## Checklist for Adding Cepheid Xpert®HCV Point of Care Test in New York

☐ **Cepheid Customer Account**

- An account with Cepheid will need to be created to order Xpert®HCV test cartridges and for customer support: https://www.cepheid.com/en-US/support/order-management.html

☐ **Ordering Controls**

- Controls are not manufactured by Cepheid. An account with Zeptometrix will need to be created to order device controls: https://www.zeptometrix.com/

☐ **Limited Service Laboratory (LSL) Registration Certificate to conduct CLIA-waived testing:**

- LSL Registration Certificate is required and should indicate "*HCV, Rapid*".
- Programs conducting HCV testing in the field should also include "*Community Screening*".
- If *HCV*, *Rapid* is not currently listed on the certificate, a DOH-4236(e) must be completed and submitted to the Clinical Laboratory Evaluation Program (CLEP). LSLs information, forms and an agency level registry, can be found on CLEP's website: http://www.wadsworth.org/regulatory/clep/limited-service-lab-certs.

☐ **Policies and Procedures**

- HCV testing policies and procedures to 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.

☐ **Training**

- **Cepheid – Xpert®HCV Device Training** - Device training for staff can be provided by reviewing Cepheid online training materials or by a qualified person with knowledge of how to perform the test. Staff competency must be assessed and documented. Cepheid training videos for sample collection and sample transfer to cartridge:
  - Video 1: https://youtu.be/lqYlyY8nWkk Video 2: https://youtu.be/LTyxrfFN7XQ
- Staff competency performing the tests must be assessed and documented.

☐ **Reporting HCV RNA Test Results to the New York State Department of Health (or New York City) Surveillance**

- 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 ribonucleic acid (RNA) test results, regardless of test type or test result (detectable/undetectable), are required to be reported to the NYS Department of Health via the Electronic Clinical Laboratory Reporting System (ECLRS). Reporting of the Xpert®HCV diagnostic test results can be reported in the following ways:
  - Utilizing an interface between your electronic health record and ECLRS.
  - Direct entry into ECLRS via the Health Commerce System (HCS): https://commerce.health.state.ny.us/
    - To request access to HCS: https://apps.health.ny.gov/pub/ctrldocs/paperless_edoc2.pdf
    - To request ECLRS access: https://commerce.health.state.ny.us/hpn/cgi-bin/applinks/comments/request_std.cgi
  - Entry into SimpleReport. SimpleReport is a fast, free, and easy way for your organization to report results to public health departments. https://www.simplereport.gov/using-simplereport/
- Additional NYC reporting information can be found here: https://www.nyc.gov/site/doh/providers/health-topics/hepatitis.page
- For additional questions about reporting HCV RNA results email: hepbc.surveillance@health.ny.gov.

**For AIDS Institute Funded Programs Only: Reporting HCV RNA Test Results in the AIDS Institute Reporting System (AIRS)**

- *Some* AIDS Institute-funded agencies who have AIRS will be required to enter Cepheid Xpert®HCV RNA test information in the HCV Rapid Testing Module. For these programs, all clients tested (regardless of HCV antibody testing and RNA result) will be entered.
- For additional information on AIRS entry, email: hepatabc@health.ny.gov.

**For questions regarding Xpert®HCV point of care testing, email: hepatabc@health.ny.gov**
**Or visit our webpage:**
**https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/providers/point_of_care.htm**