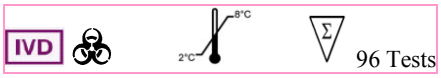
AccuDiag™ HBsAg ELISA

REF 1701-12



BLOOD VIRUS SCREENING HEPATITIS B VIRUS SURFACE ANTIGEN ELISA

Test	HBsAg ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	Sandwich-ELISA Antibody Coated Plate
Detection Range	Qualitative: Positive & Negative Control
Sample	50ul
Specificity	99.64%
Sensitivity	99.75%
Total Time	~ 90 min
Shelf Life	12 Months from the manufacturing date

** Read the package insert carefully and completely before performing the assay. Follow the instructions and do not modify them. Only by strict adherence to these instructions, the erroneous results can be avoided and the optimal performance of Diagnostic Automation, Inc.(DAI) HBsAg ELISA achieved.*

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INTENDED USE

DAI HBsAg ELISA is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of HBsAg in human serum or plasma. It is intended for screening of blood donors and for diagnosing of patients related to infection with hepatitis B virus.

SUMMARY AND EXPLANATION

Hepatitis B virus (HBV) is an enveloped, double-stranded DNA virus belonging to the Hepadnaviridae family and is recognized as the major cause of blood transmitted hepatitis together with hepatitis C virus (HCV). Infection with HBV induces a spectrum of clinical manifestations ranging from mild, inapparent disease to fulminant hepatitis, severe chronic liver diseases, which in some cases can lead to cirrhosis and carcinoma of the liver. Classification of a hepatitis B infection requires the identification of several serological markers expressed during three phases (incubation, acute and convalescent) of the infection. Now several diagnostic test are used for screening, clinical diagnosis and management of the disease. Hepatitis B surface antigen or HBsAg, previously described as Australia antigen, is the most important protein of the envelope of Hepatitis B Virus. The surface antigen contains the determinant "a", common to all known viral subtypes and immunologically distinguished in two distinct subgroups (ay and ad). HBV has 10 major serotypes and four HBsAg subtypes have been recognized (adw, ady, ayw, and ayr). HBsAg can be detected 2 to 4 weeks before the ALT levels become abnormal and 3 to 5 weeks before symptoms develop. The serological detection of HBsAg is a powerful method for the diagnosis and prevention of HBV infection and ELISA has become an extensively used analytical system for screening of blood donors and clinical diagnosis of HBV in infected individuals.

TEST PRINCIPLE

For detection of HBsAg, Diagnostic Automation, Inc HBsAg ELISA uses antibody "sandwich" ELISA method in which, polystyrene microwell strips are pre-coated with monoclonal antibodies specific to HBsAg. Patient's serum or plasma sample is added to the microwell together with a second antibody conjugated the enzyme horseradish peroxidase (the HRP-Conjugate) and directed against a different epitope of HBsAg. During incubation, the specific immunocomplex formed in case of presence of HBsAg in the sample, is captured on the solid phase. After washing to remove sample serum proteins and unbound HRP-conjugate, Chromogen solutions containing tetramethyl-benzidine (TMB) and urea peroxide are added to the wells. In presence of the antibody-antigen-antibody (HRP) "sandwich" immunocomplex, the colorless Chromogens are hydrolyzed by the bound HRP-conjugate to a blue-colored product. The blue color turns yellow after stopping the reaction with sulfuric acid. The amount of color intensity can be measured and it is proportional to the amount of antigen captured in the wells, and to its amount in the sample respectively. Wells containing samples negative for HBsAg remain colorless.

SPECIMEN COLLECTION AND PREPARATION

1. **Specimen Collection:** No special patient's preparation required. Collect the specimen in accordance with the normal laboratory practice. Either fresh serum or plasma specimens can be used with this assay. Blood collected by venipuncture should be allowed to clot naturally and completely – the serum/plasma must be separated from the clot as early as possible as to avoid haemolysis of the RBC. Care should be taken to ensure that the serum specimens are clear and not contaminated by microorganisms. Any visible particulate matters in the specimen should be removed by centrifugation at 3000 RPM (round per minutes) for 20 minutes at room temperature or by filtration.
2. Plasma specimens collected into EDTA, sodium citrate or heparin can be tested, but ***highly lipaemic, icteric, or hemolytic specimens should not be used*** as they can give false results in the assay. ***Do not heat inactivate specimens***. This can cause deterioration of the target analyte. Samples with visible microbial contamination should never be used.
3. DAI HBsAg ELISA is intended ONLY for testing of individual serum or plasma samples. Do not use the assay for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
4. **Transportation and Storage**: Store specimens at 2-8°C. Specimens not required for assaying within 7 days should be stored frozen (-20°C or lower). Multiple freeze-thaw cycles should be avoided. For shipment, samples should be packaged and labeled in accordance with the existing local and international regulations for transportation of clinical samples and ethological agents.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. **Microwell Plate**
   Blank microwell strips fixed on white strip holder.
   The plate is sealed in aluminum pouch with desiccant.
   8×12-well strips per plate.
   Each well contains monoclonal antibodies reactive to HBsAg (anti-HBs).
   The microwell strips can be broken to be used separately. Place unused wells or strips in the plastic sealable storage bag together with the desiccant and return to 2~8°C. Once open, stable for 4 weeks at 2~8°C.

2. **Negative Control**
   Yellowish liquid filled in a vial with green screw cap.
   1ml per vial.
   Protein-stabilized buffer tested non-reactive for HBsAg.
   Preservatives: 0.1% ProClin 300.
   Ready to use as supplied.
   Once open, stable for 4 weeks at 2~8°C.
3. **Positive Control**
   Red-colored liquid filled in a vial with red screw cap.
   1ml per vial.
   HBsAg diluted in protein-stabilized buffer.
   Preservatives: 0.1% ProClin 300.
   Ready to use as supplied. Once open, stable for 4 weeks at 2~8°C.
4. **HRP-Conjugate Reagent**
   Red-colored liquid filled in a white vial with red screw cap.
   7ml per vial.
   Horseradish peroxidase-conjugated anti-HBs antibodies.
   Ready to use as supplied. Once open, stable for 4 weeks at 2~8°C.
5. **Wash Buffer**
   Colorless liquid filled in a clear bottle with white screw cap. Buffer solution containing surfactant 30ml per bottle.
   DILUTE BEFORE USE The concentration must be diluted **1 to 20** with distilled/deionized water before use. Once diluted, stable for one week at room temperature or for two weeks at 2-8°C.
6. **Chromogen Solution A**
   Colorless liquid filled in a white vial with green screw cap.
   8ml per vial.
   Urea peroxide solution.
   Ready to use as supplied.
   Once open, stable for 4 weeks at 2~8°C.
7. **Chromogen Solution B**
   Colorless liquid filled in a black vial with black screw cap.
   8 ml per vial.
   TMB solution (Tetramethyl-benzidine) solution
   Ready to use as supplied.
   Once open, stable for 4 weeks at 2~8°C.
8. **Stop Solution**
   Colorless liquid filled in a white vial with white screw cap.
   8 ml per vial. Diluted sulfuric acid solution (0.5M H_2SO_4)
   Ready to use as supplied.
   Once open, stable for 4 weeks at 2~8°C.
9. **Plastic Sealable Bag**
   For enclosing the strips not in use.
10. **Cardboard Plate Cover**
    1 Sheet
    To cover the plates during incubation and prevent evaporation or contamination of the wells.
11. **Package Insert**
    1 copy

Materials required but not provided

1. Freshly distilled or deionized water
2. Disposable gloves and timer
3. Appropriate waste containers for potentially contaminated materials.
4. Dispensing system and/or pipette (single or multichannel), disposable pipette tips
5. Absorbent tissue or clean towel
6. Dry incubator or water bath, 37±0.5°C
7. Microwell plate reader, single wavelength 450nm or dual wavelength 450nm and 630nm
8. Microwell aspiration/wash system

PRECAUTIONS

This kit is intended **FOR IN VITRO USE ONLY**

FOR PROFESSIONAL USE ONLY

The ELISA assay is a time and temperature sensitive method. To avoid incorrect result, strictly follow the test procedure steps and do not modify them.

1. Do not exchange reagents from different lots or use reagents from other commercially available kits. The components of the kit are precisely matched for optimal performance of the tests.
2. Make sure that all reagents are within the validity indicated on the kit box and of the same lot. Never use reagents beyond their expiry date stated on labels or boxes.
3. **CAUTION - CRITICAL STEP:** Allow the reagents and specimens to reach room temperature (18-30°C) before use. Shake reagent gently before use. Return at 2-8°C immediately after use.
4. Use only sufficient volume of sample as indicated in the procedure steps. Failure to do so, may cause in low sensitivity of the assay.
5. Do not touch the bottom exterior of the wells; fingerprints or scratches may interfere with the reading. When reading the results, ensure that the plate bottom is dry and there are no air bubbles inside the wells.
6. Never allow the microplate wells to dry after the washing step. Immediately proceed to the next step. Avoid the formation of air bubbles when adding the reagents.
7. Avoid assay steps long time interruptions. Assure same working conditions for all wells.
8. Calibrate the pipette frequently to assure the accuracy of samples/reagents dispensing. Use different disposal pipette tips for each specimen and reagents in order to avoid cross-contaminations.
9. Assure that the incubation temperature is 37°C inside the incubator.
10. When adding specimens, do not touch the well's bottom with the pipette tip.
11. When measuring with a plate reader, determine the absorbance at 450nm or at 450/630nm.
12. The enzymatic activity of the HRP-conjugate might be affected from dust and reactive chemical and substances like sodium hypochlorite, acids, alkalis etc. Do not perform the assay in the presence of these substances.
13. If using fully automated equipment, during incubation, do not cover the plates with the plate cover. The tapping out of the remainders inside the plate after washing, can also be omitted.
14. All specimens from human origin should be considered as potentially infectious. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure the personal safety.
15. **WARNING:** Materials from human origin may have been used in the preparation of the Negative Control of the kit. These materials have been tested with tests kits with accepted performance and found negative for antibodies to HIV 1/2, HCV, TP and HBsAg. However, there is no analytical method that can assure that infectious agents in the specimens or reagents are completely absent. Therefore, handle reagents and specimens with extreme caution as if capable of transmitting infectious diseases. Bovine derived sera have been used for stabilizing of the positive and negative controls. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE free-geographical areas.
16. Never eat, drink, smoke, or apply cosmetics in the assay laboratory. Never pipette solutions by mouth.
17. Chemical should be handled and disposed of only in accordance with the current GLP (Good Laboratory Practices) and the local or national regulations.
18. The pipette tips, vials, strips and specimen containers should be collected and autoclaved for not less than 2 hours at 121°C or treated with 10% sodium hypochlorite for 30 minutes to decontaminate before any further steps of disposal. Solutions containing sodium hypochlorite should NEVER be autoclaved. Materials Safety Data Sheet (MSDS) available upon request.
19. Some reagents may cause toxicity, irritation, burns or have carcinogenic effect as raw materials. Contact with the skin and the mucosa should be avoided but not limited to the following reagents: Stop solution, the Chromogens, and the Wash buffer.

20. The Stop solution 0.5M H2SO4 is an acid. Use it with appropriate care. Wipe up spills immediately and wash with water if come into contact with the skin or eyes.
21. ProClinTM 300 0.1% used as preservative, can cause sensation of the skin. Wipe up spills immediately or wash with water if come into contact with the skin or eyes.

INDICATIONS OF INSTABILITY DETERIORATION OF THE REAGENT: Values of the Positive or Negative controls, which are out of the indicated quality control range, are indicators of possible deterioration of the reagents and/or operator or equipment errors. In such case, the results should be considered as invalid and the samples must be retested. In case of constant erroneous results and proven deterioration or instability of the reagents, immediately substitute the reagents with new one or contact DAI technical support for further assistance.

- ProClin 300, Sphrases: S26-28-36/37/39-45-60-61, R phrases: 43
- Do not eat and drink at the laboratory
- Ware protective clothing and eye protection
- Biohazard: danger

SPECIAL INSTRUCTIONS FOR WASHING

1. A good washing procedure is essential to obtain correct and precise analytical data.
2. It is therefore recommended to use a good quality ELISA microplate washer, maintained at the best level of washing performances. In general, no less than 5 automatic washing cycles with dispensing of 350-400µl/well, are sufficient to avoid false positive reactions and high background (all wells turn yellow).
3. To avoid cross-contaminations of the plate with sample or HRP-conjugate, after incubation do not discard the content of the wells, but allow the plate washer to aspirate it automatically.
4. Assure that the microplate washer liquid dispensing channels are not blocked or contaminated and sufficient volume of Wash buffer is dispensed each time into the wells.
5. In case of manual washing, we suggest to perform at least **5cycles**, dispensing 350-400µl/well and aspirating the liquid for **5times**. If poor results (high background) are observed, increase the washing cycles or soaking time per well.
6. In any case, the liquid aspirated out the strips should be treated with a sodium hypochlorite solution(final concentration of 2.5%) for 24 hours, before liquids are disposed in an appropriate way.
7. The concentrated Washing buffer should be diluted **1 to 20** before use. If less than a whole plate is used, prepare the proportional volume of solution.

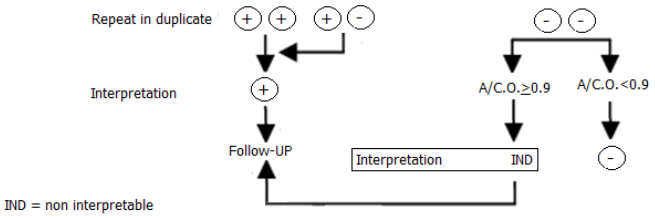
ASSAY PROCEDURE

1. **Reagents preparation:** Allow the reagents to reach room temperature **(18-30°C)**. Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed, resolubilize by warming at 37°C until crystals dissolve. Dilute the Wash buffer (20X) as indicated in the instructions for washing. Use distilled or deionized water and only clean vessels to dilute the buffer. All other reagents are **READY TO USE AS SUPPLIED**.
2. **Microwells Preparation:** Mark three wells as Negative control (e.g. B1, C1, D1), two wells as Positive control (e.g. E1, F1) and one Blank (e.g. A1, neither samples nor HRP-Conjugate should be added into the Blank well). If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted. Use only number of strips required for the test.
3. **Adding Sample and HRP-Conjugate:** Add 50µl of Positive control, Negative control, and specimen into their respective wells. **Note: Use a separate disposal pipette tip for each specimen, Negative and Positive Control as to avoid cross-contamination.** Add 50µl **HRP-Conjugate** to each well except the Blank, and mix by tapping the plate gently.
4. **Incubating:** Cover the plate with the plate cover and incubate for **60 minutes at 37°C**.
5. **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5times** with diluted Wash buffer. Each time, allow the microwells to soak for **30-60seconds**. After the final washing cycle, turn the plate down onto blotting paper or clean towel, and tap it to remove any remainders.
6. **Coloring:** Dispense **50µl** of Chromogen A and **50µl** Chromogen B solution into each well including the **Blank**, and mix by tapping the plate gently. Incubate the plate at **37° for 15minutes avoiding light**. The enzymatic reaction between the Chromogen solutions and the HRP-Conjugate produces blue color in Positive control and HBsAg positive sample wells.
7. **Stopping Reaction:** Using a multichannel pipette or manually, add **50µl** Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and HBsAg positive sample wells.
8. **Measuring the Absorbance:** Calibrate the plate reader with the Blank well and read the absorbance at **450nm**.If a dual filter instrument is used, set the reference wavelength at **630nm**. Calculate the Cut-off value and evaluate the results (**Note:** read the absorbance within **10 minutes** after stopping the reaction).

RESULTS

- **Negative Results (A/C.O. <1):** Specimens giving absorbance less than the Cut-off value are negative for this assay, which indicates that no hepatitis B virus surface antigen has been detected with DAI HBsAg ELISA, therefore the patient is probably not infected with HBV and the blood unit do not contain hepatitis B virus surface antigen and could be transfused in case that other infectious diseases markers are also absent.
- **Positive Results (A/C.O.≥1):** Specimens giving an absorbance equal to or greater than the Cut-off value are considered initially reactive, which indicates that hepatitis B virus surface antigen has probably been detected using DAI HBsAg ELISA. All initially reactive specimens should be retested in duplicates using DAI HBsAg ELISA before the final assay results interpretation. Repeatedly reactive specimens can be considered positive for hepatitis B virus surface antigen with DAI HBsAg ELISA.
- **Borderline:** (**A/C.O. = 0.9-1.1**): Specimens with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline and retesting of these specimens in duplicates is required to confirm the initial results.

Follow-up, confirmation and supplementary testing of any positive specimen with other analytical system (e.g. PCR) is required. Clinical diagnosis should not be established based on a single test result. It should integrate clinical and other laboratory data and findings.



- If, after retesting of the initially reactive samples, both wells are negative results (A/C.O.<0.9), these samples should be considered as non-repeatable positive (or false positive) and recorded as negative. As with many very sensitive MELISA assays, false positive results can occur due to the several reasons, most of which are connected with, but not limited to, inadequate washing step.
- If after retesting in duplicates, one or both wells are positive results, the final result from this ELISA test should be recorded as repeatedly reactive.

Repeatedly reactive specimens could be considered positive for hepatitis B virus surface antigen and therefore the patient is probably infected with HBV and the blood unit must be discarded.

- After retesting in duplicates, samples with values close to the Cut-off value should be interpreted with caution and considered as "borderline" zone sample, or uninterpretable for the time of testing.

QUALITY CONTROL

Each microplate should be considered separately when calculating and interpreting the results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each specimen absorbance (A) value to the Cut-off value (C.O.) of the plate. If the Cut-off reading is based on single filter plate reader, the results should be calculated by subtracting the Blank well A value from the print report values of specimens and controls. In case the reading is based on dual filter plate reader, do not subtract the Blank well A value from the print report values of specimens and controls.

1. **Calculation of Cut-off value:** **Cut-off value (C.O.) = *Nc × 2.1**

***Nc** = the mean absorbance value for three negative controls.

Important: If the mean A value of the negative controls is lower than 0.05, take it as 0.05.

Quality control (assay validation): The test results are valid if the Quality Control criteria are fulfilled. It is recommended that each laboratory must establish appropriate quality control system with quality control material similar to or identical with the patient sample being analyzed.

- The A value of the Blank well, which contains only Chromogen and Stop solution, is < 0.080 at 450 nm.
- The A values of the Positive control must be ≥ 0.800 at 450/630nm or at 450nm after blanking.
- The A values of the Negative control must be < 0.100 at 450/630nm or at 450nm after blanking.

If one of the Negative control values does not meet the Quality control range specifications, it should be discarded and the mean value is calculated again using the remaining two values. If more than one negative control OD value does not meet the Quality control range specifications, the test is invalid and must be repeated.

EXAMPLE:

1. **Quality Control**
Blank well A value: A1=0.025 at 450nm (Note: blanking is required only when reading with single filter at 450)

Well No:	B1	C1	D1
Negative controls A values after blanking:	0.020	0.012	0.016
Well No:	E1	F1	
Positive control A values after blanking:	2.421	2.369	

All control values are within the stated quality control range
2. **Calculation of Nc:** = (0.020+0.012+0.016) = 0.016 (Nc is lower than 0.05 so take it as 0.05)
3. Calculation of Cut-off value: Cut-off (C.O) = 0.05 x 2.1 = 0.105

PERFORMANCE CHARACTERISTICS

Clinical Specificity: The clinical specificity of this assay was determinate by a panel of samples obtained from 2500 healthy blood donors and 300 undiagnosed hospitalized patients. The repeatedly reactive samples and samples confirmed positive with the reference test were not included in the calculation of specificity.

	Sample	-	+	Confirmed positive	Specificity	False positive
donors	2500	2444	56	53	99.88%	3
patients	300	273	27	26	99.64%	1

Clinical Sensitivity: The clinical sensitivity of this HBsAg ELISA was calculated by a panel of samples obtained from 670 hepatitis B patients with well-characterized clinical history based upon reference assays for detection of HBsAg, HBeAg, anti-HBs, anti-HBe, and anti-HBc. Licensed HBsAg ELISA test was used as a confirmatory assay. The evaluation results are given below. Results obtained in individual laboratories may differ.

	Sample	-	+	Confirmed positive	Sensitivity	False Negatives
Acute	200	0	200	200	100%	0
Chronic	400	1	399	400	99.75%	1
Recovery	70	65	5	5	100%	0

Analytical Specificity:

1. No cross reactivity observed with samples from patients infected with HAV, HCV, HIV, CMV, and TP.
2. No interference from rheumatoid factors up to 2000U/ml observed.
3. No high dose hook effect up to HBsAg concentrations of 200000ng/ml observed during clinical testing.
4. Frozen specimens have been tested too to check for interferences due to collection and storage.

Analytical Endpoint Sensitivity (lower detection limit):
The assay shows sensitivity at the Cut-off of 0.5 ng/ml (adr) and 0.5 ng/ml (adw, ay).

LIMITATIONS OF PROCEDURE

1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
2. Antigens may be undetectable during the early stage of the disease. Therefore, negative results obtained with DAI HBsAg ELISA are only indication that the sample does not contain detectable level of hepatitis B virus surface antigen and any negative result should not be considered as conclusive evidence that the individual is not infected with HBV or the blood unit is not infected with HBV.
3. If, after retesting of the initially reactive samples, the assay results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive ELISA assays, false positive results can occur due to the several reasons, most of which are related but not limited to inadequate washing step.
4. The most common assay mistakes are: using kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add specimens or reagents, improper operation with the laboratory equipment, timing errors, the use of highly hemolyzed specimens or specimens containing fibrin, incompletely clotted serum specimens.
5. The prevalence of the marker will affect the assay's predictive values
6. This assay cannot be utilized to test pooled (mixed) plasma. DAI HBsAg ELISA has been evaluated only with individual serum or plasma specimens.
7. DAI HBsAg ELISA is a qualitative assay and the results cannot be used to measure antigen concentration.

STORAGE

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between 2-8 ºC, **do not freeze**. To assure maximum performance of this HBsAg ELISA kit, during storage protect the reagents from contamination with microorganism or chemicals.

REFERENCES

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SUMMARY OF THE ASSAY PROCEDURE:	
Add Sample / Controls	50µl
Add HRP-Conjugate	50µl
Incubate	60minutes
Wash	5times
Coloring	50µl A + 50µl B
Incubate	15minutes
Stop the reaction	50µl stop solution
Read the absorbance	450nm or 450/630 nm

ISO 13485
ISO 9001

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