Luminex®
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Guava® Instrument Cleaning Fluid (ICF) Package Insert

Technical Support
Telephone: 512-381-4397
North America Toll Free: 1-877-785-2323
International Toll Free: + 800-2939-4959
Email: *support@luminexcorp.com*
www.luminexcorp.com

RUO

For Research Use Only. Not for use in diagnostic procedures.

4600-0150, Rev M
Catalog No. 4200-0140
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Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727
U.S.A.

Symbols Glossary

You will encounter these symbols throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

Symbol	Meaning	Symbol	Meaning
	Caution		Biological risks
	Serial Number		Consult instructions for use
	Manufacturer		Contains sufficient for <n> tests
	Catalog number		Batch code
	Use by date		Storage temperature range
	For Research Use Only. Not for use in Diagnostic Procedures		Warning.

Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-2323

Contact outside the U.S. and Canada by calling: +1 512-381-4397

International: + 800-2939-4959

Fax: 512-219-5114

Email: *support@luminexcorp.com*.

Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter *http://www.luminexcorp.com* in your browser's address field.

This manual can be updated periodically. To ensure that you have a current version, contact Technical Support.

Description

The Guava® easyCyte™ and Guava Muse® Systems operate with minimal maintenance and servicing, but the flowcell and fluid system require regular cleaning to ensure proper performance.

Guava Instrument Cleaning Fluid (ICF) cleans the fluid system of the Guava easyCyte or Guava Muse System by effectively removing sample clogs and buildup from cell debris, proteins, and reagent dye residues. Although Guava ICF is supplied ready to use with no dilution required, you can mix Guava ICF with bleach as described in this package insert for a more effective cleaning and disinfecting solution.

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Materials Provided

- Guava® Instrument Cleaning Fluid (ICF) (Part No. 4200-0140, 100 mL)

Materials Required but not Provided

- Guava® easyCyte™ or Guava Muse® Cell Analyzer
- Bleach (5% to 6% sodium hypochlorite)
- Micropipettor
- Disposable micropipettor tips
- Microcentrifuge tubes with screw caps, 1.5 mL (VWR, Cat. No. 16466-030, or equivalent)
- Disposable gloves
- Deionized (DI) water

Warnings and Precautions

1. For Research Use Only. Not for use in diagnostic procedures.
2. Guava® Instrument Cleaning Fluid (ICF) is for laboratory use only.
3. Perform the procedure given in this package insert as described. Any deviation from the outlined protocols may result in assay failure or cause erroneous results.
4. Guava ICF contains potassium hydroxide and detergents. Avoid direct contact with skin, eyes, and mucous membranes. The detergent can cause irritation and damage. Pre-existing skin conditions and allergies to detergents can be aggravated by exposure. Consult the Safety Data Sheet (SDS) for additional safety information.
5. Do not use the kit or any kit components past the expiration date indicated on the kit carton label. Do not interchange kit components from different kit lots. Lot numbers are identified on the kit label.
6. Guava ICF is a skin and eye irritant.

Causes skin and serious eye irritation. If on skin, wash with plenty of soap and water. If in eyes, rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Get medical advice/attention.

7. Wear appropriate personal protective equipment (PPE), including a lab coat and disposable gloves, when performing procedures.
8. When using Guava ICF to clean your Guava PCA, Guava easyCyte™ System, or Muse® Cell Analyzer, hhandle all materials as if capable of transmitting infection. Dispose all materials with proper precautions in accordance with federal, state, and local regulations. Avoid specimen contact with skin and mucous membranes. Do not pipette by mouth.
9. Do not pipette by mouth.
10. Safety Data Sheets (SDS) are available by contacting Luminex Corporation or visiting our website at *www.luminexcorp.com*.

Reagent Storage, Handling, and Stability

- Store Guava® Instrument Cleaning Fluid (ICF) RUO at room temperature. Do not freeze.

  NOTE: Do not use the kit or any components past the expiration date indicated on the kit carton label. Do not interchange kit components from different kit lots. Lot numbers are identified on the kit label.

- Store Guava ICF in a closed container. Keep the container capped when not in use.
- Guava ICF has a highly basic pH. Store segregated from acidic reagents.

  NOTE: Some settling of suspended particles may occur during prolonged storage. Invert the bottle prior to use to resuspend any settled material.

Assay Procedure

Prepare Guava® Instrument Cleaning Fluid (ICF)

To improve overall Guava® easyCyte™or Guava® Muse® System performance by removing buildup from cell samples and reagent residues, use Guava Instrument Cleaning Fluid (ICF) in the Quick Clean procedure periodically throughout the day, always followed by at least one Quick Clean with water. To extensively clean and disinfect the Guava easyCyte or Guava Muse System, use Guava ICF with 10% bleach in the cleaning procedure at the end of each day. Luminex recommends cleaning the system if your Guava Check, easyCheck™, or System Check results

fail to reach the expected number of events after running Quick Clean. In addition, you can clean the system to clear stubborn clogs.

Do not leave bleach or any other cleaning agent on the instrument overnight or for an extended period of time. Prolonged exposure to strong cleaning agents will damage the flowcell. Always flush the instrument extensively with water after using any cleaning reagent. At the end of a cleaning cycle always leave the capillary tip submerged in a 1.5 mL tube of fresh deionized water.

NOTE: If acquiring whole blood or lysed whole blood samples, first perform the cleaning procedure with water only to prevent any protein precipitation in the capillary or fluidics tubing. Then repeat the cleaning procedure as described below. For more information, refer to the appropriate system user's guide.

Prepare Guava® Instrument Cleaning Fluid (ICF) for Cleaning

1. Invert the Guava® Instrument Cleaning Fluid (ICF) bottle several times to mix.
2. Dispense approximately 1.3 mL of Guava ICF into a 1.5 mL microcentrifuge tube.
3. Cap the tube until ready for use.

Prepare Guava® Instrument Cleaning Fluid (ICF) with Bleach for Cleaning and Disinfecting

Luminex recommends this 10% bleach mixture for cleaning and disinfecting the Guava® easyCyte™ and Guava Muse® Systems. Prepare the Guava ICF with 10% bleach mixture frequently (at least every few days) to maintain effectiveness.

1. Mix 1 part bleach with 9 parts Guava ICF (for example, 1 mL bleach plus 9 mL Guava ICF) in a clean container.
2. Cap the container and mix well.
3. Add approximately 1.3 mL of Guava ICF with 10% bleach, for a final concentration of 0.5% to 0.6% hypochlorite to a 1.5 mL microcentrifuge tube or 1.0 mL to a titer tube.

   NOTE: For cleaning the flowcell, Luminex recommends using a solution of <0.6% sodium hypochlorite. For decontamination of biological waste, Luminex recommends using 5 mL of 5% to 6% sodium hypochlorite, unless otherwise stated by your safety guidelines.
4. Cap the tube until ready for use.

Clean the Instrument

For details about cleaning procedures, as well as additional cleaning and maintenance procedures, refer to the appropriate system user's guide.

Clean the Guava® Muse® System

NOTE: Always check the fluid levels in the cleaning and waste bottles whenever you run the Complete Clean procedure. Ensure the cleaning solution bottle is filled with Instrument Cleaning Fluid (ICF).

1. Select **Muse System Cleaning** under the Essential Tools at the main menu.
2. Select **Complete System Clean**.
3. Select **Run Complete Clean**.
4. Follow the prompts to load ICF, followed by deionized (DI) water.
   Select **Finish** if you are done, or **Next Cleaning** to run the Complete System Clean again. Always leave a tube of water on the system after cleaning and when shutting down.

Clean the Guava® easyCyte™ Single-Loader (SL) Systems

1. Click **Cleaning** from the main menu. The Guava® Clean screen appears.
2. Click **Start Cleaning**. Load a tube of deionized (DI) water, then click **OK**.
3. After approximately 4 minutes, a message appears prompting you to load a tube of cleaning solution. Load a tube of Guava Instrument Cleaning Fluid (ICF) with 10% bleach. Ensure that there is sufficient cleaning fluid in the cleaning solution vial. Click **OK**.
4. After approximately 3 minutes, a message appears prompting you to load a tube of DI water. Load a tube containing about 1 mL of clean DI water, then click **OK**.
   Click **Main Menu** to return to the GuavaSoft™ main menu, or click **Exit** to close GuavaSoft. Always leave a tube of water on the Guava easyCyte™ when it is turned off.

Clean the Guava® easyCyte™ High-Throughput (HT) (Automated) Systems

1. Click **Cleaning** from the main menu. The Guava® Clean screen appears.
2. Click **Start Cleaning**. The tray ejects and a dialog box appears. Load the following tubes:
   - Deionized (DI) water in w1 through w6 and tube position 1
   - 100 µL of straight bleach in tube position 2
   - bleach in Instrument Cleaning Fluid (ICF) (1 part to 9 parts) in tube positions 3 and 4
   - DI water in any position 5-9, then click to select the location
3. Click **Main Menu** to return to the GuavaSoft™ main menu, or click **Exit** to close GuavaSoft.

Clean the Guava® PCA System

1. Click **Clean and Shut Down** from the main menu. The Guava® Clean screen appears.
2. Click **Start Cleaning**. Load a tube containing Guava Instrument Cleaning Fluid (ICF) or Guava ICF with 10% bleach. Click **OK** at the prompt.
3. After approximately 3 minutes, a message appears prompting you to load a tube of deionized (DI) water. Load a tube containing about 1 mL of deionized (DI) water, then click **OK**. After approximately 3 minutes, End of Cleaning appears at the bottom of the screen.

4. Click **Main Menu** to return to the CytoSoft™ main menu or click **Exit** to close CytoSoft.

   NOTE: If you want to continue with data acquisition, launch the desired CytoSoft application and allow the laser to warm up for 5 minutes before resuming data acquisition.

5. Leave a tube of deionized (DI) water on the Guava PCA.

Clean the Guava® easyCyte™ Mini System

1. Click **Clean and Shut Down** from the main menu. The Guava® Clean screen appears.
2. Click **Clean Only** or **Clean and Shut Down**.
   a. Load a tube containing Guava Instrument Cleaning Fluid (ICF) or Guava Instrument Cleaning Fluid (ICF) with 10% bleach.
   b. Ensure that there is sufficient cleaning fluid in the cleaning solution vial. Click **OK**.
3. After approximately 2 minutes, a message appears prompting you to load a tube of deionized (DI) water. Load a tube containing about 1 mL of deionized (DI) water, then click **OK**.
4. If you selected **Clean Only**, after approximately 5 minutes, End of Cleaning appears at the bottom of the screen.
5. Click **Main Menu** to return to the CytoSoft™ main menu, or click **Exit** to close CytoSoft. If you selected **Clean and Shut Down** the system will automatically power off.
6. Leave a tube of deionized (DI) water on the Guava easyCyte™ Mini when it is turned off.

Clean the Guava® PCA-96, PCA-96 AFP, and easyCyte™ Systems

1. Click **Clean and Shut Down** from the main menu. The Guava® Clean screen appears.
2. Click **Start Cleaning**. The tray ejects and a dialog box appears.
   a. Load two tubes containing Guava ICF or Guava ICF with 10% bleach into tube locations w1 and w4.
   b. Load four tubes containing deionized (DI) water into tube locations w2, w3, w5, and w6.
   c. Click **OK**. The tray loads and cleaning begins. After approximately 15 minutes, the cleaning procedure is finished and Ready to Start appears again at the bottom of the screen.
3. Click **Main Menu** to return to the CytoSoft™ main menu, or click **Exit** to close CytoSoft.

Clean a Clogged Flowcell

Occasionally while using an application, data acquisition may slow or fail to reach the expected number of events, indicating a clog. Cleaning the instrument with Guava® Instrument Cleaning Fluid (ICF) can improve performance.

If, after cleaning a clogged flowcell, the fluid system still appears to be clogged, refer to the appropriate system user's guide for more troubleshooting tips or contact Luminex Technical Support for assistance.

Clean a Clogged Flowcell for Single-Loader (SL) Instruments

1. If the sample seems to be running slowly, click **Abort**.
2. Load a tube containing a small amount of bleach for disinfecting, and then click **Backflush**. Discard the tube after performing this step.

3. Click **Quick Clean**. Follow the prompts and load a tube containing Guava® ICF or Guava ICF with 10% bleach. Click **OK**. The cleaning solution runs for approximately 30 seconds.
4. Load a tube containing deionized (DI) water, then click **Quick Clean** again.
5. Verify that the deionized (DI) water tube is loaded, and then click **OK** to rinse out the cleaning fluid.
6. Repeat as necessary to remove the clog.

Clean a Clogged Flowcell for High-Throughput (HT) (Automated Instruments)

If a sample in an automated instrument seems to be running slowly, pause any running worklist, then complete the following steps to clean a clogged flowcell.

1. Eject the tray to load one tube containing a small amount of bleach for disinfecting, one tube containing clean water and one tube containing Guava® Instrument Cleaning Fluid (ICF) or Guava Instrument Cleaning Fluid (ICF) with 10% bleach, if necessary.
2. Reload the tray, and then click **Backflush**.
3. Follow the prompts to use the tube with 20% bleach.
4. Click **Quick Clean**. Follow the prompts to indicate the location of the tube containing Guava Instrument Cleaning Fluid (ICF) or Guava Instrument Cleaning Fluid (ICF) with 10% bleach.
5. Click **OK**. The cleaning solution runs for approximately 30 seconds.
6. Click **Quick Clean** again, this time indicating the location of the tube with water.
7. Click **OK** to rinse out the cleaning fluid.
8. Repeat as necessary to remove the clog.

Clean a Clogged Flowcell for the Muse® Instrument

1. If the sample seems to be running slowly, click **Abort**.
2. Select **Clean**, then select **Backflush** and follow the prompt to load a tube with 20% bleach. Discard the tube after performing this step.
3. Select **Quick Clean**. Follow the prompt but load a tube containing Guava® Instrument Cleaning Fluid (ICF) or Instrument Cleaning Fluid (ICF) with 10% bleach. Select **Clean**. The cleaning solution runs for approximately 30 seconds.
4. Select **Quick Clean** again. Load a tube of deionized (DI) water, then select **Clean**.
5. Remove the tube and select **Close**.
6. Repeat as necessary to clear the clog.

Troubleshooting

1. If the data acquisition rate slows or does not reach the target number of events, stop the acquisition and clean the instrument. If you are having fluidics problems and are using the Guava® ViaCount™ module, Luminex recommends running Guava Check, easyCheck™, or System Check to assess instrument counting performance before continuing with ViaCount.

2. If a clog is difficult to clear using Quick Clean, perform a Backflush, then repeat the Quick Clean several times using Guava Instrument Cleaning Fluid (ICF) and deionized (DI) water. If the flow rate is still slow, perform a Complete System Clean procedure until the acquisition rate is normal.
3. If Guava Check, easyCheck, or System Check shows a low particles/mL count and the scatter and fluorescence intensity results are normal, partial clogging is likely. Run Quick Clean using Guava ICF and again with DI water. If the acquisition rate is still below normal, run Clean and Shutdown with two cycles (Guava PCA) or one cycle (all other Guava System).
4. Use Guava ICF periodically to clear the fluid system of buildup from cell samples and reagent residue. Run Quick Clean with Guava ICF followed by water.
5. Sticky or clumpy cell samples often require intermittent use of Guava ICF with Quick Clean. Always follow a Quick Clean with deionized (DI) water. Doing so rinses the flowcell and prevents sample contamination. Contact Luminex Technical Support for additional assistance.
6. If white, cloudy material is observed settling at the bottom of the Guava Instrument Cleaning Fluid (ICF) bottle, invert the bottle 5 to 10 times in order to return the material to suspension. Guava Instrument Cleaning Fluid (ICF) may also be warmed to 37°C to reduce cloudiness.

For more troubleshooting information, refer to the Guava® easyCyte™ or Muse® System user's guide, or contact Luminex Technical Support.

Limitations of the Procedure

1. The results are dependent upon proper use of reagents, products, and instruments.