# Universal Data Collection
## DHBD Surveillance Laboratory
### Test Methods
#### Hepatitis B Tests

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Method</th>
<th>Units</th>
<th>Interpretation</th>
<th>Interference</th>
</tr>
</thead>
</table>
| aHBc       | 1. Reaction of sample with HBc recombinant Ag-coated wells 2. Detection with HRP-labeled mouse monoclonal anti-HBc by luminescence | Signal/cutoff ratio (s/c) using stored cutoff | >1.10  
≥0.90 and ≤1.10  
<0.90  
Retests:  
2/3 > 1.00  
2/3 ≤ 1.00 | Negative  
Retest in duplicate  
Positive | Heterophilic abs to animal proteins |
| aHBs       | 1. Reaction of sample with human HBsAg-coated wells 2. Detection with HRP-labeled human HBsAg (ad and ay subtypes) by luminescence | 0-1000 IU/mL  
Traceable to WHO First IRP for Ab to HBsAg (1977) | ≤0.90  
<5.00  
≥5.00 | Negative  
Positive | Transfusion w/in 3-6 mos.  
Immunosuppression  
IgM anti-rubella virus  
Turbidity  
Plasma |
| HBsAg      | 1. Reaction of samples with mouse monoclonal anti-HBs (a-region)-coated wells 2. Detection with HRP-labeled mouse monoclonal anti-HBs by luminescence | Signal/cutoff ratio (s/c) using stored cutoff | <0.90  
≥0.90 and ≤5.00  
>5.00  
Retests:  
2/3 < 1.00  
2/3 ≥ 1.00 and ≤5.00  
2/3 > 5.00 | Negative  
Retest in duplicate  
Positive  
Indeterminate  
Positive | Lower s/c values in citrate  
Turbidity  
Heterophilic abs to animal proteins  
Recently vaccinated  
Mutant strains |
| HBCM (Anti-HBc IgM) | 1. Reaction of sample with biotinylated mouse monoclonal anti-human IgM 2. Capture of immune complex on streptavidin-coated wells 3. Reaction with recombinant HBC Ag complexed with HRP-labeled mouse monoclonal anti-HBc IgM 4. Detection by luminescence | Signal/cutoff ratio (s/c) using stored cutoff | <0.90  
≥0.90 and ≤1.10  
>1.10  
Retests:  
2/3 < 1.00  
2/3 ≥ 1.00 | Negative  
Retest in duplicate  
Positive  
Negative  
Positive | Lower s/c values in citrate  
Turbidity  
Neonate  
Heterophilic abs to animal proteins |

October 12, 2005
## Hepatitis C Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Instrument</th>
<th>Method</th>
<th>Units</th>
<th>Interpretation</th>
<th>Interference</th>
</tr>
</thead>
</table>
| AHCV  | Abbott AxSYM | 1. Reaction of sample with microparticles coated with recombinant HCV antigen (HCr43, c200, c100-3)  
2. Capture of microparticles by matrix  
3. Detection with alkaline-phosphatase-labeled goat polyclonal anti-IgG by fluorescence | Signal/cutoff ratio (s/c) using stored cutoff | ≤0.80  
≥0.80 and ≤1.20  
>1.20  
Retests:  
2/3 <0.80  
2/3 ≥0.80 and ≤1.20  
2/3 >1.20 | Negative  
Retest in duplicate  
Positive  
Negative  
Indeterminate  
Positive | | | |
| HCV RNA | Prism 7000 | 1. RNA extracted on m1000  
2. RT-PCR on Prism to quantitate RNA | IU/mL  | <50  
≥50 | Negative  
Positive | | | |
| RIBA | Send out | Strip immunoblot assay for bands 5-1-1 (p)/c100 (p), c33c, c22p, and NS5 with hSOD as control  
Performed by Quest Diagnostics | | | | | | |

## Hepatitis A Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Instrument</th>
<th>Method</th>
<th>Units</th>
<th>Interpretation</th>
<th>Interference</th>
</tr>
</thead>
</table>
| aHAV | Abbott AxSYM | 1. Reaction of sample with microparticles coated with HAV (human)  
2. Competitive binding with anti-HAV-alkaline phosphatase complex  
3. Measurement of fluorescence | Signal/cutoff ratio (s/c) using stored cutoff | ≤1.00  
>1.00 and ≤1.20  
>1.20  
Retests:  
2/3 ≤1.00  
2/3 >1.20  
2/3 >1.00 and ≤1.20 | Positive  
Retest in duplicate  
Negative  
Positive  
Negative  
Indeterminate | | | |
| aHAV IgM | Abbott AxSYM | 1. Sample reacted with microparticles coated with anti-human IgM  
2. Reaction with HAV (human)  
3. Detection with conjugated mouse monoclonal anti-HAV  
4. Measurement of fluorescence | Signal/cutoff ratio (s/c) using stored cutoff | ≤0.80  
≥0.80 and ≤1.20  
>1.20  
Retests:  
2/3 <0.80  
2/3 >1.20  
2/3 ≥0.80 and ≤1.20 | Negative  
Retest in duplicate  
Positive  
Negative  
Positive  
Indeterminate | | | |

Interferences for Hepatitis C tests: Immunosuppression, rheumatoid factor
Interferences for Hepatitis A tests: Immunosuppression, HBVc IgM, elevated IgG, human anti-mouse antibodies