June 14, 2019

Discontinue HIV-1 IFA Confirmatory Test Effective September 2019

Overview:

CTS received notification from Sanochemia Pharmazeutika AG of their intent to immediately discontinue production of Fluorognost HIV-1 IFA test kits routinely used for confirmation of HIV-1 antibody-reactive donations. Based on our current testing volume, CTS has sufficient HIV-1 IFA reagent inventory to continue performing this confirmatory test through the end of August 2019.

The Bio-Rad GS HIV-1 Western blot is the only alternative HIV-1 antibody confirmation test approved for donor samples found reactive with the licensed HIV-1/2 Plus O donor screening test. The CTS Medical Advisory Board is exploring this and other options which might be available for CTS clients in the future. Until a final decision is made, you need to be aware that CTS will discontinue HIV-1 IFA testing no later than September 1, 2019.

Impact to the Clients:

- Your facility procedures, forms and letters that specifically reference HIV-1 IFA will require modification by September 1, 2019.
- CTS will provide additional communication when a final decision for replacement of the HIV-1 IFA has been made.

Client Action Items

- Evaluate current procedures, forms and letters to determine those directly referencing the HIV-1 IFA test.
- Evaluate potential changes to your computer systems related to addition of a different test for HIV-1 antibody confirmation.
- Identify the resources that will be required to make revisions once CTS communicates a decision for replacement of this test.

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).