HBsAg

Hepatitis B surface antigen

cobas®

Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
Follow the applicable government regulations and local guidelines for quality control.

Calculation

The analyzer automatically calculates the cutoff based on the measurement of Cal1 and Cal2.
The cutoff for the Elecsys HBsAg immunoassay was established by testing a 175 member panel of well characterized HBsAg specimens with three kit lots, followed by testing on two kit lots with over 2800 specimens including subjects at various risk for HBV infection, sensitivity, specificity and seroconversion panels and dilution series of both international reference materials and HBsAg positive samples. Using these data, the cutoff value that allowed for optimal discrimination between negative and positive specimens was determined.

Cutoff Formula:
Cutoff value = 1.2 x (signal $_{Cal1}$ - background*) + 0.05 x (signal $_{Cal2}$ - background*)

The sample results are reported as reactive or non-reactive, and in the form of a cutoff-index (signal of sample - background*/cutoff).

*background = 0.7 x signal $_{Cal\ 1}$

Interpretation of the results

Samples with a cutoff index < 1.0 are non-reactive in the Elecsys HBsAg test. These samples are considered negative for HBsAg and do not need further testing.
Samples with a cutoff index ≥ 1.0 are reactive in the Elecsys HBsAg test. All samples found to be reactive in the initial test must be retested in duplicate with the Elecsys HBsAg assay.
If the results in the follow-up test are "non-reactive" in both cases, then the sample is deemed negative for HBsAg.
If at least one of the repeat measurements is reactive, then the sample is deemed repeatedly reactive. Repeatedly reactive samples must be investigated using an independent neutralization test (Elecsys HBsAg Confirmatory Test). Samples confirmed by neutralization with human anti-HBs are regarded as positive for HBsAg.

- Results obtained with the Elecsys HBsAg assay may not be used interchangeably with values obtained with different manufacturers' assay methods.
- The magnitude of an Elecsys HBsAg assay result cannot be correlated to an endpoint titer.
- Heparin and citrate have been shown to lower the signal/cutoff (s/c) values in some HBsAg reactive samples. High negative results (0.80 - 0.99 s/c) obtained on samples collected with these anticoagulants should be interpreted accordingly. Supplemental tests may be required.

Limitations - Interference

The assay is unaffected by icterus (bilirubin < 30 mg/dL), hemolysis (Hb < 1.4 g/dL), lipemia (triglycerides < 1500 mg/dL) and biotin < 40 ng/mL (criterion: recovery within ± 10 % of initial value).
In patients receiving therapy with high biotin doses (i.e. > 5 mg/day) no sample should be taken until at least 8 hours after the last biotin administration.
No false negative findings due to the high-dose hook effect are observed up to a HBsAg concentration of 1.5 million IU/mL as established with spiked samples.
As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes. In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies (such as HAMA), streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. It is recognized that presently available methods for the detection of hepatitis B surface antigen may not detect all potentially infected individuals. A nonreactive test result does not exclude the possibility of exposure to or infection with hepatitis B. Nonreactive test results in individuals with prior exposure to hepatitis B may be due to antigen levels below the detection limit of this assay or lack of antigen reactivity to the antibodies used in this assay.
Individuals recently vaccinated for hepatitis B may give a transient positive result for HBsAg because of its presence in the vaccine.[7]
Assay performance characteristics have not been established for any other specimen matrices than serum, plasma treated with sodium heparin, K_3-EDTA or sodium citrate.
The ability of the Elecsys HBsAg assay to detect HBV mutants has not been determined. Testing using alternative methodologies may be warranted if signs, symptoms, and risk factors are indicative of viral hepatitis and other laboratory tests are nonreactive for the diagnosis of viral hepatitis.

Expected values

Of 1445 prospective subjects participating in the Elecsys HBsAg clinical study on the Elecsys 2010 analyzer, 41.5 % (n = 600) were first time blood donors, asymptomatic for viral hepatitis. All of these subjects were enrolled in Sacramento, CA. The group was Caucasian (61 %), African American (10 %), Hispanic (2 %), Asian (1 %) with 26 % electing not to provide this information. The group was 58 % male and 42 % female ranging in age from 17 to 73 years. There were no confirmed positive results for HBsAg by either the reference or the Elecsys test system among these subjects. The table below summarizes the Elecsys HBsAg negative and confirmed positive results by age range and gender.

		Elecsys HBsAg immunoassay				
Age	Gender	Pos	Percent	Neg	Percent	Total
< 10	Male	0	NA	0	NA	0
	Female	0	NA	0	NA	0
10 - 19	Male	0	NA	177	100	177
	Female	0	NA	115	100	115
20 - 29	Male	0	NA	71	100	71
	Female	0	NA	42	100	42
30 - 39	Male	0	NA	45	100	45
	Female	0	NA	46	100	46
40 - 49	Male	0	NA	35	100	35
	Female	0	NA	32	100	32
50 - 59	Male	0	NA	16	100	16
	Female	0	NA	13	100	13
60 - 69	Male	0	NA	2	100	2
	Female	0	NA	4	100	4
70 - 79	Male	0	NA	1	100	1
	Female	0	NA	1	100	1
80 - 89	Male	0	NA	0	NA	0
	Female	0	NA	0	NA	0
90 - 99	Male	0	NA	0	NA	0
	Female	0	NA	0	NA	0
Unknown	Male	0	NA	0	NA	0
	Female	0	NA	0	NA	0
Totals	Male	0	NA	347	100	347
	Female	0	NA	253	100	253
	All	0	NA	600	100	600

The 845 remaining subjects were enrolled from populations considered at risk for viral hepatitis due to lifestyle or behavior. Of these, 448 were outpatients of a health screening clinic, 299 were hospitalized patients and 98 were IV drug users. All 98 IV drug users were enrolled in Baltimore, MD. Of the hospitalized and health screening clinic patients, 444 of the subjects were enrolled in Memphis, TN and 303 in Miami, FL. This collective group was African American (26 %), Caucasian (19 %), Hispanic (5 %), Asian (< 1 %) or other (< 1 %) with 49 % electing not to provide this information. The group was 49 % male and 51 % female ranging in age from 8 to 94 years. Six (6) of these subjects were confirmed positive by both the reference and the Elecsys assay. A follow-up specimen taken 28 days later from the same subject was confirmed positive by both assays showing that the first Elecsys result was correct. The table below summarizes the Elecsys HBsAg negative and confirmed positive results by age range and gender.