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RUO	See external label	2°C-8°C	Σ=96 tests	REF Cat # 1520-12

AccuDiag™ HIV 1&2 Ag/Ab ELISA

4th Generation

Cat # 1520-12

"Export Use Only"

Test	HIV 1&2 Ag/Ab
Method	ELISA: Enzyme Linked Immunosorbent Assay
Principle	ELISA: Sandwich; Double antigen & Antibody
Detection Range	Qualitative : Positive, negative and cutoff calibrators
Sample	100 µL serum
Specificity	100%
Sensitivity	100%
Total Time	~ 105 min
Shelf Life	12 -18 Months

***** *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 **HIV 1, 2 Ab/Ag ELISA Test** is an ELISA kit that distinguishes itself as a fourth generation ELISA for HIV detection. The HIV 1, 2 Ab/Ag ELISA kit is an enzyme-linked immunosorbent assay for the qualitative identification of antigens or antibodies to HIV (Human Immunodeficiency Virus) type 1 and/or type 2 in human serum/plasma. The purpose of the HIV 1,2 Ab/Ag ELISA kit is for blood donor screening and as an aid in the clinical diagnosis of HIV infection as it is related to AIDS (Acquired Immunodeficiency Syndrome)."Export Use Only"

SUMMARY

Serological evidence of infection with HIV may be procured by testing for presence of HIV antigens or antibodies in serum of patients suspected of HIV infection. It is important to isolate HIV from AIDS, ARC (AIDS related complex) and patients with high risk for AIDS. Initial infection with HIV usually leads to acute flu-like illness and its relation with AIDS at this stage is not always known. Because HIV 1 and 2 are the causing agents of AIDS and its related conditions, acute phases of HIV infection can lead to an asymptomatic carrier stage, which then progresses to clinical AIDS in approximately 50% of infected patients within ten years after seroconversion. During both acute phase and symptomatic phase of AIDS, HIV antigens can be detected. Through the entire infection period (from acute phase through ending stages of AIDS) antibodies to HIV 1 and/or HIV 2 can be detected.

The HIV 1, 2 Ab/Ag ELISA Kit has high sensitivity and specificity, and involves a simple operation procedure. HIV can be present in cellular and cell-free fractions of human blood, and because the main path of infection with HIV involves blood transfusion (aside from sexual transmission), donated blood or plasma should be tested for HIV contamination. The HIV 1, 2 Ab/Ag ELISA kit is the most suitable for testing high volume blood screening specimens. Worldwide, these HIV ELISA kits are used in routine blood screening and clinical diagnosis.

The first HIV ELISA tests were commercially available in 1985 and since that time three more generations of tests have been established. The first generation of HIV ELISA kits were involved with viral lysate antigens which originated with viruses grown in human T-lymphocyte lines. High rates of false-positives resulted because of traces of host cell components where the virions propagated could give rise to cross contamination.

Improved HIV ELISA kits evolved with the cloning of the HIV genome. These ELISA kits became immediately available and were based on recombinant proteins and/or synthetic peptides - known as second generation. Having these biotechnology methods available allowed predominant expression of important immunoreactive regions of the proteins. Thus, more combined HIV-1/HIV-2 ELISA tests were produced. What also occurred was the production of larger and purer amounts of recombinant antigen. This resulted in their being bonded to the solid-phase surface with much tighter control over protein ratios and concentrations. These first and second generation HIV ELISA kits were based on indirect ELISA. Only through an enzyme-labeled anti-human IgG antibody, could they identify IgG antibodies.

Third generation HIV ELISA kits used a different method. These HIV ELISA tests could identify all antibodies, for example IgG and IgM, which greatly increased the ELISA test's sensitivity compared to previous first and second generation. These third generation ELISA kits used a double antigen sandwich method where antibodies were identified because the solid phase polystyrene plates were coated with antigens, and with the aid of another enzyme-labeled antigen. These third generation HIV ELISA kits would identify antibodies in a much shortened window period (the time in which there is no detectable antibody production). Detection was 11 days sooner than second generation for

detection of IgM antibodies which are only present during the early stages of infection.

Fourth generation HIV ELISA kits further reduced the window period of antibody identification. Since becoming commercially available in 1998, fourth generation HIV ELISAs can detect HIV antigens (p24) and antibodies simultaneously. Thus, with the identification of HIV antigens (p24), these new HIV ELISA kits shortened the window period to 16 days. As a result, HIV infection was detected 8 days earlier than the previous third generation ELISA tests.

PRINCIPLE OF THE ASSAY

The principle of the HIV 1 & 2 Ab/Ag ELISA kit is a two-step incubation, sandwich enzyme immunoassay. In this assay, anti-HIV (p24) antibodies are pre-coated on the polystyrene microwell strips along with recombinant HIV antigens (recombinant HIV-1gp41, gp120, and recombinant HIV-2gp-36). Before the first incubation stage, biotinylated anti-HIV (p24) antibodies are added to the wells, together with the patient's serum/plasma sample. If any specific HIV 1/2 antibodies are present in the sample, they will be captured inside the wells at the time of first incubation. At the same time, what will also be captured is the HIV p24 antigen (if present). This capture is considered a double antibody sandwich complex which is comprised of the coated antibodies-p24 bioitinylated antibodies. After this, unbound serum proteins are washed from the microwells.

During the second incubation stage, enzyme Horseradish Perioxidase (HRP) is added in order to detect the captured HIV p24 antigen-biotinylated antibody complex (or HIV 1/2 antibodies). The HRP has been conjugated to second HIV 1 & 2 recombinant antigens and to avidin.

Detection of p24: After p24 has been captured inside the wells, avidin will react with the biotin and attach the HRP to the Ab-p24-Ab complex.

Detection of HIV 1/2 antibody: After HIV 1/2 antibodies have been captured inside the wells, these captured antibodies will bind to the HRP-conjugated antigens, forming Ag-Ab-Ag(HRP) sandwich immunocmplex.

After these stages, the unbound conjugate is removed by washing the microwells. Added to the wells at this point are the chromogen solutions. A blue-colored product is produced when the chromogens are hydrolyzed by the bound HRP in wells containing the Ag-Ab-Ag (HRP) and/or Ab-per-Ab(HRP) sandwich immunocomplexes. After stopping the reaction with sulfuric acid, the blue color turns yellow. The color intensity can be gauged proportionally to the amount of antibodies or p24 captured in the wells, and to the sample, respectively. Colorless wells appear when the samples are negative for anti-HIV 1/2 or p24.

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 wells per plate. Each well contains recombinant HIV 1/2 antigens and anti-p24 antibodies. 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.
- **NEGATIVE CONTROL** 1vial
  Yellowish liquid filled in a vial with green screw cap 1ml per vial. Protein-stabilized buffer tested non-reactive for HIV 1/2.

Preservatives: 0.1% ProClin 300.
Ready to use as supplied.
Once open, stable for one month at 2-8°C.

- **ANTIBODY POSITIVE CONTROL-1 (HIV 1)** 1vial
  Red-colored liquid filled in a vial with red screw cap 1ml per vial
  Antibodies to HIV 1 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
- **ANTIBODY POSITIVE CONTROL-2 (HIV 2)** 1vial
  Red-colored liquid filled in a vial with yellow screw cap. 1ml per vial
  Antibodies to HIV 2 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.
- **ANTIGEN POSITIVE CONTROL** 1vial
  Red-colored liquid filled in a vial with blue/brown screw cap. 1ml per vial
  HIV p24 recombinant antigen 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 REAGENTS** 1vial
  Red-colored liquid filled in a white vial with red/orange screw cap.
  12ml per vial, Horseradish peroxidase conjugated HIV 1/2 antigens.
  Horseradish peroxidase conjugated avidin.
  Ready to use as supplied.
  Once open, stable for one month at 2-8° C.
- **BIOTIN-CONJUGATE REAGENT** 1vial
  Blue liquid filled in a vial with blue screw cap. 3.5ml per vial
  Biotinylated anti-HIV p24 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.
- **STOCK WASH BUFFER** 1bottle
  Colorless liquid filled in a clear 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 at 2-8℃.
- **CHROMOGEN SOLUTION A** 1vial
  Colorless liquid filled in a white vial with green screw cap. 6ml 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/brown screw cap. 6ml per vial,
  TMB solution (Tetramethyl benzidine 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 yellow/white screw cap. 6ml per vial,
  Diluted sulfuric acid solution (2.0M $H_2 2SO_4$).
- **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 plate reader, single wavelength 450nm or dual wavelength 450nm and 630nm.
10. Microwell aspiration/wash system.

SPECIMEN COLLECTION , TRANSPORTING 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.

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 of 350-400µl/well are sufficient to avoid false positive reactions and high background.
3. To avoid cross-contaminations of the plate with sample or HRP-conjugates, 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 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 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 liquids are wasted in an appropriate way.
7. The concentrated Washing solution should be diluted **1 to 20** before use. For one plate, mix 50ml 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 HIV (1+2) Ag&Ab 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 bef ore, 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. The use of automatic pipettes is recommended.
10. Assure that the incubation temperature is 37℃ inside the incubator.
11. When adding samples, avoid touching the well's bottom with the pipette tip.
12. When reading the results with a plate reader, it is recommended to determine the absorbance at 450nm or at 450nm with reference at 630nm.
13. All specimens from human origin should be considered as potentially infectious.
14. 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.
15. 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.
16. The pipette tips, vials, strips and sample containers should be collected and autoclaved for 1hour at

121℃ or treated with 10% sodium hypochlori te for 30 minutes to decontaminate before any further steps for disposal.

17. 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.
18. The enzymatic activity of the HRP-conjugates 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.
19. Materials Safety Data Sheet (MSDS) available upon request.
20. 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, resolubilize by warming at 37℃ until crystals dissolve. Dilute the Wash Buffer **1 to 20** with distilled or deionized water. Use only clean vessels to dilute the buffer.

Step2 Numbering Wells: Set the strips needed in strip-holder and number sufficient number of wells including three Negative controls **(e.g.B1, C1, D1)**, three Positive controls (one for HIV1, one HIV2 and one for HIV Ag controls- (**e.g. E1, F1,G1)** and one Blank **(e.g. A1**, neither samples nor HRP-Conjugate should be added into the Blank well). Use only number of strips required.
- If the results will be determined by using dual wavelength plate reader, the requirement for use of Blank well could be omitted.
- Where appropriate, the requirement for use HIV-2 positive control could be omitted.

Step3 Adding Biotin-conjugated reagent: Add 20µl of biotinylated anti-HIV p24 antibodies into each well except in the Blank.

Step4 Adding Samples: Add **100µl** of Positive controls, Negative controls, and Specimen into their respective wells. **(Note: to avoid cross-contamination use a separate disposable pipette tip for each specimen, Negative or Positive Control).**

Step5 Incubating(1): Cover the plate with the plate cover and incubate for **60 minutes 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.

Step6 Washing(1): 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 the plate down onto blotting paper or clean towel, and tap it as to remove any remaining liquids.

Step7 Adding HRP-Conjugate: Add **100µl** HRP-Conjugates into each well except in the Blank.

Step8 Incubating(2): Cover the plate with the plate cover and incubate for **30minutes** at **37℃.**

Step9 Washing(2): After the end of the incubation, remove and discard the plate cover. Wash each well **5 times** with diluted Wash buffer as in **Step5.**

Step10 Coloring: Dispense **50µl** of Chromogen A and **50µl** Chromogen B solution into each well including the **Blank**, cover the plate with plate cover 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 produces blue color in positive control and HIV 1/2 positive for antigens/antibodies sample wells.

Step11 Stopping Reaction: Remove and discard the plate cover. Using a multichannel pipette or manually, add **50µl** Stop Solution into each well and mix gently. Intensive yellow color develops in Positive control and HIV 1/2 positive for antigens/antibodies sample wells.

Step12 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 **15minutes** after stopping the reaction)

INTERPRETATION OF RESULTS AND QUALITY CONTROL

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'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 the Cut-off value: C.O. = *Nc + 0.12

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

Example:

1. Calculation of Nc:

Well No:	B1	C1	D1
Negative controls OD value:	0.032	0.031	0.027

Nc=0.030

2. Calculation of Cut-off: (C.O)=0.030+0.12=0.150

If one of the Negative control values does not meet the Quality control range specifications, it should be discarded and the mean value calculating 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 HIV 1/2 antibodies or p24 antigen have been detected with this HIV (1+2) Ag&Ab ELISA kit, therefore the patient is probably not infected or the blood unit do not contain antibodies to HIV 1/2 or p24 antigen and could be transfused.

Positive Results (S/C.O.≥ 1): Samples giving an absorbance equal to or greater than the Cut-off value are considered initially reactive, which indicates that HIV 1/2 antibodies and/or p24 antigen have probably been detected using this HIV (1+2) Ag&Ab ELISA kit. Retesting in duplicates of any initially reactive sample is recommended. Repeatedly reactive samples could be considered positive for antibodies or p24 antigen to HIV 1/2 and therefore the patient is probably infected with the virus. Any blood unit containing antibodies/antigens to HIV should be immediately discarded. **Borderline (S/C.O. =0.9-1.1) :** Samples with absorbance to Cut-off ratio between 0.9 and 1.1 are considered borderline and retesting of these samples in duplicates is recommended to confirm the results. Repeatedly positive samples could be considered positive for antibodies or p24 antigen to HIV 1/2. Follow-up and supplementary testing of any positive samples with other analytical system (e.g. WB, PCR) is required before establishing of the final diagnosis.

The **analytical sensitivity** of this kit for HIV p24 antigen detection is about 5pg/ml.

LIMITATIONS

1. Non-repeatable positive result may occur due to the general biological characteristics of the ELISA method. The assay is designed to achieve very high performance characteristics of sensitivity and specificity and the "sandwich" model minimizes the unspecific reactions due to interference with unknown matters in sample. Antibodies or p24 may be undetectable during the early stages of the disease and in some immunosuppressed individuals.
2. Any positive results should be confirmed with another available method and interpreted in conjunction with the patient clinical information.
3. Common sources for mistakes are: kits beyond the expiry date, bad washing procedures, contaminated reagents, incorrect assay procedure steps, insufficient aspiration during washing, failure to add samples or reagents, equipment, timing, volumes, sample nature and quality.
4. The prevalence of the marker will affect the assay's predictive values.
5. 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.
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. The assay cannot distinguish between infections with HIV-1 and HIV-2.
8. The assay cannot distinguish between positive antibody and positive p24 antigen results.
9. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

INDICATIONS OF INSTABILITY 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 expiration indicated on the kit box and reagent labels.

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