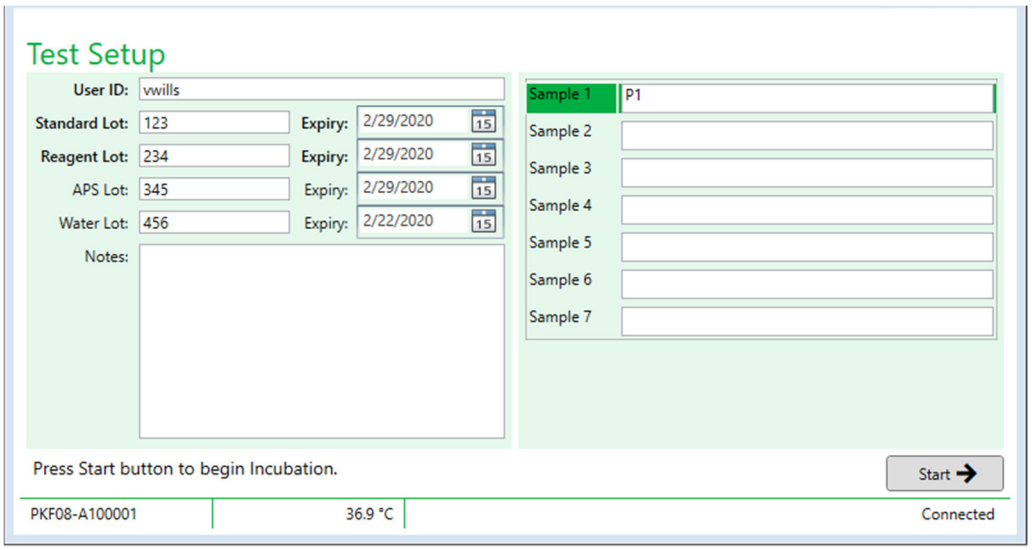


Figure 8. BG Analytics® Test Setup Screen – Example of Filled Information

4.2 Incubation Step

Follow the steps described below to perform a 10-minute incubation step:

1. On the **Incubating** screen, the wells are ready for tube insertion when the well status is "Empty" (Figure 9). The first well on the left is labeled as Standard and it is dedicated for STAT STD vial, while the remaining wells, labeled as 1 to 7, are dedicated to patient samples.

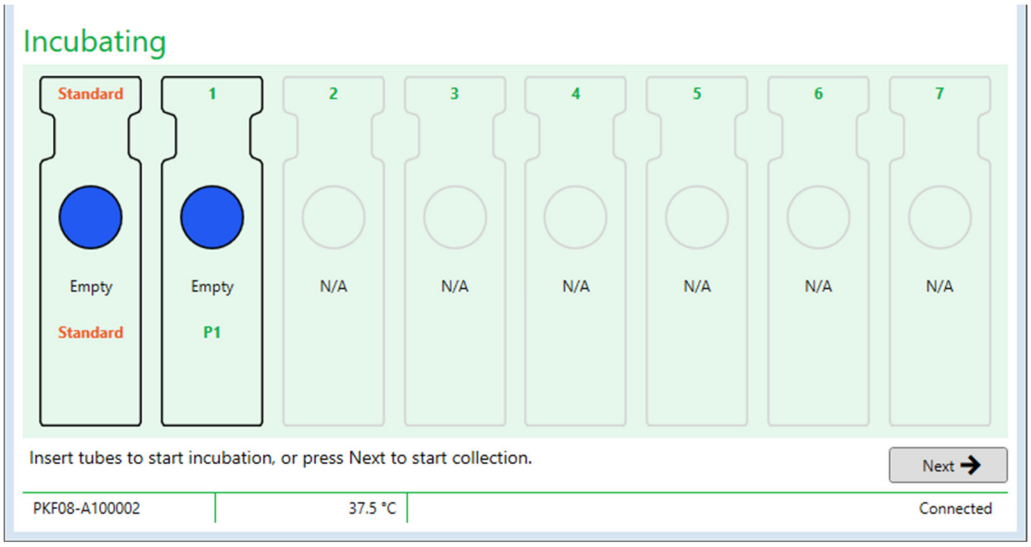


Figure 9. BG Analytics® Incubating Screen

2. Insert each tube in its respective well in PKF08 to start the incubation step (Figure 10). Each well is individually timed.

   a. If a tube is mistakenly inserted into a well with no Sample ID, the well status changes to "Invalid" and does not trigger timer countdown.

b. The mistake can be corrected by removing the tube from the “Invalid” well and transferring into the correct well.

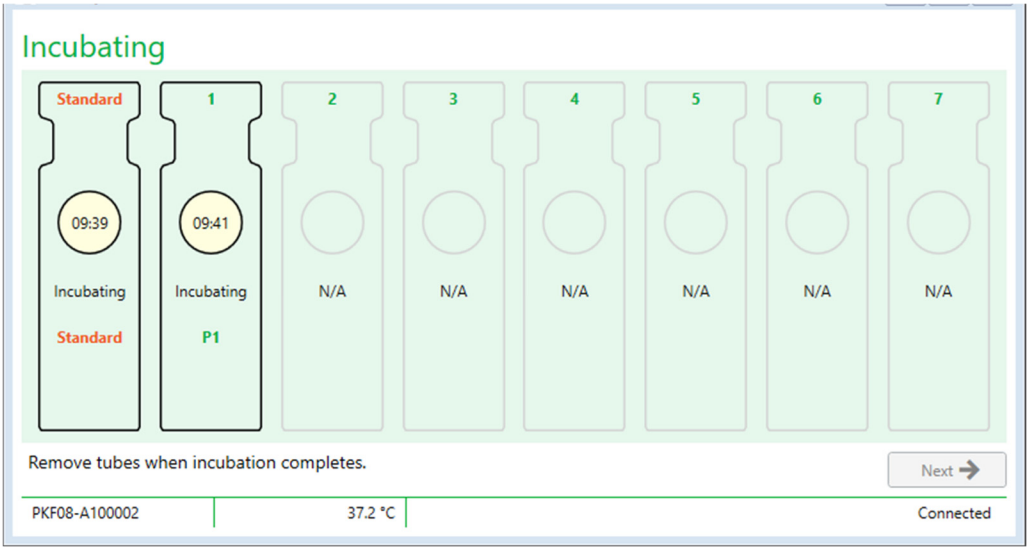


Figure 10. BG Analytics® Incubating Screen with STAT STD Inserted in Well Standard and One (1) Patient Sample Tubes Inserted in Well no. 1

Note: Incubation of the sample with added APS is a critical step in the Fungitell STAT® procedure and should always be included. BG Analytics® does allow skipping the incubation step for situations when all tubes are incubated in a third-party incubating device (e.g. incubating heat block). To skip the incubation step, click Next. BGA will display the following notification: “You are about to skip incubation; this action cannot be undone. Would you like to continue to data collection?”. Click Yes to proceed to the next screen.

3. Once the well status changes to “Done Incubating” remove the tube(s) and transfer to a tube rack.

- Once all tubes are removed, BGA displays a notification: “Incubation has finished. Would you like to proceed to data collection?” Click **Yes** to proceed to **Collecting Data** screen. It is imperative that this is verified before proceeding to Collecting Data.

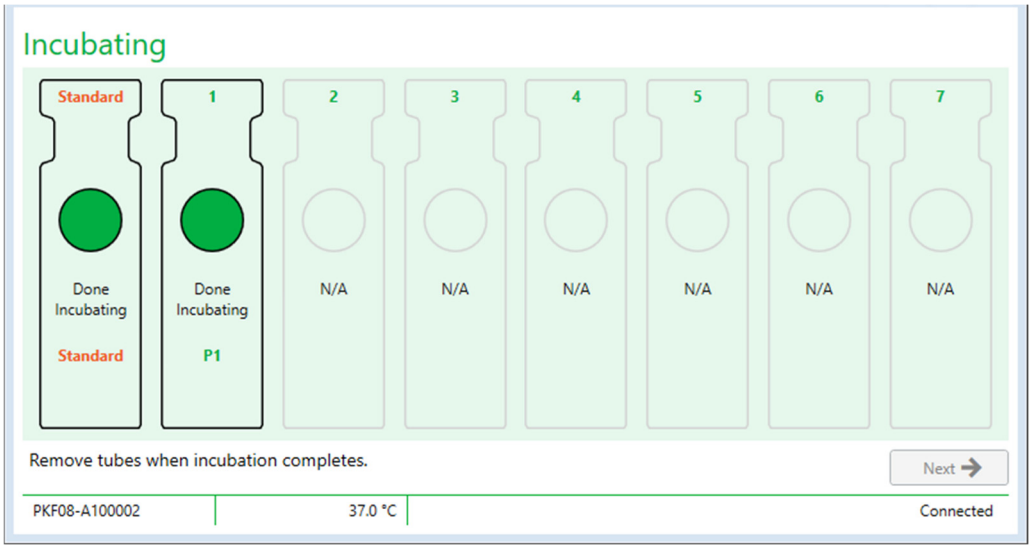


Figure 11. BG Analytics® Incubating Screen after 10-minute Incubation Period is Reached

4.3 Running the Test

Follow the steps described below to execute the assay:

1. On **Collecting Data** screen, the status for each well with Sample ID is "Ready**"** (as shown in Figure 12).

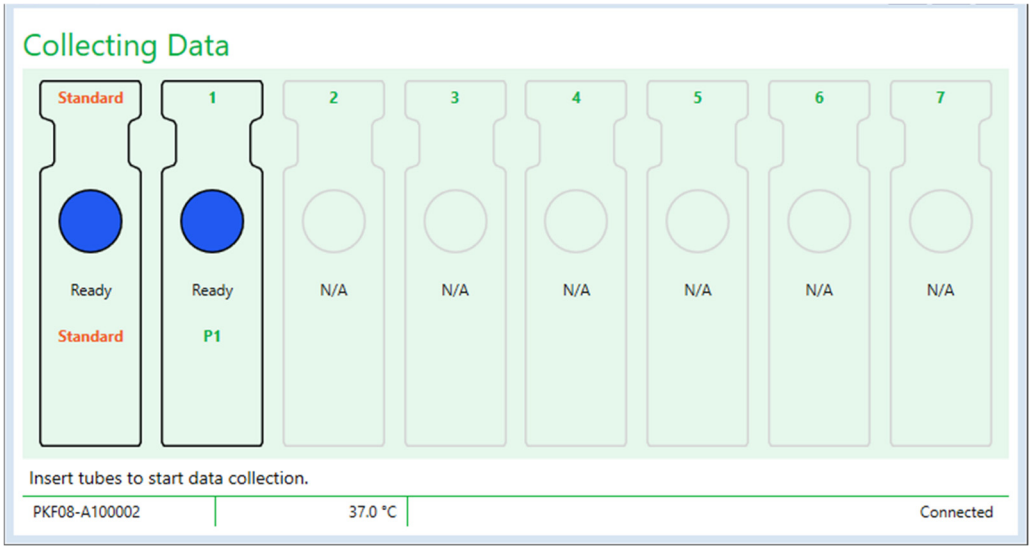


Figure 12. BG Analytics® Collecting Data Screen, Ready for Data Collection

2. Insert STAT RGT tube containing STAT STD into the well labeled as **Standard** on PKF08 and in BG Analytics®.
   i. Failure to include a STAT STD with each test will invalidate the entire test. Refer to Table 6 in **Section 7 Interpretation of Results** for more information.
3. The **Standard** well status changes from "Ready" to "Collecting" and the timer starts the countdown for a 40-minute assay.
   i. If the well status does not change, the tube insertion was unsuccessful, and no data will be collected. Refer to **Section 8 Troubleshooting** for more information.
4. Continue in the same manner with all STAT RGT tubes containing patient sample (as shown in Figure 13).
   i. Each sample STAT RGT tube must be inserted into the well with a matching Sample ID. If a sample STAT RGT tube is mistakenly inserted into a well with an incorrect Sample ID, the tube can be removed and transferred into the correct well within a 10-second grace period.
   ii. All tubes have to be inserted within 5 minutes of inserting the first tube. When the timer of the first inserted tube reaches 35:00, the status of any well with a Sample ID but no tube will change to "Never Inserted". This state is terminal: BGA will no longer register insertion of any additional tubes.

iii. If a sample STAT RGT tube is mistakenly inserted into a well with no Sample ID (shown as N/A), the well status changes to “Invalid” and does not trigger the timer countdown. The tube can be removed immediately and transferred into the correct well.

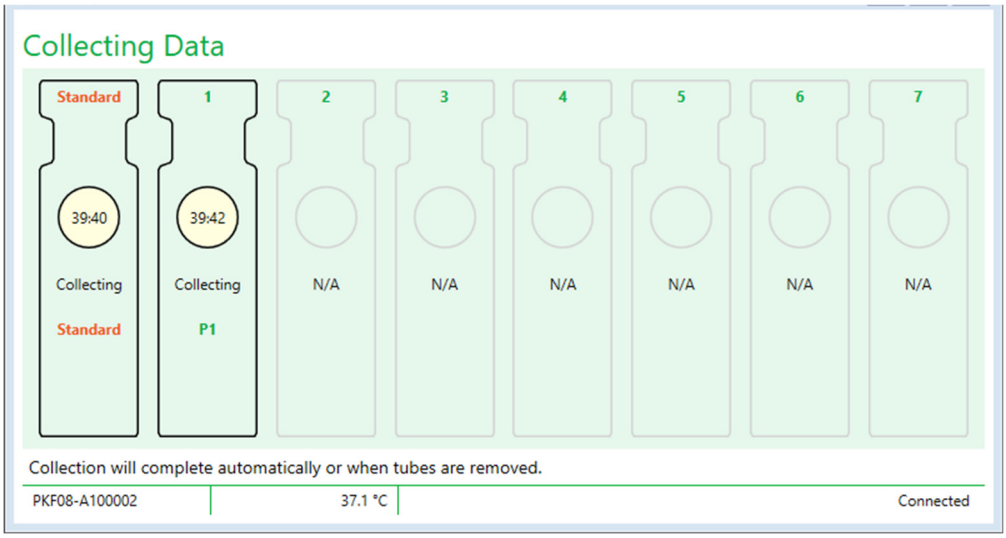


Figure 13. BG Analytics® Collecting Data Screen with STAT STD in Well Standard and One (1) Patient Tube in Well no. 1

5. Ensure that each sample STAT RGT tube is inserted into its respective well; the well Sample ID must match the patient sample ID.
6. Allow each well to collect data points for 40 minutes (2400 seconds) at 37°C ± 1°C.
   i. While **Collecting Data**, the user should not attempt to close the BGA software. If the user attempts to close BGA, a notification will display: “The Assay is still in process. Do you want to exit?”.
7. Collection of data will complete automatically for each well after 40 minutes.
8. Upon completion of the test in all wells, BGA automatically proceeds to the **Complete** screen and displays “The test has finished” (as shown in Figure 14).

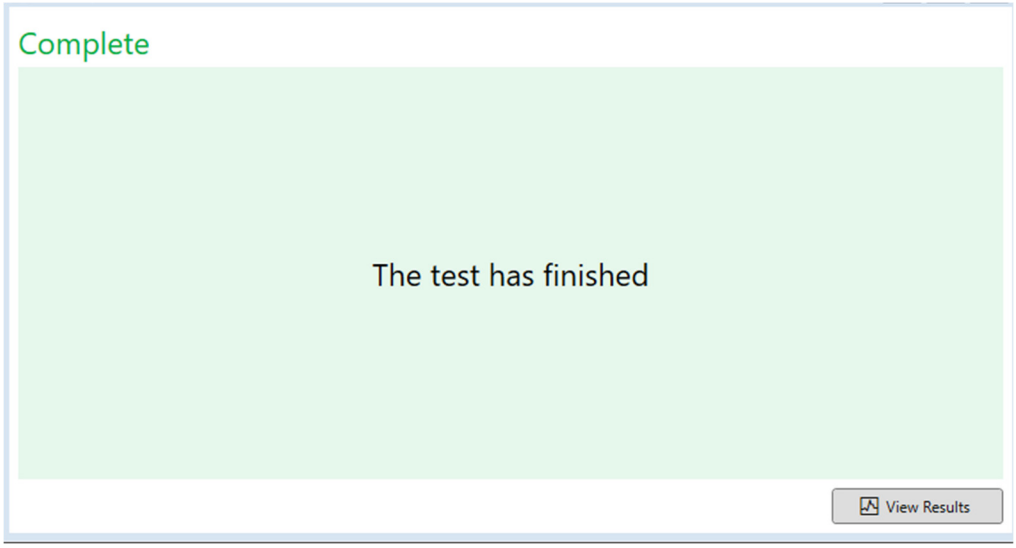


Figure 14. BG Analytics® Complete Screen

Note: Not allowing the Standard to run to completion will yield Invalid Standard status for the test.

5 Data Analysis

This section explains:

- How to access completed assays
- The structure of **Test Results** reports and their delivery
- How to search for target information

5.1 Access to Test Data Immediately after Data Completion

1. On **Complete** screen, click **View Results**.
2. BGA will instantly generate a report for the completed assay as **BG Analytics® Test Result** screen (as shown in Figure 15).

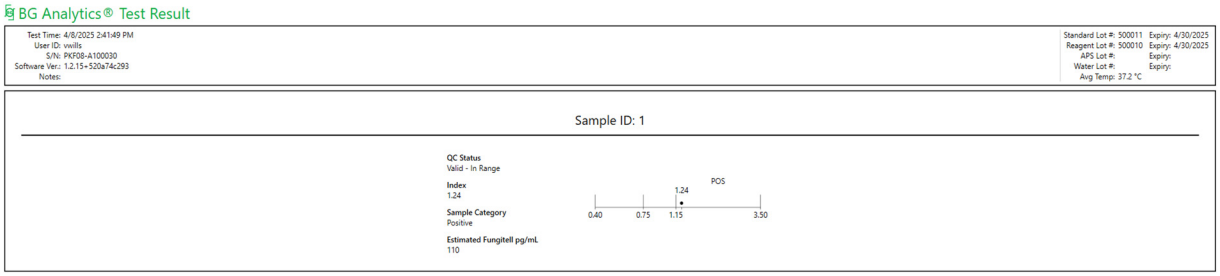


Figure 15. BG Analytics® Test Result Screen

3. For information on the structure of the report, proceed to Section 5.3 Structure of Test Result Report.
4. Click **Print** to print the test results as one (1) Sample ID per page.

5.2 Access Test Data of Previously Completed Assays (Test History)

1. From **Home** screen, click **View Results**.

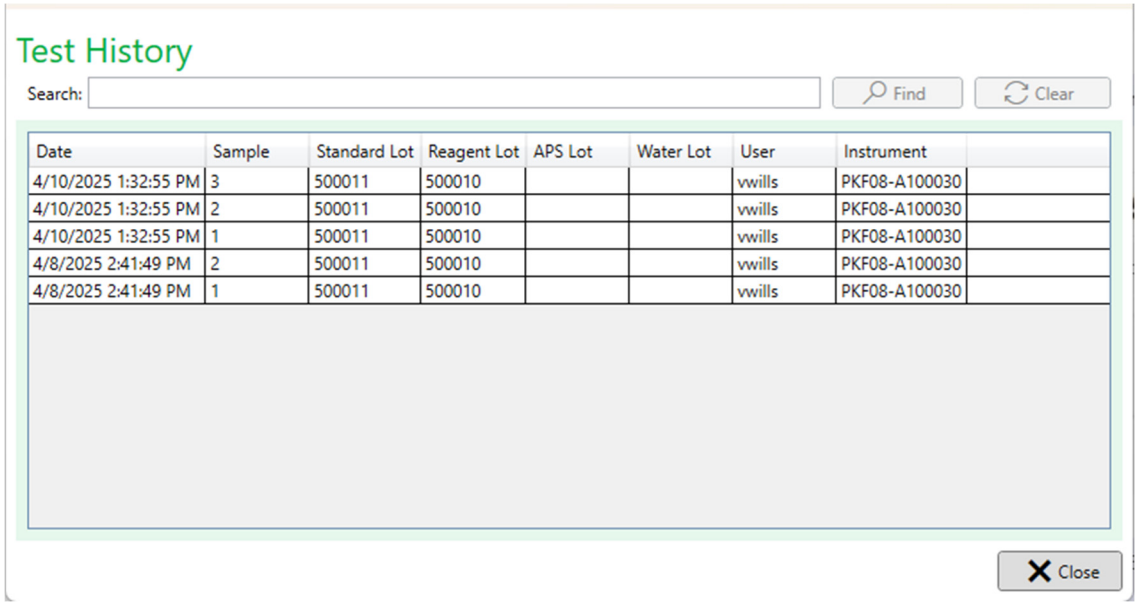


Figure 16. BG Analytics® Test History Screen

2. On the Test History screen, each line reflects individual Sample IDs. If seven (7) samples were tested in a single test, the software will list seven (7) individual test reports with identical date and time stamps.

3. Second column from the left lists Sample ID.
4. Double-click the line that contains the desired Sample ID.
5. For information on the structure of test reports, proceed to Section 5.3 Structure of Test Result Report.
6. Click Print to print the test results as one (1) Sample ID per page.

5.3 The Structure of **Test Result** Report

BG Analytics® will display **Test Result** report. An example of a report is shown in Figure 17.

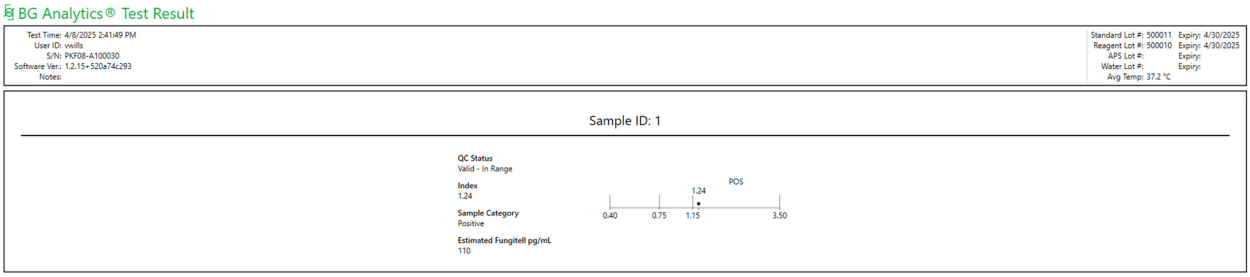


Figure 17. BG Analytics® Test Results Report for Sample with a Positive Result

- The report is built for one (1) sample per page. At most, the report will consist of seven (7) samples (and thus seven (7) pages). Each page of the report includes:
  - Header:
    - On the left-hand side: Test Date/Time, User ID, PKF08 Serial Number, Software version, Notes (if any)
    - On the right-hand side:
      - Lot numbers of Standard (STAT STD), Reagent (STAT RGT), APS, water and their respective expiry dates.
      - Average temperature recorded during the test.
  - Main body:
    - Sample ID
      - Quality Control (QC) Status
      - Index
      - Sample Category
      - Estimated Fungitell® pg/mL (an estimated pg/mL value relative to the predicate Fungitell® assay (Associates of Cape Cod Inc.'s (ACC) catalog No. FT001) for reference only)
      - Index graphic (*shown only if QC Status for the Sample is valid*):
        - Index values (rounded to two decimal places) plotted on a log scale graphic:

        a. Index value falling within the range of 0.40 to 3.50 will be marked within the graphic. Indeterminate Index will be marked between 0.75 and 1.15. An example of a sample with valid QC Status and Positive Index value is shown in Figure 17.

        b. Index value falling outside the range of 0.40 to 3.50 will be marked at either limit of the graphic with an indicator pointing in the direction of the value.

      - Kinetic Trace of Sample (*shown only if QC Status for the Sample is invalid*):
        - Plotted as Delta OD (405 -–495 nm) vs. Time (s) with the Y-intercept, slope and R values determined between 1900 and 2400 seconds to allow further analysis of the sample (see

Section 8 Troubleshooting for more information). An example of a sample with invalid QC Status is shown in Figure 18.

- The QC Status for Samples that are invalid is presented in detail in Table 7 (Section 7.2 Sample Results Interpretation).

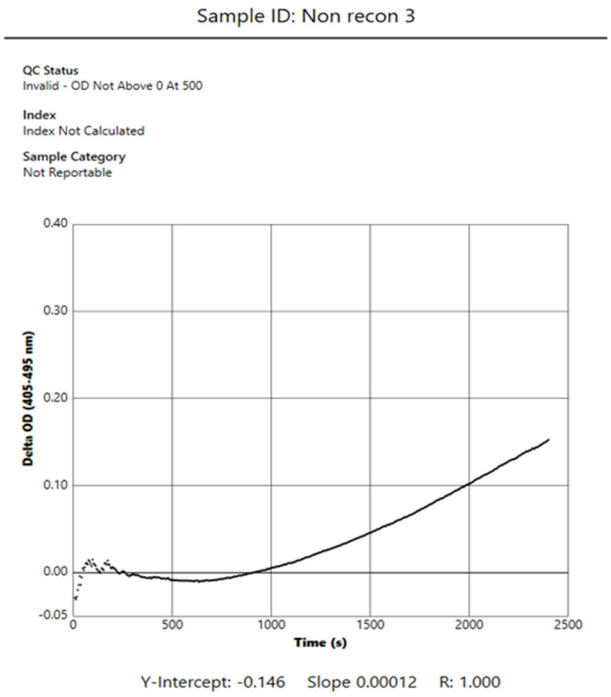


Figure 18. BG Analytics® Test Results Report for a Sample with Invalid QC Status – Kinetic Trace

5.4 Delivery of Test Results

Test results can be either printed or exported. Refer to your local document control policy and the applicable regulations.

5.4.1 Printing of Test Results

1. Click **Print** to produce a hard copy of the results.
2. Confirm **Print** on the General tab.
3. The report should be printed on A4 or letter format paper.
4. Confirm that the data displayed on the screen were correctly printed on the report.
5. When completed, click **Close**.

5.4.2 Export of the Test Results

1. Click **Export** to export the contents of the report as **BG Analytics® Files**.
2. Select the location where the exported file should be saved.
3. Enter the **File Name**.
4. Click **Save**.
5. Confirm that the data displayed in the **BG Analytics® Files** file are correctly exported.
6. When complete, click **Close**.

5.5 Searching for Target Information

Using the **Search** function, the user can search within the local database by:

- Sample ID
- Standard (STAT STD) lot number
- Reagent (STAT RGT) lot number
- APS lot number
- Water lot number
- User ID
- Instrument Serial Number

To search for a specific value:

1. Launch BG Analytics®.
2. Click **View Results**.
3. Click into **Search** box and enter the value (e.g. Sample ID).
4. Click **Find** to display all the results for the specific Sample ID.
5. Before performing another search, click **Clear**.

The search results can be sorted by clicking over the header of the respective column.

6 Data Cleanup

Depending on your requirements, a periodic data cleanup may be performed manually.
This can be done by restoring BG Analytics® software to factory defaults:

1. On the computer, go to **Start.**
2. Right-click on **BG Analytics®**.
3. Click **More** and navigate to **App settings**.
4. Click **Reset**.

7 Interpretation of Results

The Fungitell STAT® test results can be used as an aid to the presumptive diagnosis of Invasive Fungal Infection. For more information, refer to Fungitell STAT® Instructions for Use (PN002603).

The reported average temperature should be 37°C ± 1°C for the run to be valid.

Each Sample ID will have three main areas determined:

1. **QC Status:** determines the validity of Standard and Sample
2. **Index:** may calculate the rate of Sample relative to the rate of Standard
3. **Sample Category:** interprets Sample result based on QC Status and Index value

- **Estimated Fungitell® pg/mL: may display estimated Fungitell® pg/mL values**

BG Analytics® automatically determines the QC status for Standard and all well IDs representing Samples. The QC status is displayed on the Test Result Report using the following logic:

7.1 For Standard

If Standard fails to meet at least one of the QC criteria, the entire test is invalid and all samples have to be run again. To aid troubleshooting, kinetic Trace of Standard is displayed as shown in Figure 19. Plotted as Delta OD (405–495 nm) vs. Time (s) with the Y-intercept, slope and R values determined between 1900 and 2400 seconds.

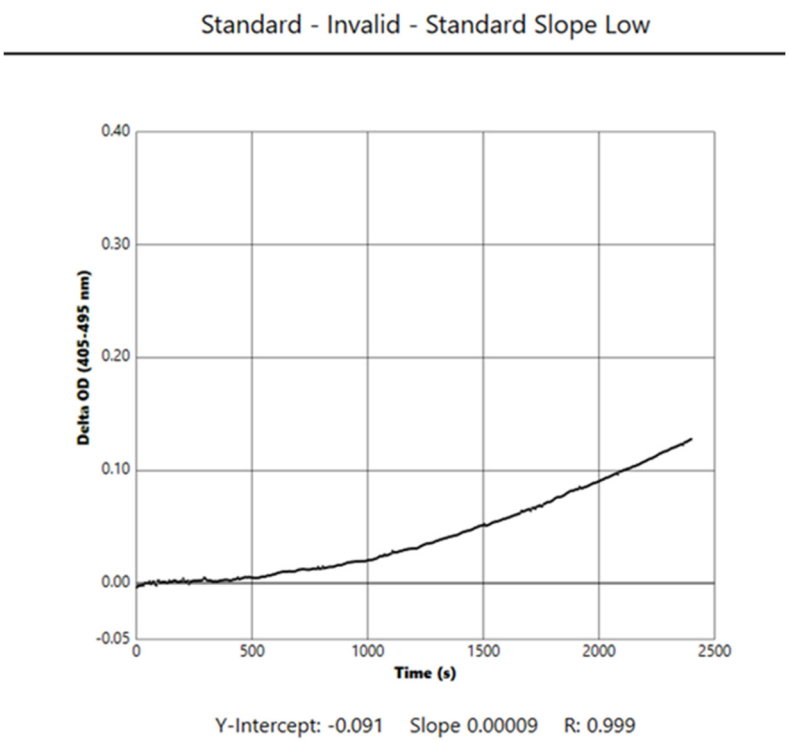


Figure 19. BG Analytics® Test Results Report for the Standard with Invalid QC Status – Kinetic Trace

- All the samples included on the test will be reported as:
  - **QC Status**: Invalid – Standard with additional notification as shown in Table 6
  - **Index**: Index Not Calculated – an Index value cannot be calculated
  - **Sample Category**: Not Reportable
  - **Estimated Fungitell pg/mL**: pg/mL Not Calculated

See **Section 8 Troubleshooting** for more information on any invalid results.

QC Status	Root Cause
Invalid - Standard Missing Data	Standard does not contain enough data to evaluate
Invalid - Standard Correlation Coefficient	The R value for the linear regression of the slope (rate) determination between 1900 and 2400 sec. for the Standard is < 0.980
Invalid - Standard Slope Low	The rate determination between 1900 and 2400 sec. for Standard is < 0.00010 OD/second
Invalid - Standard Slope High	The rate determination between 1900 and 2400 sec. for the Standard is > 0.00024 OD/second
Invalid - Standard Curve Shape	The mathematical description of the curve shape for the Standard does not meet the requirements

Table 6: A List of Invalid QC Status Scenarios for Standard

- **If Standard meets all the QC criteria, the test is valid and the Sample QC Status will be evaluated by BGA as described in detail in Section 7.2 Sample Results Interpretation.**

7.2 Sample Results Interpretation

- If Sample fails to meet at least one of the QC criteria, BGA reports the sample result as:
    - **QC Status**: Invalid - additional notification as shown in Table 7
    - **Index**: Index Not Calculated **Sample Category**: Not Reportable
    - Estimated Fungitell® pg/mL: pg/mL Not Calculated

  BGA also displays a Kinetic Trace of the Sample to provide an additional tool for further analysis.
  See **Section 8 Troubleshooting** for more information on any invalid results.

QC Status	Root Cause
Invalid - Missing Data	Sample does not contain enough data to evaluate
Invalid – OD Not Above 0 at 500	The kinetic trace of the sample was not positive at or after the initial 500 seconds
Invalid - End OD	The kinetic trace of the sample does not have an average OD > -0.005 at the end of the test (2390 seconds)
Invalid – Sample Slope	The slope between 1900 and 2400 sec. for the Sample is not numerically positive
Invalid - Correlation Coefficient	The R value the linear regression of the slope (rate) determination between 1900 and 2400 sec. for the Sample is < 0.980
Invalid - Curve Shape	The mathematical description for the curve shape of the Sample does not meet the requirements

Table 7: A List of Invalid QC Status Scenarios for the Sample

- If Sample QC Status is determined to be valid but the sample result is identified as above or below range, BGA reports the result as shown in Table 8 (no Index Graphic and no Kinetic Trace for Sample shown):

QC Status	Index	Sample Category	Interpretation
Valid – Above Range	Index Not Calculated	Positive	(1→3)-β-D-glucan detected: this result does not define the presence of disease and should be used in conjunction with other clinical findings to establish a diagnosis
Valid – Below Range	Index Not Calculated	Negative	(1→3)-β-D-glucan not detected*

Table 8: BG Analytics® Sample Interpretation

- If Sample QC Status is determined to be valid and an Index value is calculated, BGA reports the results as shown in Table 9 (Index Graphic shown, no Kinetic Trace for Sample shown):

QC Status	Index	Sample Category	Interpretation
Valid – In Range	≥ 1.15	Positive	(1→3)-β-D-glucan detected: this result does not define the presence of disease and should be used in conjunction with other clinical findings to establish a diagnosis
Valid – In Range	0.74 < Index < 1.15	Indeterminate	(1→3)-β-D-glucan detected: this result suggests possible fungal infection (additional sampling and testing is recommended; frequent sampling and testing improves the utility of the assay)
Valid – In Range	≤ 0.74	Negative	(1→3)-β-D-glucan not detected*

Table 9: BG Analytics® Sample Interpretation

***Note: Further information for samples where (1→3)-β-D-glucan was not detected: The laboratory performing the test should inform the ordering physician that not all fungal infections result in elevated levels of serum (1→3)-β-D-glucan. Some fungi, such as the genus Cryptococcus[1,2] produce very low levels of (1→3)-β-D-glucan. *Mucorales*, such as *Absidia*, *Mucor* and *Rhizopus*[1,3] are not known to produce (1→3)-β-D-glucan. Similarly, *Blastomyces dermatitidis*, in its yeast phase, produces little (1→3)-β-D-glucan, and blastomycosis patients usually have undetectable levels of (1→3)-β-D-glucan in the Fungitell STAT®[4]. For more information, refer to Fungitell STAT® Instructions for Use (PN002603).**

8 Troubleshooting

Note: For technical assistance, contact the Global Technical Services department of Associates of Cape Cod, Inc. via telephone at 001-800-848-3248 or email at techservice@acciusa.com **(US team) or TechnicalServices@acciuk.co.uk (UK/EU team).**

8.1 PKF08 Incubating Kinetic Tube Reader

8.1.1 No Power

No power to LCD screen or LEDs adjacent to the wells.

- Check that the power cord is plugged into the power outlet.
- Turn on the power button.

If the problem persists, contact Technical Services department.

8.1.2 Well LEDs Green with No Tubes Inserted

- A tube detection switch may be in ON position: move a 12x65 mm flat-bottom borosilicate tube in and out of the well a few times to release the switch.

If the problem persists, contact Technical Services department.

8.1.3 Well LEDs Red with Tubes Inserted

- A tube detection switch may be in OFF position: move a 12x65 mm flat-bottom borosilicate tube in and out of the well a few times to release the switch.

If the problem persists, contact Technical Services department.

8.1.4 A Tube Cannot Be Fully Inserted into a Well

The wells of the PKF08 instrument are designed to fit 12x65 mm flat-bottom borosilicate tubes that the Fungitell STAT® STD and RGT are supplied in. If the tube fits into the well part way, but will not go all the way down, the well may contain foreign material.

⚠**WARNING: Canned air should never be used to remove debris from a well of the PKF08 instrument. It may result in debris lodged within the light path thus damaging the well electronics.**

- Turn PKF08 off, unplug and turn upside down to allow any loose debris to fall out.
- Inspect the well in question for debris or broken glass.
- The well may be vacuumed using a micro-vacuum, available at computer or electronics stores.

If the problem persists, contact Technical Services department.

8.1.5 Failure to Insert the Tubes Completely into Each Well

It is imperative to insert every tube completely into the PKF08 instrument both during incubation and data collection. The tube detection mechanism can be triggered with the tube inserted partially (well LED light will change from red (no tube) to green (with tube)). However, incubation and data collection may be impaired and thus result in an invalid standard and/or sample result:

- Not fully inserting the tubes during **Incubating** may result in inadequate treatment conditions.
- Not fully inserting the tubes during **Collecting** may result in inadequate reaction conditions and/or impact the observation of the change in absorbance.

8.1.6 PKF08 light intensity is low

The PKF08 goes through a self-test prior to setting up a new assay. The intensity of all LEDs must be detected as no less than 17,000. If the intensity is below the expected value, BGA will not proceed beyond the self-test. Ensure that the well cover is always on when the instrument is not in use to prevent disposition of debris and particles which would cause optical interference.

Using a flashlight, inspect the inside of each well to determine if there is any debris. To remove the particle material, power down the instrument and unplug the power and communication cables. Pick up the PKF08 and turn upside down. Gently shake the PKF08 to allow the particles to fall out. Place the instrument back and reconnect, then power back up and test again. Contact Technical Services department for additional assistance, if needed.

8.1.7 Temperature Out of Range

The PKF08 is equipped with a NIST-traceable temperature microchip which detects the temperature of the heat block within the reader. This temperature is transmitted to the BGA software and displayed in the footer of the software during active connection to PKF08. The average temperature during the data collection period is also shown in the header of the Report after the test is completed.

If the transmitted temperature is outside of 37°C ± 1°C following a 20-minute equilibration, contact Technical Services department.

8.1.8 Communication between PKF08 and BG Analytics® Lost while Assay is in Progress

BGA will report communication issues with PKF08 and will attempt to reconnect while the test is in progress. BGA will set the background color of the footer to red while in **Incubating** or **Data Collecting** mode and will display a textual message “Disconnected”. BGA will terminate the assay in progress if the communication is lost for more than 120 seconds.

Ensure that the communication cable is fully inserted into the communication port on PKF08. Avoid physically contacting the connection with PKF08 following install to prevent the communication cable from loosening in the communication port.

Re-insert the communication cable. There may be impact on the reportable data depending on the timing of when the communication was lost. If the issue is resolved within 120 seconds, BGA will continue to collect data.

If the problem persists, contact Technical Services department.

8.2 BG Analytics® Software

8.2.1 Software Fails to Open

Depending on the error message shown, this may be due to corruption of the local database during the lifecycle of the software. Contact Technical Services department for assistance.

8.2.2 The Footer of Multiple Screens Displays: “Disconnected”

Loss of communication with PKF08 after being previously connected and turned on results in the footer of Verifying Instrument, Test Setup and Collecting Data screens displaying “Disconnected”. Reset the instrument by turning it off and on. Ensure that both ends of the communication cable are pushed all the way in. Alternatively, try a different USB port on the host computer or try a different USB cable.

If the problem persists, contact Technical Services department.

8.2.3 Home Screen Hangs on: “Verifying PKF08 DV Reading (405 nm)”

Ensure that only one instance of BG Analytics® software is open. Close all other instances. Re-launch BGA and attempt to run self-test again.

If the problem persists, contact Technical Services department.

8.2.4 Tubes Not Detected in the Software during Data Collection

Well LEDs turn green after tubes are inserted but the software does not recognize them.

- Wait up to 10 seconds to let the software refresh the data on the screen.

If the problem persists, contact Technical Services department.

8.2.5 Home Screen or Test Setup Screen Hangs On: “Please Remove All Tubes”

Tubes were left in PKF08: the well LED is green when tubes inserted. Remove all the tubes to proceed.

8.2.6 Power Outage

In the event of a power failure while an assay is in progress, the assay will likely be lost and have to be repeated. To prevent the loss of data due to power failure, both the PKF08 instrument and the host computer should be connected to a UPS.

8.2.7 SQLite Database Failure

If the database fails while an assay is in progress, the assay may be lost and may have to be repeated depending on when within the test the failure occurred. A database failure can be caused by insufficient disk space. The database should be periodically backed up to a different location as described in **Section 3 Setting Up the System.**

For further information, contact Technical Services department.

8.2.8 Computer Hardware Failure

If the computer fails while an assay is in progress, the assay will be lost and will have to be repeated. Database loss can be prevented by backing up the local database to a different location as described in Section 3.

Following a computer failure, BG Analytics® may have to be re-installed and verified on a new host computer.

For further assistance, contact Technical Services department.

8.3 Errors in Preparation of Standard and Samples

8.3.1 Incorrect Placement of Standard or Samples in PKF08 in Incubating Mode

There is no impact on the results as long as the tubes are labeled correctly to prevent mix-up when inserting in data collection mode.

8.3.2 Incorrect Volume of Standard or Sample(s) Added to Incubating Step

The Standard or Sample tubes should be removed from the instrument (after **Done Incubating** or during **Incubation**). BGA will display **Empty** for the well where tube was removed (while other wells will be unaffected). The tube should be discarded and the preparation(s) repeated into a new tube. The new tube should then be inserted back into the same well. BGA will re-start the incubation.

8.3.3 Incorrect Placement of STAT STD in PKF08 in Collecting Data Mode

It is imperative that STAT RGT containing STAT STD is placed in the well labeled **Standard** on PKF08. The result of STAT STD is used to calculate the Index value based on which patient samples are categorized upon assay completion. Failure to place the STAT RGT containing STAT STD in well **Standard** on PKF08 is not identifiable by the BGA software and it will result in an incorrect sample interpretation.

⚠ **WARNING: If there is any doubt about the handling or placement of STAT RGT containing STAT STD, the entire test must be invalidated and performed again**.

8.3.4 Incorrect Placement of Sample Tubes in PKF08 in Collecting Data Mode

STAT RGT vials containing patient samples must be inserted into the correct wells of PKF08 as defined in BGA on **Test Setup** screen (well 1 to 7). All Sample tubes have to be inserted into their respective wells within 5 minutes of inserting the first tube. To avoid confusion, the first inserted tube should routinely be STAT RGT containing STAT STD. Once the timer of the first inserted tube reaches 35:00, the status of any well(s) without a tube will change to “Never Inserted”. This is terminal and BGA will no longer register insertion of any additional tubes.

If a tube is mistakenly inserted into a well with no descriptor, the well status will change to “Invalid” and the timer countdown will not trigger. The tube can be removed and transferred into another well with the correct descriptor.

If a tube is mistakenly inserted into a well with an incorrect descriptor, BGA allows a 10-second grace period to pull the tube out and transfer it into the correct well.

8.3.5 Tube Removed During Data Collection

If a tube is removed from a well with a descriptor, BGA will display the status of the well as **Removed**. Upon completion of the test, BGA will attempt to perform calculations depending on the well descriptor:

- For the Standard: the QC status will always be reported as Standard Invalid. This will invalidate the test. The Standard and all Samples will have to be re-run.
- For the Sample: there may be a reported result depending on when exactly the tube was removed and what QC criteria were observed. If the Sample is reported as invalid, the Sample has to be re-run.

8.4 QC Status Invalid

8.4.1 Invalid – Standard Missing Data

Standard is missing data and does not contain enough data to evaluate. The test is invalid: a new Standard and Sample(s) have to be re-run.

Potential root causes:
• STD vial was removed before the completion of the assay: refrain from removing vials 10 seconds post-insertion.
• Communication between the PKF08 and BGA was lost while assay was in progress (the background color of the BG footer will change to red and a textual message will be displayed “Disconnected”. BGA will terminate the assay in the communication is lost for more than 120 seconds): Ensure that the USB cable is fully inserted into the communication port on PKF08. Avoid any physical contact with the connection following the original install to prevent the communication cable from loosening in the port. If the cable is loose, turn off the PKF08, remove the USB cable on both ends, re-insert properly. Replace the USB cable, if needed (standard AB USB).

8.4.2 Invalid - Standard Correlation Coefficient

The correlation coefficient (R) of Standard calculated from the kinetic data between 1900 and 2400 seconds must be ≥ 0.980. If R of Standard is < 0.980, test is invalid and Standard and Sample(s) have to be re-run following the IFU.

Potential root causes:
• STAT STD or RGT were used past the expiration after reconstitution (beyond 1 hour): both STD and RGT should be used within 1 hour of reconstitution.
• The same vial of STD was used twice: STD should be used only once.
• Physical disturbances (especially during 1900 – 2390s) occurred: prevent any physical disturbances (e.g. vibration).

8.4.3 Invalid - Standard Slope High

The slope of Standard calculated from the kinetic data between 1900 and 2400 seconds must be within the range of 0.00010 – 0.00024 OD/second. If the slope is > 0.00024 OD/second, test is invalid and Standard and Sample(s) have to be re-run.

Potential root causes:
• STD reconstitution too low: it is critical to follow the reconstitution volumes for LRW and APS as stated on the STD clamshell.
• Systemic contamination of LRW or APS: adhere to strict aseptic technique and use freshly opened vials of both.

8.4.4 Invalid - Standard Slope Low

The slope of Standard calculated from kinetic data between 1900 and 2400 seconds must be within the range of 0.00010 – 0.00024 OD/second. If the slope is < 0.00010 OD/second, test is invalid and Standard and Sample(s) have to be re-run.

Potential root causes:
• STD reconstitution too high: it is critical to follow the reconstitution volumes for LRW and APS as stated on the STD clamshell.

• Pipetting technique during transfer of STD to RGT vial: the liquid should be pipetted using Toxipets and should be placed directly on top of reconstituted RGT solution.
• Handling RGT vials: after reconstitution, RGT becomes a proteinaceous solution which is sensitive to physical stress. It should never be over-vortexed. Vortexing time and speed for RGT is 1 – 2 seconds at no more than 2000 RPM.
• Transferring prepared RGT vial into PKF08: the RGT vial containing the sample should be transferred to a designated PKF08 well promptly 1 minute after the adding the sample.

8.4.5 Invalid - Standard Curve Shape

The kinetic curve of Standard must have an upward increasing curve shape consistent with the examples in Figure 19. If the curve shape is inconsistent with the examples given, the test is invalid: a new Standard and Sample(s) have to be re-run.

Potential root causes:
• STD not handled correctly, contaminated or re-used: ensure following operational use of STAT STD as described in the IFU. Reconstitute a new STD vial before each run closely following handling and aseptic techniques.
• Contaminated vial of LRW and/or APS: use freshly open vials of each LRW and APS daily.

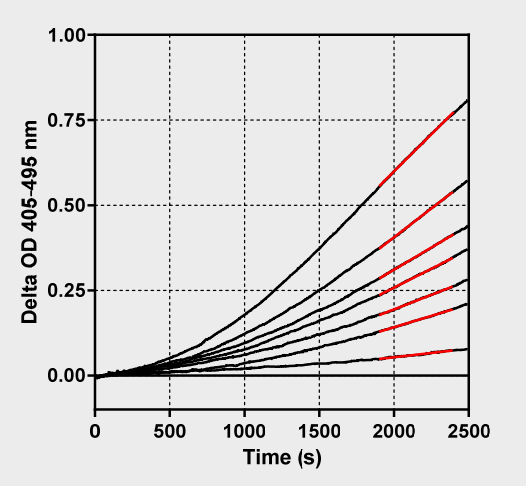


Figure 19. Fungitell STAT® Examples of Appropriate Kinetic Curve Shapes

8.4.6 Invalid - Missing Data

The Sample is missing data. This would be most likely caused by end user removing the sample tube during data collection. Alternatively, it may be caused by a loss of communication between the host computer and PKF08 during collection period. In this case, the Standard is affected as well and thus the test would be invalid: a new Standard and Sample(s) must be re-run after re-establishing the communication with the reader.

Potential root causes:
• Sample vial was removed before the completion of the assay: refrain from removing vials 10 seconds post-insertion.
• Communication between the PKF08 and BGA was lost while assay was in progress (the background color of the BG footer will change to red and a textual message will be displayed “Disconnected”. BGA will terminate the assay in the communication is lost for more than 120 seconds): Ensure that the USB cable is fully inserted into the communication port on PKF08. Avoid any physical contact with the connection following the original install to prevent the communication cable from loosening in the port. If the cable is loose, turn off the PKF08, remove the USB cable on both ends, re-insert properly. Replace the USB cable, if needed (standard AB USB). In this case, the Standard is affected as well and thus the test would be invalid: a new Standard and Sample(s) must be re-run after re-establishing the communication with the reader.

8.4.7 Invalid – OD Not Above 0 At 500

The kinetic trace of the Sample must be positive at and after the first 500 seconds of the collection period. If the trace is not positive, the Sample is invalid and has to be re-run. Re-sampling may be required.

Potential root causes:
• Sample condition (e.g. presence of interfering substances, incompatible sample composition, incorrect volumes used): re-sampling may be needed. The correct sample volume is 75µL.
• STAT RGT was inappropriately reconstituted, handled or contaminated: after reconstitution, RGT becomes a proteinaceous solution which is sensitive to physical stress. It should never be over-vortexed. Vortexing time and speed for RGT is 1 – 2 seconds at no more than 2000 RPM.

8.4.8 While the respective sample is invalid, other Samples included in the assay run may be evaluated.Invalid - End OD

The kinetic curve of the Sample must have an OD > - 0.005 at the end of the collection period. If the OD is ≤ -0.005, the Sample is invalid and has to be re-run.

Potential root causes:
• No patient sample (or low volume of patient sample) was added to STAT RGT tube: the correct sample volume is 75µL
• Sample condition (presence of interfering substances, presence of optical artifacts): re-sampling may be needed.
While the respective sample is invalid, other Samples included in the assay run may be evaluated.

8.4.9 Invalid – Sample Slope

The slope of the Sample calculated from the kinetic data between 1900 and 2400 seconds must be a positive value. If the slope is not positive, the Sample is invalid and has to be re-run. Re-sampling may be required.

Potential root cause:
Sample condition (presence of interfering substances, presence of optical artifacts): re-sampling may be required.
While the respective sample is invalid, other Samples included in the assay run may be evaluated.

8.4.10 Invalid - Correlation Coefficient

The correlation coefficient (R) of the Sample calculated from the kinetic data between 1900 and 2400 seconds must be ≥ 0.980. If the R value for Sample is < 0.980, the Sample is invalid and has to be re-run. Re-sampling may be required.

Potential root causes:
• Sample condition (presence of interfering substances, presence of optical artifacts): Re-sampling may be required.
• Physical disturbances (especially during 1900 – 2390s) occurred: prevent any physical disturbances (e.g. vibration).
While the respective sample is invalid, other Samples included in the assay run may be evaluated.

8.4.11 Invalid - Curve Shape

The kinetic curve of the Sample must have an upward increasing curve shape consistent with the examples in Figure 19. If the kinetic curve shape is inconsistent with the examples given, the Sample is invalid and has to be re-run. Re-sampling may be required.

Potential root causes:
• Sample condition (presence of interfering substances, presence of optical artifacts, high background noise): re-sampling may be required.
• High background noise: re-sampling may be required.
• Delayed insertion of RGT vial containing the said sample into PKF08: insert the RGT vial containing the sample within 1 minute of adding the sample.
• Re-use of a previously run RGT vial: always use a new RGT vial.

While the respective sample is invalid, other Samples included in the assay run may be evaluated.

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.

9 Symbols Used

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

10 Revision History

Rev 2: Added Downloading procedure, Materials supplied, Materials required but not supplied, Authorized representative, Revision History, Symbol used and Reference sections. The lower cutoff limit for the QC Criterion: Invalid-End OD QC was changed from ≤0.03 OD to ≤-0.005. OD, within the Index Sample field “NaN” was changed to “Index Not Calculated”. Minor clarifications and formatting.
Rev 3: Removed Authorized rep, EC REP name and address.
Rev 4: Updated UK address Germany. Update symbols used. 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.
Rev 5: Updated logo and reference to the ACC website to www.fungitell.com. Updated system requirements at Table 2 to include Microsoft Windows 11 option. Added paragraph 7. Operational use of PKF08 at section 3.1 to emphasize proper use and maintenance of the instrument. Updated the result reporting to include estimated Fungitell® pg/mL at sections 1.2, 5.1, 5.3 and 7 and kinetic trace display when standard fails QC criteria at Figure 19. Updated Section 8. Troubleshooting with a new address for the UK/EU technical service team and Section 8.1.6 PKF08 light intensity is low. Minor syntax updates throughout.

11 References

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[4] Girouard, G., Lachance, C., and Pelletier, R. 2007. Observations of (1→3)-ß-D-Glucan detection as a diagnostic tool in endemic mycosis caused by Histoplasma or Blastomyces. J. Med. Mycology 56: 1001-1002.

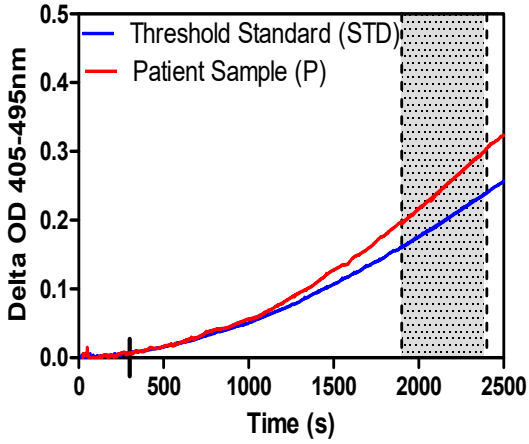
Appendix A: Glossary of Terms

Below is a list of the terms and acronyms used in this document and the meaning of each.

Term	Meaning
DV	Digital Value
OD	Optical Density
Delta OD	The difference in OD at two different wavelengths (OD 405 nm – OD 495 nm), where 405 nm is the primary wavelength and 495 nm is the secondary wavelength (used to eliminate background noise).
Rate	The slope of the linear fit of optical density vs time in seconds over the interval 1900 to 2400 seconds.
Correlation coefficient	The R value, defined as the standard Pearson Correlation coefficient of OD vs time over the interval 1900 to 2400 seconds.
Slope	In this application Slope = Rate
QC	Quality Control criteria
(1→3)-β-D-glucan	A class of polysaccharides with repeating units of glucose. They are part of the cell wall in fungi, algae, some bacteria and plants, where they contribute mechanical strength and integrity to the cell wall.
STAT STD	A reaction tube containing STANDARD (supplied with Fungitell STAT® kit)
STAT RGT	A reaction tube containing REAGENT (supplied with Fungitell STAT® kit)
APS	Alkaline Pre-treatment Solution

Appendix B: Index Value Calculation

The region highlighted in grey is the area of the slope determination (1900 to 2400 seconds (s)), the red line is an example Patient sample and the blue line is the Fungitell STAT® Standard. The slope of the sample (i.e. 0.00022 OD/s) divided by the slope of the 80 pg/mL Fungitell STAT® Standard (i.e. 0.00016 OD/s) leads to an Index of 1.4 for the sample. Slope and rate are synonymous in this application



Well	Slopes (OD/s)	Index	Sample Info
1	0.00016	1.0	STD
2	0.00022	1.4	P

Figure 20. Example of Fungitell STAT® Kinetic Curves and Data Analysis

Contact Information

Corporate Headquarters

Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445 USA
Tel: (888) 395-2221 or (508) 540-3444
Fax: (508) 540-8680
E-mail: custservice@acciusa.com
www.acciusa.com

United Kingdom/Europe

Associates of Cape Cod, Intl, Inc.
Unit 1 F/G/H Academy Business Park
Lees Road, Knowsley
Liverpool L33 7SA
United Kingdom
Tel: (44) 151–547–7444
Fax: (44) 151–547–7400
E-mail: info@acciuk.co.uk
www.acciuk.co.uk

EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33-
Suite 123 2595 AM The Hague
The Netherlands

