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IVD | See external label | 8°C / 2°C | Σ 96 tests | REF 1778-12

AccuDiag™ HBcAb IgM

Cat # 1778-12

Test	HBcAb IgM ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	ELISA - Indirect; Antigen Coated Plate
Detection Range	Qualitative Positive; Negative control & Cut off
Sample	100 ul Serum
Specificity	99.3%
Sensitivity	98.4%
Total Time	~ 75 min
Shelf Life	12 -18 Months from the manufacturing date

- *Laboratory results can never be the only base of a medical report. The patient history and further tests have to be taken into account*

INTENDED USE

The intended use for this **HBcAb IgM ELISA test** is for clinical lab diagnosis and handling of hepatitis B-infected patients. The HBcAb IgM ELISA is an enzyme-linked immunosorbent assay for the qualitative identification of IgM class antibodies to hepatitis B core antigen in human serum/plasma.

SUMMARY

The effects of HBV infection range anywhere from mild to severe hepatitis, which includes chronic liver problems, such as carcinoma and cirrhosis. As part of the Hepadnaviridae family, HBV is an enveloped, double-stranded DNA virus that is a primary cause of hepatitis transmission through blood. In order to classify hepatitis B infection, the serological markers need to be identified during the three phases of the infection - incubation, acute, and convalescent. The main component of the virus is Hepatitis B core antigen (HBcAg). This core antigen is comprised of a single polypeptide of approximately 17kD that is discharged upon disaggregation of the core particles. At least one immunological determinant is present in the antigen.

Shortly after the onset of HBsAg, antibodies to HBcAg (anti-HBc total antibody and IgM) appear and are always present. In isolated cases, a Hepatitis B infection can be contracted without immunologically detectable anti-HBc. This is found usually in immunosuppressed patients. During the acute stages of hepatitis infection, particles of anti-HBc IgM synthesis are detectable. This presence confirms reactivation of HBV in hepatocites and causes permanent IgM low titers. The presence of IgM and total anti-HBc signifies a recent or ongoing HBV infection. A laboratory diagnosis, or a confirmation of a negative HBV infection, can be reached when this test is performed concurrently with tests for other HBV serological markers.

PRINCIPLE OF THE ASSAY

The principle of the HBcAb IgM ELISA is based on a two-step incubation, solid phase antibody capture ELISA. Polystyrene microwell strips are pre-coated with antibodies intended for human immunoglobulin M proteins (anti-u chain). At the first incubation stage, the serum/plasma of the patient is added. At this point, any IgM-class antibodies will be captured inside the wells. Next, wash out IgG-class antibodies and any other sample components. It is at this time that the specific anti-HBc IgM captured on the solid phase is identified by the addition of purified HBcAg, which is marked with anti-HBc monoclonal antibody conjugated to horseradish peroxidase (HRP-Conjugate). At the time of the second incubation, the HRP-conjugated antigens will only react with anti-HBc IgM antibodies. Chromogen solutions are added, after the wells are washed, to remove the unbound HRP-conjugate.

The colorless chromogens are hydrolyzed by the bound HRP-conjugate and turn to a blue-colored product in the presence of (anti-u chain)-(anti-HBc IgM)-(HBcAg-Ab (HRP)) immunocomplex. After the reaction is stopped with sulfuric acid, the blue color turns yellow. The color intensity can be gauged proportionally to the amount of antibody captured in the wells, and to the amount in the sample, respectively. Colorless wells appear when samples are negative for anti-HBc IgM.

Assay principle scheme: Antibody Capture ELISA

Ab(p)+IgM(s)→[Ab(p)–IgM(s)]+ENZ→[Ab(p)–IgM(s)–ENZ]→blue→yellow (+)
Ab(p) →[Ab(p)]+ENZ→[Ab(p)]→ no color (-)

Incubation1	**Incubation2**	**Immobilized Complex**	**Coloring Results**
30min.	30 min.		15 min.

Ab(p)–pre-coated anti-IgM antibodies (anti-μ chain);

IgM(s)–anti-HBc IgM antibodies in sample;
ENZ– HRP conjugated HBcAg labeled with antibody;

COMPONENTS


96 Tests

- **MICROWELL PLATE** 1plate
  Blank microwell strips fixed on white strip holder.
  The plate is sealed in aluminium pouch with
  desiccant. 8×12/12×8-well strips per plate.
  Each well contains anti-IgM antibodies (anti-μ chain).
  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℃.
- **NEGATIVE CONTROL** 1vial
  Yellowish liquid filled in a vial with green screw cap.
  0.5ml per vial.
  Protein-stabilized buffer tested non reactive for anti-HBc IgM.
  Preservatives: 0.1% ProClin 300. Ready to use as supplied.
  Once open, stable for one month at 2-8°C.
- **POSITIVE CONTROL** 1vial
  Red-colored liquid filled in a vial with red /orange screw cap.
  0.5ml per vial.
  anti-HBc IgM antibodies diluted in protein-stabilized buffer.
  Preservatives: 0.1% ProClin 300.
  Ready to use as supplied.
  Once open, stable for one month at 2-8°C.

- **HRP-CONJUGATE REAGENT** 1vial (12ml)
  Red-colored liquid filled in a white a vial with red / orange screw cap.
  Horseradish peroxidase-conjugated purified HBcAg, labeled
  with monoclonal anti-HBc.
  Ready to use as supplied.
  Once open, stable for one month at 2-8°C.
- **STOCK WASH BUFFER** 1bottle
  Colorless liquid filled in a clear bottle with white screw cap.
  50 ml per bottle.
  PH 7.4 20 × PBS (Contains Tween-20 as a detergent).
- **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℃.
- **CHROMOGEN SOLUTION A** 1vial
  Colorless liquid filled in a white vial with green screw cap.
  7ml per vial.
  Urea peroxide solution.
  Ready to use as supplied.
  Once open, stable for one month at 2-8°C.

- **CHROMOGEN SOLUTION B** 1vial
  Colorless liquid filled in a Black vial with Black screw cap.
  7ml per vial.
  TMB solution.(Tetramethylbenzidine dissolved in citric acid).
  Ready to use as supplied.
  Once open, stable for one month at 2-8°C.
- **STOP SOLUTION** 1vial
  Colorless liquid filled in a white vial with white screw cap.
  7ml per vial.
  Diluted sulfuric acid solution (2.0M H_2SO_4).
- **PLASTIC SEALABLE BAG** 1unit
  For enclosing the strips not in use.
- **CARDBOARD PLATE COVER** 2sheets
  To cover the plates during incubation and prevent evaporation or contamination of the wells.
- **PACKAGE INSERTS** 1copy

ADDITIONAL MATERIALS AND INSTRUMENTS REQUIRED BUT NOT PROVIDED

1. Freshly distilled or deionized water.
2. Disposable gloves and timer.
3. Appropriate waste containers for potentially contaminated materials.
4. Disposable V-shaped troughs.
5. Dispensing system and/or pipette (single or multichannel), disposable pipette tips.
6. Absorbent tissue or clean towel.
7. Dry incubator or water bath, 37±0.5℃.
8. Microshaker for dissolving and mixing conjugate with samples.
9. Microwell prate reader, single wavelength 450nm or dual wavelength 450nm and 630nm.
10. Microwell aspiration/wash system.
11. Normal saline solution for dilution of the samples.

SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE

1. **Sample Collection:** Either fresh serum or plasma samples can be used for 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 hemolysis of the RBC. Care should be taken to ensure that the serum samples are clear and not contaminated by microorganisms. Any visible particulate matters in the sample should be removed by centrifugation at 3000 RPM for at least 20 minutes at room temperature, or by filtration on 0.22u filters. Plasma samples collected into EDTA, sodium citrate or heparin may be tested, but highly lipaemic, icteric, or hemolized samples should not be used as they could give erroneous results in the assay. Do not heat inactivate samples. This can cause sample deterioration.
2. **Transportation and Storage:** Store samples at 2-8℃. Samples not required for a ssaying within 3 days should be stored frozen (-20℃ 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 transport of clinical samples and ethological agents.
3. **Sample preparation:** The samples must be diluted 1:1000 with normal saline

SPECIAL INSTRUCTIONS FOR WAHSING

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. Anyway, we recommend calibrating the washing system on the kit itself in order to match the declared analytical performances. Assure that the microplate washer's 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 solution should be diluted **1 to 20** before use. For one plate, mix 50 ml of the concentrate with 950ml of water for a final volume of 1000ml diluted Wash Buffer. If less than a whole plate is used, prepare the proportional volume of solution.

STORAGE AND STABILITY

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

PRECAUTIONS AND SAFETY

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

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 as to achieve optimal performance during testing.
2. Make sure that all reagents are within the validity indicated on the kit box and are of the same lot. Never use reagents beyond the expiry date stated on reagents labels or on the kit box.
3. **CAUTION - CRITICAL STEP:** Allow the reagents and samples to stabilize at room temperature (18-30℃) before use. Shake reagent gently be fore, and return to 2-8℃ 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 microwell reading.
6. When reading the results, ensure that the plate bottom is dry and there are no air-bubbles inside the wells.
7. 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.

8. Avoid assay steps long time interruptions. Assure same working conditions for all wells.
9. Calibrate the pipette frequently to assure the accuracy of samples/reagents dispensing. Always use different disposal pipette tips for each specimen and reagents as to avoid cross-contaminations. Never pipette solutions by mouth.
10. The use of automatic pipettes is recommended.
11. Assure that the incubation temperature is 37℃ inside the incubator.
12. When adding samples, avoid touching the well's bottom with the pipette tip.
13. When reading the results with a plate reader, it is recommended to determine the absorbance at 450nm or at 450nm with reference at 630nm.
14. All specimens from human origin should be considered as potentially infectious.
15. Materials from human origin may have been used in the kit. These materials have been tested with tests kits with accepted performance and found negative for antibodies to HIV ½, 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. Strict adherence to GLP (Good Laboratory Practice) regulations can ensure the personal safety. Never eat, drink, smoke, or apply cosmetics in the assay laboratory.
16. Bovine derived sera may have been used in this kit. Bovine serum albumin (BSA) and fetal calf sera (FCS) are derived from animals from BSE/TSE free-geographical areas.
17. The pipette tips, vials, strips and sample containers should be collected and autoclaved for 1hour at 121℃ or treated with 10% sodium hypochlorite for 30minutes to decontaminate before any further steps for disposal.
18. The Stop solution (2M H_2SO_4) is a strong acid. Corrosive. Use it with appropriate care. Wipe up spills immediately or wash with water if come into contact with the skin or eyes. ProClin 300 used as a preservative can cause sensation of the skin.
19. The enzymatic activity of the HRP-conjugate might be affected from dust, reactive chemical, and substances like sodium hypochlorite, acids, alkalins etc. Do not perform the assay in the presence of such substances.
20. Materials Safety Data Sheet (MSDS) available upon request.
21. If using fully automated microplate processing system, 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.

ASSAY PROCEDURE

Step1 Reagents Preparation: Allow the reagents and samples to reach room temperature (18-30℃) for at least 15-30minutes. Check the Wash buffer concentrate for the presence of salt crystals. If crystals have formed in the solution, resolubilize by warming at 37℃ until crystals disso lve. Dilute the Wash Buffer **1 to 20** with distilled or deionized water. Use only clean vessels to dilute the Wash buffer. 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 or 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.

Step2 Adding Sample: Add **100µl** of samples and 100µl Positive and Negative controls and into their respective wells. **Note: Use a separate disposal pipette tip for each specimen, Negative and Positive Controls as to avoid cross-contamination.**

Ste3 Sample Incubation(1): Cover the plate with the plate cover and incubate for **30minutes** at **37℃** . It is recommended to use thermostat-controlled water tank to assure the temperature

stability and humidity during the incubation. If dry incubator is used, do not open the door frequently.

Step4 Washing(2): At the end of the incubation, remove and discard the plate cover. Wash each well **5** times with diluted Washing buffer. Each time allow the microwells to soak for **30-60seconds**. After the final washing cycle, turn down the plate onto blotting paper or clean towel and tap it to remove any remaining liquids.

Step5 Adding HRP Conjugate: Add **100µl** of HRP-Conjugate Reagent into each well except for the Blank.

Step6 HRP-Conjugate Incubation(2): Cover the plate with the plate cover and incubate for **30minutes at 37℃** .

Step7 Washing(2): Remove and discard the plate cover. Aspirate the liquid and rinse each well **5times** with Wash buffer **(as step 5)**. After the final washing cycle, turn the strip plate and tap out any remainders.

Ste8 Coloring: Add **50µl** of Chromogen A and **50µl** Chromogen B solution into each well including the **Blank**. 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 anti-HBc IgM positive sample wells.

Step9 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 anti-HBc IgM positive sample wells.

Step10 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 5minutes after stopping the reaction). If positive, dilute sample at 1:1000 and re-test.

INTERPRETATION OF RESULTS AND QUALITY CONTROL

Each microplate should be considered separately when calculating and interpreting results of the assay, regardless of the number of plates concurrently processed. The results are calculated by relating each sample's optical density (OD) 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 OD value from the print report values of samples and controls. In case the reading is based on dual filter plate reader, do not subtract the Blank well OD from the print report values of samples and controls.

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

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

Example of Cut-off Calculation:

1. Calculation of Nc:

Well No	B1	C1	D1
Negative controls OD values	0.02	0.012	0.016

Nc=0.016 (Nc is lower than 0.05 so take it as 0.05)

2. Calculation of Cut-off value (C.O)=0.05 x 2.1=0.105

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.

2. Quality control range:

The test results are valid if the Quality Control criteria are verified. 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.

1. The OD value of the Blank well, which contains only Chromogens and Stop solution, is less than 0.080 at 450 nm.
2. The OD value of the Positive control must be equal to or greater than 0.800 at 450/630nm or at 450nm after blanking.
3. The OD value of the Negative control must be less than 0.100 at 450/630nm or at 450nm after blanking.

3. Interpretations of the results:

(S = the individual absorbance (OD) of each specimen)

Negative Results (S/C.O. <1): samples giving absorbance less than the Cut-off value are negative for this assay, which indicates that no IgM-class antibodies to hepatitis B core antigen have been detected with this anti-HBc IgM ELISA kit. Therefore, there are no serological evidences for resent infections with HBV and the patient is probably not infected with the virus.

Positive Results (S/C.O.≥1): samples giving an absorbance greater than, or equal to the Cut-off value are initially reactive, which indicates that IgM-class antibodies to hepatitis B core antigen have probably been detected with this anti-HBc IgM ELISA kit. Any reactive samples should be retested in duplicates. Repeatedly reactive samples could be considered positive for anti-HBc IgM. Positive results with anti-HBc IgM detection indicate possible recent infection with HBV.

Borderline (S/CO =0.9-1.1): Samples with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline samples and retesting of these samples in duplicates is recommended. Repeatedly positive samples can be considered positive for anti-HBc IgM.

The result from this assay should not be used alone to establish the infection state.

TEST PERFORMANCE AND EXPECTED RESULTS

The **clinical specificity** of this assay has been determinate by a panel of samples obtained from 2500 healthy blood donors and 230 undiagnosed hospitalized patients. The repeatedly reactive samples and samples confirmed positive with the reference test were not included in the calculation of specificity.

The **clinical sensitivity** of this anti-HBc IgM ELISA kit has been calculated by a panel of samples obtained from 548 hepatitis B patients with well-characterized clinical history based upon reference assays for detection of HBsAg, HBeAg, anti-HBs, anti-HBe, and anti-HBc. This panel included samples from acute, chronic and recovered hepatitis B patients. Licensed anti-HBc IgM ELISA test was used as a confirmatory assay. The evaluation results are given below. Results obtained in individual laboratories may differ.

Specificity	Samples	-	+	Confirmed positive	Specificity	False pos.
Donors	2500	2492	8	5	99.87%	3
Patients	230	210	20	20	100%	0
TOTAL	2730	2702	28	25	99.93%	3
Sensitivity	**Samples**	**-**	**+**	**Confirmed positive**	**Sensitivity**	**False neg.**
Acute	318	3	314	315	99.68%	1
Chronic	128	110	18	18	100%	0
TOTAL	446	113	332	333	99.84%	1
Recovery	102	101	1	1	100%	0

Marker prevalence in follow up of patients infected with HBV:

Days Since infection	Number of samples	+	-	Detected prevalence of anti-HBc IgM
0	10	2	8	20%
1-10	12	3	8	25%
11-20	13	4	7	30%
21-30	9	8	1	88%
31-50	9	9	0	100%
51-70	14	14	14	100%
71-100	11	11	11	100%
101-120	8	8	8	100%
121-150	3	3	3	100%
151-170	2	1	1	50%
171-200	1	0	1	0%
Total:	92	63	29	68.48%

Analytical Specificity:

1. No cross reactivity observed with samples from patients infected with HAV, HCV, HIV, CMV, TP, and HTLV.
2. No interferences from rheumatoid factors up to 2000U/ml were observed during clinical testing. The assay performance characteristics are unaffected from elevated concentrations of bilirubin, hemoglobin, and triolein.

Reproducibility		Within run		Between run	
Specimen Type	No.	Mean OD	CV%	Mean OD	CV%
Weak positive	10	0.352	8.1%	0.302	8.5%
Moderate positive	10	0.884	7.3%	0.805	7.6%
Strong positive	10	1.821	4.6%	1.783	5.1%
Positive control	10	2.0	4.3%	1.958	4.4%

LIMITATIONS

1. Non- repeatable reactive results may be obtained with any ELISA test due to the general characteristics of this diagnostic method. A negative result with an antibody detection test does not preclude the possibility of infection. Antibodies could also be undetectable during the early stages of the disease and in some immunosuppressed individuals.
2. 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.
3. Any positive results must be interpreted in conjunction with the patient clinical information and other laboratory results.
4. Common sources for mistakes: kits beyond the expiry date, bad washing procedures and wrong washing buffer concentration, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add samples or reagents, equipment, timing, volumes, sample nature and quality.
5. The prevalence of the marker will affect the assay's predictive values.
6. False negative results can occur from inhibition of specific IgM in the presence of high titers of specific IgG. The removal of IgG can be helpful to prevent false negative results and methods for this are given elsewhere.

7. This kit is intended ONLY for testing of individual serum or plasma samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
8. This is a qualitative assay and the results can not be used to measure antibodies concentrations.

INDICATIONS OF INSTABILITY OR DETERIORATION OF THE REAGENTS

1. Values of the Positive or Negative controls, which are out of the indicated Quality control range, are indicator 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 classified as due to deterioration or instability of the reagents, immediately substitute the reagents with new ones.
2. If after mixing of the Chromogen A and B solutions into the wells, the, the color of the mixture turns blue within few minutes, do not continue carrying out the testing and replace the reagents with fresh ones.

VALIDITY

Please do not use this kit beyond the expiry date indicated on the kit box and reagent labels.

SUMMARY OF THE ASSAY PROCEDURE:	
Dilute sample with normal saline	**1:1000**
Add sample	**100µl**
Incubate	**30minutes**
Wash	**5 times**
Add HRP-Conjugate	**100µl**
Incubate	**30minuties**
Wash	**5times**
Coloring	**50µl A + 50µl B**
Incubate	**15minutes**
Stop the reaction	**50µl stop solution**
Read the absorbance	**450nm or 450/630 nm**

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