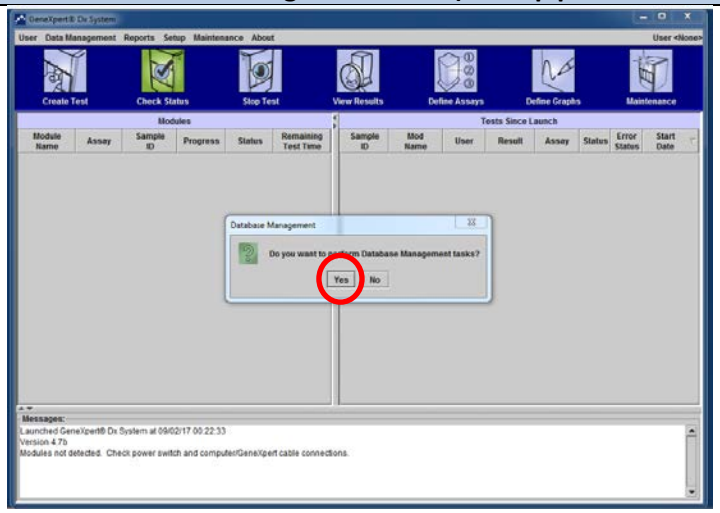
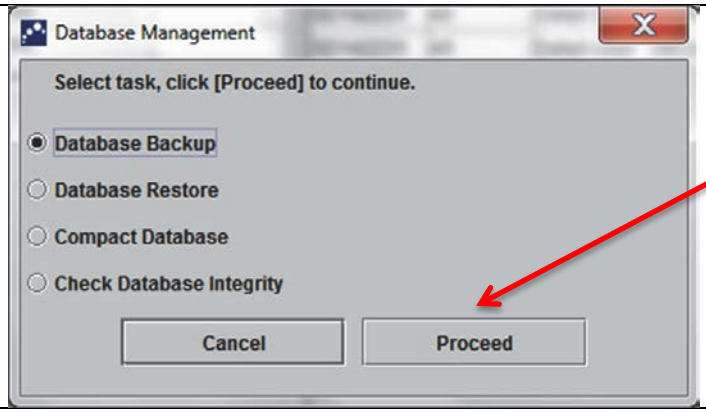
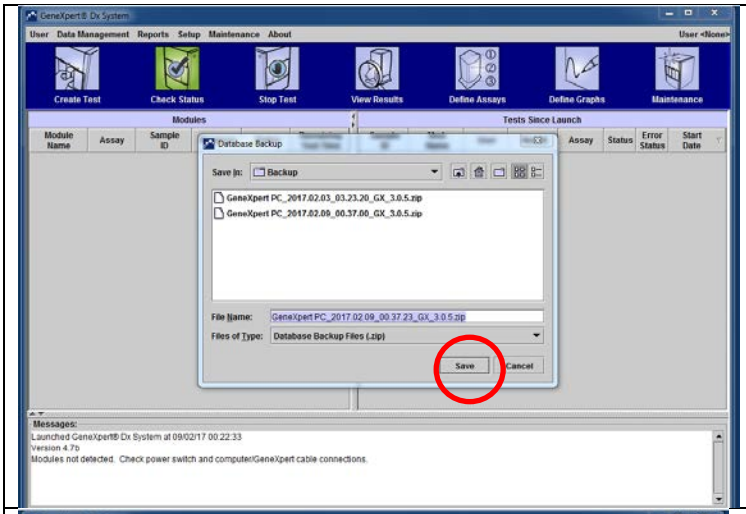
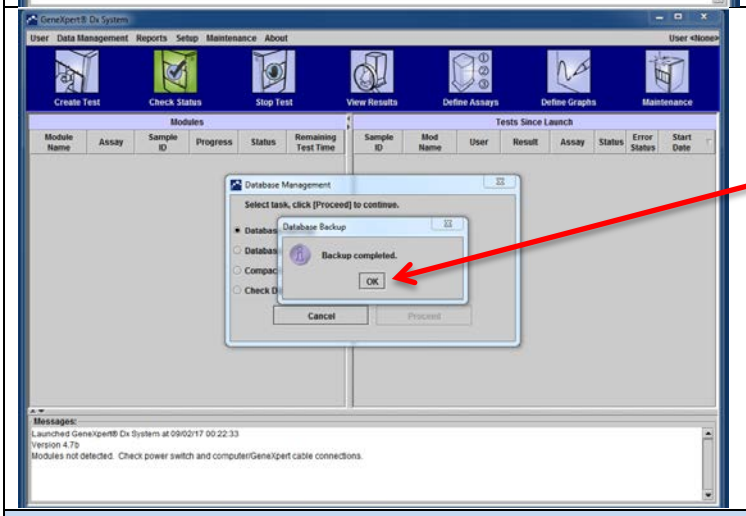
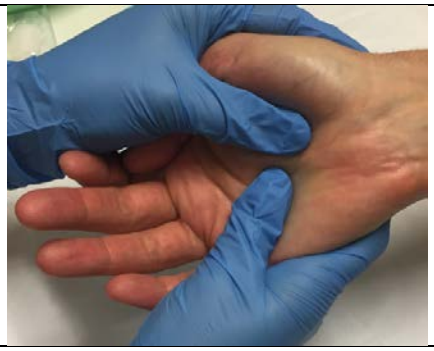
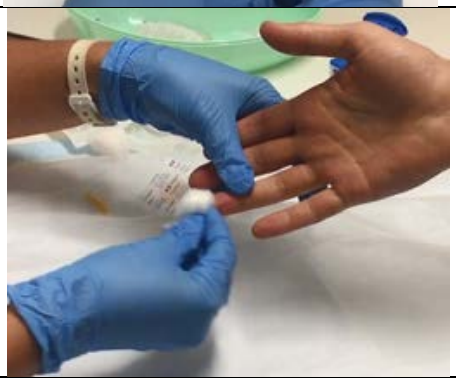
Finger Stick GeneXpert HCV Point of Care Testing

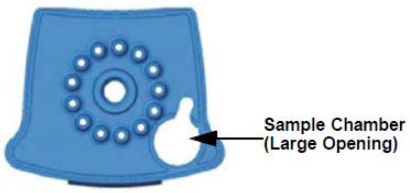
STEP 1: Setting Up the GeneXpert Machine
1. Ensure laptop and GeneXpert machine are connected 2. Turn on the laptop **FIRST**. 3. Turn on the GeneXpert machine **SECOND**. ** If you turn on the GeneXpert machine first, the laptop will not recognise the machine.
STEP 2: Logging into the GeneXpert Machine
1. On the desktop is an icon titled “Cepheid”. Select this icon by double clicking. 2. Enter password “cphd” and press return. 3. The GeneXpert Software will open by itself. You may need to wait 10-20 seconds before you see the software appear.
STEP 3: Database management tasks (Backup previous tests)

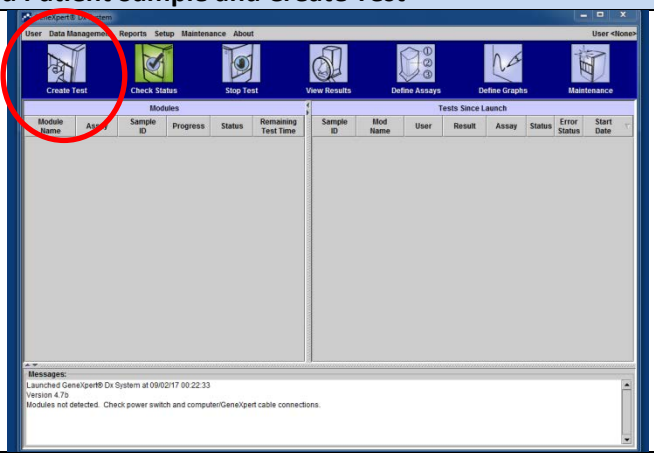
	Once the program opens it will ask you if you wish to perform DATABASE MANAGEMENT TASKS. Select yes.
	The database backup screen will appear. Select proceed

	The database backup screen will appear. PRESS SAVE to back up data Please back up data in both the computer and the USB that is supplied with the laptop. This USB will be used to send backup and archive data to The Kirby Institute as requested.
	Once backup is complete you will see a message stating: BACKUP COMPLETE
STEP 4: Check the Cartridge for Damage	
	Use one GeneXpert cartridge for each patient sample. **IMPORTANT:** Cartridge must be used within 1 hour of opening the cartridge.

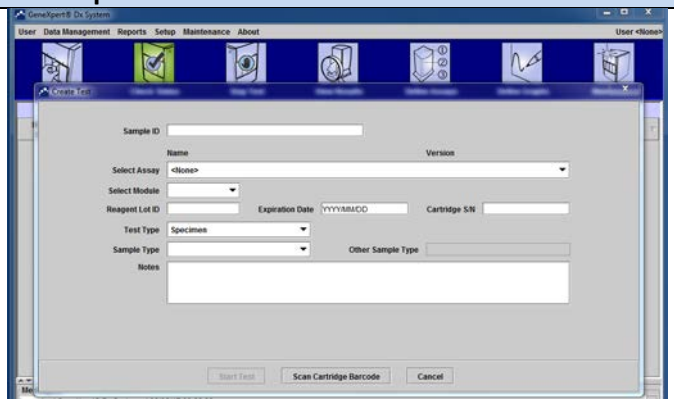
	Check the cartridge to make sure it isn't damaged. Check the outside for damage. Open the lid and check it is clean and clear. If you see any debris, damage or crystals discard this cartridge and select another one for the test.
	At the back of the cartridge is the PCR Tube/Optical Window. DO NO TOUCH THIS. If it is damaged discard this cartridge and select another one for the test.
STEP 5: Perform the Finger Prick and Collect Blood	
	You may need to massage the hand and lower part of the finger to maintain blood flow to the fingertip. You can also encourage patients to warm their own hands by rubbing their hands together, shaking them and performing fist pumps. Alternatively, you can apply a heat pack over the area, or place the finger under warm running water.
	Position the hand palm-side up. Select the least calloused fingertip of the ring, middle or index finger. You may use the thumb if it is the least calloused finger.

	Use an alcohol swab to clean the participants finger. Allow the finger to air dry.
	Pick up a new sterile lancet. Show the lancet to the patient to reassure them that the lancet is new and unused. Remove the yellow protective piece from the top of the lancet before using.
	Place the lancet in the centre of the fingertip with the large yellow circle pointing away from the patient. Hold the finger and firmly press the lancet against the finger when making the puncture. Dispose of the lancet in a biohazard sharps container.
	Wipe away the first drop of blood with a sterile gauze pad or cotton ball. Keep the finger in a downward position and gently massage to maintain blood flow.

Collecting Blood Sample	
	Hold the minivette at an angle so that the plunger is below the minivette tip and the blood filling the minivette easily. Collect the blood drops using the capillary tip until the blood has reached the filter and the minivette is full. **IMPORTANT:** You will need to minimise the air bubbles in the minivette during sample collection to ensure that the full volume of sample is collected.
	Place a cotton ball on the participants' finger once the minivette is full and ask them to hold it in place where the fingerstick was performed.
	Place a band aid on the participant's finger.
STEP 6: Place Minivette into Cartridge	
	Place minivette into the **LARGE** sample opening. The wings of the minivette tube should sit flush against the top of the cartridge cover to ensure that the sample is delivered to the bottom of the cartridge. 

	Press the plunger of the minivette. Make sure you hold onto the Cartridge while doing this so that you don't knock it over and spill the contents. **Close the lid of the cartridge.** **IMPORTANT:** Start the test immediately after adding the blood sample.
STEP 7: Dispose of the Minivette	
	Remove the minivette and discard into a biohazard waste bin.
Step 8: Load Patient Sample and Create Test	
	On the laptop, open the GeneXpert software if not already open. Click on the 'Create Test' button in the top left corner.

Step 9: Enter Sample Details



Enter the Sample ID, Serial number, assays and sample type.

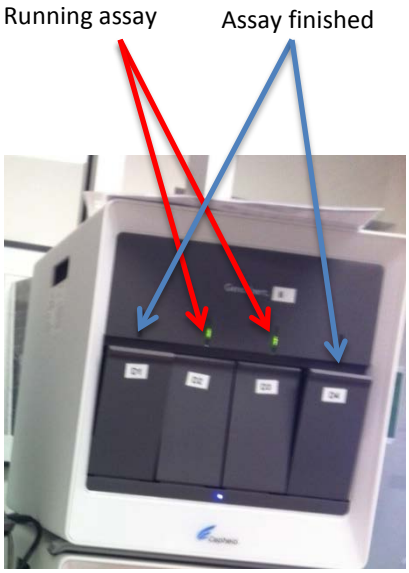
- **Sample ID:** 1510 – 5 Digit Site Number – 2 Digit Patient Number
- **Assay:** HCV Finger Stick
- **Test Type:** Select 'Specimen'
- **Cartridge Serial Number (S/N):** Enter the serial number last.

No need to add information or make changes to: Sample Type, Reagent Lot ID, expiration date, notes or select module.

IMPORTANT: Cartridges used in this study don't have a barcode. When prompted to scan cartridge barcode press cancel instead and proceed to enter details manually as above.

Once all the information is entered and is correct select START TEST.

Step 10: Load Cartridge



The machine will select the module for you and indicate which to one to use by a green light.

Load the cartridge into the module marked with green blinking lights and push close the door.

The machine will perform and probe check.

Once the probe check is complete the test will begin. The time remaining for the test will be displayed on the laptop.

Step 11: Dispose of the Cartridge

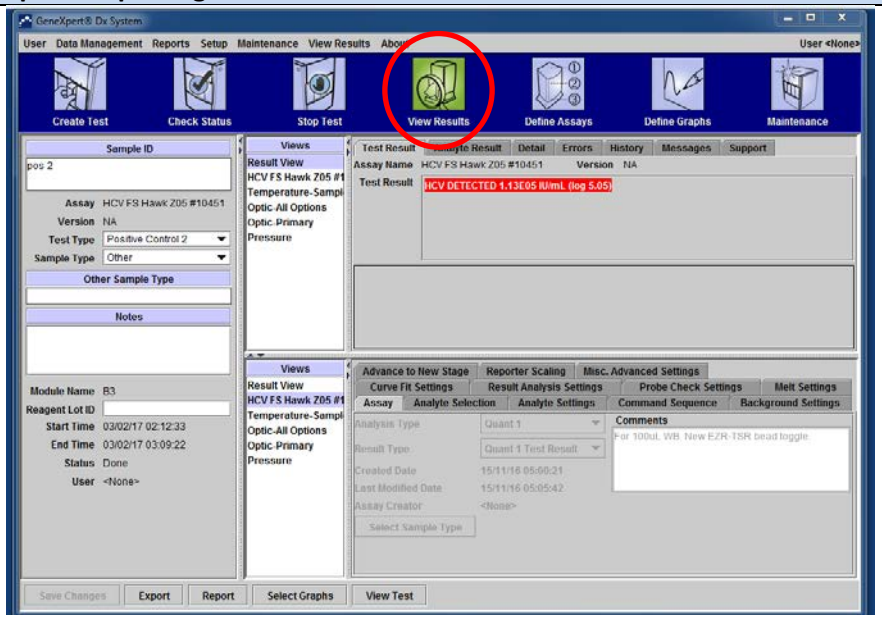
Once the test is complete remove the cartridge from the module and into a biohazard waste bin.

****DO NOT open the cartridge after use****

Return the module doors to the closed position.

IMPORTANT: Each module will perform the PCR reaction independently to the other modules. You can load samples at different timepoints.

Step 12: Reporting Results

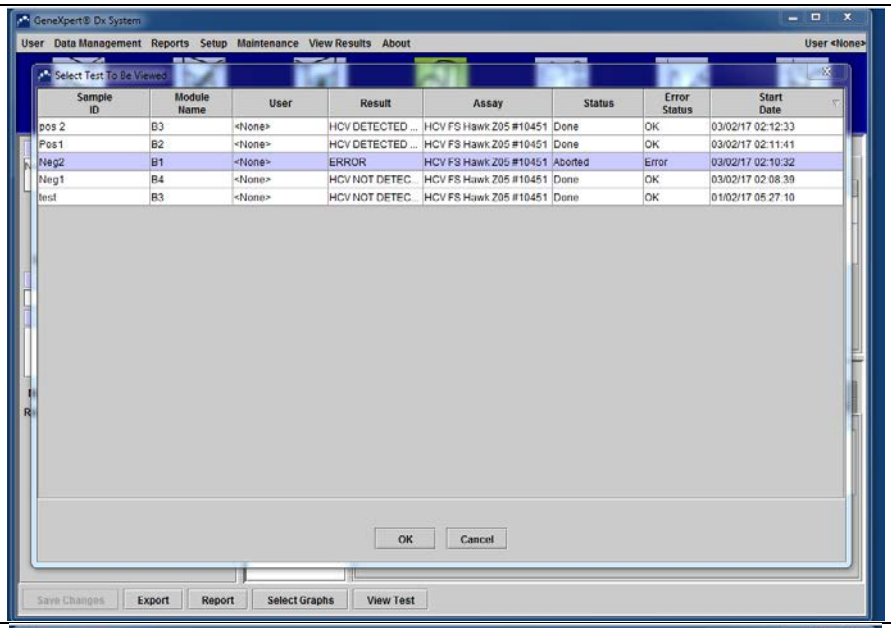


Click on View Results button.

The result will be displayed below in the 'test Result ' tab

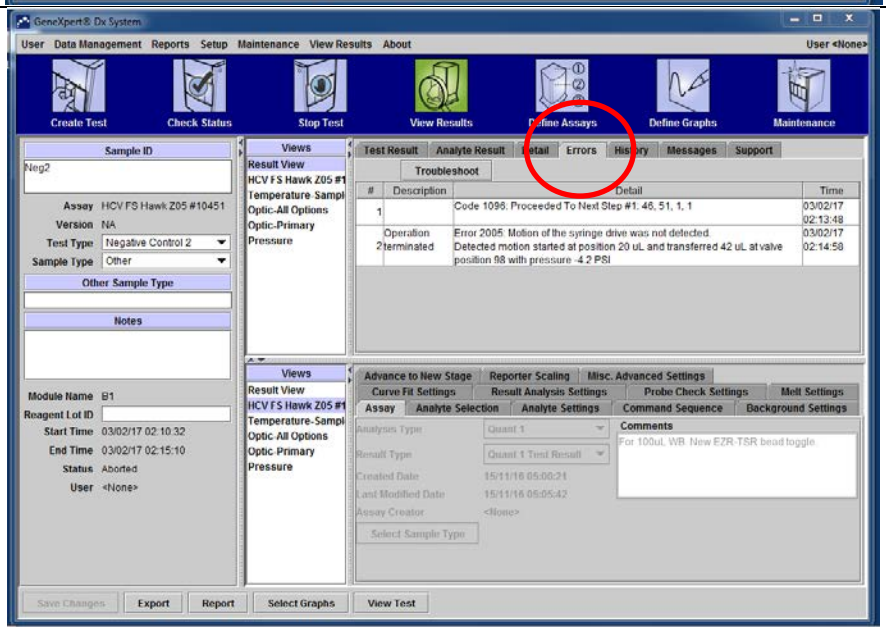
If a sample has detected HCV RNA, you will need to record the quantity detected.

e.g. 1.13 E06 IU/ml.



For a result with an error outcome, please record the error code in OpenClinica that applies to the sample.

In the event that the outcome of the test is indicated as a 'no result', this should be recorded as an error in OpenClinica.

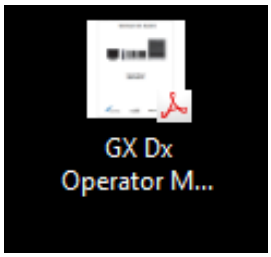


The errors code can be found by selecting the "errors' tab on the view results screen.

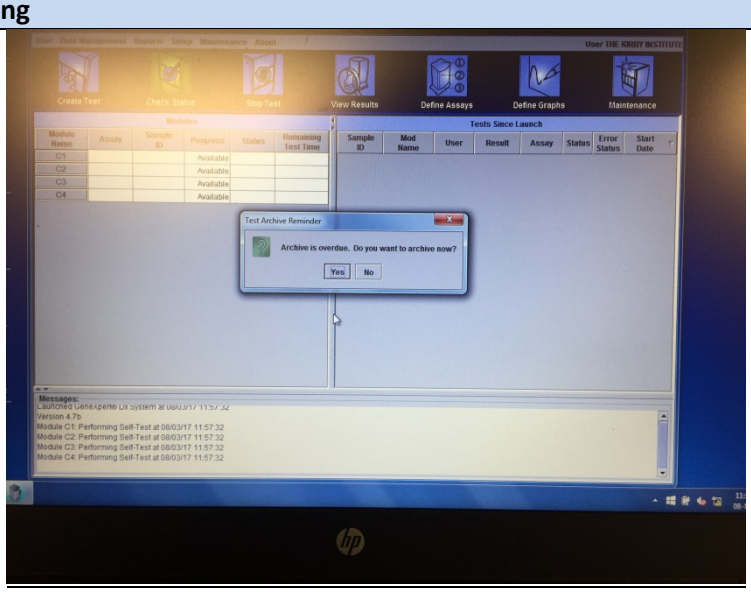
e.g. Error 2005

Enter this error code in OpenClinica.

A full list of error numbers and their corresponding message and causes and solutions can be found in **Appendix 1.**

	Should you want to find out more information about an error code you can search the Cepheid POC machine manual. The manual will be saved on the computer desktop as Gx Dx Operator Manual v4.7b ENGLISH Double click on the icon to open the manual. Use the CONTROL F function to open a 'find' window. Type in the code number as shown in the error screen and the function will find the relevant error code within the document.

Archiving



Archive the test result on the laptop and the usb provided.

Do not remove the usb from the laptop.

Step 14: Turning off the machine

Once you have completed all tests and completed archiving.

Turn off the GeneXpert machine FIRST and the laptop SECOND.

Step 15: Maintenance

Appendix 2 – Maintenance Log.

GeneXpert System Maintenance Log

Month and Year: _____

Name of Institution: _____

GeneXpert Serial Number: _____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance																															
Clean work area																															
Close all module doors																															
Discard used cartridges																															
Technicians Initials																															
Weekly Maintenance																															
Power down the GeneXpert instrument																															
Power down the GeneXpert Computer																															
Technicians Initials																															

There are daily and weekly maintenance jobs that are needed to keep the machine functioning properly.

The daily maintenance tasks only need to be completed on days in which you use the machine. Please indicate on the maintenance log if a machine was not used on a certain day.

These need to be recorded in the Maintenance Log which can be found in Appendix 2.

<table>
<tr>
<td> 


 </td>
<td><u>Daily maintenance</u>

1. Clean work area with diluted bleach or 70% ethanol with Kim wipes. Clean off any excess bleach with 70% ethanol.
2. Close all module doors.
3. Discard used cartridges.
4. Fill out the maintenance log found in Appendix 2.

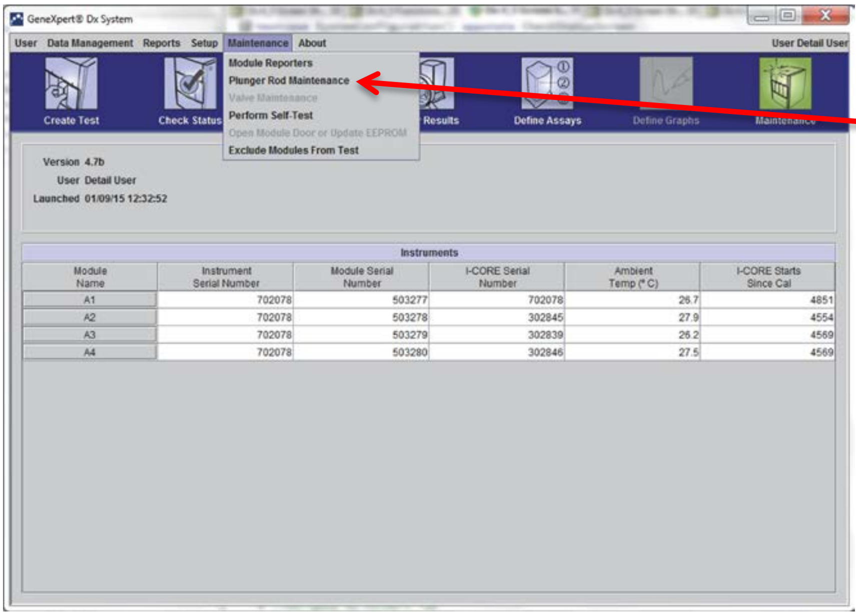
IMPORTANT: Do not leave the bleach on the machine for more than 2min.</td>
</tr>
<tr>
<td>  </td>
<td><u>Weekly maintenance</u>

1. Power down the GeneXpert instrument.
2. Power down the GeneXpert computer.
3. Fill out the maintenance log found in Appendix 2.</td>
</tr>
<tr>
<td> 
</td>
<td><u>Quarterly Maintenance – Clean instrument surfaces</u>

1. Clean instrument surfaces with 10% bleach followed by 70% ethanol.
2. Fill out the maintenance log found in Appendix 2

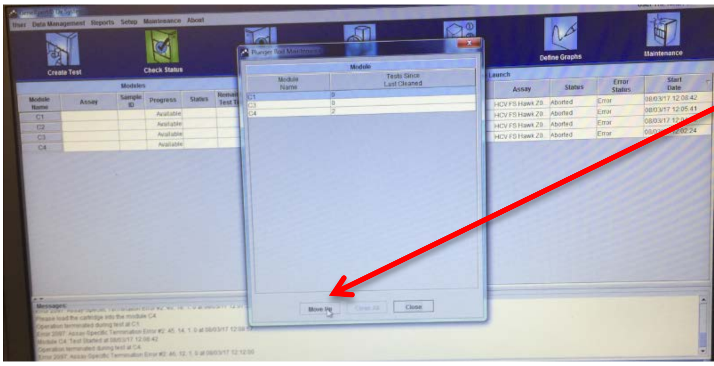
Do not allow the bleach to remain on surfaces for more than 2 minutes.</td>
</tr>
</table>

Quarterly Maintenance - Clean plunger rods and cartridge bays



1. Ensure there are no cartridges left in the bays
2. Select Plunger Rod maintenance from the maintenance menu
3. Select clean

4. The plunger rod will lower down for cleaning
5. Use a lint-free wipe to wipe the plunger rod with 10% bleach
6. Use the same lint free wipe to wipe the walls, ceiling, corners and edges of the cartridge bay
7. Wait 2 minutes before cleaning off with ethanol



8. After the plunger rod and cartridge bay have been cleaned return to the plunger maintenance dialog box
9. Select move up
10. Plunger rod will return to the resting position
11. Close door
12. Fill out the maintenance log found in Appendix 2

Trouble shooting	
Clinical Project Coordinator Kirby Institute Email: darlo-c@kirby.unsw.edu.au Phone: (02) 9385 9668	Ms Jomar Rivas, Application Specialist Email: Jomar.Rivas@cepheid.com Mr Chris Hum, Application Specialist Email: Chris.Hum@cepheid.com Phone: 1800 130 821 Please Cc your Clinical Project Coordinator into any correspondence sent to Cepheid.

Appendices

Appendix 1 – Error messages

Table 9-3. Errors that occurred during a test that is not aborted

Error code	Error message	Possible causes	Solution
1001	The actual temperature n °C has drifted too far away from the setpoint of m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater component or a related component failed. Environment temperature is too warm. Fan Failure.	Report the temperature value in the error message to Cepheid Technical Support. Check room temperature. Check fans are functional and fan filters are clean.
1002	The temperature difference of n °C exceeds the limit of m °C. The temperatures for heaters A and B are p °C and q °C. (n, m, p, and q are temperature values that the software displays. The values can vary.)	The difference between the temperatures of the two thermistors has exceeded the acceptable difference of 5 °C.	Call Cepheid Technical Support.
1004	The internal instrument temperature n °C was out of range of m1 °C to m2 °C. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The ambient temperature is not within the required range. • The environmental conditions do not meet the requirements. • The ambient temperature sensor failed. • Broken or dirty fans	Check the following: • The instrument has at least 5 cm (2 in) of clearance on each side. • The laboratory environmental conditions meet the requirements specified in Chapter 4. • Fans are moving. • Clean fan filters. If the instrument meets all the requirements and the error persists, call Cepheid Technical Support.
1005	Optic signal of n from detector #m using LED #p exceeded the limit of q. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The signal from the reporter is too high. • The door is not closed properly. • A hardware component failed.	Try one or more of the following solutions: • Use a different cartridge. • Make sure the door is closed completely. If the error recurs, call Cepheid Technical Support and provide the information presented in the error message.

Table 9-3. Errors that occurred during a test that is not aborted (Continued)

Error code	Error message	Possible causes	Solution
1006	Detector #n dark signal of m exceeded the limit of p. (n, m, and p are values that the software displays. The values can vary.)	The detector or the electronics failed.	Call Cepheid Technical Support and provide the information presented in the error message.
1007	The n V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)	The power supply voltage is out of range.	Record the information in the error message. If the error recurs in multiple runs, call Cepheid Technical Support.
1017	The measured temperature of the optical system was n °C which was not within the acceptable range of m1 °C to m2 °C. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The optical block thermistor failed. • The ambient temperature is too high.	Rerun the test. If the error recurs, call Cepheid Technical Support.
1018	A valve positioning error of n count(s) was detected at the end of the run. (n is a value that the software displays. The value can vary.)	A valve component failed. Cartridge integrity compromised.	Rerun the test. If the error recurs, call Cepheid Technical Support.

9.13.2.2 Operation terminated errors

Table 9-4 lists errors that might appear when a test is aborted. The operation-terminated error messages appear in the View Results window (Figure 9-19). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 9-4. Errors that might appear when a test is aborted

Error code	Error message	Possible causes	Solution
2003	Module is already running a test with test ID n while performing command ID m. (m and n are ID numbers that the software displays. The number can vary.)	Software communication failed.	Call Cepheid Technical Support.

Table 9-4. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2005	Motion of the syringe drive was not detected. Detected motion started at position n ul and transferred m ul at valve position p with pressure q PSI. (n, m, p, and q are values that the software displays. The values can vary.)	A syringe stall was detected.	Try one or more of the following solutions: • Use a new cartridge. • Restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
2006	Valve motion was not detected. Valve started at position n. Last detected at position m. (n and m are values that the software displays. The values can vary.)	The valve drive failed. Improper interface between cartridge and valve body.	Try one or more of the following solutions: • Open the module and reposition the cartridge. • Use a new cartridge. • Restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
2008	Syringe pressure reading of n PSI exceeds the protocol limit of m PSI. (n and m are pressure values that the software displays. The values can vary.)	One or more of the following causes might have caused the error: • The filter is clogged by debris in sample. • Pressure sensor failed.	Try one or more of the following solutions: • Use a new cartridge. • Run a cartridge containing buffer only. If the error persists, call Cepheid Technical Support.
2009	Syringe pressure reading of n PSI is below the protocol limit of m PSI. (n and m are pressure values that the software displays. The values can vary.	The filter is clogged.	Try one or more of the following solutions: • Use a new cartridge. • Run a cartridge containing buffer only. If the error persists, call Cepheid Technical Support.
2012	An inaccurate valve move to position n was detected. The valve was detected to stop at position m. (n and m are values that the software displays. The values can vary.)	A component of the valve drive failed.	Use a new cartridge. If the error persists, call Cepheid Technical Support.

Table 9-4. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2014	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/module's/optical block thermistor failed.	Check the following: • The ambient temperature • The internal temperature of the instrument • Two inches of clearance, refer to Chapter 2 (Installation) If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.
2016	The system was unable to find the valve home position.	The valve position sensor failed.	Perform self-test and try again with another cartridge. If the error persists, call Cepheid Technical Support.
2017	The door latch sensor is still on after a cartridge eject operation.	One or more of the following might have caused the error: • A syringe component failed. • The door or a related component failed. • The door sensor failed.	To remove the cartridge: 1. In the GeneXpert Dx System window, click Maintenance on the toolbar. 2. On the Maintenance menu, click Open Module Door. 3. Select the module. 4. Click Open Door to open the module door. After you remove the cartridge, restart the system. See Section 2.14 for instructions.
2022	Failed to get to desired temperature of n °C. The temperature reached m °C. (n and m are temperature values that the software displays. The values can vary.)	Environmental temperature is above or below the acceptable range.	Check the following: • The ambient temperature • The internal temperature of the instrument • Two inches of clearance, refer to Chapter 2 (Installation) If the ambient and internal temperatures are within the acceptable range and you continue to see the error message, call Cepheid Technical Support.
2024	An ultrasonic horn failure occurred with n% duty cycle, m Hz and actual p% amplitude. Setpoint amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	The ultrasonic horn failed.	Use a new cartridge. If the problem persists, call Cepheid Technical Support.

Table 9-4. Errors that might appear when a test is aborted (Continued)

Error code	Error message	Possible causes	Solution
2026	The ultrasonic horn current was detected to be out of the normal range.	The ultrasonic horn failed.	Call Cepheid Technical Support.
2032	The ultrasonic horn could not be tuned properly. The tuning frequency value was n Hz. (n is a value the software displays. The value can vary.)	The ultrasonic horn failed.	Use a new cartridge. If the problem persists, call Cepheid Technical Support.
2034	The optical signal from Detector n/ LED n did not reach the expected value. Expected value=m, Actual value=p. (n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • The LED is not working. • The detector is not working. • The associated circuit is experiencing problems.	Restart the test. If the error recurs, restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
2035	An ultrasonic failure occurred with n% duty cycle, m Hz and actual p% amplitude. Setpoint amplitude was q%. (n, m, p, and q are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • Cartridge issue • Dirt on the horn surface • The ultrasonic horn failed.	Restart the test. If the error recurs, restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
2126	Module was reset.	Intermittent power supply failure. Power supply cable or connector failure.	Restart system. If problem persists, call Cepheid Technical Support.
2127	Module communication loss was detected.	Ethernet cable between PC and GX instrument. Communication cable between gateway and GX Module.	Unplug and replug instrument ethernet cable, then restart system. If problem persists, call Cepheid Technical Support.

Table 9-5. Errors that might appear during the cartridge loading process

Error code	Error message	Possible causes	Solution
2011	Unable to initialize pressure sensor to n. Sensor value of m was obtained. (n and m are pressure values that the software displays. The values can vary.)	The force sensor failed.	Restart the test. If the error recurs, restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
2018	Attempt to load a cartridge while the door is still closed.	One of the following might have caused the error: • The valve motor failed. • A syringe component failed. • The door-latch sensor failed.	Restart the system. See Section 2.14 for instructions. Open door. If the error recurs, call Cepheid Technical Support.
2025	One of the following messages is displayed: • The system failed to find the plunger home position. Plunger moved down looking for ADC = n. ADC value m was detected and stall occurred. • The system failed to find the plunger home position. Upward move with minimum force value of n was completed without reaching force value less than m. (n and m are values that the software displays. The values can vary.)	The plunger components or the force sensor failed.	To determine if the error is caused by a failed instrument module or a bad cartridge: 1. Restart the test using the same cartridge and load it into the same instrument module. 2. If the error recurs, restart the test using the same cartridge but load it into a different instrument module. If the test progresses successfully in the new module, the previous module requires repair. Call Cepheid Technical Support. 3. If the error occurs in the second instrument module, restart the test using a new cartridge and load it into the original module. If the test progresses successfully, the previous cartridge was bad. If the error persists, call Cepheid Technical Support.
2037	The cartridge integrity test failed at valve position <n>. The pressure change of f.ff PSI did not exceed the requirement of f.ff PSI. The pressure increased from f.ff PSI to f.ff PSI during the test.	The cartridge integrity test failed.	Restart the system. See Section 2.14 for instructions. Open door. If the error recurs, call Cepheid Technical Support.

Table 9-6. Error messages that might appear during the self-test process

Error code	Error message	Possible causes	Solution
4001	A problem with the memory of the I-CORE was detected.	A hardware component failed	Restart the system. See Section 2.14 for instructions. Open door, select module, and update EEPROM. If the error recurs, call Cepheid Technical Support.
4002	A problem with the main memory of the GeneXpert module was detected.	A hardware component failed.	Restart the system. See Section 2.14 for instructions. If the error recurs, call Cepheid Technical Support.
4003	A problem of the ultrasonic horn system was detected.	The ultrasonic drive circuitry failed.	Restart the system. See Section 2.14 for instructions. If the error recurs, call Cepheid Technical Support.
4004	Valve motion was not detected.	A component of the valve drive failed.	Remove any cartridges from the module, and then restart the system. If the error recurs, perform a self-test manually (Section 9.8). If the error persists, call Cepheid Technical Support.
4006	Syringe drive movement was not detected.	The stall sensor failed during cartridge loading because: • The cartridge was not positioned correctly. • A component of the syringe drive failed.	Restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
4008	The n-V power supply was detected to be m V. (n and m are voltage values that the software displays. The values can vary.)		Restart the system. See Section 2.14 for instructions. If the error persists, call Cepheid Technical Support.
4009	Heater A operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The values can vary.)	A heater A component failed.	Perform self-test. If the error persists, call Cepheid Technical Support.

Table 9-6. Error messages that might appear during the self-test process (Continued)

Error code	Error message	Possible causes	Solution
4010	Cooling fan operation was not verified. Measured temperature of n °C exceeded the limit of m °C. (n and m are temperature values that the software displays. The values can vary.)	A cooling component failed.	Make sure that the air vents are not blocked. The instrument must have at least 5 cm (2 in) of clearance on each side. Perform self-test. If the error recurs, call Cepheid Technical Support.
4011	The reported dark value of n for detector m was too high. (n and m are values that the software displays. The values can vary.	The module door was not closed completely, or a hardware component failed.	Make sure the module door is closed completely. If the error recurs, record the value in the error message, and then call Cepheid Technical Support.
4012	Heater B operation was not verified. Measured temperature changed from n °C to m °C. (n and m are temperature values that the software displays. The value can vary.)	A heater B component failed.	Perform self-test. If the error persists, call Cepheid Technical Support.
4013	An inaccurate valve move was detected. The valve was programmed to stop at position n but stopped at position m. (n and m are position values that the software displays. The values can vary.)	A valve error has occurred.	Remove any cartridge from the module. Perform a self-test manually (Section 9.8). If the error recurs, call Cepheid Technical Support.
4014	The optical signal from Detector n/ LED n did not reach the expected value. Expected value = m, Actual value = p. (n, m, and p are optical signal values that the software displays. The values can vary.)	An optics component failed.	Call Cepheid Technical Support.
4015	The measured temperature of the optical system is n which was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	An optical block thermistor failed.	Restart the system. See Section 2.14 for instructions. If the error recurs, call Cepheid Technical Support.
4016	GX module program corruption. Unable to continue the test	1) Possible RAM failure 2) Possible EMI 3) Firmware defect	Call Cepheid Technical Support.

Table 9-6. Error messages that might appear during the self-test process (Continued)

Error code	Error message	Possible causes	Solution
4017	The digital temperature reading of n for Thermistor A/Thermistor B/Ambient Thermistor/Optic Thermistor was not within the acceptable range of m1 to m2. (n, m1, and m2 are temperature values that the software displays. The values can vary.)	The heater A/heater B/module's/optical block thermistor failed.	Restart the system. See Section 2.14 for instructions. If the error recurs, call Cepheid Technical Support.
4019	The optical ramp test for LED n resulted in non-monotonic results at DAC setting of nnn. The reference detector readings were nnn and nnn.	LED is broken.	Restart the system. See Section 2.14 for instructions. If the error recurs, call Cepheid Technical Support.

9.13.2.5 Post-run analysis errors

Table 9-7 lists errors that might appear during the post-run analysis (data reduction) process. The post-run analysis error messages appear in the View Results window (Figure 9-19). To contact Cepheid Technical Support, see the Assistance section in the Preface for the contact information.

Table 9-7. Data reduction errors

Error code	Error message	Possible causes	Solution
5001	Unable to verify positive analyte [x] using curve fitting. (x is the analyte name)	A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5002	Failed to verify valid amplification curve for reporter. The shape factor of n was below the minimum of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5003	Failed to verify valid amplification curve for reporter. The shape factor of n was higher than the maximum of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5004	Failed to verify valid amplification curve for reporter. The normalized sum of errors of n was greater than the limit of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.

Table 9-7. Data reduction errors (Continued)

Error code	Error message	Possible causes	Solution
5005	Failed to verify valid amplification curve for reporter. The slope to vertical scaling ratio of n was higher than the limit of m. (n and m are values that the software displays. The values can vary.)	A component of the cartridge is defective, causing the positive amplification curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5006	X probe check failed. Probe check value of n for reading number m was above the maximum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • An incorrect amount of reagent was inserted into the cartridge. • The reagent is bad. • Fluid transfer failed.	Check the following: • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5007	X probe check failed. Probe check value of n for reading number m was below the minimum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • An incorrect amount of reagent was inserted into the cartridge. • The reagent is bad. • Fluid transfer failed. • The sample was processed incorrectly in the cartridge.	Check the following: • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5008	X probe check failed. Probe check delta value n between reading number m and reading number p was below the minimum of q. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • An incorrect amount of reagent was inserted into the cartridge. • The reagent is bad. • Fluid transfer failed.	Check the following: • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5009	X probe check failed. Probe check delta value n between reading number m and reading number p was above the maximum of q. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	One or more of the following might have caused the error: • An incorrect amount of reagent was inserted into the cartridge. • The reagent is bad. • Fluid transfer failed.	Check the following: • Reagents are added to the cartridge correctly. • Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.

Table 9-7. Data reduction errors (Continued)

Error code	Error message	Possible causes	Solution
5010	Unable to verify positive analyte [x] using curve fitting. X readings were available, but the minimum number of readings required is y. (x is the analyte name; y is a value software displays)	A component of the cartridge is defective, causing the positive growth curve to have an abnormal shape.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.
5011	Signal loss detected in the amplification curve for analyte [analyte [x]. n decrease in signal with m% decrease at cycle p. (X is the analyte name; n, m, and p are values that the software displays. The values can vary.	Loss of tube pressure.	Use a new cartridge. If the error recurs, call Cepheid Technical Support and provide the information in the error message.

Appendix 2 – Maintenance Logs.

GeneXpert System Maintenance Log

Month and Year: _____

Name of Institution: _____

GeneXpert Serial Number: _____

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance																															
Clean work area																															
Close all module doors																															
Discard used cartridges																															
Technicians Initials																															
Weekly Maintenance																															
Power down the GeneXpert instrument																															
Power down the GeneXpert Computer																															
Technicians Initials																															

GeneXpert System Maintenance Log

Year: _____

Name of Institution: _____

GeneXpert Serial Number: _____

Month	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec
Quarterly Maintenance												
Clean plunger rod and cartridge bays												
Clean instrument surfaces												
Technicians Initials												