**Cepheid GeneXpert Instrument Procedure**

1. **PRINCIPLE:**
   1. The GeneXpert Dx system automates and integrates sample preparation, nucleic acid amplification, and 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 in tabular and graphic formats.
2. **PROCEDURE FOR OPERATION:**
   1. Turning on the instrument:
      1. Turn the power switch at the back of the instrument to the ON position.
      2. Turn the computer ON, then enter the appropriate username and password.
      3. The GeneXpert Dx software starts automatically. Enter username and password if applicable.
      4. Click the **Check Status** button, and verify all modules are available.
   2. Creating a Test:
      1. Click the **Create Test** button on the main menu of the GeneXpert Dx software.
      2. Enter the appropriate information in the Patient and Sample ID fields.
         1. For patient samples:
            1. Highlight the Patient ID field and in the window that appears, select **Manual Entry**, then type the appropriate Soft Molecular Order number.
            2. Highlight the Sample ID field and in the window that appears, select **Manual Entry**, then type the patient’s first and last name.
         2. For controls:
            1. Highlight the Patient ID field and in the window that appears, select **Manual Entry**, then type the control name (Ex. YYYYMMDD\_Heterozygous Control).
            2. Highlight the Sample ID field and click **Cancel** in the window that appears.
      3. Verify the Patient and Sample ID fields contain the correct information.
      4. Scan the barcode on the assay cartridge when prompted by the software.
      5. Change the Select Module field as needed.
      6. Verify the Select Assay field is displaying the correct assay(s).
         1. For patient samples:
            1. Refer to the assay worksheet to select **only** the ordered tests. Be careful to select the correct test. If the incorrect test is run, the sample will need to be repeated.
         2. For controls:
            1. Verify all assays in the multiplex are selected.
      7. Click the **Start Test** button to begin the test.
      8. Load the cartridge into the module with the blinking green light. Close the module door until it locks shut, once the door is properly closed, the green light will stop blinking.
   3. Loading Assay Definition File:
      1. **Note:** Importing the Assay Definition File, located in the kit, is only required when adding a new assay for the first time or when an assay has been updated at the discretion of the company.
      2. Insert the assay definition CD, located in the kit, into the computer’s DVD drive.
      3. On the GeneXpert Dx software main menu, click **Define Assays**.
      4. Click the **Import** button at the bottom of the Define Assays screen.
      5. In the Import Assay window that appears, open the Look in dropdown to select the DVD drive.
      6. Open the GeneXpert Systems folder, then select the .gxa file.
      7. Click **Import**.
         1. The newly imported assay will now appear in the Assay List found in the Define Assays window.
   4. View Results and Generate/Print a Report:
      1. Click the **View Results** button on the main menu of the GeneXpert Dx software.
      2. To print the report:
         1. Click the **Report** button at the bottom of the View Results window.
         2. Mark the checkbox for all applicable reports to be printed.
         3. Select **Preview PDF**.
         4. In the Adobe Acrobat window, select **File** and in the dropdown that appears, click **Print**.
         5. In the Print window, verify the HP LaserJet P1006 printer is defaulted, then click **Print**.
      3. To view results:
         1. Click the **View Test** button at the bottom of the View Results window.
         2. In the Select Test to be Viewed window, double click the appropriate sample and test.
         3. The View Results window will appear with the test result and curve information.
   5. Generate a Patient ID report:
      1. Click the **Reports** button on the main menu of the GeneXpert Dx software.
      2. In the dropdown that appears, select **Patient Report**.
      3. In the Patient Report window that appears, enter the patient ID in the patient ID field.
      4. Click **Preview PDF**.
      5. In the Adobe Acrobat window, select **File** and in the dropdown that appears, click **Print**.
      6. In the Print window, verify the HP LaserJet P1006 printer is defaulted, then click **Print**.
   6. Shutting down the instrument:
      1. Verify there are no tests running on the instrument.
         1. Click the Check Status button to view the module status screen.
      2. Exit the GeneXpert Dx software by clicking the red **X** button on the upper right of the screen.
      3. Select the windows home button; click **Power**, followed by **Shut down**.
      4. Turn the power switch at the back of the instrument to the OFF position.
         1. **Note:** Wait 2 minutes before restarting the system.
3. **MAINTENANCE:**
   1. Record completed maintenance on the appropriate Cepheid GeneXpert Instrument Maintenance log found in the Cepheid Instrument binder.
   2. All errors and instrument issues must be recorded on the Cepheid GeneXpert Instrument Error log.
   3. Daily:
      1. Clean work area:
         1. Follow standard daily cleaning practices according to the Molecular Genomic Laboratory Quality Management Program.
      2. Close all module doors:
         1. Check that all module doors are closed daily to avoid contamination of the modules.
      3. Discard used cartridges:
         1. Remove any used cartridges from the modules and discard in a biohazard sharp’s container.
   4. Weekly:
      1. Power cycle the GeneXpert instrument and Computer:
         1. Verify there are no tests running on the instrument.
            1. Click the Check Status button to view the module status screen.
         2. Exit the GeneXpert Dx software by clicking the red **X** button on the upper right of the screen.
         3. Select the windows home button, click **Power**, followed by **Shut down**.
         4. Turn the power switch at the back of the instrument to the OFF position.
         5. Wait 2 minutes before restarting the system.
         6. After 2 minutes, turn the power switch at the back of the instrument to the ON position.
         7. Turn the computer ON, then enter the appropriate username and password.
         8. The GeneXpert Dx software starts automatically.
         9. Enter GeneXpert Dx software username and password.
         10. Click the **Check Status** button, and verify all modules are available.
   5. Monthly:
      1. Environmental Control:
         1. Place 55 uL of deionized water in a 1.5 mL tube.
         2. Wet a swab with deionized water and wipe all prep surfaces, keyboard, and instrument doors.
         3. Place the swab in the previously prepared 1.5 mL tube.
         4. Aliquot 50 uL of the deionized water into the sample well of the assay cartridge.
         5. The control must be run in a different module each month. Refer to the previous month maintenance sheet to determine which module the control should be run.
         6. Run the cartridge on the instrument per standard assay procedure.
         7. Print a result report from the Cepheid GeneXpert and place in the appropriate instrument binder.
            1. Click the **View Results** button on the main menu of the GeneXpert Dx software.
            2. Click the **Report** button at the bottom of the View Results window.
            3. Mark the checkbox for all applicable reports to be printed.
            4. Select **Preview PDF**.
            5. In the Adobe Acrobat window, select **File** and in the dropdown that appears, click **Print**.
            6. In the Print window, verify the HP LaserJet P1006 printer is defaulted, then click **Print**.
         8. Result control in Soft Molecular per standard procedure.
         9. If the environmental sample is positive:
            1. Clean all areas that were tested.
            2. Repeat testing using one sample for each surface area:

Countertop

Keyboard

Instrument doors

* + 1. Archive tests: Performed by Senior Technologist or designee
       1. Click the **Data Management** button on the main menu of the GeneXpert Dx software.
       2. In the dropdown that appears, click **Archive Test**.
       3. Highlight all tests from the previous month and click **Select highlighted** followed by **OK**.
       4. A warning will appear verifying the tests should be archived, select **Proceed**.
       5. In the Save window, a file name is generated automatically, click **Save**.
       6. A warning will appear verifying the archive was successful, click **OK**.
       7. Proceed to the folder where the archived tests are saved. The archived tests can be found in the folder C:\GeneXpert\export.
       8. Plug the Secure Key flash drive into the Cepheid computer.
       9. Navigate to the Archive export folder.
       10. Highlight the applicable archive files, right click, and in the dropdown that appears, select **Cut**.
       11. Navigate to the Secure Key folder, then click **Paste**.
       12. Remove the Secure Key flash drive and plug it into a network computer.
       13. Save the files in the Cepheid folder on the MGPGenomicData$ drive.
    2. Clean plunger rod and cartridge bays
       1. Verify all modules are empty.
       2. Click the **Maintenance** button on the main menu of the GeneXpert Dx software.
       3. In the dropdown that appears, click **Plunger Rod Maintenance**.
       4. In the Plunger Rod Maintenance window, select **Clean All**.
       5. A warning will appear, select **OK**.
       6. The plunger rods in the selected modules will lower into the cartridge bay.
       7. Thoroughly moisten a lint-free wipe with 1:10 solution of bleach.
       8. Vigorously wipe the plunger rod with the lint-free wipe. Using the same wipe, clean the walls, ceiling, corners, and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door.
       9. Discard the lint-free wipe.
       10. Wait 2 minutes after wiping with the bleach solution.
       11. Thoroughly moisten a new lint-free wipe with 1:10 solution of bleach.
       12. Vigorously wipe the plunger rod with the lint-free wipe. Using the same wipe, clean the walls, ceiling, corners, and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door.
       13. Discard the lint-free wipe.
       14. Wait 2 minutes after wiping with the bleach solution.
       15. Thoroughly moisten a new lint-free wipe with 1:10 solution of bleach.
       16. Vigorously wipe the plunger rod with the lint-free wipe. Using the same wipe, clean the walls, ceiling, corners, and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door.
       17. Discard the lint-free wipe.
       18. Wait 2 minutes after wiping with the bleach solution.
       19. After the third and final bleach clean, thoroughly moisten a lint-free wipe with 70% ethanol.
       20. Vigorously wipe the plunger rod with the lint-free wipe. Using the same wipe, clean the walls, ceiling, corners, and edges of the cartridge bay, then wipe the inside of the door and the top lip of the door.
       21. Repeat the 70% ethanol clean a second time.
       22. Once cleaning is complete, click **Move Up**, then click **Close**.
       23. Close all module doors.
    3. Clean instrument surfaces:
       1. Verify all tests have completed before attempting to move the instrument.
       2. Shut down the instrument if necessary.
       3. Thoroughly moisten a lint-free wipe or paper towel with 70% ethanol.
       4. Wipe all surfaces outside the instrument. Change wipes frequently while performing the cleaning.
       5. Wipe the table surfaces surrounding the GeneXpert. Change wipes frequently while performing the table surface cleaning.
  1. Yearly:
     1. Preventative Maintenance of the GeneXpert Cepheid instrument is performed by Cepheid Technical Services.
  2. As Needed:
     1. Print system log report: The System Log reports can be used to provide incidents of instrument module self-tests and errors to Cepheid when a module failure has been encountered.
        1. In the GeneXpert System main menu, click **Reports**, then in the dropdown that appears select **System Log**.
        2. Specify the following criteria to view trends of interest:
           1. Date Range
           2. Modules
           3. Show: errors only or all entries
        3. Once log criteria have been selected, click **Generate Report File**.
        4. Plug the Secure Key flash drive into the Cepheid computer.
        5. In the Generate Report File dialog box that appears, navigate to the Secure Key flash drive, then click **Save**.
        6. In the System Log report window, click **Close**.
        7. Remove the Secure Key flash drive and plug it into a network computer.
        8. Save the files in the appropriate CMB\_Tests run folder and forward to Cepheid Technical Support as needed.
     2. Perform a manual self-test:
        1. The GeneXpert Dx system automatically performs a self-test during startup. However, a self-test can be manually initiated on any of the modules to reset and check for hardware failure problems.
           1. Verify all cartridges have been removed from the appropriate module(s).
           2. In the GeneXpert Dx System window, click **Maintenance** on the menu bar, followed by **Perform Self-Test**.
           3. In the Module Self-Test window, select the module to be checked, then click **Self-Test**.
           4. A warning will appear, click **OK**.
           5. When the self-test finishes, the software changes the module status to Available, which indicates the self-test passed.
           6. If the self-test failed, contact Cepheid Technical Support.

1. **TROUBLESHOOTING:**
   1. See Table 1 below for a list of possible hardware problems that might occur.

**Table 1:** Hardware Problems

|  |  |  |
| --- | --- | --- |
| **Problem** | **Possible Cause** | **Solution** |
| The system does not start. | The instrument is not connected to the power outlet. | Check the instrument power connections. |
| Module not detected. | Network cable not connected or incorrect cable installed.  Software launched before instrument turned on.  The IP address is not assigned correctly. | Check network cable.  Exit software and relaunch with instrument powered on.  Change IP Address Setting. |
| Barcode scanner failure. | Symbology unsupported.  Scanner barcode cable not plugged in. | GeneXpert Dx software supports Code 39, Codebar, Code 128 (A, B and C), linear barcode symbologies and Interleave 2 of 5.  Unplug scanner and re-plug into computer. |
| The cartridge is stuck inside the instrument module. | Module mechanical failure. | To remove the cartridge:   * In the GeneXpert Dx System window, click **Maintenance** on the toolbar. * On the Maintenance menu, click **Open Module Door or Update EEPROM**. * Select the module. * Click **Open Door** to open the module door.   If the door does not open, cycle the instrument power and repeat the above steps. |
| The instrument module red light is flashing. | Module mechanical failure | Confirm no cartridge is in the module.  Perform self-test manually. See section III, E, 3.  If the error recurs, contact Cepheid Technical Support. |
| Test report is not printed at the end of run. | Printer offline.  Printer out of paper and/or toner. | Check:   * Printer on-line * Paper present * Toner OK |
| Unable to create a test. | Modules not available.  No assay selected.  Module not calibrated for reporters used in assay.  The ambient temperature of the module is above 55˚C. | Check that the modules are not disabled.  Check the assay is selected.  Calibrate the assay dyes.  Check module temperature in Maintenance screen. If your room is in the recommended temperature range and the module is above 55 ˚C, contact Cepheid Technical Support. |
| Unable to start test. | Reporters out of calibration. | Check module reporters in maintenance window:  Reporters for assay are present.  Calibration status is valid. |

* 1. Refer to section 9.19.2 of the Cepheid GeneXpert Operator Manual v6.4 on the desktop of the Cepheid laptop for information about error messages, possible causes and solutions.

1. **CONTACT INFORMATION:**
   1. Cepheid United States Technical Support
      1. Email: [techsupport@cepheid.com](mailto:techsupport@cepheid.com)
      2. Phone: 1-888-838-3222, Option 2
      3. Fax: 408-716-2550
2. **REFERENCES:**
   1. GeneXpert Operator Manual v6.4, Document# 302-4070, Rev. B (December 2020).
   2. GeneXpert IV System Service Manual, Document# 300-6985, Rev. A (August 2008).
   3. GeneXpert Dx Reference Guide, Document# 301-8343, Rev. B (July 2018).