GenMark Dx

ePlex

Quick Reference Guide

GenMark Diagnostics, Inc.
5964 La Place Court
Carlsbad, CA 92008
USA
+1 760 448 4300

CE IVD

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Limited Warranty/Limited Liability

GenMark Diagnostics warrants to the original purchaser that products will be free from defects in workmanship or materials for a period of one (1) year from date of purchase under normal use. The sole and exclusive remedy under this limited warranty is repair or replacement of defective products or parts thereof. Repair or replacement products or parts thereof will be furnished solely on an exchange basis and are obtainable only by the original purchaser. The original purchaser shall return the defective product, or part thereof, properly packaged with postage or shipping costs prepaid to GenMark Diagnostics. Loss or damage during shipment shall be at the risk of the purchaser.

This limited warranty does not include repair or replacement necessitated by accident, neglect, misuse, relocation, unauthorized repair, or modification of the product. The above limited warranty is the sole warranty provided by GenMark Diagnostics. No other warranties, expressed or implied, including warranties of merchantability or fitness for a particular purpose, are provided whatsoever. GenMark Diagnostics shall have no liability for any direct, indirect, consequential, or incidental damages arising out of the use, the results of use or the inability to use the product. Some products may be deemed non-returnable due their biological status. Accordingly, prior to returning a defective or service-requiring product, please contact GenMark's technical services department to evaluate and arrange a return.

Patents

The ePlex instrument and eSensor® electrochemical detection technology are proprietary to GenMark Diagnostics, Inc. and, depending on specific application and configuration, embodied in one or more of United States Patent Nos. 7,312,087, 7,172,897, 6,602,400, 9,498,778, 9,410,663, 10,391,489, 9,453,613 and additional foreign and domestic patents and pending applications.

Licensing inquiries should be directed to GenMark's Legal Department at 5964 La Place Court, Carlsbad, CA 92008.

Unless otherwise agreed to in writing, by using the ePlex instrument, Recipient acknowledges that Recipient has read, accepts and agrees to be bound by and comply with the Terms and Conditions available on GenMark's website which can be amended from time to time by GenMark without consent. If Recipient does not accept and agree to be bound by the Terms and Conditions, Recipient will immediately cease any further use of the instrument.

Trademark and Copyright Statements

Intended Use

The ePlex® instrument is an automated in vitro diagnostic device designed to perform multiplexed nucleic acid tests for the simultaneous detection and identification of nucleic acid targets by processing single-use cartridges developed and manufactured by GenMark Diagnostics, Inc.

Chapter 1. Preface

About this Manual

The ePlex Quick Reference Guide provides instructions how to operate the ePlex system. The instructions within this manual assume user has basic software computer skills.

Getting Help

For any questions concerning how to set up, use, or maintain the ePlex instrument that are not covered in this manual, refer to the following available resources:

- ePlex instrument help – Can be accessed from the ePlex user interface by selecting the Help icon on the toolbar:

- Package Insert – Information specific to the preparation and performance of each assay is located on the GenMark Customer Resource Center at https://customer.genmarkdx.com/.

If you are in the United States, contact GenMark Technical Support for additional assistance, questions, or issues concerning the ePlex system. For inquiries or concerns outside the United States, contact GenMark Technical Support or your authorized GenMark representative.

Before contacting GenMark Technical Support please have the following information:

1. Last four digits of the ePlex Serial Number
2. Error Messages (if applicable)

United States

GenMark Technical support is available 24 hours a day, 7 days a week to provide the highest level of customer support and satisfaction.

GenMark Diagnostics, Inc.
5964 La Place Court
Carlsbad, CA 92008
Phone: 1 800 eSensor (1 800 373 6767), Option 2
Email: technicalsupport@genmarkdx.com

International Locations

GenMark Diagnostics, Inc.
5964 La Place Court
Carlsbad, CA 92008
Phone: 1 800 eSensor (1 800 373 6767), Option 2
Email: technicalsupport.eu@genmarkdx.com

Chapter 2. Compliance and Safety

General Safety Precautions

Before operating the ePlex system, make sure you read the ePlex operator manual entirely and ensure you are familiar with the safety information. Operating the ePlex system outside the procedures specified in the ePlex Operator manual can result in exposure to hazards that can cause injury to personnel, damage the system, or adversely impact system performance.

Safety Symbols

Sections marked with safety symbols contain important safety information for optimal operation of the ePlex system. Attention to these advisories may prevent harm to operator, damage to the system, or compromised test results.

Warning: A hazard or operational warning. Not following the specified directions or guidelines could result in harm to the operator, damage to the system, or compromised test results. Indicates a possibility of adverse reactions, injury, or death to the user or other personnel if the precautions or instructions are not observed.

Electrical Warning: A hazard or operational warning. Not following the specified directions or guidelines could result in harm to the operator including electric shock.

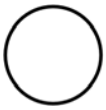
Biohazard Warning: A hazard or operational warning. Not following the specified directions or guidelines could result in harm to the operator including exposure to biohazardous material.

Note: A note identifies important details that apply to specific cases or tasks.

Additional symbols may be used on the ePlex test kits and are explained in the associated Package Insert.

Symbols Used in the Manual and on ePlex Instrument Labels

	*In vitro* diagnostic medical device		European Union Conformity
	Manufacturer		Authorized representative in the European Community
	Serial number		Catalog number

	Consult instructions for use		WEEE - Do not throw in trash
	RoHS Directive		ETL Listed Mark
	Caution		Biological Risk
	Electrical Risk		Note
	On		Off

Compliance

The ePlex system has been tested according to the applicable regulatory requirements and directives. References can be found in the Declaration on Conformity.

Warnings and Hazards

Follow standard laboratory precautions when operating the ePlex system. The warnings listed in this section apply to the ePlex system and its accessories.

GenMark does not take any responsibility for unauthorized modifications to the ePlex system or for failure of operating personnel to heed the warnings and cautions. Any equipment used in a manner not specified in this manual may become unsafe. Review all warnings in this section before operating the ePlex system.

System Handling Warnings

- The ePlex system must be assembled, installed, and qualified by GenMark authorized personnel.
- Do not modify the ePlex system hardware or software without written authorization from GenMark or a GenMark authorized representative.
- Do not add or connect any accessories to the ePlex system without authorization from GenMark or a GenMark authorized representative.
- Do not attempt repairs or service on the ePlex system or accessories without authorization from GenMark or a GenMark authorized representative.

- In the event of an observed leak, contact GenMark Technical Support.
- Follow all written and on-screen instructions for safe and effective use of the ePlex system.
- Only properly trained personnel should operate and perform any repair or service on the ePlex system.
- Do not remove any covers or panels without authorization from GenMark or a GenMark authorized representative.
- For routine surface cleaning, do not spray any fluids directly on the ePlex instrument, accessories or components.
- Do not shut off main power to the ePlex system while the system is starting or running. Please use the ePlex software to properly shutdown or restart the ePlex system.
- Use only GenMark approved cartridges on the ePlex system.
- Always backup current database prior to restoring a new database or purging data.
- Do not attempt to reuse ePlex cartridges.
- Avoid pressing down on the top label of the cartridge prior to running the cartridge.
- When manually starting a run, ensure accession ID is accurate.
- In the case of a software downgrade, data generated with the newer software may be lost after downgrading. Backup database prior to downgrade.
- Restoring a database may result in lost data on the currently installed database. Ensure you backup the current database before restoring the database.
- Do not attempt to lift or move the ePlex system without authorization from GenMark or a GenMark authorized representative.
- See original equipment manufacturers instructions for safe operation of ePlex accessories.
- Inform your local competent authority about any serious incidents which may occur when using this instrument and components.

Environmental Warnings

- Do not operate the ePlex system outside of the required environmental specifications.
- Do not operate the ePlex system above elevations of 2000 meters (6,700 feet).
- Prior to preparing an ePlex instrument run, clean all work surfaces with appropriate cleaning solution.
- Do not use the ePlex instrument in close proximity to sources of strong electromagnetic radiation as these devices may interfere with the ePlex system operation.
- Ensure at least 7.62cm (3") clearance around and on top of the ePlex system for adequate ventilation and cooling.

Cartridge Handling Warnings

- Avoid touching the transfer device's tip. Follow assay specific Package Insert.
- Do not place accession ID barcode outside of the designated barcode placement area on the ePlex

cartridge.

- Inspect all ePlex cartridges for damage prior to use.
- Do not insert an ePlex cartridge if the cartridge has any signs of leaks or fluid.
- Do not invert ePlex cartridges after dispensing sample into sample port.
- Avoid touching inside the sample port on the ePlex cartridge.
- Do not attempt to reopen the sample cap on the ePlex cartridge after closing the cap.
- Always handle samples cautiously and keep all samples upright to prevent splashing or spilling.

Biological Hazards

- Follow universal precautions for biohazards when handling all samples and when performing all maintenance activities.
- Wear safety equipment or apparel, including gloves, safety glasses, and lab coats when working with patient samples.
- Complete sample transfer in a biosafety hood.
- Treat all samples and controls as potentially infectious material.
- Dispose of processed ePlex cartridges as biohazardous waste upon removal from the ePlex system.
- Do not attempt to open or disassemble ePlex cartridges at any time.
- Leaks from the ePlex system or cartridges may contain biohazardous materials.
- Consult biological hazards listed in the ePlex assay Package Insert.

Electrical Hazards

- Never touch any switches or outlets with wet hands or wet gloves.
- Never disconnect power connections to the ePlex instrument while running.
- Perform only maintenance and service procedures in this manual or authorized by GenMark or a GenMark authorized representative.
- Do not operate the ePlex system if any liquid has leaked inside or on the ePlex system or cartridge.
- Shutdown ePlex software before turning off front power button or main power switch.
- Turn off the power using both the front power button and rear power switch before disconnecting the AC power cord.
- Do not place open liquid contains on or around the ePlex system.
- Do not insert anything other than the ePlex cartridge or test cartridge into the bay on the ePlex tower.

Chapter 3. Operation

The workflow for processing a cartridge on the ePlex system includes the following:

1. Apply an accession ID barcode to the cartridge matching the accession barcode on the primary sample.

Note: Ensure both barcodes match prior to transferring sample.

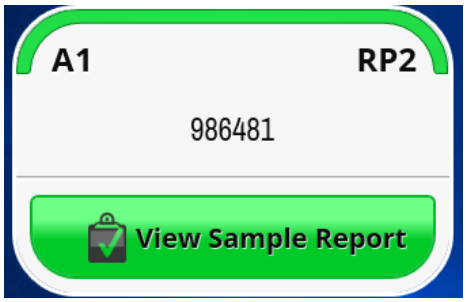
2. Transfer sample into the sample port on the cartridge in accordance with the associated test panel Package Insert.

Note: Sample cap is clear enabling user to confirm sample was added to the cartridge after closing the cap.

3. Rotate cap 90° clockwise and close the cap to seal the cartridge.

4. Scan the cartridge barcodes. Upon successful scan of both the cartridge ID barcode and the accession ID barcode the scanner will beep once and LED on the scanner will blink green indicating a successful scan.
5. Insert cartridge into any ready bay indicated by a blinking white LED. The system will match the accession ID to that bay and automatically starts the run.
6. Upon run completion, the bay will automatically eject the cartridge and prepare the Detection Report for display, print, or export using View Sample Report on the Bay icon or Bay Details view.

7. Select View Sample Report to view the detection Report.



Navigating the User Interface

The ePlex user interface is organized into four main views: Run, Reports, Settings and Tools.

The default view is the Run view. To move from one screen to the next, select the Navigation icon in the lower left hand corner of the toolbar and choose the desired view from the menu.

The toolbar is visible at the bottom of the screen in all screen views. The toolbar includes:

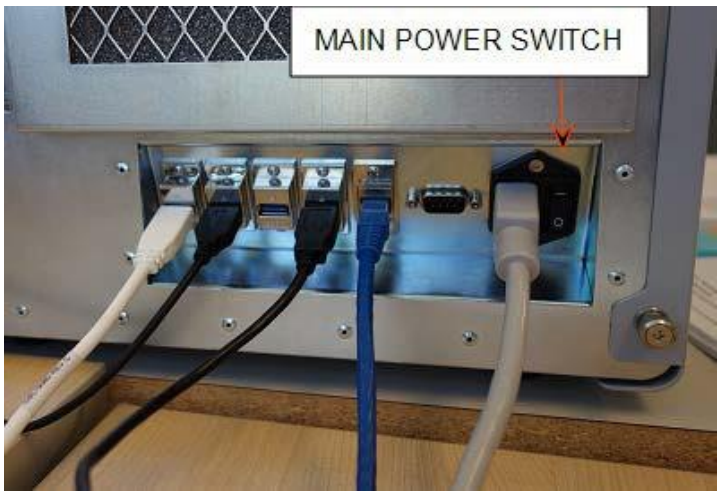
1. Navigation icon
2. Pending Test Orders icon
3. Manual Entry icon
4. Bay Errors icon (shown when applicable)
5. Alerts icon (shown when applicable)
6. Remote Access/Bomgar Button icon
7. Help icon
8. Screen Capture icon
9. Current User icon
10. Logout icon
11. Current Date/Time
12. Restart icon

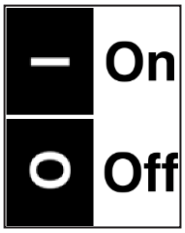
Chapter 4. Using the System

Power on the System

To turn on the ePlex instrument:

1. Ensure the main power switch is in the "On" position indicated by "-" The main power switch controls power to the entire ePlex System.





2. Press the power button on front of the base to illuminate the switch and turn the ePlex instrument on. The front power switch controls power to the ePlex integrated PC.

Note: If the ePlex instrument does not turn on, check the main power switch in the back left corner of the Instrument.

Electrical Warning: Once the instrument is running, the main power switch in the back left corner of the base will shut down the ePlex instrument immediately. All samples running at the time of shutdown will be lost.

Electrical Warning: Turn off the power using the front power button before disconnecting the AC power cord.

Electrical Warning: Never touch any switches or outlets with wet hands or wet gloves.

Electrical Warning: Perform only maintenance and service procedures in this manual or authorized by GenMark or a GenMark authorized representative.

Electrical Warning: Do not operate the ePlex system if any liquid could have leaked inside or on the ePlex

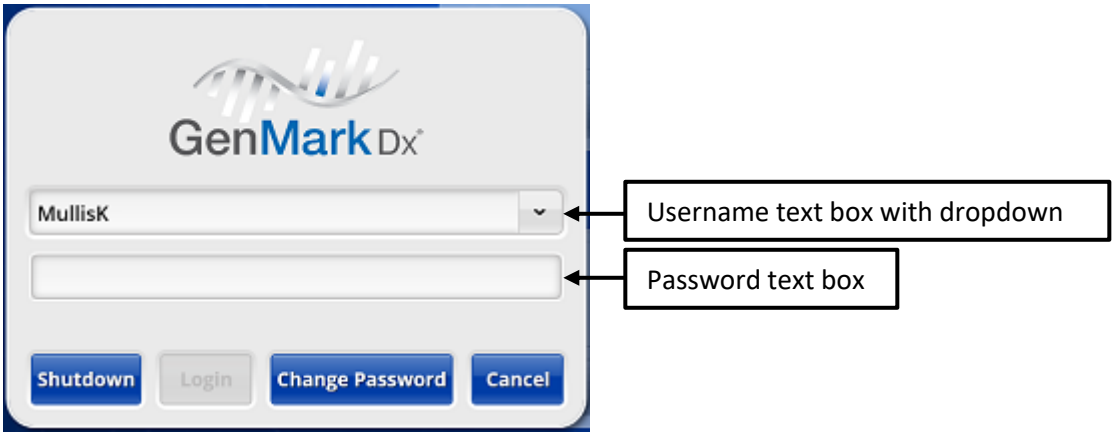
system or cartridge.

Electrical Warning: Turn off the power using the front power button before disconnecting the AC power cord.

Electrical Warning: Do not place open liquid contains on or around the ePlex system.

Electrical Warning: Do not insert anything other than the ePlex cartridge or test cartridge into the bay slot on the ePlex tower.

Logging In



To login to the ePlex instrument:

1. Select the username text box.
2. Enter the username and select Enter (alternatively, select the username from the drop-down list).
3. Select the password text box.
4. Enter the password and select Enter. The software will open in the Run view.

OR

When using the barcode scanner, simply scan the user barcode of an active user and you will be logged in and the software will go to the Run view.

A sample user barcode:

joesmith

Note: Username and password are encrypted within the user barcode.

Note: Any user can login at any given time without interrupting ongoing runs. The ePlex instrument does not allow for concurrent user logins.

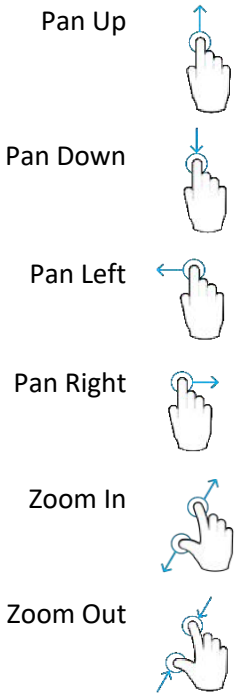
Using the Touchscreen

The ePlex graphical user interface allows users to easily navigate through the software simply by touching the screen.

The following guidelines apply when using the touchscreen:

- Touch buttons, text boxes and field headings only once; there is no need to double-touch anywhere on the ePlex interface.
- Touch delay may occur on certain screens including the Bay Configuration screen as the ePlex instrument is gathering information from the bays.
- After selecting certain functions you may see the Loading icon please be patient as the ePlex instrument is processing the request.

- The following multi-touch gestures are enabled when viewing reports:



- To enter information into a specific field, first highlight that field by selecting within the text box. The on-screen keyboard will appear, allowing users to begin entering text. Select Enter when complete.
- Select the SHIFT key to display symbols in place of the numbers on the on-screen keyboard.

- To hide the on-screen keyboard, touch the blue X in the upper right-hand corner of the keyboard, touch outside the keyboard or select Esc to hide the keyboard.

Preparing Cartridges

Prepare cartridges according to the procedures detailed in the associated ePlex Panel Package Insert located at https://customer.genmarkdx.com/.

The following sections in this manual assume that each cartridge has been properly loaded in compliance with laboratory standards and safety protocols.

Before inserting the cartridges into the ePlex instrument, check that they are properly labeled, cap is closed completely and confirm the accession ID barcode on each sample tube and cartridge match.

Starting a Run

A user can start a run by any of the following methods:

1. Manual Entry
2. Barcode Scanner
3. Pending Test Orders (PTO) Manual Run

Manual Entry

1. Go to the Run view.
2. Select the Manual Entry icon from the toolbar.

3. Enter an accession ID using the on-screen keyboard or barcode scanner and select Enter.
4. When prompted, scan the 2D cartridge ID barcode.
5. Insert the cartridge into any ready bay with a blinking white LED.

Note: A flag will be noted on the Detection Report stating "Manual start of a sample test" if using the Manual Entry workflow.

Note: Ensure manually entered accession ID is accurate before starting test.

Barcode Scanner

1. Go to the Run view.
2. Scan the cartridge by holding it under the barcode scanner.

Note: Both the customer applied accession ID barcode and the cartridge ID barcode are required for a successful cartridge scan. Scanner will beep once and LED on the scanner will blink green upon successful scan of both barcodes.

3. Insert the cartridge into any ready bay with a blinking white LED.

Note: Using the barcode scanner is the recommended workflow on the ePlex cartridge as it minimizes transcription errors.

Note: If downloading test orders, upon scanning an accession ID, the ePlex instrument will check for a matching pending test order and start the run.

Pending Test Orders (PTO) Manual Run

1. Go to the Run view.
2. Select the Pending Test Orders icon from the toolbar.

3. Select an available pending test order from the list.

4. Select Run.
5. Insert the cartridge into any ready bay with a blinking white LED.

Note: Positive sample identification is not valid using the PTO manual workflow. A flag will be noted on the Detection Report stating "Manual start of a sample test" if using the PTO manual workflow.

Using the Barcode Scanner

The barcode scanner can be used to complete the following activities:

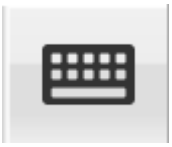
1. Log in with a User barcode.

joesmith

2. While on the Run view, the barcode scanner will simultaneously read the accession ID barcode and cartridge ID barcode from a cartridge to start a run.

Note: To start a run using the barcode scanner workflow, user must be on the Run view.

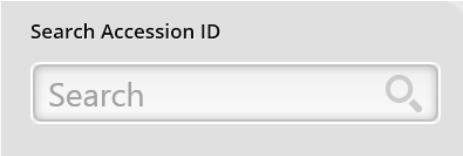
3. External control barcodes can be generated by the software and scanned with the barcode scanner when running external controls on the ePlex instrument.



4. After selecting the Manual Entry icon, the barcode scanner can be used to enter the Accession ID (while the on-screen keyboard is visible).
5. User barcodes can be used to electronically sign a report.

joesmith

6. While on the Reports > Sample Results tab, the barcode scanner can be used to enter an accession ID in the search field.



Barcode Scanning Tips

For effective barcode scanning follow these guidelines:

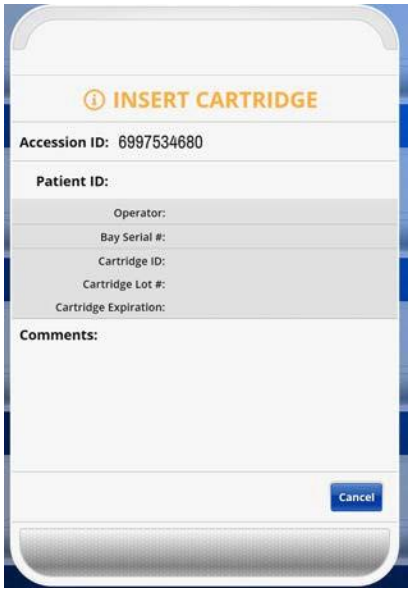
- Ensure room has adequate ambient lighting.
- Hold the ePlex cartridge in hand without covering any barcodes.

- Maintain at least a cartridge length between the bottom of the scanner and the cartridge.
- Move cartridge in a horizontal position with arrows pointing to the back of the ePlex instrument, aiming the red crosshairs for the scan location shown below.

Note: If the ePlex instrument cannot successfully scan barcodes, refer to starting a run using manual entry.

Inserting Cartridges into the ePlex Instrument

Once the ePlex instrument has the information needed to start a run, the user interface will instruct the user to enter the cartridge into any ready bay indicated by blinking white LEDs.



Insert the cartridge with the label facing up and arrows facing the bay as shown below.

Color Status Indicators

Both the Bay icon and the bay LEDs on the physical bays will have the following matching color status indicators for each state.

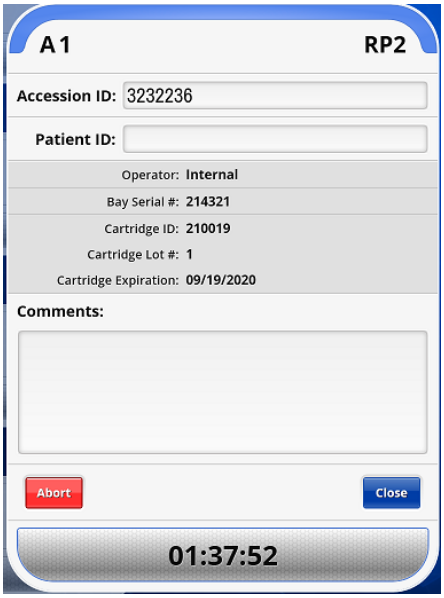
Color	LED Activity	Status
White	Solid	Ready
White	Blinking	Insert Cartridge
Blue	Solid	Running
Green	Blinking	Run Complete
Red	Urgent Blinking	Error
Off	N/A	Disabled

Note: A blinking LED indicates a user action is required.

Monitoring the Run

The Run view displays the Bay icons with colors matching the physical bay LEDs.

Selecting the Bay icon with a running bay will open the Bay Details view, which contains additional information for the bay and test cartridge.



Entering/Editing Accession ID, Patient ID, and Comments

Once cartridge initialization has passed, and while the run is in progress, the user may enter or edit the Accession ID, Patient ID, and Comments from the Bay Details view.

Note: Edits can only be made while the run is in progress and must be saved before the run completes.

1. Select a Bay icon that is running to display the Bay Details view.
2. Select the Accession ID text box.

Note: The accession ID may only be edited if the run was starting with a Manual Entry workflow.

3. Edit the Accession ID and select Enter.
4. Select the Patient ID text box.
5. Add or edit the Patient ID and select Enter.
6. Select the Comments text box.
7. Add or edit the comments and select Enter.
8. Select Save.
9. Select Close.

Bay Errors

The Bay Error icon is visible in the toolbar of any screen of the user interface if any bay is in the error state.

Selecting the Bay Error icon displays the Bay Error Summary view and includes bay location, date/time of the error and bay error message(s).

Bay errors can cause invalid tests and should be reported to GenMark Technical Support.

Alert Notifications

The Alert icon is visible on the toolbar if there are any outstanding warning alerts that have not been viewed. A warning alert is used to notify a user of a system warning.

The Alert icon will display the Tools > System Events screen displaying all alerts and will contain a numeric code and informational message.

Alert notifications are informational alerts that will not invalidate a test and do not need to be reported to GenMark Technical Support.

Aborting a Run

User Aborted Run

1. Select the Bay icon in a running state to display the Bay Details view.
2. Select Abort.

3. Enter optional comments and select Abort.

Note: A Detection Report will be created with invalid results with a message indicating the test was aborted by user.

Note: If run is aborted, the aborted test cartridge cannot be run again on the ePlex instrument.

Cartridge Removal

Upon test completion, the bay status LEDs will blink green on both the Bay icon and the physical bay. The user may remove the used cartridge and promptly discard it according to laboratory biological waste disposal procedures. Used cartridges cannot be re-used and should be disposed of immediately unless instructed by GenMark personnel.

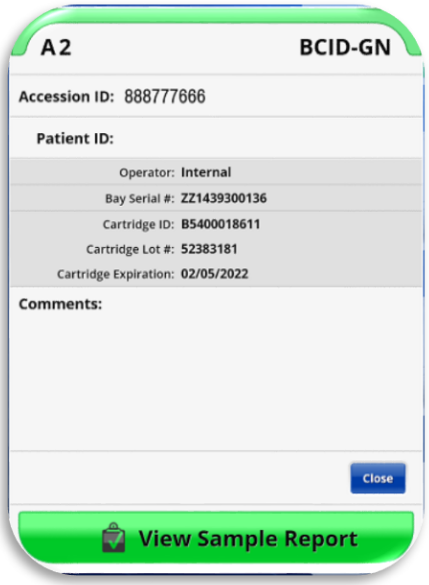
Note: Upon removal of used cartridges, do not turn cartridges upside down.

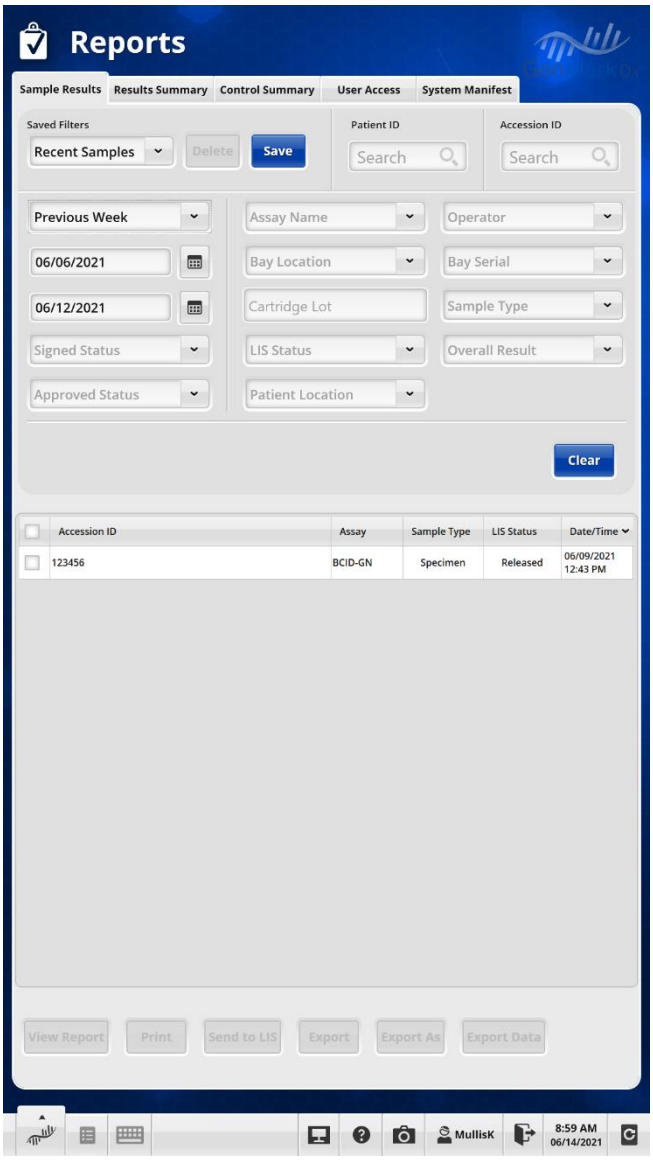
Note: If cartridge does not properly eject after run completes press cartridge in and release. If cartridge still does not eject, contact Technical Support.

Generating and Viewing Reports

To view a Detection Report for a sample that was run on a particular bay, select the green View Sample Report button on the Bay icon or Bay Details view.

Detection Reports can also be viewed from the Reports > Sample Results tab.





Document Revision Information	
Rev. A 04/2016	Original document
Rev. B 10/2016	Updated Intended Use information
Rev. C 12/2016	Updated Intended Use information to plan for future panel offerings
Rev. D. 05/2017	Updated labeling for IVD clearance
Rev. E. 06/2017	Updated EMERGO address
Rev. F. 12/2019	Updated compliance and certification information
Rev. G. 06/2021	Updated formatting and content to reflect new software additions
Rev H. 09/2021	IVDR Requirements

The summary of safety and performance report can be found using the following link:
https://ec.europa.eu/tools/eudamed