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	 See external label		 96 Tests	 1870-12
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AccuDiag™ HDV IgG ELISA

Cat # 1870-12

Test	HDV IgG ELISA
Method	Enzyme Linked Immunosorbent Assay
Principle	Indirect ELISA: Antigen Coated Plate
Sample	10 ul
Specificity	100%
Sensitivity	100%
Total Time	~ 80 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 DAI HDV-IgG ELISA achieved.*

INTENDED USE

DAI HDV-IgG ELISA is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG antibodies to hepatitis D virus in human serum or plasma. It is intended for use in clinical laboratory for diagnosis and management of patients related to infection with hepatitis D virus.

SUMMARY

Hepatitis D is a liver diseases caused by Hepatitis D virus (Delta agent) – a defective (36 nm – 43 nm) enveloped RNA virus, which requires co-infection with Hepatitis B virus (HBV) for its replication. Transmitted percutaneously or sexually through contact with infected blood or blood products, HDV is associated with the most severe forms of chronic and acute hepatitis in many Hepatitis B – HBsAg positive patients. Since the infection with HDV requires infection with HBV, the development of the disease depends on whether the two viruses infect simultaneously (coinfection) or whether the newly infected HDV patient is also a chronic HBV carrier (superinfection). The co-infection with HDV can lead to severe acute hepatitis disease with low risk of chronic stage development. Chronic HBV carrier patients superinfected with HDV are at risk to develop chronic HDV disease, which can lead to cirrhosis in 70%-80% of the patients. The serological diagnosis of HDV is based on detection of specific HDV antibodies (anti-HDV) or antigens. The anti-HDV IgG antibodies are indicator of past or current delta infection. High titers of the antibodies may be indicative of chronic or active infection. During HBV-HDV, co-infection detectable concentrations of anti-HDV IgG appear after the tenth week of exposure to the viruses and clearance during convalescence indicates recovery. During HDV superinfection, detectable levels of antibodies appear four to six weeks after exposure and failure to clear indicate possible progression to long, chronic carrier stage.

PRINCIPLE OF THE ASSAY

The DAI HDV IgG ELISA is based on solid phase, two-step incubation indirect ELISA method. Polystyrene microwell strips are pre-coated with recombinant HDV antigens. During the first incubation step, anti-HDV specific antibodies, if present, will be bound to the solid phase pre-coated HDV antigens. The wells are washed to remove unbound serum proteins, and anti-human IgG antibodies (anti-IgG) conjugated to the enzyme horseradish peroxidase (HRP-Conjugate) are added. During the second incubation step, these HRP-conjugated antibodies will be bound to any antigen-antibody(IgG) complexes previously formed and the unbound HRP-conjugate is then removed by washing. Chromogen solutions containing Tetramethylbenzidine (TMB) and urea peroxide are added to the wells and in presence of the antigen-antibody-anti-IgG(HRP) 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 antibody captured in the wells, and to the amount of antibody in the sample respectively. Wells containing samples negative for HDV IgG remain colorless.

COMPONENTS

In Vitro Diagnostic Only. This kit contains reagents sufficient for testing of maximum of 91 specimens in a test run.



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 recombinant HDV antigen.
 The microwell strips can be broken to be used separately.

Place unused wells 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.

- **NEGATIVE CONTROL** 1vial
 Blue-colored liquid filled in vial with green screw cap 0.5 ml per vial
 Protein- stabilized buffer tested non-reactive for HDV IgG.
 Preservatives: 0.1% ProClin 300.
 Ready to use as supplied. Once open, stable for 4 weeks at 2-8°C.
- **POSITIVE CONTROL** 1vial
 Red-colored liquid filled in a vial with red screw cap. 0.5 ml per vial
 Purified anti-HDV IgG antibodies 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.
- **HRP-CONJUGATE REAGENT** 1vial
 Red-colored liquid filled in a white vial with red screw cap.12 ml per vial.
 Horseradish peroxidase-conjugated anti-human IgG antibodies.
 Preservatives: 0.1% ProClin 300.
 Ready to use as supplied. Once open, stable for 4 weeks at 2-8°C.
- **SPECIMEN DILUENT** 1vial
 Blue-colored liquid filled in a white vial with blue crew cap.12ml per vial.
 Buffer solution containing protein.
 Preservatives :0.1% ProClin 300.
 Ready to use as supplied. Once open, stable for 4 weeks at 2-8°C.
- **STOCK WASH BUFFER** 1bottle
 Colorless liquid in a white bottle with white screw cap.
 50ml per bottle PH 7.4 20× PBS (Containing Tween-20 as a detergent).
DILUTE BEFORE USE The concentrate 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
 when stored at 2-8°C.
- **CHROMOGEN SOLUTION A** 1vial
 Colorless liquid filled in a white vial with green screw cap. 7 ml per vial.
 Urea peroxide solution. Ready to use as supplied.
 Once open, stable for 4 weeks at 2-8°C.
- **CHROMOGEN SOLUTION B** 1vial
 Colorless liquid filled in a black vial with black screw cap. 7 ml per vial.
 TMB (Tetramethyl benzidine) solution.
 Ready to use as supplied. Once open, stable for 4 weeks at 2-8°C.
- **STOP SOLUTION** 1vial
 Colorless liquid filled in a white vial with yellow screw cap. 7 ml per vial
 Diluted sulfuric acid solution (0.5M H₂SO₄). Ready to use as supplied.
- **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 INSERT** 1 copy

ADDITIONAL MATERIALS AND INSTRUMENTS REQUIRED BUT NOT PROVIDED

Freshly distilled or deionized water, disposable gloves and timer, appropriate waste containers for potentially contaminated materials, dispensing system and/or pipette, disposable pipette tips, absorbent tissue or clean towel, dry incubator or water bath, $37\pm 1^{\circ}\text{C}$, plate reader, single wavelength 450nm or dual wavelength 450/630nm, microwell aspiration/wash system.

SPECIMEN COLLECTION, TRANSPORTATION AND STORAGE

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 HDV-IgG 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 $2-8^{\circ}\text{C}$. Specimens not required for assaying within 1 week 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.

STORAGE AND STABILITY

The components of the kit will remain stable through the expiration date indicated on the label and package when stored between $2-8^{\circ}\text{C}$, do not freeze. To assure maximum performance of DAI HDV-IgG ELISA kit, during storage protect the reagents from contamination with microorganism or chemicals.

PRECAUTIONS AND SAFETY

To be used only from qualified professionals

The ELISA assay is time and temperature sensitive. 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 ($18-30^{\circ}\text{C}$) before use. Shake reagent gently before use. Return at $2-8^{\circ}\text{C}$ 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. ProClin™ 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 Diagnostic Automation, Inc. technical support for further assistance.

ASSAY PROCEDURE

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**.

1. **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.
2. **Adding Diluent:** Add **100µl** of Specimen Diluent into each well except the Blank.

3. **Adding Sample:** Add **10µl** of Positive control, Negative control, and Specimen into their respective wells except the Blank. **Note: Use a separate disposal pipette tip for each specimen, Negative Control, Positive Control to avoid cross-contamination. Mix by tapping the plate gently.**
4. **Incubating:** Cover the plate with the plate cover and incubate for **30 minutes at 37°C.**
5. **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Wash Buffer. Each time allow the microwells to soak for **30-60 seconds.** After the final washing cycle, turn down the plate onto blotting paper or clean towel, and tap it to remove any remainders.
6. **Adding HRP-Conjugate:** Add **100µl** of HRP-Conjugate into each well except the Blank.
7. **Incubating:** Cover the plate with the plate cover and incubate for **30 minutes at 37°C.**
8. **Washing:** At the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Wash Buffer. Each time allow the microwells to soak for **30-60 seconds.** After the final washing cycle, turn down the plate onto blotting paper or clean towel and tap it to remove any remainders.
9. **Coloring:** Add **50µl** of Chromogen A and **50µl** of Chromogen B solutions into each well including the Blank. Incubate the plate at **37°C for 15 minutes avoiding light.** The enzymatic reaction between the Chromogen solutions and the HRP-Conjugate produces blue color in Positive control and HDV IgG positive sample wells.
10. **Stopping Reaction:** Using a multichannel pipette or manually, add **50µl** of Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and HDV IgG positive sample wells.
11. **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).

INSTRUCTION FOR WASHING

1. A good washing procedure is essential in order 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 of 350-400µl/well are sufficient to avoid false positive reactions and high background.
3. To avoid cross-contaminations of the plate with specimen 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 carry out **5 washing cycles**, dispensing 350-400µl/well and aspirating the liquid for **5** times. 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 at a final concentration of 2.5% for 24 hours, before they are wasted in an appropriate way.
7. The concentrated Wash buffer should be diluted **1 to 20** before use. If less than a whole plate is used, prepare the proportional volume of solution.

QUALITY CONTROL AND CALCULATION OF THE RESULT

Each microplate should be considered separately when calculating and interpreting the results, regardless of the number of plates concurrently processed. The results are calculated by relating each sample 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.

Calculation of Cut-off value (C.O.) = *Nc + 0.12

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

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 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 450nm)

Well No.:	B1	C1	D1
Negative control 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: = $(0.020+0.012+0.016)/3 = 0.016$

3. Calculation of the Cut-off: (C.O.) = $0.016 + 0.12 = 0.136$

INTERPRETATIONS OF THE RESULTS

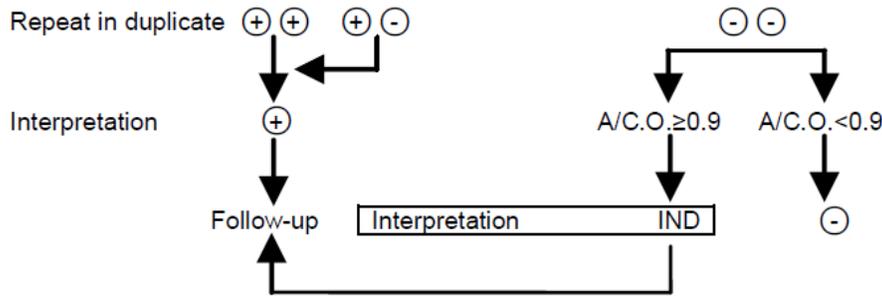
Negative Results (S/C.O. <1): Specimens giving A value less than the Cut-off value are negative for this assay, which indicates that no IgG antibodies to HDV have been detected with DAI HDV-IgG ELISA. Therefore, there are no serological indications for possible current infection with hepatitis D virus.

Positive Results (S/C.O. ≥ 1): Specimens giving A value equal to or greater than the Cut-off value are considered initially reactive, which indicates that IgG antibodies to HDV have probably been detected with DAI HDV-IgG ELISA. Any initially reactive samples should be retested in duplicates. Repeatedly reactive samples could be considered positive for IgG antibodies to HDV. Therefore, there are indications for possible current infection with hepatitis D virus..

Borderline (S/CO =0.9-1.1) : Specimens with A value 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.

**INITIAL RESULTS INTERPRETATION AND FOLLOW-UP
ALL INITIALLY REACTIVE OR BORDERLINE SAMPLES**



IND = non interpretable

- 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 ELISA assays, false positive results can occur due to the several reasons, most of which are connected with, but not limited to, inadequate washing step. For more information regarding DAI ELISA Troubleshooting, please refer to DAI's "ELISAs and Troubleshooting Guide".
- 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 IgG antibodies to HDV and therefore the patient is probably infected with HDV.
- 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.

PERFORMANCE CHARACTERISTICS

This kit has been standardized using anti-HDV quality control positive sera obtained from HDV positive patients with well-characterized clinical conditions.

1. **Sensitivity:** The clinical sensitivity of this assay has been calculated by a panel of samples obtained from 2500 hepatitis B acute and chronic patients. In this panel, 2400 samples were found HBsAg positive. After testing with HDV RT-PCR, 150 individuals were diagnosed infected with HDV. After testing with this HDV IgG ELISA kit, 48 of the RT-PCR confirmed hepatitis D positive samples were found positive for HDV IgG and 48 samples were confirmed HDV IgG positive when tested with another commercially available HDV antibody ELISA kit. The sensitivity was determinate to be 100%.

2. **Specificity:** The clinical specificity of this assay has been evaluated by a panel of samples from 500 healthy individuals. No false positive results observed, which indicates 100% specificity of the test.

3. Analytical Specificity:

No cross reactivity was observed with specimens from patients infected with HAV, HCV, HIV, HBV, HTLV, CMV, and TP.

No interference was observed from rheumatoid factors up to 2000U/ml during clinical testing.

The assay performance characteristics are unaffected from elevated concentrations of bilirubin, hemoglobin, and triolein.

Frozen specimens have been tested too to check for interferences due to collection and storage.wan

LIMITATIONS



1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient clinical information.
2. Antibodies may be undetectable during the early stage of the disease and in some immunosuppressed individuals. Therefore, negative results obtained with DAI HDV-IgG ELISA are only indication that the sample does not contain detectable level of IgG antibodies to HDV and any negative result should not be considered as conclusive evidence that the individual is not infected with HDV.
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. For more information regarding DAI ELISA Troubleshooting, please refer to DAI's "ELISAs and Troubleshooting Guide", or contact DAI technical support for further assistance.
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 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.
7. This kit is a qualitative assay and the results cannot be used to measure antibody concentration.

REFERENCES:

1. Purcell RH and Gerin JL, Hepatitis Delta virus. In: Fields Virology, 3rd ed. Philadelphia, Lippincott-Raven, 1996
2. Hadziyannis SJ. Hepatitis delta: an overview. In: Rizzetto M, Purcel RH, Gerin JL, and Verme G, eds. Viral hepatitis and liver disease, Turin, Edizoni Minerva medica, 1997
3. Lai MCC. The molecular biology of hepatitis Delta virus. Annual Review of Biochemistry, 1995 64:259-286
4. Centers for Disease Control and Prevention. Epidemiology and Prevention of Viral Hepatitis A to E: An Overview 2000

SUMMARY OF THE ASSAY PROCEDURE:

Add sample diluent	100µl
Add sample/controls	10µl
Incubate	30 minutes
Wash	5 times
Add HRP-Conjugate	100µl
Incubate	30 minutes
Wash	5 times
Coloring	50µl A + 50µl B
Incubate	15 minutes
Stop the reaction	50µl stop solution
Read the absorbance	450nm or 450/630nm

SUMMARY OF THE MAJOR COMPONENTS OF THE KIT:



Microwell plate	One/ 96 well
Negative/Positive control	One each/ 0.5ml
HRP-Conjugate	One/ 12ml
Sample diluent	One/ 12ml
Wash Buffer	One/ 50ml
Chromogen A/B	One each/7ml
Stop Solution	One each/7ml

Date Adopted	2017-07-21
Reference No. 1870-12	DAI- AccuDiag™ HDV IgG ELISA
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