

Blood Systems Laboratories

2424 West Erie Drive
Tempe, AZ 85282
CLIA # 03D0911463

2205 Highway 121
Bedford, TX 76021
CLIA # 45D0959393

INTERPRETATION INFORMATION SHEET

INTERPRETATION OF SUPPLEMENTAL ANTI-HCV RESULTS

Anti-HCV RIBA* Strip Immunoblot Assay (SIA) is performed when antibody HCV is demonstrated in the absence of HCV RNA (as indicated by a non-reactive HIV-1/HCV NAT or dHCV test. In the RIBA* test system, recombinant HCV antigens and synthetic HCV encoded peptides are immobilized as individual bands on nitrocellulose strips. Band patterns develop with intensities proportional to the amount of specific antibody bound to each of the recombinant antigens or synthetic peptides on the strips. The HCV recombinant antigens present are: NS5 and c33c. The synthetic peptides present are c100p and 511p combined in one band and c22p. In addition, a recombinant antigen to superoxide dismutase (SOD) is present and serves as a control for nonspecific reactivity.

Current Test Interpretation:

Negative:	No bands of 1+ or greater reactivity to any of the four HCV recombinant antigens or synthetic peptides; or SOD band alone having 1+ or greater reactivity.
Indeterminate:	Any single HCV band having 1+ or greater reactivity; or any HCV band(s) having 1+ or greater reactivity with the SOD band (1+ or greater).
Positive:	At least two HCV Bands having 1+ or greater reactivity and less than 1+ reactivity to the SOD band.

* RIBA HCV 3.0 SIA (RIBA is a trademark of the Chiron Corporation, Emeryville, CA).

All hepatitis C (HCV) tests performed work together to indicate the likely medical status of the donor; the most likely scenarios are described in the table below.

Anti-HCV EIA	HIV-1/HCV NAT (Mx)	dHCV NAT	HCV RIBA 3.0	Most Likely Interpretation
Reactive	Reactive	Reactive	Not performed	<ul style="list-style-type: none"> ▪ Active HCV infection (viremic) ▪ Risk of spreading to others through blood or plasma and possible sexual activity ▪ Requires further medical evaluation and possibly treatment
Reactive	Non-reactive	Not performed	Positive*	<p>dHCV Positive:</p> <ul style="list-style-type: none"> ▪ Low-level active HCV infection ▪ Low risk of spreading to others through blood or plasma and possibly sexual activity ▪ Requires further medical evaluation to confirm viremia and consider treatment <p>dHCV Negative:</p> <ul style="list-style-type: none"> ▪ Past (resolved) HCV infection rendered inactive as a result of natural immune response to infection (or treatment if autologous donor) ▪ Very low-level active HCV infection with virus levels undetectable by NAT, or ▪ In a few cases, may be a false-positive EIA and RIBA results, meaning it is not a true infection ▪ Low or no risk of spreading HCV to others ▪ Requires further medical evaluation to confirm absence of viremia
Reactive	Non-reactive	Not performed	Indeterminate	<ul style="list-style-type: none"> ▪ In the absence of risk behavior, likely a false-positive reaction ▪ Consider further medical evaluation if HCV risk behavior
Reactive	Non-reactive	Not performed	Negative	<ul style="list-style-type: none"> ▪ No hepatitis C infection in low risk individuals ▪ False-positive reaction
Non-reactive	Reactive	Reactive	Not performed	<ul style="list-style-type: none"> ▪ HCV NAT Yield

* dHCV is performed to determine if viremia exists