Ultrio Elite HIV-1/2, HCV, HBV NAT
Test Code: 30805

Please contact Client Services to set up a Pre-transplant account to order this assay.

Clinical and Procedure

Clinical Utility
The Procleix Ultrio Elite Assay is a qualitative in vitro nucleic acid amplification test to screen for human immunodeficiency virus type 1 (HIV-1) RNA, hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA, and detect human immunodeficiency virus type 2 (HIV-2) RNA in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, and source plasma, and from other living donors. This assay is not intended for use as an aid in diagnosis of infection with HIV-1, HIV-2, HCV or HBV. See package insert for more information.

About This Assay

Epidemiological studies identified HIV-1 and HIV-2 as the etiological agents of acquired immunodeficiency syndrome (AIDS), hepatitis C virus (HCV), and hepatitis B virus (HBV) as causative agents of transfusion-associated hepatitis. HIV, HCV, and HBV are transmitted primarily by exposure to infected blood or blood products, certain body fluids or tissues, and from mother to fetus or child.

Current detection of HIV-1 infection in the blood bank setting is based on nucleic acid testing (NAT) for HIV RNA detection and serologic screening for anti-viral antibodies with confirmation by additional more specific supplemental antibody tests. The addition of NATs has reduced the window period of detection by 6 to 11 days in donations tested individually, significantly reducing the risk of HIV transmission by transfusion.

Diagnosed cases of HIV-2 are observed primarily in West Africa or where exposure through immigration or travel has occurred. Assays that detect the antibodies against both HIV-1 and HIV-2 are commonly used for screening blood donations worldwide. HIV-1 and HIV-2 may be discriminated using rapid immunoassays. The residual risk for potential HIV-2 transfusion is estimated to be extremely low, but it has not been possible to confirm these estimates directly. Screening for HIV-2 RNA should reduce the risk even further.

Current detection of HCV infection in the blood bank setting is based on NAT for HCV RNA detection and serologic screening for anti-viral antibodies. The introduction of NATs for HCV RNA has allowed detection of HCV infection approximately 59 days earlier than the current antibody-based tests.

Current detection of HBV infection in the blood bank setting is based on NAT for HBV DNA detection and serological screening for HBsAg by enzyme immunoassay (EIA) with confirmation by neutralization tests and anti-hepatitis B core antigen (anti-HBc) assays. A model based on HBV doubling time was used to develop an estimate of approximately 38 to 44 days between infection and HBsAg detection using current tests. Studies indicate that NATs for HBV DNA will allow detection of HBV infection several weeks before HBsAg detection. NAT with enhanced sensitivity for HBV can detect low levels of HBV DNA in serologically negative samples during early stages of infection and in HBc antibody-positive/HBsAg-negative samples during later stages of infection.

Procedure
The Procleix Ultrio Elite Assay involves three main steps which take place in a single tube on the Procleix Panther System: 1) Sample preparation/ target capture 2) HIV RNA, HCV RNA, and HBV DNA target amplification by Transcription-Mediated Amplification (TMA) and 3) Detection of the amplification products (amplicon) by the Hybridization Protection Assay (HPA). The Procleix assays incorporate an Internal Control for monitoring assay performance in each individual reaction tube.
Specimens found to be reactive in the Procleix Ultrio Elite Assay may be run in individual Procleix Ultrio Elite HIV, HCV, and/or HBV Discriminatory Assays to determine if they are reactive for HIV, HCV, HBV or any combination. The Procleix Ultrio Elite HIV, HCV, and HBV Discriminatory Assays utilize the same three main steps as the Procleix Ultrio Elite Assay (sample preparation/target capture, TMA and HPA); the same assay procedure is followed with one difference: HIV-specific, HCV-specific, or HBV-specific probe reagents are used in place of the Procleix Ultrio Elite Assay Probe Reagent. The Procleix Ultrio Elite HIV Discriminatory Assay will not distinguish between samples reactive for HIV-1 and those reactive for HIV-2. Test performed by VRL Eurofins, 6933 S. Revere Parkway, Centennial, CO 80112. This test has been cleared or approved for diagnostic use by the U.S. Food and Drug Administration. See package insert for more information.

**Turnaround Time**
Within 24 hours from receipt of specimen.

**Specimen Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Order Code</th>
<th>CPT Code</th>
<th>NY Approved</th>
<th>Volume</th>
<th>Assay Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>30805</td>
<td>87516, 87521, 87535</td>
<td>Yes</td>
<td>2.5 mL (min 1.5 mL)</td>
<td>Qualitative</td>
</tr>
<tr>
<td>Serum</td>
<td>30805</td>
<td>87516, 87521, 87535</td>
<td>Yes</td>
<td>2.5 mL (min 1.5 mL)</td>
<td>Qualitative</td>
</tr>
</tbody>
</table>

**Special Instructions**
- Collect whole blood in an EDTA, lavender top tube. Whole blood in ACD, Lithium Heparin, Sodium Citrate, or Sodium Heparin tubes are also accepted. Do not freeze whole blood.
- Sample sent in original vacutainer tube can be shipped ambient and must be received within 72 hours.
- If not shipping original container, centrifuge and transfer 2.5 mL (min 1.5 mL) of the plasma to a sterile, screw top tube. Can be shipped ambient temperature when received within 72 hours refrigerated when received within 13 days or frozen received within 280 days.

**Shipping**
All specimens must be labeled with patient's name and collection date. A Viracor/VRL Eurofins Pre-Transplant test requisition form must accompany each specimen. Multiple tests can be run on one specimen. Ship specimens FedEx Priority Overnight® to: VRL Eurofins, 6933 S. Revere Parkway, Centennial, CO 80112

**Causes for Rejection**
Whole blood frozen, serum frozen, specimens beyond their acceptable length of time from collection as listed in the specimen handling, or specimen types other than those listed.

**Disclaimer**
Specimens are approved for testing in New York only when indicated in the Specimen Information field above. The CPT codes provided are based on VRL Eurofins' interpretation of the American Medical Association's Current Procedural Terminology (CPT) codes and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. VRL Eurofins assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.