

## Blood Systems Laboratories

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### INTERPRETATION INFORMATION SHEET

#### Hepatitis Serology

HBsAg ChLIA (Abbot PRISM™): This chemiluminescent assay (ChLIA) detects the presence of Hepatitis B surface antigen (HBsAg).

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 which can be neutralized by the confirmatory test procedure may be designated as positive for HBsAg.

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.

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 antigen 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 to Hepatitis B core antigen (HBc) and is indicated as an aid in prevention 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 indicated 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. However use of HCV nucleic acid assays will provide more definite indicators of current viral load 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. Blood Systems currently uses the Version 3.0 assay for EIA and RIBA\*.

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. 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).

# INTERPRETATION INFORMATION SHEET

## Hepatitis C Virus and Hepatitis B Virus Nucleic Acid Testing (NAT) Polymerase Chain Reaction testing (PCR)

Procleix HIV-1/HCV Assay: This assay utilizes target amplification nucleic acid probe technology for the detection of HIV-1 and HCV RNA. The screen assay is referred to as “multiplex testing” which does not discriminate between HIV-1 and HCV RNA. Specimens found to be reactive upon multiplex testing are then tested in HIV-1 and HCV Discriminatory Assays (dHIV and dHCV assays) to determine if they are reactive for HIV, HCV, both or neither. 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 reagents to determine the presence of Hepatitis C Virus.

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.