Murex HIV Ag/Ab Combination

Enzyme immunoassay for improved detection of seroconversion to human immunodeficiency virus types 1 (HIV-1, HIV-1 group O) and detection of anti-HIV-2 antibodies.

The assay is intended to screen individual human donors for the presence of HIV p24 antigen and antibodies to HIV-1, including group O, and HIV-2 or as an aid to the diagnosis of HIV infection.

Customer Service
For additional product information, please contact your local customer service organization.

This instructions for use must be read carefully prior to use. The instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.
INTENDED USE
Enzyme immunoassay for improved detection of seroconversion to human immunodeficiency virus type 1 (HIV-1, HIV-1 group O) and detection of HIV-2 antibodies.
The assay is intended to screen individual human donors for the presence of HIV p24 antigen and antibodies to HIV. Identifying group O and HIV-2 at an early stage in the diagnosis of HIV infection.

SUMMARY AND EXPLANATION OF THE TEST
Two types of human immunodeficiency virus, HIV-1 and HIV-2, have been described and implicated as causes of the Acquired Immunodeficiency Syndrome (AIDS). Both are retroviruses which are transmitted by exposure to certain infected body fluids, primarily blood and genital secretions, and by transfusional passage. Infection by HIV-1 has been reported worldwide, HIV-2 infection has been reported as occurring mainly in West Africa and some European countries.
The two types of virus show substantial antigenic cross-reactivity in their gag and pol proteins, but the envelope glycoproteins are less cross-reactive.

It is necessary for screening purposes to use epitopes from the envelope proteins of both viruses in addition to major cross-reacting gag or pol proteins to ensure detection of antibodies against both types of virus at all stages following infection. Variants of HIV-1, classified as group O, have been identified in samples from Cameroon and Europe. Group O is highly divergent from the originally known subtypes of HIV-1. Group O is classified as group M. Specific epitopes from the Envelope region of the virus can be used to detect antibody to group O in infected individuals; reliance on cross-reactive to the known subtypes of HIV is not satisfactory. The earliest specific antibody responses following infection by HIV may be of immunoglobulin M (IgM) followed by a response in immunoglobulin G (IgG). Maximum sensitivity for detection of anti-HIV seroconversion is achieved by assays which respond to both IgM and IgG, whilst HIV core antigen is typically detectable during a short period prior to antibody seroconversion.

Matrix HIV Ag(Ag) Combination is designed to detect reactive HIV core antigen in addition to IgG, IgM and IgA to the envelope glycoprotein and the core reacting pol proteins of HIV-1 and HIV-2. Consequently, potentially infectious samples of serum, EDTA plasma or clotted plasma can be identified.

PRINCIPLE OF THE PROCEDURE
Matrix HIV Ag(Ag) Combination is based on microwells coated with synthetic peptide representing immunoreactive regions of HIV-1 (O) and HIV-2, recombinant proteins derived from the envelope regions of HIV-1 and HIV-2 and HIV pol protein, together with monoclonal antibodies raised against p24 of HIV-1. The Conjugate is a mixture of the same antigen epitopes, and different monoclonal antibodies, also raised against p24, all labelled with horseradish peroxidase.

Two specimens and control sera are incubated in the wells and reactive HIV core and/or antibodies to HIV in the sample or control sera bind to the antibodies and/or antigens on the microwell sample and any excess antibodies are then washed away. In a subsequent step, Conjugate is added which in turn binds to any reactive HIV core and/or specific antibody already bound to the reagents on the well. Samples not containing reactive core antigen or specific antibody will not cause the Conjugate to bind to the wells.

Unbound Conjugate is washed away and a solution containing 3,3',5,5'- tetramethylbenzidine (TMB) and hydrogen peroxide is added to the wells. Wells with bound Conjugate develop a blue green colour which is compared to an orange colour which may be used as a control after the reaction has been stopped with sulphuric acid.

REAGENTS
DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS
See also Warnings and Precautions.

1. Coated Wells
One plate (TGF19-09) or five plates (TGF19-11) of 96 microwells coated with HIV antigens and monoclonal antibodies.
Allow the wells to reach room temperature (18 to 30°C) before removal from the bag.
Place unused wells in the sealed storage bag provided and return to 2 to 8°C.

2. Sample Diluent
One bottle containing 8 ml (TGF19-09) or 18 ml (TGF19-11) of a green/frozen buffer solution, bovine and murine protein, detergent and preservatives. Contains 0.016% ProClin® 300 preservative.

3. Conjugate
One bottle (TGF19-09) or three bottles (TGF19-11) containing 1.1 ml of HIV antigens and monoclonal antibodies conjugated to horseradish peroxidase and freeze dried. When reconstituted each bottle is sufficient for up to two plates.

4. Conjugate Diluent
One bottle (TGF19-09) or three bottles (TGF19-11) containing 22ml of a yellow solution containing al buffer, bovine protein, safranin and detergent, sufficient to reconstitute one bottle of Conjugate. Contains 0.1% ProClin® 300 preservative.

Reconstitution of Conjugate
Tap the bottle of Conjugate gently on the bench to remove any material adhering to the rubber stopper. Pour the whole contents of the bottle of conjugate diluent into the bottle of conjugate, recap the stopper and mix by gentle inversion. Allow to rehydrate for at least 30 minutes with occasional swirling. The reconstituted conjugate will be red in colour. Reconstituted conjugate may be returned to and pooled in the plastic conjugate diluent bottles if required.

5. Anti-HIV Positive Control
One bottle containing 17 ml of inactivated human serum in a buffer containing bovine protein. Contains 0.05% ProClin® preservative.

6. Anti-HIV2 Positive Control
One bottle containing 17 ml of inactivated human serum in a buffer containing bovine protein. Contains 0.05% ProClin® preservative.

7. HIV-1 p24 Positive Control
One bottle containing 17 ml of p24 (recombinant antigen) in a buffer containing bovine protein. Contains 0.05% ProClin® preservative.

8. Negative Control
Two bottles containing 2.5 ml of normal human serum diluted in a bovine protein buffer. Contains 0.05% ProClin® preservative.
9. Substrate Dihuant
One bottle containing 35 ml of a colourless solution of tri-sodium citrate and hydrogen peroxide.

10. Substrate Concentrate
One bottle containing 35 ml of 3,3',5,5'-tetramethylbenzidine (TMB) and stabilizers in an orange solution.

Substrate Solution
To prepare the Substrate Solution add a volume of colourless Substrate Dihuant to an equimolar volume of orange Substrate Concentrate in either a clean glass or plastic vessel.

It is important that this order of addition is followed and that any pipettes and glassware used to prepare Substrate Solution are clean. Alternatively, the Substrate Solution may be made by pouring the entire contents of the bottle of Substrate Dihuant into the bottle of Substrate Concentrate. One bottle of Substrate Solution provides sufficient reagent for at least five plates.

- Table 1:

<table>
<thead>
<tr>
<th>Volume of Substrate Concentrate and Substrate Dihuant Required</th>
<th>Number of Plates</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 10 24 32 40 48 66 96 104 120 144 168 192</td>
<td>1 2 3 4</td>
</tr>
</tbody>
</table>

11. Wash Fluid
One (Q79 09) or two (Q79 11) bottles containing 256 ml of 20 times working strength Glycine/ Borate Wash Fluid. Contains 0.2% Boric acid preservative.

Add one volume of Wash Fluid Concentrate to 10 volumes of distilled or deionized water to give the required volume or dilute the entire contents of one bottle of Wash Fluid to a final volume of 256 ml. Crystals may be observed in the Wash Fluid Concentrate but these will dissolve when the Wash Fluid is diluted to working strength. When diluted the Wash Fluid contains 0.01% Boric acid preservative.

The Wash Fluid from this kit may be used interchangeably with the Glycine/Borate Wash Fluid from any other Muras kit.

Store the working strength Wash Fluid at 18 to 30°C in a closed vessel under which conditions it will retain activity for one month.

NOTE: The Wash Fluid may develop a yellow colour on storage. This will have no effect on the performance of the assay provided the Wash Fluid is fully aspirated from the wells.

NOTE: Although the Substrate Solution and Wash Fluid are interchangeable, they must not be used beyond the expiry date printed on the component labels.

WARNINGS AND PRECAUTIONS

**IVD**

The reagents are for in vitro diagnostic use only.

For professional use only.

Please refer to the manufacturer’s safety data sheet and the product labelling for information on potentially hazardous components.

Low levels of formic acid may be observed in the kit Controls and product performance is not affected by this. This is a product of certain assays batches used to manufacture the controls.

HEALTH AND SAFETY INFORMATION

CAUTION: This kit contains components of human origin. The human sera used for manufacture have been screened and found reactive or non-reactive for analysis as shown in Table 2 below.

- Table 2:

<table>
<thead>
<tr>
<th>Component</th>
<th>Reactive for</th>
<th>Non-reactive for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control</td>
<td>N/A</td>
<td>HBsAg, antibodies to HCV, HIV-1 and HIV-2</td>
</tr>
<tr>
<td>Positive Control 1</td>
<td>antibodies to HCV</td>
<td></td>
</tr>
<tr>
<td>Positive Control 2</td>
<td>antibodies to HIV-2</td>
<td></td>
</tr>
<tr>
<td>Positive Control 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additionally, human sera used for positive controls are also tested for antibodies to HCV and may be reactive.

All reagents used have been inactivated prior to use in reagent preparation. However, all material of human origin should be considered as potentially infectious and it is recommended that this kit and test specimens be handled using established good laboratory practice.

Pursuant to EC Regulation 1782/2002 (10)(P): In vitro diagnostic reagents are classified and labelled as follows:

- **Warning**
  - Skin sens.: 1.1017

**Symbols & Pictograms**

- **Hazard Statement**: R391: May cause an allergic skin reaction
- **Precautionary Statement**: P280 Wear protective gloves/protective clothing/eye protection/face protection
- **P363 Wash contaminated clothing before reuse. P332+P313 If skin irritation or rash occurs: Get medical advice/attention.**

- **Containers**: Reaction mass of: 1-hydroxy-3-methyl-4-[4-(4-methyl-1H-imidazol-2-yl)-1H-imidazol-5-yl]benzene ± 0.1% PicoGlut 300 which is classified hazardous per EC Regulation 1272/2008.
Residues: SUBSTANCE | CONC.

ClassIonization: Eye irrit. (9.49)

Signal Word: Warning

Symbols / Phrases:

Hazard Statement: P404 Close airtight eye/face irritation;
P338 Wear protective gloves/protective clothing;
P337+P319+P338 F: IN EYES: Wash eyes with several minutes. Remove contact lenses if present and easy to do. Continue

Purport to EC Regulation 1907/2006 (CLP). WASH EYES & FLUSH is labelled as EUH271, safety data sheets available on www.chemical.com

1. Potentially contaminated materials should be disposed of safely according to local requirements.

2. Spillage of potentially infectious material should be removed immediately with absorbent paper tissue and the contaminated area sterilized for, for example, 10% sodium hypochlorite before work is continued. Sodium hypochlorite should not be used on acid containing spills unless the spill area is first wiped dry.

Materials used to clean spills, including gloves, should be disposed of as potentially hazardous waste. Do not contain neutralized waste containing sodium hypochlorite.

3. Neutralized acids and other liquid waste should be decontaminated by adding a sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to 1.0% sodium hypochlorite may be necessary to remove effective decontamination.

4. Do not pipette by mouth. Wear protective gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

5. If any of the reagents come into contact with the skin or eyes wash the area extensively with water.

6. Sulphuric acid required for the Stop Solution and hydrochloric acid used for washing glassware are corrosive and should be handled with appropriate care. If either comes into contact with the skin or eyes wash thoroughly with water.

ANALYTICAL PRECAUTIONS:

1. Do not use the reagents beyond the stated expiry date. Microbiological contamination of reagents must be avoided as this may reduce the life of the product and cause erroneous results.

2. Do not modify the Test Procedure or substitute reagents from other manufacturers or in other lots unless the reagent is stipulated as interchangeable. Do not replace any of the recommended incubation times.

3. Allow all reagents and samples to come to 18 to 20°C before use.

4. Immediately after use return reagents to the recommended storage temperature.

5. Any glassware to be used with the reagents should be thoroughly washed with 2N hydrochloric acid and then rinsed with distilled water or high quality deionized water.

6. Avoid the use of self-decating freezers for the storage of reagents and samples.

7. Do not expose reagents to strong light or high hypochlorite fumes during storage or during incubation steps.

8. Do not allow wells to become dry during the assay procedure.

9. Do not cross-contaminate reagents. Dilute a pipette for use with the Substrate Solution of enzyme assays. A pipette should also be dedicated for use with the Controls.

10. The Sample Diluent in this assay has the potential to cause false positive results in anti-hepatitis B surface antigen (anti-HBs) assays if reagent cross contamination occurs.

11. Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate.

12. Do not contaminate microwells with dust from disposable gloves.

13. When using fully automated processors:

(a) It is not necessary to use plate lids and top dry the wells.

(b) Do not allow system fluids to contaminate samples or reagents.

(c) The possibility of cross contamination between assay needs to be included when validating assays on fully automated processors.

14. Ensure the assay is run within the temperature limits defined in the assay protocol.

15. Do not use CO2 incubators.

16. Do not store the Stop Solution in a shallow dish or return it to a stock bottle after use.

17. The possibility of cross contamination between assays needs to be included when validating assay protocols on instrumentation.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE:

1. Serum, EDTA plasma or citrate plasma samples may be used. Ensure that the serum samples are fully clotted. Remove any visible particulate matter from the sample by centrifugation. If samples are prepared using liquid anti-coagulants e.g. citrate plasma, the dilution effect should be considered.

SPECIMEN TRANSPORT AND STORAGE:

Store samples at 2 to 6°C. Samples not required for assay within 72 hours should be removed from the ice or cold pack and stored frozen at -18°C or colder.

Avoid multiple freeze-thaw cycles After thawing reverse samples are thoroughly mixed before testing.

PROCEDURE:

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Stop Solution (0.5 M to 2M Sulphuric Acid), e.g. add between 3.0 ml (for 0.5M) and 11 ml (for 2.0M) of analytical grade concentrated sulphuric acid (18M) to about 80 ml of distilled or deionised water and then make up to 100 ml with more water. Alternatively, the following reagent can be used: 1N Sulphuric Acid (Code No164), in 1:10 dilution. 114 ml of 1.2

2. Freshly distilled or high quality deionised water is required for dilution of Wash Fluid, for preparation of the Stop Solution and for use in conjunction with automated washers.

3. Microliterettes and Multichannel microtiterettes of appropriate volume.

4. Incubator capable of maintaining the temperature limits defined in the assay protocol.

5. Modified Herring Block (Code SF002-02). For use in laboratory incubators. The modified herring block should ideally be kept in the incubator used. If this is not possible it must be placed in the incubator at least four hours before beginning the assay.

6. Instrumentation:

(a) Automated microplate strip washer.

(b) Microplate reader.

(c) Fully automated microplate processor.

7. All instruments must be validated before use.

Please contact your representative for details of recommended systems, software protocols for instrumentation and validation procedures.

Disposable Reagent Trays (Code SF24-01).

8. Sodium hypochlorite for decontamination. (Refer to Health and Safety Information).

9. Sodium hydroxide solution (0.1M). (Refer to Analytical Precautions)
TEST PROCEDURE

Please read Analytical Precautions carefully before performing the test.

Addition of the various components of the assay to the wells may be confirmed visually by examining the plates for the following colours:

Sample Diluent is green/brown in colour. On addition of Sample or Control the colour will change to blue/green. The colour change will vary from sample to sample but some change should always be visible. The addition of sample or control may be confirmed using a microplate reader at 670 nm or 620 nm with a reference of 690 nm.

Conjugate Diluent is red in colour. The addition of Conjugate may be confirmed using a microplate reader at 490 nm with a reference of 590 nm.

Substrate Solution is initially pale yellow with any reactive wells becoming blue green. On addition of Stop Solution the blue green colour of the reagents will change to orange, while the negatives will change to pink. The addition of Substrate Solution may be confirmed using a microplate reader at 450 nm (no reference).

SEM AUTOMATED PROCESSING

Step 1 Reconstitute and mix the Conjugate, prepare the Substrate Solution and Wash Fluid.

Step 2 Use only the number of wells required for the test. Avoid touching the tops or bottoms of the wells.

Step 3 Add 25 μl of Sample Diluent to each well.

Step 4 Add 100 μl of Samples or 100 μl Controls to the wells.

For each plate use the first column of wells for the assay Controls. Add the Controls to the designated wells after dispensing the samples.

Dipette 100 μl of the Negative Control into each of three wells A1 to C1 and 200 μl of the positive and HIV-1 and HIV-2 Positive Controls into wells D1 to F1 respectively. Use of a white background will aid visualisation of sample addition.

Step 5 Cover the wells with the lid and incubate for 20 minutes at 37°C ± 1°C.

Step 6 At the end of the incubation time wash the plate as described under Wash Procedures.

Step 7 Immediately after washing the plate, add 100 μl of Conjugate to each well.

Step 8 Cover the wells with the lid and incubate for 30 minutes at 37°C ± 1°C.

Step 9 At the end of the incubation time wash the plate as described under Wash Procedures.

Step 10 Immediately after washing the plate, add 100 μl of Substrate Solution to each well.

Step 11 Cover the wells with a lid and incubate for 30 minutes at 37°C ± 1°C. Keep away from direct sunlight. A blue green colour should develop in wells containing reactive samples.

Step 12 Add 50 μl of Stop Solution (0.5M to 0.5M sulphuric acid) to each well.

Step 13 Within 15 minutes read the absorbance at 450 nm using 620 nm to 690 nm as the reference wavelength if available. Blank the instrument on air (no plate in the carriage).

WASH PROCEDURES

Protocols for recommended washers and procedures for verifying washers and analyzers can be obtained from your representative. The following protocol is recommended:

a) Protocol for automated stripwasher

Perform 5 wash cycles using working strength Wash Fluid. Ensure, where possible, that:

(i) Flow through washing with a volume of 500 μl/well is used with instrumentation supplied by DiStrix. When using other instrumentation for which this is not possible, ensure that the well is completely filled.

(ii) The dispensing height is set to completely fill the well, with a slight positive meniscus, without causing an overflow.

(iii) The time taken to complete one aspirate/wash/saturate cycle is approximately 30 seconds.

(iv) Ensure that no liquid is left in the well (by use of a double aspirate step in the final cycle where possible).

(v) After washing is completed, invert the plate and tap out any residual Wash Fluid onto absorbent paper.

NOTE: Do not allow the wells to become dry during the assay procedure.

Washers must be rinsed with distilled or deionised water at the end of the test to avoid blockage and corrosion.

FULLY AUTOMATED PROCESSORS

Contact your representative for details of currently available validated protocols. For instrumentation without established validated protocols, the following guidelines are recommended:

1. Do not programme times shorter than specified in the procedure.

2. For each incubation at 37°C, programmed times may be increased by up to 5 minutes.

3. Wells containing Sample Diluent may be left for up to 60 minutes at 19-33°C prior to the addition of Sample and for up to 60 minutes after the addition of samples or Controls before starting step 5 in the assay protocol.

4. Ensure all Analytical Precautions are followed.

Protocols written following these guidelines must be fully validated prior to use according to local procedures.

RESULTS

CALCULATION OF RESULTS

Each plate must be considered separately when calculating and interpreting results of the assay.

Approved software may be used for calculation and interpretation of results.

Negative Control

Calculate the mean absorbance of the Negative Controls.

Example:

Well 1 - 0.084, Well 2 - 0.066, Well 3 - 0.026

Total - 0.246

Mean Negative Control - 0.246/3 - 0.082

If one of the Negative Control Wells has an absorbance more than 0.16 O.D. above the mean of all three, discard that value and calculate the new Negative Control mean from two remaining replicates.

Cut-off value

Calculate the cut-off value by adding 0.169 to the mean of the Negative Control replicates (see above).

Mean Negative Control - 0.082

Cut-off Value - 0.082 + 0.169 - 0.250
QUALITY CONTROL
Results of an assay are valid if the following criteria for the controls are met:

- Negative Control: The mean absorbance is less than 0.15.
- Positive Controls: The absorbance of each of the Positive Controls is more than 0.8 above the mean absorbance of the Negative Control.
- Assays which do not meet these criteria should be repeated.

In the unlikely event of the results repeatedly failing to meet either the Quality Control criteria or the expected performance of the test, please contact your representative.

INTERPRETATION OF RESULTS
Non-reactive Results: Samples giving an absorbance less than the Cut-off value are considered negative in this assay.

Reactive Results: Samples giving an absorbance equal to or greater than the Cut-off value are considered reactive in the assay (see Limitations of the Procedure).

Unless local procedures are otherwise, all samples must be tested in duplicate using the original source. Samples that are reactive in at least one of the duplicate mixes are considered reactive reactive in Murex HIV AgAb Combination and are presumed to contain reactive HIV core antigen and/or antibodies to HIV-1 or HIV-2. Such samples must be further investigated and the results of this assay considered with any other clinical and/or assay information. Samples that are non-reactive in both wells are considered non-reactive for HIV core antigen and HIV antibodies.

No sample addition: Absorbance values significantly higher than the Negative Control may be obtained in wells where the sample has been unblotted but all the reagents have been added.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of the Murex HIV AgAb Combination has been determined by testing samples from random blood donors, patients with AIDS diagnosed according to CDC criteria, patients with AIDS Related Complex (ARC), other patients with known antibody to HIV (including group C), patients with confirmed HIV-2 infection and patients at risk of HIV infection or in other clinical categories. In addition, its performance on commercially available seroconversion panels has been evaluated.

- Diagnostic Sensitivity: A total of 499 specimens from patients with confirmed HIV-1 infection were tested and found to be reactive with Murex HIV AgAb Combination. The specimens were taken from patients at various stages of HIV infection and included 68 specimens from patients with HIV-1 subtype C infection and 28 from patients infected with HIV-1 subtype B and 1 specimen infected with HIV-1 subtype D.

In addition, a total of 100 specimens from patients with confirmed HIV-2 infection were also tested and found to be reactive with Murex HIV AgAb Combination and found to be reactive.

The diagnostic sensitivity of the Murex HIV AgAb Combination on this population of specimens is therefore estimated to be 100% (95/95) with a lower 95% confidence limit of 99.32% (90/90) by the binomial distribution.

- Diagnostic Specificity: A total of 500 commercial HIV-1 seroconversion panels were tested with Murex HIV AgAb Combination. The presence of both core (p24) and an envelope (gp120/160) band on Western blot as the reference criteria. The Murex HIV AgAb Combination detected antibody to HIV earlier or in the same sample as Western blot in all the panels.

- Sensitivity on AFFISAPS HIV Ag standard: Sensitivity of Murex HIV AgAb Combination on the AFFISAPS HIV Ag standard was determined at three testing centres.

The data shown in Table 5 was obtained during this testing but may not be exactly reproducible on other testing occasions.
LIMITATIONS OF THE PROCEDURE
1. The Test Procedure and Interpretation of Results must be followed.
2. This test has only been evaluated for use with individual (unreacted) serum, EDTA plasma, or citrate plasma samples.
3. A negative result with an antigen/antibody detection test does not preclude the possibility of infection with HIV.
4. A positive result with Murex HIV Ag/Ab Combination should be confirmed by at least one other test.
5. Non-repeatable reactive results may be obtained with any EIA procedure.
The most common sources of error are:
   a) Improper delivery of Sample, Conjugate or Substrate into the wells.
   b) Contamination of Substrate with Conjugate.
   c) Contamination of conjugates from other assays.
   d) Blockage or partially blocked washer probes.
   e) Insufficient aspiration leaving a small volume of Wash Fluid in the wells.
   f) Failure to ensure that the bottom surface of the wells is clean and dry, and that no air bubbles are present on the surface of the liquid in the wells before a plate is read.
   g) Failure to read at the correct wavelength (450 nm) or use of an incorrect reference wavelength (not 620 nm to 680 nm).
6. The use of highly haemolysed samples, incompletely clotted sera, plasma samples containing fibrin or samples with microbial contamination may give rise to erroneous results.
7. This test has not been evaluated for use with samples from cadavers.

BIBLIOGRAPHY

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EGD3541GB

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