July 22, 2019

Confirmatory Algorithm and Assay Changes Effective September 30, 2019

Overview:

On June 13, 2019, CTS provided information regarding the manufacturer’s discontinuation of HIV-1 IFA test kits. The original communication indicated that CTS inventory would be exhausted by September 1, 2019 but we now have sufficient inventory to last until September 30, 2019.

This communication provides details for the replacement of HIV-1 IFA as well as three other minor reflex algorithm changes that will implement with samples received for confirmatory testing beginning September 30, 2019. Quantitative RPR testing for non-donor samples submitted directly to Phoenix Special Testing Department will also be discontinued. Updated versions of the CTS Interpretation Information Sheets for HIV and Hepatitis will be provided as soon as they are available and will be posted on the CTS website the day of implementation.

As your facility evaluates the impact of the HIV reflex testing change, please be aware that FDA is reviewing the Geenius HIV 1/HIV 2 assay for potential HIV antibody confirmation. If and when approval is granted, CTS will implement the Geenius assay to replace both the HIV-1 Western blot and the HIV-2 ELISA and streamline the HIV confirmatory algorithm. Your facility computer system and/or procedures will be impacted on September 30, 2019 by the replacement of HIV-1 IFA with GS HIV-1 Western blot and could be impacted again when the Geenius assay is approved for use as a confirmatory test.

HIV-1 IFA Replacement:

All Prism HIV repeatedly reactive donation samples which are not confirmed by discriminatory HIV NAT reactivity will receive the GS HIV-1 Western blot instead of HIV-1 IFA.

- No other changes to the routine HIV antibody reflex algorithm will be made at this time.
- All samples submitted to Phoenix Special Testing using the CTS-00172 request forms for HIV re-entry will be tested with the GS HIV-1 Western blot instead of HIV-1 IFA, as applicable.
- The fee for HIV-1 Western blot using the CTS-00172 or CTS-00173 form is $125 per sample.

The GS HIV-1 Western blot test result interpretation will be reported from the CTS SD_Net confirmatory computer system. An example of the Special Testing Department result report. Link to referral lab example report.
For clients receiving electronic confirmatory result files, the test code will be GSHIV1WB.

- Results will be reported as Negative, Positive, Indeterminate, Unreadable, Invalid or Not Tested (QNS, Hemolyzed, Unacceptable Sample Age, etc.).

The GS HIV-1 Western blot test will be performed by a qualified referral laboratory. [Link to HIV-1 WB package insert](#). CTS will ship samples several times per week to limit impact on turn-around time for HIV confirmatory testing.

- The CTS result report will contain the CTS accession number and the original source ID number (DIN) along with the qualitative test interpretation reported by the referral lab.
- All positive results will be re-sent by fax or email along with a copy of the referral lab report which will include the blot banding pattern, CTS accession number and referral lab accession number.
  - The CTS accession number will provide linkage between the two result reports.
- Referral lab reports will not be provided for negative or not tested results, but will be available for indeterminate results upon request.

### Modification to HBC Reactive reflex testing:

The reflex testing algorithm for HBC reactive donations will be modified so that dHBV reflex testing will be done for all HBC reactive donations that are NAT negative or not tested and HBsAg nonreactive or not tested (regardless of HIV or HCV reactivity).

- The current HBC reflex requires that the donation be NAT negative/not tested, HBsAg nonreactive/not tested, HIV nonreactive/not tested and HCV nonreactive/not tested.
- Effective with samples received on or after September 30, 2019, donations that are HIV or HCV reactive but meet the other criteria (HBC RR, NAT negative/not tested, HBsAg nonreactive/not tested) will be routed for dHBV testing.

### Roche MPX 2.0 to cobas MPX Conversion:

CTS has been notified by the referral lab performing Roche MPX testing that they are changing from Roche MPX 2.0 to Roche cobas MPX. [Link to cobas MPX package insert](#).

- The newer version of the Roche MPX test will be used for potential NAT yield reflex testing and for any CTS-00172 Re-Entry requests that specify Roche testing.
- Individual test names will display on the Special Testing result report as cobas HBV NAT, cobas HCV NAT and cobas HIV NAT.
  - For clients receiving electronic confirmatory result files, the test codes will be CHBVNAT, CHCVNAT and CHIVNAT.
  - There will be no change to results or result codes.
- The Roche cobas MPX testing will continue to be provided through a referral laboratory as indicated on the CTS result reports and interpretation information sheets.

### Anti-HBs testing for HBV NAT Yields:
The reflex testing algorithm for HBV NAT yield donations (Prism HBsAg nonreactive, Procleix dHBV reactive, and cobas MPX HBV reactive) will be modified to add anti-HBs testing.

- The Monolisa anti-HBs assay will be performed to provide additional information for research purposes. [Link to anti-HBs package insert](#)
- Results will be reported as Reactive, Nonreactive, Borderline or Not Tested (QNS, Hemolyzed, Unacceptable Sample Age, etc.).
  - For clients receiving electronic confirmatory result files, the test code will be MOHBSEIA.
- It is important to note that CTS will report the results of this test with a disclaimer due to the restrictive sample acceptability requirements in the manufacturer’s package insert:

  "Samples tested for Monolisa anti-HBs EIA do not meet acceptance criteria established by the test manufacturer’s package insert therefore valid results may not exist. Use of any final interpretation for this assay should not apply to diagnostic, clinical or donor counseling situations."

**Discontinuation of Quantitative RPR:**

This test was discontinued as part of the routine donor testing algorithm for syphilis reactive donations in December 2018, but it has still been available for clients submitting samples directly to the Phoenix Special Testing laboratory. As of September 30, 2019, this assay will no longer be performed at CTS.

**Impact to Clients:**

Your facility computer systems, procedures, forms and letters that specifically reference HIV-1 IFA, Quantitative RPR or the tests performed for HBc reactive or NAT Yield donations will require modification by September 30, 2019.

**Client Action Items**

- Evaluate current procedures, forms and letters to determine those directly referencing HIV-1 IFA as well as the tests performed for HBc reactive or NAT Yield donations or Quantitative RPR.
- Evaluate potential changes to your computer systems related to the replacement of the primary HIV-1 antibody confirmation test, the change to the HBc reactive reflex, the change from Roche cobas MPX 2.0 to cobas MPX for potential NAT Yield donations, the addition of anti-HBs for HBV NAT Yield donations and the discontinuation of Quantitative RPR.
  - Notify your customer service manager as soon as possible (no later than July 29, 2019) if you require CTS assistance for computer system validation or test and result code mapping.
- Identify the resources required at your facility to implement the applicable changes on September 30, 2019.
  - Review the updated [testing algorithm](#) and/or [algorithm flowchart](#).
  - Review the updated [assay list](#).
- Review the updated sample acceptability requirements.

Questions and Additional Information:
Please email your questions or requests for additional information to Lindsey Houghton (lhoughton@mycts.org) or O’Dina Hurlburt (ohurlburt@mycts.org).

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