

INSTRUCTIONS FOR USE

aHBe

VITROS Immunodiagnostic Products
Anti-HBe Reagent Pack

REF 680 1816

VITROS Immunodiagnostic Products
Anti-HBe Calibrator

REF 680 1817

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Intended Use

VITROS Immunodiagnostic Products Anti-HBe Reagent Pack

For the *in vitro* qualitative detection of antibodies to hepatitis B e antigen (anti-HBe) in human adult and pediatric (2 to 21 years old) serum from individuals who have symptoms of chronic hepatitis and those who have recovered from HBV infection, using the VITROS ECi/ECiQ Immunodiagnostic Systems. Further assessment of HBV infection (biochemical, serological and/or nucleic acid testing) is required to define the specific disease state. VITROS Anti-HBe test performance has not been established for the monitoring of HBV disease or therapy.

VITROS Immunodiagnostic Products Anti-HBe Calibrator

For use in the calibration of the VITROS ECi/ECiQ Immunodiagnostic Systems when used with the VITROS Anti-HBe test for the *in vitro* qualitative detection of antibodies to hepatitis B e antigen (anti-HBe).

WARNING: *Test performance characteristics have not been established in patients under the age of 2, or in populations of immunocompromised or immunosuppressed patients.*

This test has not been FDA licensed for the screening of blood, plasma and tissue donors.

Summary and Explanation of the Test

Anti-HBe is detectable in convalescent stages of HBV infection and in carriers of HBV who are able to clear HBeAg from the circulation. It usually persists for a number of years and is an indication of reduced infectivity and an improved prognosis.¹ Treatment of HBeAg positive patients with α -interferon can often induce seroconversion to anti-HBe.² Anti-HBe status can provide additional clinical information about a patient's progression to seroconversion which is important in the management of HBV infection. A positive test for anti-HBe is presumptive laboratory evidence of seroconversion and HBeAg clearance which usually leads to low or undetectable HBV DNA and normal ALT levels in chronically infected patients. However, among patients that are anti-HBe positive, a portion may continue to have elevated levels of indicators of infection. Further assessment of HBV infection (biochemical, serological and/or nucleic acid testing) is required to define the specific disease state. A clinically relevant response to anti-HBV therapy is defined as a durable anti-HBe seroconversion in initially HBeAg-positive patients, and as a durable normalization of ALT and adequate (>2000 IU/mL) and durable HBV-DNA suppression in initially HBeAg-negative patients.³

Principles of the Procedure

The VITROS Anti-HBe test is performed using the VITROS Anti-HBe Reagent Pack and the VITROS Anti-HBe Calibrator on the VITROS ECi/ECiQ Immunodiagnostic Systems using Intellicheck[®] Technology. A competitive technique is used which involves pre-incubation of anti-HBe in the sample with a fixed weight of HBeAg in the assay reagent, followed by incubation with a conjugate reagent that contains biotinylated mouse monoclonal anti-HBe antibody and horseradish peroxidase (HRP)-labelled mouse monoclonal anti-HBe antibody. The immune complex is captured by streptavidin on the wells. Unbound materials are removed by washing.

The bound HRP conjugate is measured by a luminescent reaction.⁴ A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent, is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent (a substituted acetanilide) increases the level of light produced and prolongs its emission. The light signals are read by the system. The amount of HRP conjugate bound is indicative of the level of anti-HBe present in the sample.

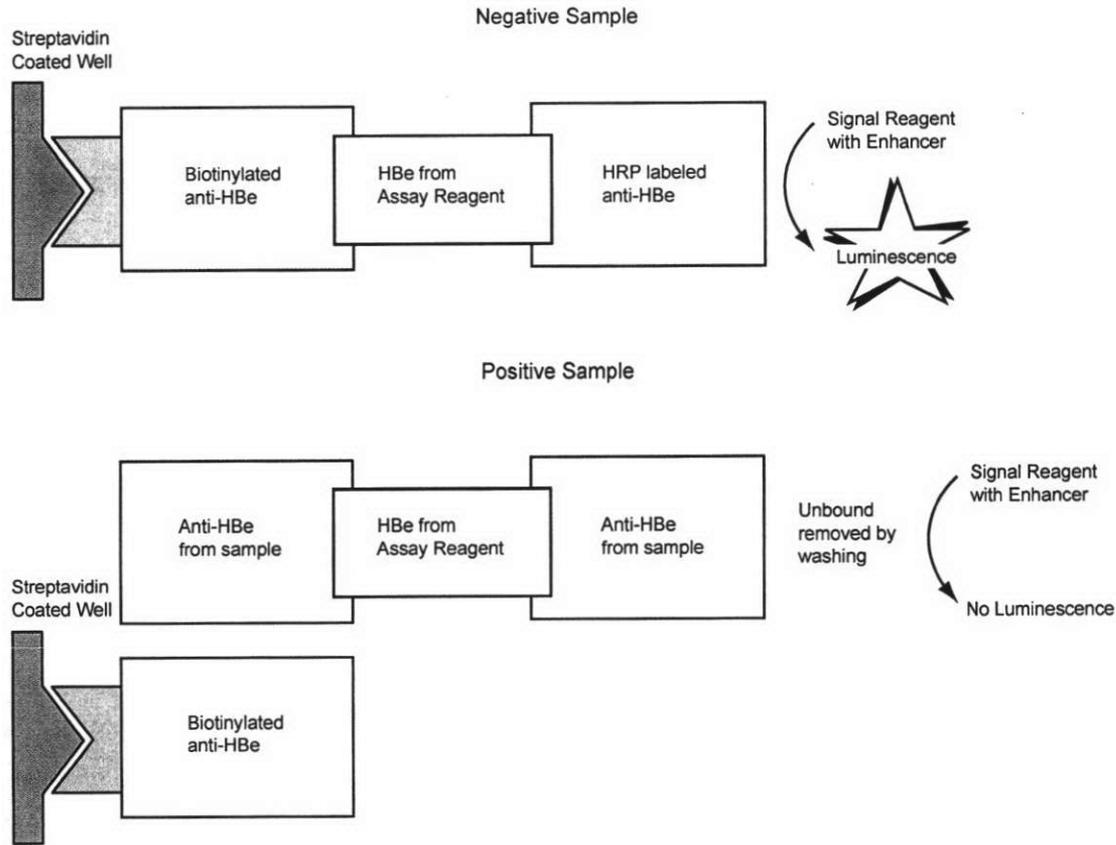
Test Type	System	Incubation Time	Time to first result	Test Temperature	Reaction Sample Volume
Competitive immunoassay	ECi/ECiQ	45 minutes	53 minutes	37 °C	80 μ L

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Warnings and Precautions

Reaction Scheme



Warnings and Precautions

For *in vitro* diagnostic use only

WARNING: Potentially Infectious Material

Treat the Reagent Pack and Calibrator as if capable of transmitting infection.

Use caution when handling material of human origin. Consider all samples potentially infectious. No test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are absent. Handle, use, store and dispose of solid and liquid waste from samples and test components, in accordance with the procedures defined by appropriate national biohazard safety guideline or regulation (e.g. CLSI document M29).^{5,6}

The VITROS Anti-HBe Calibrator contains:

Human HBeAg and Anti-HBe negative plasma obtained from donors who were tested individually and who were found to be negative for hepatitis B surface antigen, and for antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV 1+2), using FDA approved methods (enzyme immunoassays, EIA).

Human Anti-HBe positive plasma obtained from donors who were tested individually and who were found to be negative for antibodies to HCV and HIV 1+2, using FDA approved methods (EIA). The Anti-HBe positive plasma has been treated in order to reduce the titer of potentially infectious virus. However, as no testing method can rule out the risk of potential infection, handle as if capable of transmitting infection.

The VITROS Anti-HBe Reagent Pack contains recombinant HBeAg. It has been treated using β -propiolactone.

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Reagents

WARNING: Contains Kathon (CAS 55965-84-9) and 2-Chloroacetamide (CAS 79-07-2)
The VITROS Anti-HBe Reagent Pack and VITROS Anti-HBe Calibrator contain Kathon. The VITROS Anti-HBe Reagent Pack contains 2-Chloroacetamide. R43: May cause sensitization by skin contact. S24: Avoid contact with skin. S37: Wear suitable gloves.

Reagents

Reagent Pack Contents

1 reagent pack containing:

- 100 coated wells (streptavidin source, bacterial; binds ≥ 3 ng biotin/well)
- 8.4 mL assay reagent containing treated recombinant HBeAg (4.4 Units* /mL) in buffer with mouse serum, fetal calf serum, bovine serum albumin and antimicrobial agent
- 6.6 mL conjugate reagent (HRP-mouse monoclonal anti-HBe 0.3 $\mu\text{g/mL}$ and biotin-mouse monoclonal anti-HBe 5.0 $\mu\text{g/mL}$) in buffer with sheep and mouse serum, bovine serum albumin, bovine gamma globulin and antimicrobial agent

*Paul-Ehrlich-Institute Reference Serum

Reagent Pack Handling

- The reagent pack is supplied ready for use.
- The reagent pack contains homogeneous liquid reagents that do not require shaking or mixing prior to loading onto the system.
- Handle the reagent pack with care. Avoid the following:
 - allowing condensation to form on the pack
 - causing reagents to foam
 - agitation of the pack

Reagent Pack Storage and Preparation

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
Opened	On system	System turned on	≤ 12 weeks
Opened	Refrigerated	2–8 °C (36–46 °F)	≤ 12 weeks

- The VITROS Anti-HBe Reagent Pack is suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Do not freeze reagent packs.
- Load reagent packs directly from refrigerated storage to minimize condensation.
- Store opened refrigerated reagent packs in a sealed reagent pack storage box that contains dry desiccant.

Calibrator Contents

- 3 vials of VITROS Anti-HBe Calibrator (freeze-dried, anti-HBe positive human plasma in HBeAg and anti-HBe negative defibrinated and delipidized human plasma with antimicrobial agent); reconstitution volume 1.0 mL
- Lot calibration card
- Protocol card
- 8 calibrator bar code labels

Calibrator Handling

- Use only with reagent packs of the same lot number. Mix thoroughly by inversion and bring to 15–30 °C (59–86 °F) before use. Each pack contains sufficient volume for a minimum of 6 calibration events.
- Handle calibrators in stoppered containers to avoid contamination and evaporation. To avoid evaporation, limit the amount of time calibrators are on the system. Refer to the operator's guide for your system. Return to 2–8 °C (36–46 °F) as soon as possible after use, or load only sufficient volume for a single determination.

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Specimen Collection, Preparation and Storage

Calibrator Storage and Preparation

Calibrator	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	expiration date
Opened-reconstituted	Refrigerated	2–8 °C (36–46 °F)	≤13 weeks
Opened-reconstituted	Frozen	-20 °C (-4 °F)	≤13 weeks

- The VITROS Anti-HBe Calibrator is supplied freeze-dried.
- The VITROS Anti-HBe Calibrator is suitable for use until the expiration date on the carton when stored and handled as specified. Do not use beyond the expiration date.
- Reconstitute with 1.0 mL distilled water.
- Opened, reconstituted calibrators may be stored frozen. Do not freeze-thaw more than once.
- The VITROS Anti-HBe test uses 80 µL of calibrator for each determination. Transfer an aliquot of each calibrator into a sample container (taking account of the minimum fill volume of the container), which may be bar coded with the labels provided. For details on minimum fill volume of sample cups or containers, refer to the operator's guide for your system.
- The VITROS Anti-HBe Calibrator is automatically processed in duplicate.

Specimen Collection, Preparation and Storage

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

Serum

Specimens Not Recommended

- Do not use turbid specimens. Turbidity in specimens may affect test results.
- Do not use plasma samples.
- Do not use hemolysed samples as hemolysis may affect test results.
- Do not use cord blood samples.

Special Precautions

Important: *Certain collection devices have been reported to affect other analytes and tests. Owing to the variety of specimen collection devices available, Ortho-Clinical Diagnostics is unable to provide a definitive statement on the performance of its products with these devices. Confirm that your collection devices are compatible with this test.*

Specimen Collection and Preparation

- Collect specimens using standard procedures.^{8,9}
- Samples should be thoroughly separated from all cellular material on the day of collection. Failure to do so may lead to an erroneous result.
- Thoroughly mix samples by inversion and bring to 15–30 °C (59–86 °F) before use.
- The VITROS Anti-HBe test uses 80 µL of sample for each determination. This does not take account of the minimum fill volume of the chosen sample container. For details on minimum fill volume of sample cups or containers, refer to the operator's guide for your system.

Handling and Storage Conditions

- Handle samples in stoppered containers to avoid contamination and evaporation. Use a separate disposable tip if samples are manually pipetted. Avoid splashing, forming an aerosol, or cross-contaminating sample tube stoppers.
- The amount of time samples are on the system prior to analysis should be limited to avoid evaporation. This time should not exceed 2 hours. Refer to the operator's guide for your system.
- Return to 2–8 °C (36–46 °F) as soon as possible after use, or load sufficient volume for a single determination.
- Samples are not to be repeatedly frozen and thawed because this can cause analyte deterioration. Samples are to be thawed only once.

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Testing Procedure

- The Clinical and Laboratory Standards Institute (CLSI) provides the following recommendations for storing serum specimens:¹⁰
 - Store samples at room temperature for no longer than 8 hours.
 - If the test will not be completed within 8 hours, refrigerate the serum at 2–8 °C (36–46 °F).
 - If the test will not be completed within 48 hours, or for shipment, freeze the serum at or below -20 °C (-4 °F).

Testing Procedure

Materials Provided

- VITROS Immunodiagnostic Products Anti-HBe Reagent Pack
- VITROS Immunodiagnostic Products Anti-HBe Calibrator

Materials Required but not Provided

- VITROS ECi/ECiQ Immunodiagnostic System
- VITROS Immunodiagnostic Products Signal Reagent
- VITROS Immunodiagnostic Products Universal Wash Reagent
- Quality control materials such as VITROS Immunodiagnostic Products Anti-HBe Controls
- VITROS Immunodiagnostic Products Reagent Pack Storage Box (optional) with desiccant
- Calibrated pipette, distilled water and sample containers for reconstitution of VITROS Anti-HBe Calibrator

Operating Instructions

Check the reagent inventory regularly to aid the management of reagents and ensure that sufficient VITROS Signal Reagent, VITROS Universal Wash Reagent and calibrated reagent lots are available for the work planned. When performing panels of tests on a single sample, ensure that the sample volume is sufficient for the tests ordered.

For detailed information on running the test on the VITROS ECi/ECiQ Immunodiagnostic Systems, refer to the operator's guide for your system.

NOTE: Do not use visibly damaged product.

Default Test Name

The default test name which will appear on patient reports is Anti-HBe. The default short name that will appear on the test selection menus and laboratory reports is aHBe. These defaults may be reconfigured, if required. For detailed information refer to the operator's guide for your system.

Calibration

Calibration Procedure

- Calibration is lot specific; reagent packs and calibrators are linked by lot number. Reagent packs from the same lot may use the same calibration.
- A Master Calibration is established for each new reagent lot by performing multiple tests. This is the process by which a lot-specific parameter [a] which links the signal at the cutoff (cutoff value) to the calibrator signal is determined.
Cutoff value = (a x Signal of Cal 1)
- Ensure that the Master Calibration for each new reagent lot is available on your system.
- Process the calibrator in the same manner as samples. Load sufficient volume for the automatic duplicate determination. Calibration need not be programmed if bar code labels are used; Calibration will be initiated automatically.
- When the calibrator is processed the validity of the calibration is assessed against quality parameters which compares the actual signal of the calibrator with the expected signal. If the calibration is acceptable the cutoff value is calculated and stored for use with any reagent pack of that lot.
- The quality of calibration cannot be completely described by a single parameter. The calibration report should be used in conjunction with acceptable control values to determine the validity of the calibration.
- Recalibration is required after a pre-determined calibration interval, or when a different reagent lot is loaded.
- Calibration results are assessed against two quality parameters. Failure to meet either of the defined quality parameter ranges will be coded in the calibration report. For actions to be taken following a failed calibration, refer to the operator's guide for your system.

Refer to the operator's guide for your system for detailed instructions on the calibration process.

When to Calibrate

- Calibrate when the reagent pack and calibrator lot changes.
- Calibrate every 28 days.
- After specified service procedures have been performed.
- If quality control results are consistently outside of your acceptable range.

For additional information on when to calibrate, refer to the operator's guide for your system.

Traceability of Calibration

The calibration of the VITROS Anti-HBe test is traceable to an in-house reference calibrator which has been value-assigned to optimize the clinical sensitivity and specificity performance.

Calibration Model

Results are calculated as a normalized signal, relative to a cutoff value. During the calibration process a lot-specific parameter is used to determine a valid stored cutoff value for the VITROS ECi/ECiQ Immunodiagnostic Systems.

Quality Control

Quality Control Material Selection

VITROS Anti-HBe Controls are recommended for use with the VITROS ECi/ECiQ Immunodiagnostic Systems. There are 2 VITROS Anti-HBe Controls (C1 – negative and C2 –Anti-HBe positive). The performance of other commercial control fluids should be evaluated for compatibility with this test before they are used for quality control.

Control materials may show a difference when compared with other anti-HBe methods if they contain high concentrations of preservatives, stabilizers, or other non-physiological additives, or otherwise depart from a true human sample matrix.

Choose control material that has a composition similar to or identical with the patient sample matrix being analyzed.¹¹

Appropriate quality control value ranges must be established for all quality control materials used with the VITROS Anti-HBe test.

Quality Control Procedure Recommendations

- Good laboratory practice requires that controls be processed to verify the performance of the test.
- Choose control levels that check the clinically relevant concentrations. The recommendation is to run a negative control and a positive control close to the Anti-HBe decision point [Cutoff/Signal (C/S) 1.00].
- To verify system performance, analyze control materials:
 - After calibration
 - According to local regulations or at least once each day that the test is being performed
 - After specified service procedures or maintenance to critical parts or subsystems that might influence performance of the test

If quality control procedures within your laboratory require more frequent use of controls, follow those procedures.

- Analyze quality control materials in the same manner as patient specimens.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results. Investigate and determine the cause for the unacceptable control results. When the condition is corrected, retest the controls and confirm that results are within acceptable limits. Repeat all patient specimens before reporting results for this run.
- Refer to the published guidelines for general quality control recommendations.¹¹
- Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

For more detailed information, refer to the operator's guide for your system.

Quality Control Material Preparation and Storage

Refer to the manufacturer's product literature for preparation, storage, and stability information.

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Results

Results

Results are automatically calculated by the VITROS EC/ECiQ Immunodiagnostic Systems.

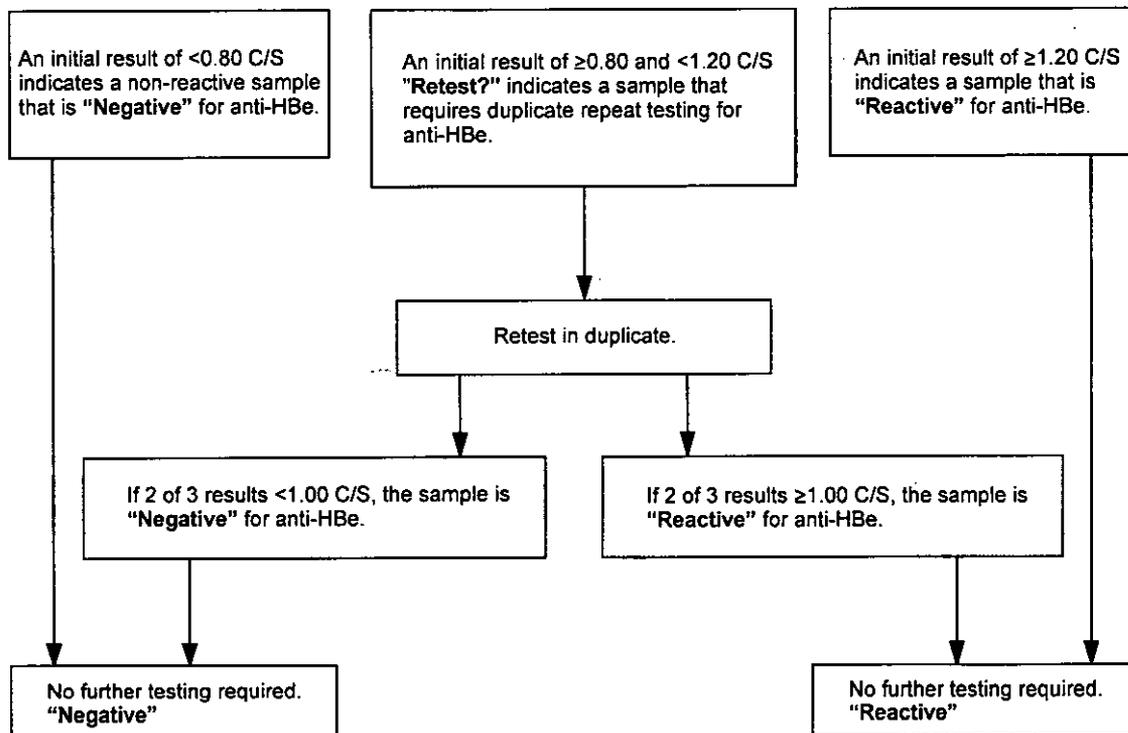
Result Calculation

Results for the VITROS Anti-HBe test are calculated as the cutoff value relative to a normalized signal (C/S). Patient sample results will be displayed by the analyzer with a "Negative", "Retest?" or "Reactive" label. An initial result labeled with "Retest?" indicates a sample that requires duplicate repeat testing for anti-HBe.

VITROS Anti-HBe Result (C/S)	<0.80	≥0.80 and <1.20	≥1.20
Result Text	Negative	Retest?	Reactive

Testing Algorithm

Final results should be manually interpreted using the algorithm below.



The following table summarizes the interpretation of results obtained with the VITROS Anti-HBe test upon completion of all testing steps required in the testing algorithm.

Interpretation of Results

VITROS Anti-HBe Test Result (C/S)	Conclusion from Testing Algorithm	Interpretation
<0.80	Negative	Sample is non-reactive and presumed negative for anti-HBe. This result should not be used alone, but in conjunction with other hepatitis B serological markers to determine disease state.
≥0.80 and <1.20	Retest in duplicate	Sample is non-reactive and presumed negative for anti-HBe if 2 of 3 results are <1.00. Sample is reactive and presumed positive for anti-HBe if 2 of 3 results are ≥1.00.
≥1.20	Reactive	Sample is reactive and presumed positive for anti-HBe. This result should not be used alone, but in conjunction with other hepatitis B serological markers to determine disease state.

Limitations of the Procedure

- Anti-HBe cannot be used alone to determine clearance of HBV infection in patients. Other indicators of infection (biochemical, serological or nucleic acid) should be taken into consideration when applying the results of the VITROS Anti-HBe test to a patient's status.
- The results from this or any other diagnostic test should be used and interpreted only in the context of the overall clinical picture.
- Results of this test may be negatively biased by hemoglobin.
- The effect of elevated serum protein levels on the VITROS Anti-HBe test was not evaluated. Each clinical laboratory should verify the performance of this test with samples with high protein content.¹²
- Materials such as commercially available controls or proficiency panel members containing azide at concentrations greater than or equal to 0.25% have been shown to interfere with this test.
- A negative test result does not guarantee that anti-HBe is not present. The detection of anti-HBe in a patient sample may indicate a reduced infectivity risk, but does not prove that the patient is non-infectious. HBV mutants lacking the ability to produce HBeAg have been reported.¹³ These may occur as 'escape' mutants in the presence of anti-HBe and such patients may be infectious.
- Heterophilic antibodies in serum or plasma samples may cause interference in immunoassays.¹⁴ These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products. Results which are inconsistent with clinical observations indicate the need for additional testing.
- Biotin levels in serum remain elevated for up to 24 hours after oral or intravenous biotin administration.¹⁵ Cautions should be taken when testing samples collected from patients receiving biotin therapy. Biotin levels up to 1 µg/dL (40.8 nmol/L) do not interfere with the VITROS Anti-HBe test.

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Expected Results

Expected Results

Two prospective adult populations were included in the study. Of the 1976 subjects in Population 1 who were tested in the VITROS Anti-HBe clinical study, 1648 were from individuals who were chronically infected, recovered, vaccinated and those not previously infected with HBV. All 1648 were either at risk for HBV due to lifestyle, behavior, occupation, or a known exposure event or had signs and symptoms of hepatitis.

The 1648 subjects in this group were enrolled in Miami, FL (51.2%), in Dallas, TX (15.0%), in Newark, NJ (6.4%), and in Chicago, IL (27.4%). The group was Caucasian (20.2%), African American (48.7%), Hispanic (25.4%), and Asian (2.2%) with the remaining 3.5% represented by other ethnic groups. The group was 52.7% male and 47.3% female and ranged in age from 5 to 89 years. The distribution of VITROS Anti-HBe reactive and non-reactive results among the chronically infected, recovered, vaccinated and those not previously infected with HBV is presented, stratified by age and gender, in the following table.

Expected Results for Study Subjects in Population 1 (N=1648)

Age Range	Gender	Reactive		Negative		Total [§]
		N [*]	Percent ^{**}	N ^{***}	Percent [†]	
≤ 15	Female	0	0.0	2	100	2
	Male	0	0.0	4	100	4
16-20	Female	2	7.1	26	92.9	28
	Male	0	0.0	19	100	19
21-30	Female	1	0.8	126	99.2	127
	Male	1	0.8	124	99.2	125
31-40	Female	1	0.6	165	99.4	166
	Male	9	4.8	177	95.2	186
41-50	Female	1	0.5	196	99.5	197
	Male	17	6.3	252	93.7	269
51-60	Female	3	1.9	158	98.1	161
	Male	11	5.8	178	94.2	189
61-70	Female	1	1.6	63	98.4	64
	Male	1	1.7	58	98.3	59
> 70	Female	0	0.0	33	100	33
	Male	1	5.9	16	94.1	17
Unknown	Female	0	0.0	1	100	1
	Male	0	0.0	1	100	1
Total		49	3.0	1599	97.0	1648

* The total number (N) of subjects in each age range/gender category with reactive VITROS Anti-HBe results.

** The total number (N) of subjects in each age range/gender category that are reactive, expressed as a percentage (%) of all subjects in that category.

*** The total number (N) of subjects in each age range/gender category with negative VITROS Anti-HBe results.

† The total number (N) of subjects in each age range/gender category that are negative, expressed as a percentage (%) of all subjects in that category.

§ The total number (N) of subjects in each age range/gender category.

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Expected Results

All subjects enrolled in Population 2 (N=311) were from an area in India with a high prevalence of HBV infection and all presented with signs or symptoms of viral hepatitis. Of the 311 subjects in Population 2 who were tested in the VITROS Anti-HBe clinical study, 208 were from individuals who were chronically infected, recovered, vaccinated and those not previously infected with HBV. The mean age of the 208 subjects was 39 years and the median age was 40 years. Approximately 87% were ≤50 years of age. The minimum age was 18 years and the maximum age was 90 years. The group was 32.2% female and 67.8% male. The VITROS Anti-HBe test was reactive in 62.5% (130/208) of the individuals in this group. The distribution of VITROS Anti-HBe reactive and non-reactive results among the chronically infected, recovered, vaccinated and those not previously infected with HBV is presented, stratified by age and gender, in the following table.

Expected Results for Study Subjects in Population 2 (N=208)

Age Range	Gender	Reactive		Negative		Total [§]
		N*	Percent**	N***	Percent [†]	
18–20	Female	2	40.0	3	60.0	5
	Male	2	25.0	6	75.0	8
21–30	Female	16	61.5	10	38.5	26
	Male	15	51.7	14	48.3	29
31–40	Female	15	60.0	10	40.0	25
	Male	22	53.7	19	46.3	41
41–50	Female	4	57.1	3	42.9	7
	Male	30	76.9	9	23.1	39
51–60	Female	2	66.7	1	33.3	3
	Male	15	88.2	2	11.8	17
61–70	Female	1	100	0	0.0	1
	Male	5	83.3	1	16.7	6
>70	Male	1	100	0	0.0	1
Total		130	62.5	78	37.5	208

- * The total number (N) of subjects in each age range/gender category with reactive VITROS Anti-HBe results.
- ** The total number (N) of subjects in each age range/gender category that are reactive, expressed as a percentage (%) of all subjects in that category.
- *** The total number (N) of subjects in each age range/gender category with negative VITROS Anti-HBe results.
- † The total number (N) of subjects in each age range/gender category that are negative, expressed as a percentage (%) of all subjects in that category.
- § The total number (N) of subjects in each age range/gender category.

Expected results for the VITROS Anti-HBe test were also determined using prospective samples from a population of pediatric subjects in Florida (N=165). The group was 47.9% male and 52.1% female, and the subjects' ages ranged from 2 through 21 years. The expected results are presented in the following table.

Expected Results for Pediatric Subjects (N=165)

Age Range	Gender	Reactive		Negative		Total [§]
		N*	Percent**	N***	Percent [†]	
2–4	Female	0	0.0	13	100	13
	Male	0	0.0	11	100	11
5–8	Female	0	0.0	18	100	18
	Male	0	0.0	17	100	17
9–12	Female	0	0.0	17	100	17
	Male	0	0.0	20	100	20
13–16	Female	0	0.0	21	100	21
	Male	0	0.0	14	100	14
17–21	Female	0	0.0	17	100	17
	Male	0	0.0	17	100	17
Total		0	0.0	165	100	165

- * The total number (N) of subjects in each age range/gender category with reactive VITROS Anti-HBe results.
- ** The total number (N) of subjects in each age range/gender category that are reactive, expressed as a percentage (%) of all subjects in that category.
- *** The total number (N) of subjects in each age range/gender category with negative VITROS Anti-HBe results.
- † The total number (N) of subjects in each age range/gender category that are negative, expressed as a percentage (%) of all subjects in that category.
- § The total number (N) of subjects in each age range/gender category.