



## Versiti DTL Test Methods (Abbott Alinity-Roche Platforms)

| TEST METHODS   |   |        |            |
|--|---|--------|------------|
| SCREENING TEST performed using the following assays:   |   |        |            |
| Test   | Assay   |        |            |
| ABO/Rh Blood Group   | Beckman Coulter PK Blood Grouping System                                  |        |            |
| Atypical Red Blood Cell (RBC) Antibody Screen  | Immucor NEO Capture-R Ready-Screen Solid Phase                            |        |            |
| STS <i>Treponema Pallidum</i> (TP)   | Beckman Coulter PK-TP System  |        |            |
| Cytomegalovirus Antibody (CMV)   | Immucor NEO Capture-CMV Solid Phase System                                |        |            |
| Chagas Antibody ( <i>T. cruzi</i> )  | Abbott Alinity Chagas CMIA  |        |            |
| Hepatitis B Core Antibody (HBc)  | Abbott Alinity HBcore CMIA  |        |            |
| Hepatitis B Surface Antigen (HBsAg)  | Abbott Alinity HBsAg CMIA   |        |            |
| Hepatitis C Virus Antibody (HCV)   | Abbott Alinity HCV CMIA   |        |            |
| Human Immunodeficiency Virus Antibody (HIV-1/2 Ab/Ag)  | Abbott Alinity HIV O Plus CMIA  |        |            |
| Human T-Lymphotropic Virus Antibody (HTLV-I/II)  | Abbott Alinity HTLV-I/HTLV-II CMIA  |        |            |
| Nucleic Acid Testing (NAT) HBV/HCV/HIV Multiplex   | Roche Cobas MPX NAT Test (Cobas 8800)                                     |        |            |
| Nucleic Acid Testing (NAT) WNV   | Roche Cobas WNV NAT Test (Cobas 8800)                                     |        |            |
| Nucleic Acid Testing (NAT) Babesia   | Roche Cobas Babesia NAT Test (Cobas 8800)                                 |        |            |
| CONFIRMATORY/SUPPLEMENTAL TEST performed using the following assays by Third Party Lab listed: |   |        |            |
| Test   | Assay   |        | Laboratory |
| Serological Test for Syphilis  | Trinity BioTech CAPTIA <i>T. Pallidum</i> -G EIA                          | AND/OR | Versiti    |
|  | ASI RPR Card Test (RPR Titer - if RPR positive)                           | OR     | Versiti    |
|  | Zeus Scientific IFA FTA-ABS Test System                                   |        | Quest      |
| Cytomegalovirus Antibody   | BIO-RAD Chemiluminescent Immunoassay (IgG/IgM Discriminatory)             |        | LabCorp    |
| Chagas Antibody  | Abbott ESA Chagas   | OR     | CTS        |
|  | Ortho <i>T.cruzi</i> Whole Cell Lysate ELISA (2nd vendor licensed screen) |        | CTS        |
| HBcore Antibody  | Ortho HBcore ELISA on Ortho Verseia (2nd vendor licensed screen)          |        | CTS        |
| HBsAg Neutralization   | Abbott Alinity HBsAg Confirmatory Neutralization CMIA                     |        | Versiti    |
| HCV Antibody   | Roche Cobas HCVNAT repeated IDT (if not originally tested IDT)            | AND    | Versiti    |
|  | Ortho HCV Encoded Antigen ELISA on Verseia (2nd vendor licensed)          |        | CTS        |
| HIV-1/2 ImmunoAssay  | BioRad Geenius HIV-1/2 Supplemental Assay                                 |        | CTS        |
| HTLV Antibody  | MP Diagnostic HTLV Blot 2.4 Western Blot                                  | OR     | CTS        |
|  | Avioq HTLV-I/II MicroELISA on Verseia (2nd vendor licensed screen)        |        | CTS        |
| HIV/HCV/HBV NAT  | Grifols Procleix Ultrio Plus NAT Test (Panther) (2nd vendor licensed)     |        | CTS        |
| WNV NAT  | Grifols Procleix WNV NAT Test (Panther) (2nd vendor licensed screen)      |        | CTS        |
| Babesia NAT  | Grifols Procleix Babesia Test (Panther) (2nd vendor licensed screen)      |        | CTS        |

|                              |                  |              |        |             |
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| Versiti – Donor Testing Lab: | FDA License      | 2132         | NY SDH | PFI: 7968   |
|                              | FDA Registration | 1873403      | PA SDH | 033850      |
|                              | CMS/CLIA         | 15D0664398   | CA DPH | COS 800236  |
|                              | AABB             | 005486       | MD SDH | PFI: 972    |
|                              | ASHI             | 08-4-IN-06-1 | IN SDH | 14-005931-1 |

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|---|----------|------------|
| LabCorp – LabCorp Indiana, Inc. (South Bend, IN)            | CMS/CLIA | 15D2171417 |
| CTS – Creative Testing Solutions (Tempe, AZ)                | CMS/CLIA | 03D0911463 |
| Quest – Quest Diagnostics Nichols Institute (Chantilly, VA) | CMS/CLIA | 49D0221801 |
| QualTex (Norcross, GA) – back-up testing lab                | CMS/CLIA | 11D2016499 |