

| Louisiana Office of Public Health Laboratories |   |
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| Test Name                                      | Hepatitis B Surface Antigen Confirmatory  |
| PHL Location                                   | Office of Public Health Laboratory Baton Rouge  |
| CPT Code                                       | 87341   |
| Synonyms                                       | HBsAg Confirmatory  |
| Brief Description of Test                      | The Genetic Systems (GS) HBSAg Confirmatory Assay 3.0 is a qualitative assay intended for the confirmation of HBsAg reactive specimens detected in the GS HBsAg EIA 3.0.  |
| Possible Results                               | Negative<br>Positive<br>Not confirmed   |
| Reference Range                                | Negative  |
| Specimen Type                                  | Serum   |
| Specimen Container(s):                         | Red top tubes, Marble top tubes, polypropylene vials  |
| Minimum volume accepted:                       | 760 µL  |
| Collection Instructions                        | <p>Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines.</p> <p>Follow the package insert for the collection tube you use.</p> <p>Label specimen with Patient Name and a 2<sup>nd</sup> unique identifier such as a chart number or medical record number. DOB is not considered unique.</p> <p>Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2<sup>nd</sup> patient identifier, gender, date of birth, date of</p> |

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|                                    | <p>collection, time of collection, test requested, and submitter's name, address, and contact number.</p> <p>Two unique identifiers <b>MUST</b> be recorded on the tube <b>AND</b> the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place.</p> <p>Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.</p> |
| Storage and Transport Instructions | <p>Specimens can be shipped refrigerated (2-8°C) and can be stored for up to 7 days.</p> <p>For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.</p>  |
| Causes for Rejection               | <p>Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.</p>   |
| Limitations of the Procedure       | <p>The package insert must be strictly adhered to when testing serum for the presence of HBsAg.</p> <p>False negative results can occur if the quantity of marker present in the sample is too low for the detection limits of the assay, or if the marker which is detected is not present during the stage of disease in which a sample is collected.</p> <p>Failure to add specimen or reagent as instructed in the procedure could result in a falsely negative test.</p>  |
| Interfering Substances             | <p>No clinically significant effect has been detected in assay results with increased levels of protein, lipids, bilirubin, or hemolysis, or after heat inactivation of patient samples.</p>   |
| References                         | <p>BioRad Genetic Systems HBsAG EIA 3.0 package insert.<br/>EVOLIS™ Operator Manual</p>  |
| Additional Information             | <p>Negative – Specimen Confirmed Negative for Hepatitis B Surface Antigen</p> <p>Positive – Specimen Confirmed Positive for Hepatitis B Surface Antigen</p> <p>Not Confirmed – The Presence or Absence of Hepatitis B Surface Antigen was Not Confirmable</p>  |
| Release Date                       | <p>03/15/2016</p>  |

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