

**Universal Data Collection  
DHBD Surveillance Laboratory  
Test Methods**

**Hepatitis B Tests**

	Instrument	Method	Units	Interpretation	Interference	
aHBc	Ortho Vitros ECi	<ol style="list-style-type: none"> <li>1. Reaction of sample with HBc recombinant Ag-coated wells</li> <li>2. Detection with HRP-labeled mouse monoclonal anti-HBc by luminescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$>1.10$ $\geq 0.90$ and $\leq 1.10$ $<0.90$ <u>Retests:</u> $2/3 >1.00$ $2/3 \leq 1.00$	Negative Retest in duplicate Positive  Negative Reactive	Heterophilic abs to animal proteins
aHBs	Ortho Vitros ECi	<ol style="list-style-type: none"> <li>1. Reaction of sample with human HBsAg-coated wells</li> <li>2. Detection with HRP-labeled human HBsAg (ad and ay subtypes) by luminescence</li> </ol>	0-1000 IU/mL Traceable to WHO First IRP for Ab to HBsAg (1977)	$<5.00$ $\geq 5.00$	Negative Positive	Transfusion w/in 3-6 mos. Immunosuppression IgM anti-rubella virus Turbidity Plasma
HBsAg	Ortho Vitros ECi	<ol style="list-style-type: none"> <li>1. Reaction of samples with mouse monoclonal anti-HBs (a-region)-coated wells</li> <li>2. Detection with HRP-labeled mouse monoclonal anti-HBs by luminescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$<0.90$ $\geq 0.90$ and $\leq 5.00$ $>5.00$ <u>Retests:</u> $2/3 <1.00$ $2/3 \geq 1.00$ and $\leq 5.00$ $2/3 >5.00$	Negative Retest in duplicate Positive  Negative Indeterminate Positive	Lower s/c values in citrate Turbidity Heterophilic abs to animal proteins Recently vaccinated Mutant strains
HBcM (Anti-HBc IgM)	Ortho Vitros ECi	<ol style="list-style-type: none"> <li>1. Reaction of sample with biotinylated mouse monoclonal anti-human IgM</li> <li>2. Capture of immune complex on streptavidin-coated wells</li> <li>3. Reaction with recombinant HBc Ag complexed with HRP-labeled mouse monoclonal anti-HBc IgM</li> <li>4. Detection by luminescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$<0.90$ $\geq 0.90$ and $\leq 1.10$ $>1.10$ <u>Retests:</u> $2/3 <1.00$ $2/3 \geq 1.00$	Negative Retest in duplicate Positive  Negative Positive	Lower s/c values in citrate Turbidity Neonate Heterophilic abs to animal proteins

## Hepatitis C Tests

Test	Instrument	Method	Units	Interpretation	Interference	
AHCV	Abbott AxSYM	<ol style="list-style-type: none"> <li>1. Reaction of sample with microparticles coated with recombinant HCV antigen (HCr43, c200, c100-3)</li> <li>2. Capture of microparticles by matrix</li> <li>3. Detection with alkaline-phosphatase-labeled goat polyclonal anti-IgG by fluorescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$<0.80$ $\geq 0.80$ and $\leq 1.20$ $>1.20$ <u>Retests:</u> $2/3 <0.80$ $2/3 \geq 0.80$ and $\leq 1.20$ $2/3 >1.20$	Negative Retest in duplicate Positive  Negative Indeterminate Positive	
HCV RNA	Prism 7000	<ol style="list-style-type: none"> <li>1. RNA extracted on m1000</li> <li>2. RT-PCR on Prism to quantitate RNA</li> </ol>	IU/mL	$<50$ $\geq 50$	Negative Positive	
RIBA	Send out	<p>Strip immunoblot assay for bands 5-1-1 (p)/c100 (p), c33c, c22p, and NS5 with hSOD as control</p> <p>Performed by Quest Diagnostics</p>		No reactive bands or hSOD band only  Reactivity to single band or any band and hSOD  Reactivity to at least two bands encoded by different parts of the HCV genome	Negative  Indeterminate  Positive	

## Hepatitis A Tests

Test	Instrument	Method	Units	Interpretation	Interference	
aHAV	Abbott AxSYM	<ol style="list-style-type: none"> <li>1. Reaction of sample with microparticles coated with HAV (human)</li> <li>2. Competitive binding with anti-HAV-alkaline phosphatase complex</li> <li>3. Measurement of fluorescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$\leq 1.00$ $>1.00$ and $\leq 1.20$ $>1.20$ <u>Retests:</u> $2/3 \leq 1.00$ $2/3 >1.20$ $2/3 >1.00$ and $\leq 1.20$	Positive Retest in duplicate Negative  Positive Negative Indeterminate	Immunosuppression, rheumatoid factor
aHAV IgM	Abbott AxSYM	<ol style="list-style-type: none"> <li>1. Sample reacted with microparticles coated with anti-human IgM</li> <li>2. Reaction with HAV (human)</li> <li>3. Detection with conjugated mouse monoclonal anti-HAV</li> <li>4. Measurement of fluorescence</li> </ol>	Signal/cutoff ratio (s/c) using stored cutoff	$<0.80$ $\geq 0.80$ and $\leq 1.20$ $>1.20$ <u>Retests:</u> $2/3 <0.80$ $2/3 >1.20$ $2/3 \geq 0.80$ and $\leq 1.20$	Negative Retest in duplicate Positive  Negative Positive Indeterminate	Immunosuppression, HBVc IgM, elevated IgG, human anti-mouse antibodies