May 7, 2018

**CTS Re-entry Testing Changes and Revised CTS-0072-Form**

**Overview:**

On Monday, July 2\textsuperscript{nd}, CTS will implement an updated CTS-00172-FORM to reflect the changes outlined on the two FDA Guidance Documents released in December 2017 titled *Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Blood and Blood Components* and *NAT for HIV-1 and HCV Testing, Product Disposition, and Donor Deferral and Reentry*.

**T. cruzi Re-entry:** When this option is selected on the revised CTS-00172-Form, licensed Ortho anti-T. cruzi EIA and Abbott PRISM Chagas (ChLIA) assays will be used to test submitted sample(s). If both tests are nonreactive the Abbott ESA Chagas will be performed. Each individual test performed will be invoiced based on the current Special Testing Service Fees.

**HIV Re-entry:** When this option is selected on the revised CTS-00172-Form, appropriate anti-HIV-1/2 Plus O and NAT assays will be used to test submitted sample(s). Clients must indicate the reactive test and manufacturer that triggered the HIV deferral so appropriate testing is performed based on the FDA guidelines. The choices are either Grifols (Procleix Ultrio Plus) or Roche for HIV NAT re-entry, or Ortho or Abbott for HIV serology re-entry. Each individual test performed will be invoiced based on the current Special Testing Service Fees.

**HCV Re-entry:** When this option is selected on the revised CTS-00172-Form, licensed Ortho anti-HCV EIA and Abbott PRISM HCV ChLIA assays, along with the applicable HCV NAT assay will be used to test the submitted sample(s). If the HCV deferral was triggered due to a reactive NAT test, clients must indicate the manufacturer: Grifols (Procleix Ultrio Plus) or Roche. Each test performed will be invoiced based on the current Special Testing Service Fees.

**Routine donor profile with re-entry:** beginning Monday July 2\textsuperscript{nd} you will be able to request a routine donor profile along with any of the re-entry test requests by checking the box near the top of revised CTS-00172-Form. Two new profiles were created, one for T. cruzi and a revised HCV profile. Both of the profiles listed below will be added to the Special Testing Service Fee Schedule.

<table>
<thead>
<tr>
<th>Item</th>
<th>Billing Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T. cruzi Reentry Donor Profile</strong> (HBsAg, HBe, HIV-1/2, HCV, HTLV, HIV/HCV/HBV NAT IDS, WNV NAT IDS, ABO/Rh, Ab Screen, MHA-TP, CMV, T cruzi EIA, T cruzi ChLIA)</td>
<td>ST5610</td>
</tr>
</tbody>
</table>
The CTS-00172-FORM will be updated to reflect these changes and the Special Testing Result Reports will indicate which tests were performed. The revised result reports will be available at the June 6 webinar. The revised Form can be viewed below.

Impact to the Clients:

- The CTS-00172-FORM has been revised to reflect the updated T. cruzi, HIV and HCV, reentry guidelines.
- Clients will be able to verify which tests have been performed for re-entry testing by referring to the test name included on the Special Testing result reports.
- For HIV re-entry clients must select either Roche or Grifols NAT testing or Ortho or Abbott serology.
- For HCV re-entry, if deferral was triggered due to a reactive NAT test, clients must select either Roche or Grifols NAT testing.
- New fees will be associated with T. cruzi and HCV re-entry profiles

Client Action Required:

- Review the webinar slides by clicking this link.
- Register for and attend a live webinar on June 6th at 12 pm CDT.
- Notify applicable staff members of the re-entry request form changes for T. cruzi, HIV, and HCV re-entry testing.
- Continue to use the CTS-00172-FORM for all re-entry requests and click here to review the changes to the form.
- Notify applicable staff members of the new fees associated with T. cruzi and HCV re-entry testing.
- Ensure staff is aware that the tests performed will be included on the Special Testing result reports.

CTS Re-entry Testing Changes

Please join us for a Webinar on Wednesday June 6th, at 1000 PDT/1100 MDT/ 1200 CDT / 1300 EDT.
Please register for CTS Re-entry Testing Changes Webinar
https://attendee.gotowebinar.com/register/4796550597436172289

After registering, you will receive a confirmation email containing information about joining the webinar.

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).