



# Technical Bulletin

## *Next Generation Hepatitis B Surface Antigen Assay*

**TO:** Medical Staff and Clients

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**DATE:** April 11, 2019

**SUBJECT:** The next generation Hepatitis B surface antigen assay captures previously undetectable mutants

Effective immediately, April 11, 2019, DLS is pleased to announce the implementation of an improved HBsAg immunoassay.

The HBsAg is one of several markers used in combination to assess a patient's hepatitis B status. Detection of HBsAg in human serum or plasma normally indicates an active infection. HBsAg is the first immunological marker to appear in acute hepatitis B infection and is generally present some days or weeks before clinical symptoms begin to appear. Under selective pressure such as immune response and/or antiviral therapy, HBV may mutate, potentially leading to escape from a host's protection after vaccination and becoming undetectable by some commercially available assays. The Elecsys® HBsAg II assay was specifically designed to detect a multitude of such mutants.

This immunoassay is for the in vitro qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2-21 years of age) serum and plasma.

In conjunction with other serological and clinical information, this assay is intended to be used to evaluate individuals at risk for infection with hepatitis B virus (HBV) or who have signs and symptoms of hepatitis. In addition, the assay may be used to screen for hepatitis B infection in pregnant women to identify neonates at high risk of acquiring HBV during the perinatal period.

There are no changes to the order code.

### ***Test Information:***

<b><i>Test</i></b>	<b><i>Tube Type</i></b>	<b><i>Unit Code</i></b>	<b><i>Test Run</i></b>
HBsAg	<i>Preferred:</i> Serum Separator Tube (serum) <i>Acceptable:</i> Sodium heparin, lithium heparin, K2-EDTA, and sodium citrate	495	6 day/week Mon-Sat

Please refer any questions to Susan Krause, at 589-5126, Dr. Wes Kim at 589-5131, Dr. Chris Whelen at 589-5242, or DLS Client Services at 589-5101.