CEPHEID GENEXPERT® XPRESS INSTRUMENT PURCHASE AND INSTALLATION

1. What is the difference between GeneXpert® Xpress and Xpert® HCV?

- The GeneXpert® Xpress is the instrument that contains two (2) or four (4) slots for testing and the integrated hub (flatscreen and scanner).
- Xpert® HCV is the name of the test cartridge that is specific to hepatitis C (HCV) Ribonucleic Acid (RNA) testing. This is what is inserted into the machine for testing.

2. My organization is located in New York State. Who do I contact at Cepheid for ordering the GeneXpert® Xpress instrument and supplies?

- Allison Bushard (Allison.Bushard@cepheid.com); mobile: 720-431-6603
- Sherri Hilton (Sherri.Hilton@cepheid.com); mobile: 240-610-8697

3. How is the instrument shipped and how long does installation take?

- Instrument is shipped Fed-Ex 2-day.
- Allot three (3) hours for setup/installation and training. There is also a virtual option for set-up.

4. How long after receipt of the instrument will installation be scheduled?

- Installation date is usually scheduled within three (3) weeks from the instrument shipping notification.

5. Who do I contact at Cepheid regarding instrument installation and set-up?

- While Cepheid will likely reach out to you first when your instrument is shipped, you can reach out to Field Application Specialist, Tracy Cook (Tracy.Cook@cepheid.com, mobile: 302-357-8616) if needed.
- A Field Application Specialist provides technical direction and support to customers on instrument operation, assay implementation, and maintenance of company products.

6. Are there any specifics of where the machine should be installed?

- Cepheid's environmental parameters for the GeneXpert® Xpress system states it's for indoor use only. The operating temperature must be between 15-30 degrees Celsius (59-86 degrees Fahrenheit) with a 20-80% relative humidity. This information is referenced in section 10.1 of the Xpert®HCV Instructions for Use.

7. Who do I contact at Cepheid for technical assistance regarding Point of Care (POC) testing questions?

- Cepheid Hotline for technical assistance: 888-838-3222
- Tracy Cook, Field Application Specialist, can also be contacted (Tracy.Cook@cepheid.com, mobile: 302-357-8616).

8. What is the Essential Care plan?

- The Essential Care plan is a one-year warranty and service contract for the instrument. The Essential Care plan is INCLUDED for the first year (325 days) with the purchase of the instrument. After the first year, it will need to be purchased annually. Additional years of coverage are optional but are strongly recommended.
- The Essential Care plan includes:
  - Unlimited technical phone support,
  - Technical support via remote access for faster system diagnostics (instrument must be connected to internet for web-based support),
  - Two (2) business day Onsite Response Time by Cepheid Customer Service Engineer,
  - One (1) Annual Xpert® Check performed onsite by Cepheid Customer Service Engineer,
  - Instrument repair coverage with unlimited labor and parts,
  - GeneXpert® Hub and laptop repair coverage including labor and parts,
  - Instrument swap (if system has one or more modular repairs. Cepheid has complete discretion for instrument swap upon approval at time of initial contact with Cepheid Technical Support).
- The Essential Care plan does NOT cover damage from operation in an unsuitable environment, use of the Instrument for purposes other than that for which it was designed, unauthorized attachments, water leaks or fire from the surrounding environment, acts of nature, unusual physical or electrical stress, modifications or repairs done by an individual other than a Cepheid Customer Service Engineer, or misuse, abuse or neglect of the Instrument.

9. What is Cepheid C360, and do I need it?

- Cepheid C360 is a cloud-based platform that collects data from GeneXpert® systems across the state that can assist with surveillance, as well as assist users with maintenance and support.
- Cepheid C360 is not required, however it is strongly encouraged and can be added at any time. See https://www.cepheid.com/en-US/systems/connectivity/cepheid-c360.html for more information.

CONTROLS, TEST KITS, AND OTHER SUPPLIES

10. What items does Cepheid provide?

- Test kits (GXHCV-10) are purchased from Cepheid and come in packs of 10. These kits reflect discounted public health pricing.
- Cepheid offers a Kit Combo Pack (GXHCV-CPAK), which includes 10 test kits, 20 pipettes, and 200 BD Microtainers. This combo pack does not include public health pricing so is more expensive than ordering the microtainers separately.
- Annual software and maintenance plans for the instrument is called the “Essential Care Plan.” While an annual Essential Care Plan is required each year, the first year’s plan is included in the purchase price of the GeneXpert® Xpress instrument.

11. Does Cepheid manufacture the controls for its Xpert® HCV point of care test?

- No, controls are manufactured by a separate vendor, Zeptometrix.

12. Is Zeptometrix the only manufacturer for controls?

- Yes, at this time Zeptometrix is the only manufacturer: https://www.zeptometrix.com

13. What controls do I need?

- NATtrol Hepatitis C Virus Positive Control - Item # NATHCV-6C-IVD
- NATtrol Hepatitis C Virus Negative Control - Item # NATHCVNEG-6C-IVD

14. What other items do I need to purchase?

- K2EDTA microtainer BD (365974). These are included in the Kit Combo Pack (GXHCV-CPAK) offered by Cepheid, which is more expensive than if purchased separately, although possibly more convenient. The microtainers can also be purchased through various vendors of your choosing.
- High-flow lancets that are capable of providing at least 250 microliters of capillary fingerstick blood. These can be purchased through various vendors of your choosing.
- Any other items that are required for fingerstick testing, such as: alcohol pads, gauze, bandages, spill pads, biohazard waste, sharps containers, etc. These can be purchased through various vendors of your choosing.
- Any items that are recommended for cleaning the work area and surfaces, such as 70% alcohol solution, 1:10 dilution bleach, etc. These can be purchased through various vendors of your choosing.

15. What are the guidelines for cleaning and disinfecting the GeneXpert® Xpress instrument?

- Refer to Chapter 5 in the GeneXpert Xpress User Guide for detailed information about cleaning and disinfecting surfaces and the instrument.

FDA APPROVALS AND TESTING LIMITATIONS

16. Is the Xpert® HCV test FDA approved for qualitative and/or quantitative HCV RNA testing?

- The Xpert® HCV test is only FDA approved for qualitative testing. This means there is no viral load done and will only give a Detected or Not Detected result.

17. Are there any FDA approval limitations on who can be tested with the Xpert® HCV test?

- The Xpert® HCV test is not FDA approved for pregnant persons or for persons under the age of 22.
- The Xpert® HCV test is intended for individuals 22 years of age and older at risk and/or with signs and symptoms of HCV infection with or without antibody evidence of HCV infection.

18. Can the Xpert® HCV test be used to determine SVR (Sustained Virologic Response)?

- No, the Xpert® HCV test is not FDA approved for SVR.

19. Can another method of blood collection be used, such as fingerstick blood collected in a lavender top EDTA tube or a venipuncture sample?

- No. FDA approval and package insert specify the sample must be a fingerstick collection of whole blood collected into the designated microtainer. Any other sample type would be considered off-label use of the test.

CALIBRATION

20. Does the GeneXpert® Xpress instrument need to be calibrated every time the physical location changes?

- o No, Cepheid does not require calibration when moved.

21. What if the instrument is on a vehicle/mobile van but stays in one spot on the van?

- o No, Cepheid does not require calibration when moved.

22. What if the instrument is on a rolling cart on city streets or on the subway?

- o No, Cepheid does not require calibration when moved.

23. Are there any other considerations with moving the instrument?

- o Consider the weight and the size of the instrument and how it will be safely transported from site to site (e.g., carrying case, rolling cart, etc.).

24. When is calibration necessary?

- o Instrument is calibrated annually using Cepheid's Technical Assistance team.

QUALITY CONTROLS

25. How often do controls need to be run following setup?

- o Controls will need to be run:
  - i. Each time a new lot of Xpert® HCV kits is received.
  - ii. Each time a new shipment of Xpert® HCV kits is received even if it is the same lot previously received.
  - iii. Each time a new operator is performing the test (i.e., operator who has not performed the test recently).
  - iv. When problems (storage, operator, instrument, or other) are suspected or identified.
  - v. If otherwise required by your institution's standard Quality Control (QC) procedures.

REMOTE SAMPLING AND INSTRUMENT TESTING CAPACITY

26. When collecting a BD microtainer sample in the field and transporting it to another site for processing, how long is the sample valid?

- o Blood sample can be in the BD microtainer for up to four (4) hours before being processed.

27. What temperature must the sample be stored during transport?

- o Sample is to be refrigerated or kept at room temperature (2-30 degrees C / 35.6-86 degrees F) until ready for processing.

28. How many test cartridges can be processed at any given time?

- o The 2-module GeneXpert® Xpress instrument can test two (2) samples simultaneously, while the 4-module instrument can test four (4) samples simultaneously.

29. What are the possible results and what do they mean?

- HCV DETECTED – HCV RNA has been detected. See Question 32.
- HCV NOT DETECTED – HCV RNA has not been detected. See Question 32.
- NO RESULT – REPEAT TEST – Test must be repeated with a new cartridge using a new transfer pipette (does not get reported in ECLRS).
- INSTRUMENT ERROR – Touch "CLEAR ERROR" and follow the on-screen instructions. When the HOME screen appears, repeat the test using a new cartridge and a new transfer pipette (does not get reported in ECLRS).

30. How long does it take to get results?

- Total testing/processing time is up to 60 minutes. Detected results may be available as early as 41 minutes (Early Assay Termination).

31. Where can I access Cepheid's Frequently Asked Questions?

- Cepheid Frequently Asked Questions: https://www.cepheid.com/en-US/tests/blood-virology-womens-health-sexual-health/xpert-hcv.html

REPORTING POINT OF CARE HEPATITIS C RNA TEST RESULTS TO THE HEALTH DEPARTMENT

32. Am I required to report hepatitis C RNA test results to the Health Department?

- Yes. As mandated under New York State (NYS) Public Health Laws 2102 and 576-C and New York City (NYC) Health Code Articles 11 and 13, all HCV RNA test results, detectable and non-detectable (see question 29), are required to be reported to the New York State Department of Health via the Electronic Clinical Laboratory Reporting System (ECLRS).

33. How can I submit hepatitis C RNA test results in ECLRS?

- There are two (2) options for reporting into ECLRS:
  i. Manual entry into the ECLRS portal in the Health Commerce System (HCS): https://commerce.health.state.ny.us/
  ii. Utilizing an interface between your electronic health record and ECLRS.

34. How do I enter hepatitis C RNA test results into the ECLRS portal?

- An ECLRS instruction manual can be found at: https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/point_of_care.htm

35. The test was performed within one of the five (5) boroughs of the metropolitan area of New York. How do I report to New York City Department of Health?

- New York City reporting information can be found here: https://www.nyc.gov/site/doh/providers/reporting-and-services/notifiable-diseases-and-conditions-reporting-central.page

TESTING POLICIES AND PROCEDURES

36. What policies will my agency need for implementing the Xpert® HCV?

- Agency-specific HCV testing policies and procedures should include all HCV testing and related procedures performed by the agency, including the collection and processing of Xpert® HCV samples, staff authorized to use the device, and reporting of RNA results. Policy should specify when, and if, an antibody rapid test should be performed prior to the diagnostic test.

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE BUREAU OF HEPATITIS HEALTH CARE AND EPIDEMIOLOGY CONTACT

37. Who can I contact at the New York State Department of Health regarding Point of Care testing implementation questions?

- For questions regarding Xpert® HCV implementation, email: hepatabc@health.ny.gov

38. Who can I contact at the New York State Department of Health regarding reporting HCV RNA results?

- For questions about reporting HCV RNA results, email: hepbc.surveillance@health.ny.gov

39. Where can I find additional New York State Point of Care testing resources?

- https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/point_of_care.htm

BILLING

40. Which Current Procedural Terminology (CPT) code should be used when billing for the hepatitis C point of care RNA test?

- The CPT code is “HCV RNA test (87521)”.
- For labs directly billing, the reimbursement is currently set to $35.09.