**INTERPRETATION INFORMATION SHEET**

**Hepatitis Serology**

**HBsAg ChLIA (Abbot PRISMTM):** This chemiluminescent assay (ChLIA) detects the presence of Hepatitis B surface antigen (HBsAg). Specimens found repeatedly reactive should be tested by a licensed, neutralizing confirmatory test. Only those specimens that can be neutralized by the confirmatory test procedure indicate infection with the Hepatitis B virus, or recent vaccination against Hepatitis B. A specimen is considered nonreactive (negative) with a value less than the cutoff and neutralization would not be applicable.

**HBsAg EIA:** This enzyme immunoassay (EIA) detects the presence of Hepatitis B surface antigen (HBsAg). Specimens found repeatedly reactive should be tested by a licensed, neutralizing confirmatory test. Only those specimens that can be neutralized by the confirmatory test procedure indicate infection with the Hepatitis B virus, or recent vaccination against Hepatitis B. A specimen is considered nonreactive (negative) with a value less than the cutoff and neutralization would not be applicable.

**HBsAg Confirmatory Neutralization:** This assay uses the principle of specific antibody neutralization to confirm the presence of HBsAg in specimens found repeatedly reactive for HBsAg. A specimen is confirmed positive if the reactivity of the neutralized specimen is reduced by at least 50% when compared to the reactivity of the non-neutralized control. A specimen is not confirmed (non-confirmed or non-neutralizable) if the reactivity of the neutralized specimen is NOT reduced by at least 50% when compared to the reactivity of the non-neutralized control.

**Anti-HBs EIA:** This enzyme immunoassay (EIA) detects the presence of antibody to Hepatitis B surface antigen (HBsAg). The detection of anti-HBs is indicative of a prior immunologic exposure to the hepatitis B virus or vaccine. An individual with positive anti-HBs is immune to hepatitis B infection.

**Anti-HBc ChLIA:** This chemiluminescent assay (ChLIA) detects the presence of total antibody (IgM and/or IgG) to Hepatitis B core antigen (HBc) and is used as an aid in reducing the incidence of Hepatitis B transmission by transfusion.

**Anti-HBc EIA:** This enzyme immunoassay (EIA) detects the presence of both IgM and IgG antibody to Hepatitis B core antigen (HBc) and is used as an aid in the diagnosis of ongoing or previous Hepatitis B viral infection.

**Anti-HCV 3.0 EIA:** This enzyme immunoassay utilizes recombinant antigens to detect antibody to Hepatitis C virus (HCV). Presence of this antibody indicates past or present HCV infection, or possibly a carrier state, but does not substantiate infectivity nor immunity. Supplemental tests, such as Recombinant Immunoblot Assay (RIBA)* may assist in more specific determination of antibody status. Use of HCV nucleic acid assays (HCV-NAT) provides more definite indicators of current viremia and substantiate infectivity.

The anti-HCV EIA 3.0 version test includes NS5, c200 and c22-3 recombinant antigens. The NS antigen is derived from the polymerase region of the HCV genome and allows antibody detection of a greater number of HCV epitopes. Creative Testing Solutions currently uses the Version 3.0 assay for EIA and RIBA*.
Anti-HCV 3.0 ChLIA: This chemiluminescent assay (ChLIA) utilizes recombinant antigens to detect antibody to Hepatitis C virus (HCV). Presence of this antibody indicates that the individual may have been infected with HCV, may harbor infectious HCV and may be capable of transmitting HCV infection. Supplemental tests, such as Recombinant Immunoblot Assay (RIBA)* may assist in more specific determination of antibody status. Use of HCV nucleic acid assays (HCV-NAT) provides more definite indicators of current viremia and substantiate infectivity. The anti-HCV EIA 3.0 version test includes recombinant antigens covering the core, NS3, NS4 and NS5 regions of the HCV genome.

Limitations: It is recognized that presently available methods for hepatitis detection are not sensitive enough to detect all potentially infectious units of blood or all possible cases of hepatitis. Also, biological false positive results may be obtained with any diagnostic test.

* RIBA HCV 3.0 SIA (RIBA is a trademark of the Chiron Corporation, Emeryville, CA). This test is currently not available from the manufacturer. There are no other FDA-approved supplemental tests on the market.
Procleix Ultrio HIV-1/HCV/HBV Assay: This assay utilizes target amplification nucleic acid probe technology for the detection of HIV-1 and HCV RNA and HBV DNA. The screen assay is referred to as “Ultrio testing” which does not discriminate between HIV-1 and HCV RNA and/or HBV DNA. Specimens found to be reactive upon Ultrio testing are then tested in HIV-1, HCV and HBV Discriminatory Assays (dHIV, dHCV, dHBV assays) to determine if they are reactive for HIV, HCV, and/or HBV. It is possible for all three discriminatory tests to be non-reactive. This may indicate a false positive Ultrio screen test. All assays have a chemiluminescent signal produced by a hybridized probe, which is measured by a luminometer and reported as Relative Light Units (RLU).

dHCV Assay: This assay utilizes HCV specific probe reagent directed against specific conserved regions in the viral genome to determine the presence of Hepatitis C Virus by Transcription Mediated Amplification (TMA).

dHBV Assay: This assay utilizes HBV specific probe reagent directed against specific conserved regions in the viral genome to determine the presence of Hepatitis B Virus by TMA.

Roche AmpliScreen HCV Assay: This assay utilizes Polymerase Chain Reaction (PCR) technology for the detection of HCV RNA. This assay detects probe-bound amplified product by colorimetric determination.

Roche Ampliscreen HBV Assay: This assay utilizes PCR technology for the detection of HBV DNA. This assay detects probe-bound amplified product by colorimetric determination.