

PKF08 Incubating Kinetic Tube Reader User Manual

2022-06-02 Rev 5.5 (this supersedes all previous versions)

PKF08-1



Manufacturer: Lab Kinetics LLC, 150 Mustang Dr., Hutto, Texas 78634 USA, www.labkinetics.com

IVD

1. Preface: Thank you for purchasing and using this PKF08 Incubating Kinetic Tube Reader. Lab Kinetics, L.L.C. is a specialist, and worldwide leader, in the manufacture of state-of-the-art high specification Kinetic Tube Readers. It is our privilege to have you as our customer. Please read this Manual carefully before operating this device. We reserve all rights to amend this Manual without notice. This product is designed for trained professionals in clinical laboratory or industrial environments.

Note: The PKF08 Incubating Kinetic Tube Reader has no independent measuring function and thus require an assay specific software and reagent for in vitro diagnostic uses.

PKF08 is registered with US FDA GUD

2. Contact Information

Customer Service:

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

EC REP

EC Representative:
Emergo Europe Prinsessegracht 20,2514 AP,
The Hague,
The Netherlands

3. Intended Use: The PKF08 is an Incubating Kinetic Tube Reader with 8 channels that reads optical signals at wavelengths 405nm and 495nm. The PKF08 is intended to provide data for the analysis of human serum samples such as, for example, with the *in vitro* diagnostic Fungitell® STAT Assay (FT007, Associates of Cape Cod, Inc). This product is intended for in vitro diagnostic purposes.

4. Functional Principle:

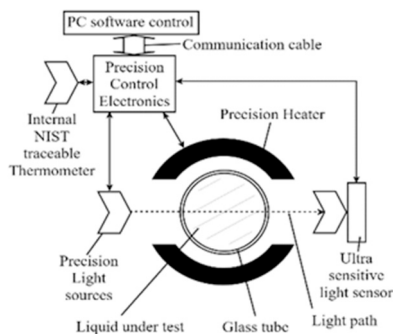


Figure 1. PKF08 Instrument Technology

The device is designed to send light level data in liquid serum samples at constant temperature and light intensity. The diagram shows how the light from a series of multiple light sources, travels through the sample, contained in a glass tube, precision heated to a precise temperature, and arrives at a special, very high sensitivity sensor which converts the light to electrical data. There are eight of these circuits, one for each of the eight tube wells in the heating mantle. The precision electronics controls these circuits to make all the necessary fine adjustments for stability control. The sample temperature is precisely controlled to 36.0 - 37.0°C and calibrated with an internal traceable NIST thermometer with lifetime calibration. The 8 measuring stations for tubes are optically independent and offer an optimal dynamic range. The PKF08 is designed for use with borosilicate glass tubes of 11.6-12 mm diameter and 65-75 mm length, filled with at least 350 µL of liquid.

5. Items Included: PKF08 Incubating Kinetic Tube Reader, Dust Cover, Power Supply, Communication Cable and User Manual.

6. Materials and Equipment required but not supplied:

- **Computer:** A computer with a USB A port that runs software for recording/analyzing/testing data
- **Software:**
 - The PKF08 does not include a software. The PKF08 is designed for use with external computer-based software.
 - The PKF08 has been validated for use with the Beta Glucan Analytics (BG Analytics®) software to perform the Fungitell STAT® assay. The BG Analytics® software together with the PKF08 are available from Associates of Cape Cod, Inc. (Cat. No. PKF08-PKG). It includes a software manual and the BG Analytics® system verification protocol.

- When using another software, the user is responsible for the software installation and the recording and processing of the test data. For this purpose, a software with a command set is required to control the PKF08 and to collect and evaluate data in accordance with the test requirements. The requirements with regard to the system and Internet security depend on the specific software and are defined as follows.
- Interface requirements:
 - o Communication connection (hardware) – Communication cable is included. USB-A end goes to the USB port of the computer, USB-B end goes to the PKF08 – see Figure 2.
 - o Communication protocol – the PC software follows the communication protocol - see section Technical Specification.
 - o Command-based control: The PKF08 responds in a defined way when it receives a command from the PC software - see section Technical Specification.
- **Glass tubes:** Borosilicate glass tubes with a diameter of 11.6 – 12 mm and a length of 65 - 75mm
- **Specific assay components and instructions for use**

7. Safety instructions

NOTICE TO THE USER: Any serious incident that has occurred in relation to this 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.

7.1 Notes for the location

The instrument should be located in a suitable workplace for optimal results:

- Temperature 10-30°C
- Too high humidity: Condensation can cause the reader to fail. The specified range of relative humidity for this reader is between 10% and 70% (non-condensing).
- Excessive ambient light: Bright sunlight or strong incandescent light can affect the optics of the reader and the readings.
- Dust: The data can be affected by foreign particles. A clean working area is necessary to ensure accurate readings.
- Assess the electromagnetic environment before commissioning the PKF08. Do not use the device near sources of strong electromagnetic radiation.
- Before connecting PKF08 to the power, make sure that:
 - at least 2 power outlets are available for the use of a computer and the PKF08
 - the socket used has the correct voltage (see the technical specifications)
 - the power cable and the socket have a grounding.
- Do not place the PKF08 under a ventilation shaft of the air conditioning system or in direct sunlight.
- Make sure the surface is flat, stable, and horizontal without vibrations.
- △ Keep the PKF08 away from water sources.

7.2 General precautions

- As thunderstorms can cause short circuits and damage this equipment, we recommend that you disconnect the device from the power outlet before a thunderstorm. We recommend that you do not plug in or unplug the device during a thunderstorm. We also recommend using a surge protector between the outlet and power supply. First, connect the power supply to the photometer before connecting the power.
- Electrostatic discharge can take place on surfaces (especially plastic) that are not grounded. Such incidents are more common when humidity is low (often in winter). Static discharge by the instrument can cause the device to function incorrectly and should be avoided. The PKF08 is designed to minimize the static discharges. However, it is advisable to repeat any test in which an electrostatic discharge has taken place.
- △ Do not open the PKF08 enclosure. There are no user serviceable parts inside, and it will void any warranty. Service shall only be carried out by trained, authorized personnel.

7.3 Instructions for use

7.3.1 Device-specific

- Do not place the PKF08 directly next to a Vortex mixer or other sources of electrical or magnetic interference or electrostatic discharge during data acquisition.
- △ In case of penetration of shards of glass and liquids into a well of the PKF08, contact Associates of Cape Cod, Inc. Technical Service.
- Keep mobile phones at least 1 meter from the PKF08 during operation.
- The PKF08 meets the emission and immunity requirements of the IEC 61326-1 standard
- Radio frequency (RF) emissions correspond to Class B.
- If there is a suspicion that the power is affected by electromagnetic interference, correct operation can be restored by increasing the distance between the device and the source of the fault.

7.3.2 Test-specific

- The operator must follow the manufacturer's instructions of the assay used to determine the appropriate software and readout parameters. The operator must also follow the manufacturer's instructions and specific recommendations for the assay used to confirm that the assay is carried out as intended and in accordance with local regulations. Failure to perform quality controls can result in incorrect test data.

- ⚠ Some tests or samples may pose a biological hazard. Appropriate safety precautions should be taken as indicated in the package leaflet of the assay. Always wear appropriate protective equipment and carry out the recommended technical checks.
- Wear protective gloves when handling biological samples that may be infectious or dangerous. Wear prophylactic gloves when handling contaminated instruments and performing the decontamination process. The gloved hands should be considered contaminated at all times; keep your gloved hands away from your eyes, mouth and nose. Wear an eye guard and surgical mask if there is a possibility of aerosol contamination.
- Interfering substances: Off-color or turbid samples such as those that are grossly hemolyzed, lipemic, or contain excessive bilirubin may cause optical interference with the assay. If such samples are tested, test results should be examined for evidence of optical interference and/or unusual kinetic patterns.

7.4 Cleaning and disinfection

To clean and disinfect the PKF08, use a lint-free cotton cloth with isopropanol (IPA) in a concentration between 70% and 91%. Protective gloves must be worn.

8. Tube Reader Installation and Operation:

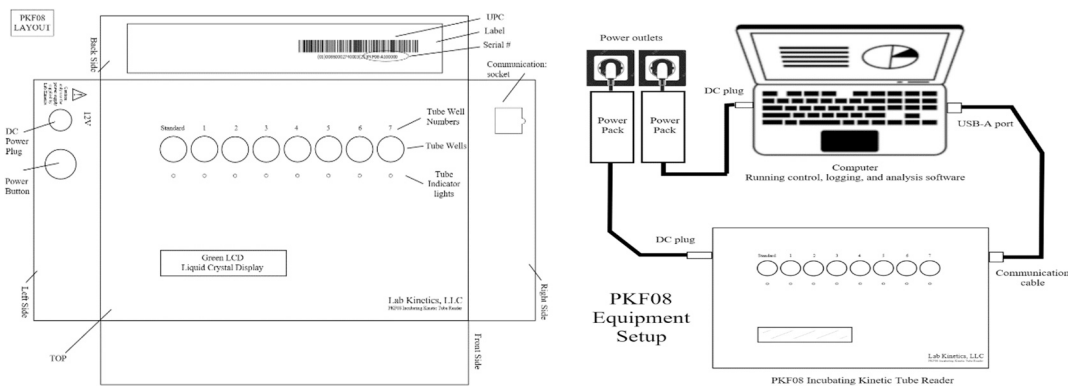


Figure 2: Display of PKF08 instrument and computer connection

1. Connect the power supply to the power outlet and the 12Vdc output of the PKF08, and then connect it to the power outlet.
2. Connect the communications cable to the computer and the PKF08.
3. Press the on/off power button on the Tube Reader, left side - a switch-on tone will be heard.
4. The warm-up takes about 10 minutes.
5. No further user settings or calibrations are required.
6. When used with the Fungitell STAT[®] assay, the user must follow the installation process in the BG Analytics[®] Software Manual and the BG Analytics[®] System Verification Protocol to verify installation, functional, and performance qualification.

9. Test execution

9.1 General

1. Start the appropriate recording/analysis software and follow the software and assay-specific instructions for use.
2. Insert the tube and start the data readings.

Note: By inserting a tube into the measuring station, the LED indicator changes from red to green. It is essential to fully insert each tube into the PKF08 instrument, both during incubation and during data collection. The tube detection mechanism can already be triggered if the tube is only partially inserted (the LED light of the measuring station changes from red (no tubes) to green (with tubes)). However, incubation and data collection may be impaired and therefore lead to invalid results.

⚠ Caution, the tubes are fragile.

3. Assay-specific data processing and analysis by the software follows.
4. The software checks the assay-specific quality control criteria.
5. Assay-specific results are displayed and available for interpretation.

9.2 Specific to Fungitell STAT[®]

1. To perform the Fungitell STAT[®] assay, follow the instructions of the Fungitell STAT[®] and BG Analytics[®] software.
2. When used with the Fungitell STAT[®] assay, the BG Analytics[®] software automatically adjusts the wavelengths, the kinetic reading interval and the measurement time.
3. For more details on the analytical and clinical performance of the Fungitell STAT[®] assay when used with this instrument, as well as specific information on the storage and preparation of serum samples, refer to the Fungitell STAT[®] Instructions for Use.
4. Calculation of measurement results

When used with the Fungitell STAT[®] assay and BG Analytics[®] software (Figure 3), the difference in optical density (delta OD) is determined at 405 and 495 nm. The slope of the optical density (rate) of the serum sample in the section between 1900 and 2400 seconds is used to calculate the results. The rate of the serum sample is compared with the rate of the Fungitell STAT[®] standard to calculate an index.

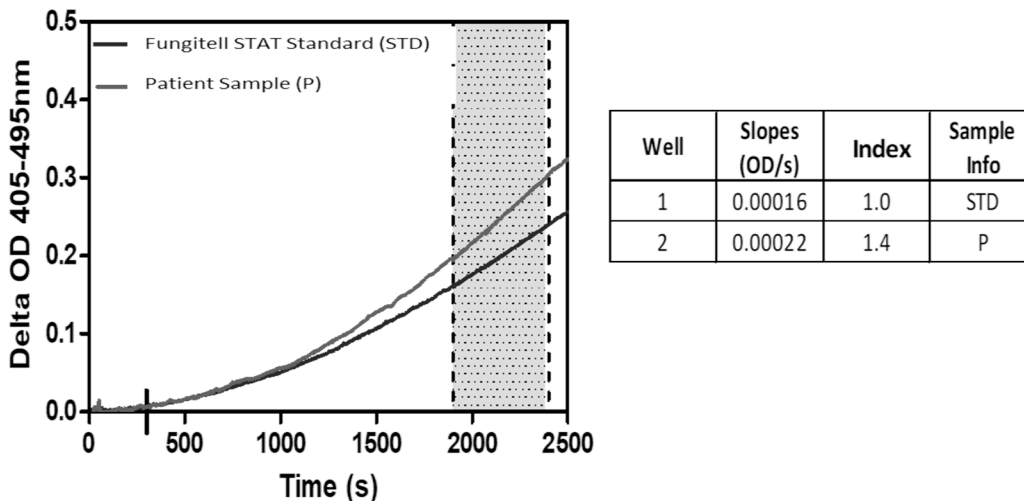


Figure 3. Example of Fungitell STAT[®] kinetic curves and data analysis

The gray highlighted area is the area of slope determination (1900 to 2400 seconds), the upper red line represents a patient sample, and the lower blue line is the Fungitell STAT[®] Standard. The slope of the sample (i.e. 0.00022 OD/s) divided by the slope of the Fungitell STAT[®] Standard (i.e. 0.00016 OD/s) gives a sample index of 1.4.

10. Maintenance:

- Surface cleaning after use.
- Calibration: Temperature and optical calibration can only be done by your PKF08 supplier. Calibration is recommended every 24 months or according to your laboratory's quality assurance program and local regulations.

11. Functions of the PKF08 reader and automatic controls

- Well LED indicators: Red - No tube inserted.
- Well LED indicators: Green - Tube is present and normal testing is in progress.
- Well LED indicators: Orange - The device is warming or running a temperature auto-calibration.
- On/off switch: The LCD (liquid crystal display) lights up green indicating the instrument is ON.
 - Switch on: There is an audible set of two rising tones in quick succession.
 - Switch off: There is an audible set of two falling tones in quick succession.
- If the block temperature rises to ~60°C a repeating "beeping" will sound and the LCD will display "TEMPERATURE ERROR". In this case, you should contact your supplier.
- The 2-line LCD (liquid crystal display) may show the following:
 - Line 1 can display the product serial number or any 16 character message directed by software.
 - Line 2 will display the wavelength '405nm', '495nm', '405nm' and '405nm' or an error message.
- When switched on, the PKF08 automatically returns to the calibrated temperature, which is automatically checked using an internal NIST-traceable thermometer.
- When using the BG Analytics[®] software, the optical calibration is automatically checked before the kinetic measurement can be started.

12. Troubleshooting: For technical assistance, contact Associates of Cape Cod, Inc.'s Technical Services Department

- No power supply: The LCD screen or the LEDs of the measuring stations do not light up.
 - Verify that the power cord is connected to the power outlet.
 - Press the power button again.

If the problem persists, contact Technical Support.

- Measuring station LED (s) do not light up: If the PKF08 is working but an LED has failed, contact Technical Support.
- LEDs glow green without tubes: A tube detection switch may be in the ON position: insert and exit the tube several times to release the switch. If the problem persists, contact Technical Support.
- LEDs glow red with tubes inserted: A tube detection switch may be in the OFF position. Insert and remove the tube several times to release the switch. If the problem persists, contact Technical Support.
- LCD display shows only mutilated information: Turn the PKF08 off and on again. If this does not resolve the issue, contact Technical Support. Note: This error does not affect the performance of the PKF08.
- A tube cannot be fully inserted into a measuring station.
 - Inspect the measuring station in question for dirt or shards of glass.

- Turn off PKF08 and unplug the power plug. Then turn the device over so that loose foreign bodies can fall out.
- ⚠ Compressed air spray should never be used to remove dirt from a measuring station of the PKF08 instrument. This can cause dirt to become stuck in the light path and damage the electronics.
- Alternatively, the measuring station can be cleaned with a micro-vacuum pump.

If the problem persists, contact Technical Support.

- Out-of-range temperature: If the temperature is outside $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ after a 20-minute calibration, contact technical support.
- Communication between PKF08 and software is lost during the test process.
 - Make sure that the communication cable is fully plugged into the PKF08 communication port.
 - After installation, avoid touching the cables so that the connection does not loosen. A physical contact with the connection to PKF08 to prevent the communication cable from dissolving in the communication port.
 - Replug the communication cable. Depending on the time and duration of the communication loss, there may be an impact on the reportable data transfer (if using the BG Analytics™ software, the data is still collected. If the problem is resolved within 120 seconds, BG Analytics™ will continue to collect data.
 - If the problem persists, contact Technical Support.
- Errors are displayed on the computer monitor: Seek advice from the software vendor.

13. Packaging: consists of carton with EVA foam lining to hold the product in place during transit and transparent polyethylene bags to keep dust away from the electronics.

14. Return of the Instrument: When the instrument is returned, use the original packaging in which the device was delivered and observe the specified "Transport and Storage Conditions."

Note: Any laboratory device used for research or clinical analysis is considered biologically dangerous and must be decontaminated before handling. Decontamination minimizes the risk to anyone who comes into contact with the device during transport, handling and maintenance. Please, contact Associates of Cape Cod, Inc.'s Technical Services Department to confirm the return procedure.

15. Disposal :

Residues of chemicals and preparations are generally considered to be hazardous wastes. The disposal of this type of waste is regulated by national and regional laws and regulations. Contact your local authorities or waste management companies for advice on the disposal of hazardous waste. The Kinetic Tube Reader is RoHS 2 compliant (2011/65/EU) and WEEE (2012/19/EU). Contact your local Representative for disposal of the instrument.

16. Features

- The PKF08 light sources have their maximum at 405 nm (± 5 nm) and 495 nm (-10 nm / $+ 20$ nm), measured using a reference method and a CV600 spectrometer. This is a special wavelength precision meter. Each light source is measured, logged and checked individually to meet specifications.
- The temperature is checked in measuring station No. 4 to the specification 36.0 to 37.0 °C. It is measured with the YSI 4610 digital reference thermometer. A PT100 temperature sensor with a length of 15 mm is used. In each PKF08, temperature stability is checked over a 60-minute period, logged to ensure that the specified specifications are met.
- Optical baseline: Specification ± 10 milli absorption units over 60 minutes measured with data acquisition software. This test is carried out without tubes and measures the stability of the optics over time.

16.1 Features of the PKF08 in conjunction with the Fungitell STAT® and BG Analytics® Software

The performance of the PKF08 instrument was evaluated when used with the BG Analytics® software to perform the Fungitell STAT®.

The Fungitell® STAT was tested for reproducibility and precision by inducing human serum with *Saccharomyces cerevisiae* (1→3)- β -D-Glucan to obtain a selection of five subjects consisting of a low negative and a highly negative, an indeterminate, a low positive and a highly positive sample. These five samples were distributed to three clinical laboratories. Each laboratory provides 150 data points (i.e. 5 samples x triples per run x two operators performing one run per day x 5 days) for a total of 450 data points. Inter-assay values (i.e. % CV) ranged from 11% to 20.4%. Intra-assay variability ranged from 0.4% to 26.8%, with 94% of CV values being 10% or below.

17. Transport and storage conditions:

- Ambient temperature: -10 to $+55^{\circ}\text{C}$
- Relative humidity: 0% to 95%

Technical Specification:

Wavelengths used:	405nm peak (± 5 nm), 495nm peak (-10 nm/ $+20$ nm)
Empty well Optical Precision:	± 10 milli OD stability over a 60 mins period.
Incubation Temperature:	36.0 - 37.0°C
Wells:	8 wells
Tube size:	$\Phi 11.6 - 12$ mm x 65 – 75 mm
Read Liquid Level:	350 μl
Read interval:	better than 5 seconds.
Communication:	HID USB-UART Bridge, Baud:500,000, D8PNS1
Expected life:	8 years
Statutory warranty:	2 years

Operating Conditions:

Ambient Temperature Range:	10~30°C
Relative humidity:	10% ~70%
Safety Classification:	Type B
Mains Voltage:	100 to 240VAC (external medical power adapter)
Mains Frequency:	50Hz/60Hz
Power requirement:	10W typical
Dimension:	6.9" x 4.7" 1.4" (175x120x35mm)
Weight (excl. power adapter):	~15oz. (425g)

Description	Standard	Directive
In Vitro Diagnostic (IVD) Device compliant		98/79/EC
Restriction of Hazardous Substances (RoHS) compliant		2011/65/ EU
Waste Electrical & Electronic Equipment (WEEE) compliant		2012/19/EU
Low Voltage (LVD)		2014/35/EU
EMC conformity:	EN 61326-1, IEC61326-2-6	2014/30/EU
• Conducted Emissions:	EN 55011	EMC testing is traceable to the United Kingdom National Accreditation Body – UKAS Safety Testing is traceable to US Accreditation Body “National Institute of Standards and technology” (NIST)
• Radiated Emissions:	EN 55011 Class B	
• ESD:	EN 61000-4-2	
• Radiated RF Immunity 1+2:	EN 61000-4-3	
• Fast Transient Burst:	EN 61000-4-4	
• Surge Immunity:	EN 61000-4-5	
• Conducted RF Immunity:	EN 61000-4-6	
• P.F.M.F. Immunity:	EN 61000-4-8	
• Dips & Interruptions:	EN 61000-4-11	
• Mains Harmonics:	EN 61000-3-2	
• Flicker:	EN 61000-3-3	
Safety conformity:	IEC 61010-1, IEC61010-2-101	

UDI (Unique Device Identification): This is a system for the identification of medical devices introduced by the FDA. Here is the GS1-128 format we use. See the product label.



(01)00860002740003(21)PK:F08-A100000

