Viral Hepatitis results and interpretation

1. **IgM anti-HBc**

The cutoff RLU is stored for each reagent lot calibration.

S/CO = Sample RLU/Cutoff RLU

## Interpretation of Results

| S/CO | Instrument Interpretation | Interpretation |
| --- | --- | --- |
| < 0.80 | Nonreactive | IgM anti-HBc not detected. Does not exclude the possibility of exposure to or infection with HBV. No retest required. |
| 0.80 to < 1.21 | Grayzone | Antibodies to IgM anti-HBc may or may not be present. Patients with specimens exhibiting grayzone test results should be retested at approximately 1 week intervals.\* |
| ≥ 1.21 | Reactive | Presumptive evidence of IgM anti-HBc. No retest required. |

\*Monitoring the level of IgM anti-HBc by retesting at approximately one week intervals will distinguish rapidly rising IgM anti-HBc levels associated with early acute hepatitis B infection from gradually decreasing or unchanging IgM anti-HBc levels often associated with late acute stage of HBV infection, 6 to 9 months from the appearance of HBsAg.

| n | HBV Reference Markers | | | | HBV Classification |
| --- | --- | --- | --- | --- | --- |
| HBsAg | IgM Anti-HBc | Total Anti-HBc | Anti-HBs |
| 8 | + | - | - | - | Early Acute |
| 17 | + | + | + | - | Acute |
| 1 | + | + | + | I | Chronic |
| 2 | + | - | + | + | Chronic |
| 51 | + | - | + | - | Chronic |
| 3 | + | - | - | + | Chronic |
| 7 | - | + | + | + | Recovering Acute |
| 2 | - | + | + | - | Recovering Acute/Undetectable HBsAg |
| 220 | - | - | + | + | Immune Due to Natural Infection |
| 34 | - | - | + | I | Distantly Immune/Anti-HBs Unknown |
| 107 | - | - | + | - | Distantly Immune/Anti-HBs Not Detected |
| 351 | - | - | - | + | Immune Due to HBV Vaccination |
| 897 | - | - | - | - | Susceptible |
| 1 | + | + | + | + | Late Acute/Recovering |
| 3 | + | - | + | I | Chronic |
| 3 | - | + | + | I | Early Recovery |
| 45 | - | - | - | I | Unknown |
| **1752** |  | | | | **Total** |

| n | HBV Reference Markers | | | | HBV Classification |
| --- | --- | --- | --- | --- | --- |
| HBsAg | IgM Anti-HBc | Total Anti-HBc | Anti-HBs |
| 1 | + | - | - | - | Early Acute |
| 3 | + | - | + | + | Chronic |
| 107 | + | - | + | - | Chronic |
| 1 | + | - | - | + | Chronic |
| 67 | - | - | + | + | Immune Due to Natural Infection |
| 5 | - | - | + | I | Distantly Immune/Anti-HBs Unknown |
| 12 | - | - | + | - | Distantly Immune/Anti-HBs Not Detected |
| 41 | - | - | - | + | Immune Due to HBV Vaccination |
| 37 | - | - | - | - | Susceptible |
| 3 | + | - | + | I | Chronic |
| **277** |  | | | | **Total** |

1. **Anti-HBc**

## Interpretation of Results

| S/CO | Instrument Interpretation | Retest Procedure |
| --- | --- | --- |
| < 0.80 | Nonreactive | No retest required. |
| 0.80 to <1.21 | Grayzone | Retest in duplicate. |
| ≥ 1.21 | Reactive | Retest in duplicate. |

Final Interpretation

| Initial Interpretation | Results with Retest | Final Interpretation |
| --- | --- | --- |
| Nonreactive | No retest required. | Nonreactive |
| Grayzone | If two of the three results are < 1.00 S/CO | Nonreactive |
| If two of the three results are ≥ 1.00 S/CO | Reactive |
| Reactive | If both retest results are < 1.00 S/CO | Nonreactive |
| If two of the three results are ≥ 1.00 S/CO | Reactive |

I = Indeterminate

Following testing with the comparator anti-HBc assay and the three reference HBV assays, Population 2 specimens were assigned an HBV classification using the reactive (+) and nonreactive (-) patterns. There were 10 unique reference marker patterns observed in the ARCHITECT CORE clinical study for Population 2.

| n | HBV Reference Markers | | | | HBV Classification |
| --- | --- | --- | --- | --- | --- |
| HBsAg | IgM Anti-HBc | Total Anti-HBc | Anti-HBs |
| 14 | + | - | - | - | Early Acute |
| 11 | + | + | + | - | Acute |
| 4 | + | - | + | + | Chronic |
| 73 | + | - | + | - | Chronic |
| 2 | + | - | - | + | Chronic |
| 6 | - | + | + | + | Recovering Acute |
| 4 | - | + | + | - | Recovering Acute/ Undetectable HBsAg |
| 219 | - | - | + | + | Immune Due to Natural Infection |
| 37 | - | - | + | I | Distantly Immune/Anti-HBs Unknown |
| 107 | - | - | + | - | Distantly Immune/Anti-HBs Not Detected |
| 341 | - | - | - | + | Immune Due to HBV Vaccination |
| 1004 | - | - | - | - | Susceptible |
| 4 | + | - | + | I | Chronic |
| 1 | - | + | + | I | Early Recovery |
| 52 | - | - | - | I | Unknown |
| **1879** |  | | | | **Total** |

| n | HBV Reference Markers | | | | HBV Classification |
| --- | --- | --- | --- | --- | --- |
| HBsAg | IgM Anti-HBc | Total Anti-HBc | Anti-HBs |
| 1 | + | - | - | - | Early Acute |
| 2 | + | - | + | + | Chronic |
| 65 | + | - | + | - | Chronic |
| 1 | + | - | - | + | Chronic |
| 61 | - | - | + | + | Immune Due to Natural Infection |
| 5 | - | - | + | I | Distantly Immune/Anti-HBs Unknown |
| 16 | - | - | + | - | Distantly Immune/Anti-HBs Not Detected |
| 40 | - | - | - | + | Immune Due to HBV Vaccination |
| 31 | - | - | - | - | Susceptible |
| 2 | + | - | + | I | Chronic |
| **224** |  | | | | **Total** |

1. **Anti-HBs**

## Interpretation of Results

Initial Results

| Anti-HBs mIU/mL (IU/L) | Instrument Interpretation | Retest Procedure |
| --- | --- | --- |
| < 8.00 | Nonreactive | No retest required. |
| ≥ 8.00 to < 12.00 | Grayzone | Retest in duplicate. |
| ≥ 12.00 | Reactive | No retest required. |

Anti-HBs Results

| Initial Result  **mIU/mL (IU/L)** | **Retest Result**  **mIU/mL (IU/L)** | **Result** | **Final Interpretation** |
| --- | --- | --- | --- |
| < 8.00 | No retest required. | Nonreactive | Individual is considered not immune to HBV infection. |
| ≥ 8.00 to < 12.00 | Both of the duplicate retest results are < 8.00. | Nonreactive | Individual is considered not immune to HBV infection. |
| One or both of the duplicate retest results are ≥ 8.00 to < 12.00. | Grayzone | The immune status of the individual should be further assessed by considering other factors, such as clinical status, follow-up testing, associated risk factors, and the use of additional diagnostic information. |
| Both of the duplicate retest results are ≥ 12.00. | Reactive | Individual is considered immune to HBV infection. |
| ≥ 12.00 | No retest required. | Reactive | Individual is considered immune to HBV infection. |

HBV Reference Markers

| HBsAga | Anti-HBc IgMa | Total Anti-HBca | Anti-HBsa |  |
| --- | --- | --- | --- | --- |
| + | - | - | - | Early Acute |
| + | + | + | - | Acute |
| + | + | + | I | Chronic |
| + | - | + | + | Chronic |
| + | - | + | - | Chronic |
| + | - | - | + | Chronic |
| + | - | + | I | Chronic |
| - | + | + | + | Recovering Acute |
| - | + | - | + | Recovering Acute |
| - | + | + | - | Recovering Acute/Undetectable HBsAg |
| - | + | + | I | Early Recovery |
| + | + | + | + | Late Acute/Recovering |
| - | + | - | - | Possible Recovering Acute/Undetectable HBsAg |
| - | - | + | + | Immune Due to Natural Infection |
| - | - | + | I | Distantly Immune/Anti-HBs Unknown |
| - | - | + | - | Distantly Immune/Anti-HBs Not Detected |
| - | - | - | + | Immune Due to HBV Vaccination |
| - | - | - | I | Unknown |
| - | - | - | - | Susceptible |

a + = reactive, - = nonreactive, I = Indeterminate

1. **Anti-HCV**

## Interpretation of Results

The cutoff is 1.00 S/CO.

Initial Alinity i Anti-HCV Results

| S/CO | Instrument Interpretation | Retest Procedure |
| --- | --- | --- |
| 0.00 to 0.79 | Nonreactive | No retest required. |
| 0.80 to 0.99 | Grayzone | Retest in duplicate. |
| ≥ 1.00 | Reactive | No retest required. |

Alinity i Anti-HCV Results

| Initial Result | Retest Result | Result | Interpretation |
| --- | --- | --- | --- |
| Nonreactive | No retest required. | Nonreactive | Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV. |
| Grayzone | Both of the duplicate retests are reactive. | Reactive | Presumptive evidence of antibodies to HCV; follow CDC recommendations[*25*](#ABB-T-anm1459903294838) for supplemental testing. |
| One or both of the duplicate retests are repeatedly in the grayzone or one retest is reactive and the other nonreactive. | Equivocal | Antibodies to HCV may or may not be present; another specimen should be obtained from the individual for further testing or follow CDC recommendations[*25*](#ABB-T-anm1459903294838) for supplemental testing. |
| Both of the duplicate retests are nonreactive. | Nonreactive | Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV. |
| Reactive | No retest required. | Reactive | Presumptive evidence of antibodies to HCV; follow CDC recommendations[*25*](#ABB-T-anm1459903294838) for supplemental testing. |

1. **HAVAb IgM**

## Interpretation of Results

| Result (S/CO) | Instrument Interpretation | Interpretation |
| --- | --- | --- |
| < 0.80 | Nonreactive  (NR) | IgM anti-HAV not detected. Does not exclude the possibility of exposure to or infection with HAV. Levels of IgM anti-HAV may be below the cutoff in early infection. |
| 0.80 to < 1.21 | Grayzone  (GZ) | IgM antibodies to HAV may or may not be present. Patients exhibiting grayzone test results should be closely monitored by redrawing and retesting at approximately one week intervals.a |
| ≥ 1.21 | Reactive  (R) | IgM anti-HAV detected. Presumptive evidence of HAV infection. A reactive IgM anti-HAV result does not rule out other hepatitis infections. |

1. **HBsAg Qualitative**

## Interpretation of Results

The cutoff is 1.00 S/CO.

Initial Results

| S/CO | Instrument Interpretation | Retest Procedure |
| --- | --- | --- |
| < 1.00 | Nonreactive | No retest required. |
| ≥ 1.00 | Reactive | Retest in duplicate |

A specimen with an S/CO of less than 1.00 is nonreactive; the specimen is considered negative for HBsAg.

Initially reactive specimens require retesting. Specimens that contain particulate matter should be recentrifuged according to directions in the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section in this package insert.

Retest Results

| Instrument Interpretation | Specimen Classification |
| --- | --- |
| Both results nonreactive | Specimen considered negative for HBsAg. |
| One or both results reactive | Specimen considered repeatedly reactive for HBsAg; confirm using the Alinity i HBsAg Qualitative II Confirmatory assay. |

Confirm repeatedly reactive specimens using the Alinity i HBsAg Qualitative II Confirmatory assay before disclosing HBsAg status to the patient.

| Number of Specimens | HBV Reference Markers | | | | HBV Classification |
| --- | --- | --- | --- | --- | --- |
| HBsAga | Anti-HBc IgM | Total Anti-HBc | Anti-HBs |
| 20 | + | - | - | - | Acute |
| 2 | + | I | + | - | Acute |
| 26 | + | + | + | - | Acute |
| 154 | + | - | + | - | Chronic |
| 6 | + | - | + | + | Chronic |
| 2 | + | - | - | + | Chronic |
| 5 | + | + | + | + | Late Acute, Recovering |
| 9 | - | + | + | + | Recovering Acute |
| 3 | - | + | + | - | Recovering Acute, Undetectable HBsAg |
| 118 | - | - | + | - | Distantly Immune, Anti-HBs Not Detected |
| 225 | - | - | + | + | Immune Due to Natural Infection |
| 414 | - | - | - | + | Immune Due to HBV Vaccination |
| 1096 | - | - | - | - | Susceptible |
| **2080** |  | | | | **Total** |

+ = Positive/Reactive, – = Negative/Nonreactive, I = Indeterminate

a For HBsAg: + = Repeatedly reactive and confirmed by neutralization when required; – = Reference HBsAg test negative or not confirmed by neutralization.

1. **HIV Ag/Ab Combo**

## Interpretation of Results

The cutoff is 1.00 S/CO.

Initial Results

| S/CO | Instrument Interpretation | Retest Procedure |
| --- | --- | --- |
| < 1.00 | Nonreactive | No retest required. |
| ≥ 1.00 | Reactive | Retest in duplicate. |

Final Interpretation

| Initial Interpretation | Results with Retest | Final Interpretation |
| --- | --- | --- |
| Nonreactive | No retest required. | Nonreactive. HIV-1 p24 Ag and HIV-1/HIV-2 Ab not detected |
| Reactive | If both retest results are  < 1.00 | Nonreactive. HIV-1 p24 Ag and HIV-1/HIV-2 Ab not detected |
| If one or both retest results are ≥ 1.00 | Reactive. Presumptive evidence of HIV-1 p24 Ag and/or HIV-1/HIV-2 Ab; perform supplemental confirmatory assay(s) |

A specimen with a final result of reactive should be investigated further with supplemental confirmatory HIV-specific tests, such as immunoblots, antigen tests, and HIV nucleic acid tests.

1. **Syphilis**

## Interpretation of Results

The cutoff is 1.00 S/CO.

| Result (S/CO) | Instrument Result | Interpretation |
| --- | --- | --- |
| < 1.00 | Nonreactive | Nonreactive for treponemal antibodies |
| ≥ 1.00 | Reactive | Reactive for treponemal antibodies |

Test results are intended to aid in diagnosis only. As with all serological tests for syphilis, results should always be interpreted in conjunction with additional treponemal or nontreponemal serologic test results (as appropriate), the patient’s clinical symptoms, medical history, and other clinical and/or laboratory findings to produce a diagnosis of syphilis by disease stage.

Diagnostic considerations should be based on treponemal and nontreponemal testing as described in the Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines, 2015.[*3*](#ABB-T-ajc1467299764385)