FDA Reentry Guidance

*T. cruzi* – Chagas, Hepatitis C and HIV

Wednesday 6/6/18

Doug Denyer
O’Dina Hurlburt, SBB(ASCP)CM
Outline

• Impact to Clients
• Review of FDA Guidance Documents
• Reentry Request Process
• Request forms and Result Reports
Impact to Clients
Impact to the Blood Center

**Evaluate:**
1. FDA Guidance requirements for reentry
2. Laboratory Information System Software
3. Internal procedures
4. Cost associated with reentering donors

**Notify:**
1. Appropriate personnel at your facility of the reentry changes

**Implement:**
1. Updated CTS–00172 Reentry Request Form
2. Updated result reports
Blood Center Tasks

1. Identify the test (serology or NAT) and manufacturer of the original HCV or HIV deferral

2. Identify applicable *T. cruzi* (Chagas) deferred donors

3. Add *T. cruzi* and HCV reentry assays
Blood Center Impact: Test Results

1. No impact to receiving reentry test results for Email or Fax

2. Modify Laboratory Information System for electronic upload
   - To accept additional HCV serology result (must include ChLIA and EIA)
   - To accept additional *T. cruzi* assays (must include ChLIA, EIA and ESA Chagas)
FDA Guidance Documents

Background, eligibility, and reentry requirements.
T. cruzi Reentry
**T. cruzi** Reentry

FDA Guidance Document –

**Background:**

1. In the 2010 Chagas Guidance, FDA recommended one-time testing of each donor using a licensed test for antibodies to *T. cruzi*.

2. FDA recommends that one-time testing alone, without donor questioning for history of Chagas disease, is adequate and appropriate to identify donors at risk for transmission of Chagas disease.

3. FDA considers donors whose follow-up samples are tested with all three currently licensed tests, and show no reactivity with any of the three tests, to be eligible for reentry.
Groups Eligible for Reentry

1. Deferred donors with negative test results on the unlicensed *T. cruzi* RIPA
2. Negative result on the investigational or licensed supplemental test for antibodies to *T. cruzi*
3. Deferred donors who have never been tested by *T. cruzi* RIPA or an investigational or licensed supplemental test
4. Deferred donors who previously answered “yes” to the pre-donation screening Chagas question
Groups **NOT** Eligible for Reentry

1. Previously deferred donors who have had positive test results with either the unlicensed *T. cruzi* RIPA test or with an investigational or licensed supplemental test for antibodies to *T. cruzi*.

2. Previously deferred donors who have had an indeterminate test result with either the *T. cruzi* RIPA test or with an investigational or licensed supplemental test.
T. cruzi Reentry, cont’d

Recommended Re–entry Process:

1. Collect a sample following the specified waiting period after a reactive donation – 6 months

2. Perform licensed anti–T. cruzi EIA and Abbott PRISM Chagas (ChLIA). If both negative, then perform Abbott ESA Chagas.

3. If all three tests are negative, the donor may be allowed to donate.

4. If any of the three tests are positive, the donor should be permanently deferred.
HIV Reentry
HIV/HCV Reentry

FDA Guidance Document

Background:

1. Each year, many donors are deferred due to false positive results on a serologic test that is not confirmed.

2. Implementation of NAT has resulted in many donor deferrals due to potentially false reactive NAT results.

3. This guidance provides directions for reentry of donors that were reactive for HIV–1/HCV NAT, HIV/HCV antibody, and/or HIV–1 p24 antigen.
HIV Reentry

Groups Eligible for HIV Reentry

1. **Group I** = HIV–1 NAT Reactive and seronegative for antibodies to HIV–1 and HIV–2

2. **Group II** = HIV–1 NAT non-reactive or not performed, RR for anti–HIV–1/2 and indeterminate (viral bands may be present), unreadable, negative, or was not performed by HIV–1 Western Blot (WB) or immunofluorescence assay (IFA)

3. **Group III** = Positive or indeterminate HIV–1 p24 Neutralization, even on more than one occasion
HIV Reentry, cont’d

Groups **NOT** Eligible for Reentry

1. HIV–1 NAT Reactive and RR for anti–HIV–1 and/or HIV–2, regardless of confirmatory results
2. HIV–1 NAT Reactive and RR for HIV–1 p24 EIA
3. HIV–1 NAT non–reactive, RR for anti–HIV–1 and/or HIV–2 and anti–HIV–1 confirmed positive
4. HIV–1 NAT non–reactive and RR for both anti–HIV–1/2 and HIV–1 p24, regardless of confirmatory results
Recommended Reentry Process:
1. Collect a sample following the specified waiting period after a reactive donation
   - 8 weeks for HIV
2. Perform applicable NAT and serology tests
3. If all tests are nonreactive, the donor may be allowed to donate
4. If the dNAT is reactive and the anti–HIV–1/2 test is negative or RR, permanently defer the donor.
HIV Reentry, cont’d

Recommended Reentry Process, cont’d:

5. If the dNAT is non-reactive and the anti–HIV–1/2 test is RR, you may conduct additional follow-up testing after a second waiting period of 8 weeks.

6. If a persistent anti–HIV–1/2 RR result is demonstrated, test the donor’s new sample using a licensed supplemental test for antibodies to HIV–1 such as a WB or IFA.
   a. If the WB or IFA test result is indeterminate, unreadable, or negative, conduct follow-up testing after one or more additional waiting periods of at least 8 weeks.
   b. If the WB or IFA test result is positive, permanently defer the donor.
HCV Reentry
HCV Reentry

Groups Eligible for HCV Reentry

1. **Group A** = HCV NAT Reactive and seronegative for anti-HCV

2. **Group B** = HCV NAT Nonreactive (or NAT was not performed), RR for anti-HCV and indeterminate, negative or was not performed by HCV RIBA
HCV Reentry, cont’d

Groups *NOT* Eligible for Reentry

1. HCV NAT Reactive and RR for anti–HCV, regardless of confirmatory results
2. HCV NAT non–reactive, RR for anti–HCV and HCV RIBA positive
HCV Reentry, cont’d

Recommended Reentry Process:

1. Collect a sample following the specified waiting period after a reactive donation
   - 6 months for HCV
2. Perform applicable NAT and two different, licensed anti–HCV screening tests.
3. If all tests are nonreactive, the donor may be allowed to donate
4. If the dNAT is reactive, regardless of anti–HCV test results, permanently defer
5. If the dNAT is non–reactive, and both of the anti–HCV tests are reactive, permanently defer the donor.
Recommended Reentry Process, cont’d:

6. If the dNAT is non-reactive and only one anti-HCV test is RR, you may reconsider the donor for reentry by testing a follow-up sample after one more waiting period of at least 6 months.

7. If an anti-HCV test is still RR on a second follow-up sample at any time after the original donation, permanently defer the donor.
CTS Re-entry Request Process

Donor eligibility, sample submission, testing, result reporting and billing.
CTS Reentry Request Process

1. Identify eligible donor and completion of waiting period
   - Minimum 6 months for *T. cruzi* reentry
   - Minimum 8 weeks for HIV reentry
   - Minimum 6 months for HCV reentry

2. Collect follow-up samples
   - One 6mL EDTA AND one 6mL serum tube

3. Complete the revised CTS reentry Request form
   - Provide applicable information as required by the revised form
   - Indicate deferral test and manufacture
   - Option is available to request routine donor panel if desired

4. Submit samples and form directly to Special Testing
5. CTS performs applicable test(s)
   - *T. cruzi* reentry: anti-*T. cruzi* EIA and Abbott PRISM Chagas, if both NR then Abbott ESA Chagas
   - HIV reentry: Discriminatory HIV and anti–HIV–1/2, with reflex confirmation if applicable
     • Indicate the reactive test and manufacturer that triggered the HIV deferral
   - HCV reentry: Discriminatory HCV and anti–HCV (both EIA and ChLIA)
     • Indicate the reactive test and manufacturer that triggered the HCV deferral

6. Results reported using existing Special Testing result reports
   - Billing will include only the test(s) actually performed
CTS Request Forms and Result Reports
Changes to CTS-00172 Form
T. cruzi Example Request

Special Testing Re-entry Request Form

Facility Name: ABC Center
Sample ID: 1234567
Collection Date/Time: 4/30/15 1200

Include routine donor profile

Anti-HBc Re-entry: Verify collection date is at least 8 weeks from reactive donation
- HBc Re-entry Series (Anti-HBc and HBsAg with triplicate Procleix dIgIV, if both tests are nonreactive)

HIV Re-entry: Verify collection date is at least 6 months from reactive donation
- HBsAg, Anti-HBc and triplicate Procleix dIgIV, with confirmatory reflex, if indicated

HCV Re-entry: Verify collection date is at least 8 weeks from reactive donation
- dHCV NAT and anti-HCV 12/24 Plus O, with confirmatory reflex if indicated
- Indicate the reactive test (and manufacturer) that triggered the deferral. (Mark only one box below)
  - NAT deferral: Procleix
  - NAT deferral: Roche
  - Serology deferral: Ortho
  - Serology deferral: Abbott

T. cruzi Re-entry: Verify collection date is at least 6 months from reactive donation
- T. cruzi Re-entry Sortos (Ortho anti-T. cruzi EIA and Abbott PRISM Chagas, with Abbott ESA Chagas reflex, if both tests are nonreactive)

Sample received at CTS Dallas/Tampa: □ Refrigerated □ Frozen □ Ambient
Initials: Date: Time:

CTU Use: Date:
**T. cruzi Example report**

Sample Summary Report
Printed: 06/04/18 08:32:21

<table>
<thead>
<tr>
<th>Test</th>
<th>Conclusion</th>
<th>Testing Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trich T. cruzi IFA</td>
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<td>08/01/18 09:23:20</td>
</tr>
<tr>
<td>Abbott PRISM Chagas OIA</td>
<td>NONREACTIVE</td>
<td>08/01/18 09:54:29</td>
</tr>
<tr>
<td>Abbott ESA Chagas</td>
<td>NEGATIVE</td>
<td>08/01/18 09:29:09</td>
</tr>
</tbody>
</table>

*Urine T. cruzi IFA: Testing Performed by Memorial Blood Center, 727 Pelham Blvd S, Paul, MN 55314, CLIA # 2400662900*

The Urine T. cruzi IFA test is licensed for use with cadaveric samples.

Abbott PRISM Chagas OIA: The Abbott PRISM Chagas test is licensed for use with cadaveric samples.

Refer to Interpretation Information Sheets available at www.mycts.org

This information has been disclosed to you from confidential records which are protected by the law. State law prohibits you from making any further disclosure of a transmissible disease result without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.
**T. cruzi Donor Panel Request**

### Special Testing Re-entry Request Form

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th>ABC Center</th>
<th>Sample ID:</th>
<th>1234567</th>
<th>Collection Date/Time:</th>
<th>04/30/2018 1200</th>
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<tbody>
<tr>
<td>Contact Name:</td>
<td>Jane Doe</td>
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<td>Contact Number:</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted By/Date:</td>
<td>05/01/2016</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type:</td>
<td>Serum</td>
<td>x</td>
<td>EDTA</td>
<td>Other (Specify)</td>
<td></td>
</tr>
</tbody>
</table>

- Include routine donor profile

**Anti-HBc Re-entry:** Verify collection date is at least 8 weeks from reactive donation

**HBc Re-entry Series** (Anti-HBc and HBsAg with triplicate Procleix dHBV, if both tests are nonreactive)

**HBV Re-entry:** Verify collection date is at least 6 months from reactive donation

- HBsAg, Anti-HBc and triplicate Procleix dHBV, with confirmatory reflex, if indicated

**HIV Re-entry:** Verify collection date is at least 6 months from reactive donation

- dHIV-1 NAT and anti-HIV 1/2 Plus O, with confirmatory reflex if indicated

AND

Indicate the reactive test (and manufacturer) that triggered the deferral: (Mark only one box below)

- NAT deferral: Procleix
- NAT deferral: Roche
- Serology deferral: Ortho
- Serology deferral: Abbott

**HCV Re-entry:** Verify collection date is at least 6 months from reactive donation

- dHCV NAT and anti-HCV (Ortho and Abbott)

If donor was deferred due to a reactive NAT test; indicate manufacturer:

- Procleix
- Roche

**T. cruzi Re-entry:** Verify collection date is at least 6 months from reactive donation

- T. cruzi Re-entry Series (Ortho anti-T. cruzi ELISA and Abbott FRISM Chagas, with Abbott ESA Chagas reflex, if both tests are nonreactive)

### Sample received at CTS Dallas/Tampa

- Refrigerated
- Frozen
- Ambient

**CTS Use Only**

<table>
<thead>
<tr>
<th>Sample Received</th>
<th>Sample Condition</th>
<th>Sub</th>
<th>Order Verification</th>
<th>Sample Centrifuged (CTS)</th>
<th>Sample Thawed (CTS)</th>
<th>Sample Frozen (CTS)</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
Sample Summary Report
Printed: 06/04/18 08:32:01

<table>
<thead>
<tr>
<th>Test</th>
<th>Conclusion</th>
<th>Testing Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott PRISM HBs:Ag CHIA Series</td>
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<td>06/01/18 06:41:20</td>
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<td>Abbott PRISM HBs:Ag CHIA</td>
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<td></td>
</tr>
<tr>
<td>Abbott PRISM HBC CHIA</td>
<td>NO REACTIVE</td>
<td></td>
</tr>
<tr>
<td>Abbott PRISM HCV CHIA</td>
<td>NO REACTIVE</td>
<td></td>
</tr>
<tr>
<td>Abbott PRISM HCV CHIA</td>
<td>NO REACTIVE</td>
<td>06/01/18 08:50:36</td>
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<td>06/01/18 06:53:06</td>
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<td>Procleix HIV-1/HCV/HBV NAT IDS</td>
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</tr>
<tr>
<td>Procleix HIV NAT IDS</td>
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</tr>
<tr>
<td>Abbott PRISM HIV 0 Plus CHIA</td>
<td>NO REACTIVE</td>
<td></td>
</tr>
<tr>
<td>Abbott PRISM HTLV-III CHIA Series</td>
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</tr>
<tr>
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<td>06/01/18 08:05:24</td>
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<tr>
<td>Syphilis Treponemal Antibody Test (MHA-TP) Series</td>
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<td>06/01/18 03:08:23</td>
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<td>Syphilis Treponemal Antibody Test (MHA-TP)</td>
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<tr>
<td>Antibody to CMV (Anti-CMV) only</td>
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<td>06/01/18 06:11:18</td>
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<td>Antibody to CMV (Anti-CMV)</td>
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<tr>
<td>ABO/Rh Only</td>
<td>A POS</td>
<td>06/01/18 06:12:54</td>
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<tr>
<td>Antibody Screen Only</td>
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<td>06/01/18 06:15:35</td>
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<tr>
<td>Antibody Screen</td>
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<td></td>
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<tr>
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<td>06/01/18 05:23:17</td>
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<tr>
<td>Ortho T. cruzi EIA</td>
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<td>06/01/18 02:24:13</td>
</tr>
<tr>
<td>Abbott PRISM Giugliano CHIA</td>
<td>NO REACTIVE</td>
<td></td>
</tr>
</tbody>
</table>
HIV Example Request

Special Testing Re-entry Request Form

Facility Name: ABC Center
Sample ID: 1234567
Collection Date/Time: 4/50/15 12:00

Contact Name: Jane Doe
Contact Number: 602-555-1234
Submitted By/Date: 5/1/18

Sample Type: Serum

Centrifugation Date/Time:
Aliquot Date/Time:
Freeze Date/Time:
Thaw Date/Time:

Include routine donor profile

Anti-HBc Re-entry: Verify collection date is at least 8 weeks from reactive donation

HBs Re-entry: Verify collection date is at least 6 months from reactive donation

HBsAg, Anti-HBc and triplicate Procleix dHBV, with confirmatory reflex, if indicated

HBV Re-entry: Verify collection date is at least 6 months from reactive donation

HV Re-entry: Verify collection date is at least 8 weeks from reactive donation

dHIV-1 NAT and anti-HIV-1/2 Plus Q, with confirmatory reflex if indicated

HCV Re-entry: Verify collection date is at least 6 months from reactive donation

dHCV NAT and anti-HCV (Ortho and Abbott)

If donor was deferred due to a reactive NAT test, indicate manufacturer:

Procleix
Roche

T.cruzi re-entry: Verify collection date is at least 6 months from reactive donation

T.cruzi re-entry Sano (Ortho anti-T. cruzi EIA and Abbott PRISM Chagas, with Abbott ESA Chagas reflex, if both tests are nonreactive)

Sample received at CTS Dallas/Tampa

Sample Received:
- Refrigerated
- Frozen
- Ambient

Sample Condition:
- Acceptable
- Hemolyzed
- Licorice

Sample Type:
- Serum
- Plasma
- Other

Order Verification:
- ID
- SD Nested
- SDFB
- LiteTrak
- Tube

Sample Centrifuged (CTS)

Sample Thawed (CTS)

Sample Frozen (CTS)
HIV Donor Panel Request

Special Testing Re-entry Request Form

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th>ABC Center</th>
<th>Sample ID:</th>
<th>1234567</th>
<th>Collection Date/Time:</th>
<th>04/30/2018 1200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name:</td>
<td>Jane Doe</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Contact Number:</td>
<td>860-123-4567</td>
<td>Sample</td>
<td>Serum</td>
<td>Centrifugation Date/Time:</td>
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<tr>
<td>Submitted By/Date:</td>
<td>05/01/2019</td>
<td>Type:</td>
<td>EDTA</td>
<td>Aliquot Date/Time:</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Thaw Date/Time:</td>
<td></td>
</tr>
</tbody>
</table>

- Include routine donor profile

**Anti-HBc Re-entry:** Verify collection date is at least 8 weeks from reactive donation

- HBc Re-entry Series (Anti-HBc and HBsAg with triplicate Proleix dHBV, if both tests are nonreactive)

**HBV Re-entry:** Verify collection date is at least 6 months from reactive donation

- HBsAg, Anti-HBc and triplicate Proleix dHBV, with confirmatory reflex, if indicated

**HIV Re-entry:** Verify collection date is at least 8 weeks from reactive donation

- dHIV-1 NAT and anti-HIV-1/2 Plus O, with confirmatory reflex if indicated

**HCY Re-entry:** Verify collection date is at least 6 months from reactive donation

- dHCV NAT and anti-HCV (Ortho and Abbott)

If donor was deferred due to a reactive NAT test, indicate manufacturer:

- Proleix
- Roche

**T. cruzi Re-entry:** Verify collection date is at least 6 months from reactive donation

- T. cruzi Re-entry Series (Ortho anti-T. cruzi BIA and Abbott PRISM Chagas, with Abbott BSA Chagas reflex, if both tests are nonreactive)

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Sample received at CTS Dallas/Tampa:

- Refrigerated
- Frozen
- Ambient

**Sample Condition:**

- Acceptable
- Hemolyzed
- Lipemic

**Sub:**

- HIV
- dHIV
- HBc
- HBV x 3
- CMV
- HBe
- Mx
- HTLV
- WNV

**ST Sample Type:**

- Serum
- Plasma
- Other

**Order Verification:**

- ID
- CD4
- Other
- $308
- LifeTrak
- Tube

**Sample Centrifuged (CTS):**

- Initial: Date Time

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**Sample Thawed (CTS):**

- Initial: Date Time

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**Sample Frozen (CTS):**

- Initial: Date Time
Sample Summary Report  
Printed: 06/04/18 08:28:54

<table>
<thead>
<tr>
<th>Test</th>
<th>Conclusion</th>
<th>Testing Completed</th>
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<tbody>
<tr>
<td>Abbott PRISM HBsAg GALLIA Series</td>
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<td>06/01/18 08:35:31</td>
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<tr>
<td>Abbott PRISM HBeAg GALLIA</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:42:45</td>
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<tr>
<td>Abbott PRISM HBe GALLIA Only</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:46:31</td>
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<tr>
<td>Abbott PRISM HCV GALLIA</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:51:47</td>
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<tr>
<td>Precise Ultras Plus Series</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:56:13</td>
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<tr>
<td>Precise HIV-1/HIV NAT IBS</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:57:41</td>
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<td>Precise dHIV-1 NAT Only</td>
<td>NONREACTIVE</td>
<td>06/01/18 08:57:41</td>
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<td>Precise WNV Series</td>
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<td>Genotypic Systems Anti-HIV 1/2 Plus 0 EIA</td>
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<td>06/01/18 09:04:29</td>
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<tr>
<td>Abbott PRISM HIV 0 Plus GALLIA Series</td>
<td>NONREACTIVE</td>
<td>06/01/18 09:06:49</td>
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<td>Abbott PRISM HIV-1/2/3 GALLIA Series</td>
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<td>06/01/18 09:06:49</td>
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<tr>
<td>Syphilis Treponema Antibody Test [MHA-TP] Series</td>
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<td>06/01/18 09:06:49</td>
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<tr>
<td>Antibody to CMV (Anti-CMV) Only</td>
<td>REACTIVE</td>
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<tr>
<td>Antibody to CMV (Anti-CMV)</td>
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<tr>
<td>ABO/Rh Only</td>
<td>A NEG</td>
<td>06/01/18 09:12:13</td>
</tr>
<tr>
<td>Antibody Screen Only</td>
<td>NEGATIVE</td>
<td>06/01/18 09:14:38</td>
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**HCV Example Request**

**Special Testing Re-entry Request Form**

<table>
<thead>
<tr>
<th>Facility Name:</th>
<th>ABC Center</th>
<th>Sample ID:</th>
<th>12234567</th>
<th>Collection Date/Time: 4/30/15 12:00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Name:</td>
<td>Jane Doe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Number:</td>
<td>802-555-1234</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Submitted By/Date:</td>
<td>5/1/16</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Include routine donor profile

**Anti-HBc Re-entry:** Verify collection date is at least 8 weeks from reactive donation
- HBc Re-entry Ser (Anti-HBc and HBsAg with triplicate Procleix dHBV, if both tests are nonreactive)

**HBV Re-entry:** Verify collection date is at least 6 months from reactive donation
- HBsAg, Anti-HBs and triplicate Procleix dHBV, with confirmatory reflex, if indicated

**HIV Re-entry:** Verify collection date is at least 8 weeks from reactive donation
- dHIV-1 NAT and anti-HIV-1/2 Plus C, with confirmatory reflex if indicated

- Indicate the reactive test (and manufacturer) that triggered the deferral: (Mark only one box below)
  - NAT deferral: Procleix
  - NAT deferral: Roche
  - Serology deferral: Ortho
  - Serology deferral: Abbott

- dHCV NAT and anti-HCV (Ortho and Abbott)
  - If donor was deferred due to a reactive NAT test, indicate manufacturer:
    - Procleix
    - Roche

**T. cruzi Re-entry:** Verify collection date is at least 6 months from reactive donation
- T. cruzi Re-entry Ser (Ortho anti-T. cruzi EIA and Abbott PRISM Chagas, with Abbott ESA Chagas reflex, if both tests are nonreactive)

**Sample received at CTS Dallas/Tampa:**
- [ ] Refrigerated
- [ ] Frozen
- [ ] Ambient

**CTS Use Only**

<table>
<thead>
<tr>
<th>Sample Received</th>
<th>Sample Condition</th>
<th>Sub</th>
<th>ST Sample Type</th>
<th>Order Verification</th>
<th>Sample Centrifuged (CTS)</th>
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</tbody>
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| [ ] Frozen | [ ] Acceptable | [ ] dHIV | [ ] ABO/Rh |
| [ ] Ambient | [ ] Hemolyzed | [ ] HBc | [ ] Anti-HBsAg |
| [ ] Refrigerated | [ ] Lipemic | [ ] HIV | [ ] dHBV x 3 |

**CTS Use Only**

| [ ] Serum | [ ] Plasma | [ ] Other |
| [ ] SD - Net | [ ] SDS - DB | [ ] Line Test |
| [ ] Lipemic | [ ] Lipemic | [ ] Lipemic |

[ ] Sample Thawed (CTS)
[ ] Sample Frozen (CTS)
# HCV Donor Panel Request

## Special Testing Re-entry Request Form

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<thead>
<tr>
<th>Facility Name:</th>
<th>ABC Center</th>
<th>Collection Date/Time:</th>
<th>04/30/2010 1200</th>
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<tbody>
<tr>
<td>Contact Name:</td>
<td>Jane Doe</td>
<td>Centrifugation Date/Time:</td>
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<tr>
<td>Contact Number:</td>
<td>662-555-1234</td>
<td>Alcohol Date/Time:</td>
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<td>Submitted By/Date:</td>
<td>05/01/2016</td>
<td>Freeze Date/Time:</td>
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<td>Type:</td>
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<td>Thaw Date/Time:</td>
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</tr>
<tr>
<td>Include routine donor profile</td>
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</tbody>
</table>

### Anti-HBc Re-entry
- Verify collection date is at least 8 weeks from reactive donation
- HBe Re-entry Series (Anti-HBc and HBeAg with triplete Procleix dHBV, if both tests are nonreactive)

### HBV Re-entry
- Verify collection date is at least 6 months from reactive donation
- HBsAg, Anti-HBe and triplete Procleix dHBV, with confirmatory reflex, if indicated

### HIV Re-entry
- Verify collection date is at least 6 weeks from reactive donation
- dHIV-1 NAT and anti-HIV-1/2 Plus O, with confirmatory reflex if indicated
- AND
- Indicate the reactive test (and manufacturer) that triggered the deferral: (Mark only one box below)
  - NAT deferral: Procleix
  - NAT deferral: Roche
  - Serology deferral: Ortho
  - Serology deferral: Abbott

### HCV Re-entry
- Verify collection date is at least 6 months from reactive donation
- dHCV NAT and anti-HCV (Ortho and Abbott)
- If donor was deferred due to a reactive NAT test, indicate manufacturer:
  - Procleix
  - Roche

### T. cruzi Re-entry
- Verify collection date is at least 6 months from reactive donation
- T. cruzi Re-entry Series (Ortho anti-T. cruzi EIA and Abbott PRISM Chagas, with Abbott ESA Chagas reflex, if both tests are nonreactive)

### Sample received at CTS Dallas/Tampa
- □ Refrigerated □ Frozen □ Ambient
- □ Intrins □ Date: □ Time:

### CTS Use Only

<table>
<thead>
<tr>
<th>Sample Received</th>
<th>Sample Condition</th>
<th>Sub</th>
<th>ST Sample Type</th>
<th>Order Verification</th>
<th>Sample Centrifuged (CTS)</th>
<th>Sample Thawed (CTS)</th>
<th>Sample Frozen (CTS)</th>
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<td>HIV</td>
<td>□ Serum</td>
<td>□ ID</td>
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<tr>
<td>□ Ambient</td>
<td>□ Hemozyed</td>
<td>HCV</td>
<td>□ Plasma</td>
<td>□ SD_Nat</td>
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<tr>
<td>□ Refrigerated</td>
<td>□ Lipemic</td>
<td>HBsAg</td>
<td>□ Other</td>
<td>□ SDB</td>
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<td>Intrins □ Date: □ Time:</td>
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# Creative Testing Solutions
HCV Example report

To: CTS Customer Service

Sample Summary Report
Printed: 06/04/18 08:29:57

<table>
<thead>
<tr>
<th>Test</th>
<th>Conclusion</th>
<th>Testing Completed</th>
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<td>06/01/18 06:35:37</td>
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<td>Abbott PRISM Hb/Ag CALIA</td>
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<td>Ortho Anti-HCV EIA Only</td>
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<td>Abbott PRISM HCV CALIA Only</td>
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<td>Abbott PRISM HTLV-III CALIA Series</td>
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<td>Abbott PRISM HIV 0 Pls CALIA Series</td>
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<td>Abbott PRISM HIV 0 Pls CALIA</td>
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<td>Abbott PRISM HIV-0 Pls CALIA Series</td>
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Questions?