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Operating the Cepheid GeneXpert Dx System

PURPOSE

The GeneXpert Dx System automates and integrates sample preparation, nucleic acid amplification, and a detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is suited for *in vitro* diagnostic applications that require hands-off processing of patient samples and provides both summarized and detailed test results data. This procedure describes how to perform basic operation of the Cepheid GeneXpert Dx System.

POLICY

- This procedure is to be followed when performing a test on the Cepheid GeneXpert Dx System.
- Only the cartridges provided in the assay specific kit are to be used for testing on the instrument.
- Routine and scheduled maintenance tasks are to be verified before operating the instrument for patient testing. Refer to *Performing Maintenance on the Cepheid GeneXpert Dx System* procedure.

PROCEDURE

Follow the instructions for basic operation of the Cepheid GeneXpert Dx

- Refer to *GeneXpert Dx System Operator Manual* for detailed and additional instructions.

Step	Action
1.	At the start of the first run, verify the instrument modules are empty. Open the module doors and remove and discard any cartridges remaining from previously completed tests.
2.	Verify the GeneXpert instrument and then computer are turned on. Launch GeneXpert software if necessary using the appropriate user name and password. <ul style="list-style-type: none"> • NOTE: The Database Management dialog box will automatically appear after the software is initially opened. Select "NO" to proceed with testing.
3.	Obtain the prepared and labeled test cartridge that will be run on the instrument.
4.	Select Create Test on the menu bar.
5.	When the Sample ID Barcode dialog box appears, scan the small Sunquest aliquot barcode label on the test cartridge or appropriate QC barcode for the QC cartridge being loaded for the sample ID.
6.	Once the sample ID is entered, the Scan Cartridge Barcode dialog box appears.
7.	Scan the printed barcode on the cartridge. The Create Test dialog box will appear once scanned and the required information will automatically populate in the Create Test window.
8.	To ensure accuracy of results, be sure to use the same cartridge that was scanned for testing.
9.	The Test Type will default to Specimen. If external control, select control option from the Test Type drop-down menu.
10.	If needed, additional information can be typed in the Notes box about the test or specimen.
11.	Select Start Test and the green light above the available instrument module door will flash.
12.	Open the instrument module door.
13.	Place the cartridge on the module bay floor. The cartridge label should face out and the cartridge should sit level on the bay floor, positioned at the heel of the bay. <ul style="list-style-type: none"> • NOTE: Take care not to touch or hold cartridge by the protruding reaction tube when loading it into an instrument module. Bent or broken reaction tubes can produce invalid results. • NOTE: Do not load a cartridge that has been dropped or shaken after the reagents/sample has been inserted. Dropping or shaking the cartridge can cause invalid results. • NOTE: Do not re-use previously tested cartridges.
14.	Close the instrument module door all the way. The door will lock and the green light will go from flashing to solid light, indicating the test has started.
15.	If needed, set a timer for the length of time the test will take to ensure results will be retrieved and reported in a timely manner.
16.	To monitor the test progress or other status indicators, select the Check Status icon on the menu bar.

	<ul style="list-style-type: none"> When a test is in progress, "NO RESULT" is shown in the Result column under Tests Since Launch on the right side of the screen.
17.	<p>To stop a test in progress, select Stop Test icon on the menu bar.</p> <ul style="list-style-type: none"> Check the box or boxes to select the test(s) in progress that are to be stopped. Click Stop and then confirm with Yes or No. Select Cancel to dismiss the Stop Test dialog box and proceed with testing. After a test is stopped in progress, the system halts the sample processing activities and terminates data collection. Do not reuse the cartridge. <p>NOTE: If an emergency stop of all testing and instrument operation is necessary, the instrument can be stopped using the power switch on the back of the analyzer. This should never be performed unless there is a significant and urgent need to stop all operations immediately.</p>
18.	When the test finishes, the instrument module door will unlock and the green light will turn off.
19.	Individual results will automatically print when the test is finished. If manual entry of results is performed, label the paper with the large Sunquest barcode label that corresponds to the patient test cartridge run.
20.	Remove cartridge completed for testing from instrument module and discard in a biohazard container.
21.	Proceed to assay specific procedure for test result interpretation and instructions for reporting.

RELATED DOCUMENTS

- Performing Maintenance on the Cepheid GeneXpert Dx System
- Performing an Xpress Flu Assay

REFERENCES

- Cepheid GeneXpert Operator's Manual

All revision dates:

Attachments:

Approval Signatures

Step Description	Approver	Date
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