DiaSorin

The Diagnostic Specialist

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Murex anti-HCV (version 4.0)

An enzyme immunoassay for the detection of antibodies to hepatitis C virus (HCV) in human serum or plasma

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.

IVD

Key to symbols used

REF	List Number	IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number	2°C 8°C	Store at 2-8°C
	Expiration Date		CAUTION: Consult accompanying documents
EC REP	Authorised Representative		Consult instructions for use
	Manufacturer		

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

INTENDED USE

Murex anti-HCV (version 4.0) is an enzyme immunoassay for the detection of antibodies to hepatitis C virus (HCV) in human serum or plasma.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C (HCV) is now recognised as the primary cause of transfusion associated NANB hepatitis[1]. HCV is a single stranded positive-sense RNA virus sharing similarity with flaviviruses and pestiviruses[2,3] and is global in distribution. Although the acute presentation of HCV infection is generally mild, often clinically asymptomatic, with only 10 to 25% of patients developing jaundice, greater than 50% of infected individuals go on to develop chronic hepatitis with serious and possibly life threatening sequelae such as cirrhosis and hepatocellular carcinoma[4,5]. Estimates of HCV prevalence in blood donors world-wide range from 0.5 to 8%[6], although with improved sensitivity and specificity of the diagnostic tests and donor selection, declining incidence has been reported. Data suggests that the incidence is from 0.1 to 1.5% in Europe and 0.6% in the USA[7].

Diagnosis of HCV is dependent on the direct detection of viral RNA by PCR or by detection of anti-HCV antibodies. Recombinant DNA techniques have been used to develop structural and non-structural proteins derived from HCV RNA with utility for antibody screening. Anti-HCV assays have evolved from first generation products incorporating NS4 proteins only through to third generation assays incorporating core (structural), NS3 protease/helicase (non-structural), NS4 (non-structural) and NS5 replicase (non-structural) proteins. Studies report that the third generation assays demonstrate significant improvements in sensitivity, particularly with regard to increased reactivity with the NS3 antigen and earlier detection of seroconversion[8].

Murex anti-HCV (version 4.0) utilises antigens from the core, NS3, NS4 and NS5 regions of the virus. Antigens have been carefully developed and selected to provide a sensitive and specific diagnostic test.

PRINCIPLE OF THE PROCEDURE

In Murex anti-HCV (version 4.0) diluted sample is incubated in microwells coated with highly purified antigens which contain sequences from the core, NS3, NS4 and NS5 regions of HCV. During the course of the first incubation any anti-HCV antibodies in the sample will bind to the immobilised antigens. Following washing to remove unbound material, the captured anti-HCV antibodies are incubated with peroxidase conjugated monoclonal anti-human IgG. During the course of the second incubation the conjugate will bind to antibody immobilised in the first step. After removal of excess conjugate, bound enzyme is detected by the addition of a solution containing 3,3',5,5'tetramethylbenzidine (TMB) and hydrogen peroxide. A purple colour will develop in the wells which contained anti-HCV positive samples.

The enzyme reaction is terminated with sulphuric acid to give an orange colour which is read photometrically. The amount of Conjugate bound, and hence colour, in the wells, is directly related to the concentration of antibody in the sample.

REAGENTS

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

See also **Warnings and Precautions.**

All components must be stored at 2 to 8°C, unless otherwise stated, under which condition they will retain activity until the expiry date of the kit.

COATED | WELLS

1. Coated Wells

One plate (7F51-06) or five plates (7F51-07) each made up of 96 microwells coated with purified HCV antigens.

Allow the wells to reach 18 to 30°C before removing from the bag. If less than the whole plate is being used, reseal unused strips in the original foil storage bag or in the plastic snap seal bag provided along with the desiccant sachet and return to 2 to 8°C for up to 6 months after the first opening.

SAMPLE | DIL

2. Sample Diluent

One bottle of 20 ml (7F51-06), or one bottle of 100 ml (7F51-07) of buffer containing proteins of bovine origin. Contains 0.05% Bronidox® and 0.1% Sodium azide as preservatives.

CONTROL | − | ⚠

3. Negative Control

One bottle containing 0.8 ml of normal human serum diluted in a buffer containing protein of bovine origin. Contains 0.05% Bronidox® preservative.

CONTROL | + | ⚠

4. Anti-HCV Positive Control

One bottle containing 0.6 ml of inactivated human serum consisting of antibodies to HCV diluted in a buffer containing protein of bovine origin. Contains 0.05% Bronidox® preservative.

CONJUGATE | DIL

5. Conjugate Diluent

One bottle (7F51-06) or three bottles (7F51-07) containing 20 ml of buffer consisting of inorganic salts and bovine protein with 0.05% Bronidox® preservative.

CONJUGATE

6. Conjugate

One bottle (7F51-06) or three bottles (7F51-07) each containing enough freeze dried horseradish peroxidase-labelled mouse monoclonal antibody to human IgG in a bovine protein base to perform 192 tests.

Reconstitute at least 15 minutes prior to use to ensure complete dissolution. Bring a bottle of Conjugate Diluent to room temperature. Tap the bottle of Conjugate gently on the bench to remove any material adhering to the rubber stopper. Carefully remove the stopper and pour the Conjugate Diluent into the bottle. Recap and allow to stand with occasional swirling and inversion.

After reconstitution, store at 2 to 8°C for up to seven days or frozen (−15°C or colder) in aliquots for up to six months. The reconstituted Conjugate can be freeze/thawed up to four times.

SUBSTRATE | DIL

7. Substrate Diluent

One bottle containing 35 ml of a colourless solution of tri-sodium citrate and hydrogen peroxide.

SUBSTRATE | CONC

8. Substrate Concentrate

One bottle containing 35 ml of 3,3',5,5'-tetramethylbenzidine (TMB) and stabilisers in a pink solution.

Substrate Solution

To prepare the Substrate Solution add a volume of colourless Substrate Diluent to an equal volume of pink 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 Diluent into the bottle of Substrate Concentrate. One bottle of Substrate Solution provides sufficient reagent for at least five plates – **see Table 1**.

Table 1
Volume of Substrate Concentrate and Substrate Diluent Required

Number of Wells											Number of Plates			
8	16	24	32	40	48	56	64	72	80	88	1	2	3	4
Substrate Concentrate (ml)														
1.0	1.5	2.0	2.5	2.5	3.0	3.5	4.0	4.5	4.5	5.0	6	12	18	22
Substrate Diluent (ml)														
1.0	1.5	2.0	2.5	2.5	3.0	3.5	4.0	4.5	4.5	5.0	6	12	18	22

Additional reagent may be required for use with automated systems. Keep away from sunlight. The Substrate Solution should be pink; if it is purple before being used, it should be discarded and fresh Substrate Solution prepared.

The prepared Substrate Solution from this kit may be used interchangeably with that from all other Murex kits which use pink coloured Substrate Concentrate. Ensure that the Substrate Solution is prepared from the Substrate Diluent and Substrate Concentrate provided together.

The prepared Substrate Solution is stable refrigerated (2 to 8˚C) or at 15 to 25˚C for up to two days but must be discarded if crystals have formed.

WASH | FLUID

9. Wash Fluid

One (7F51-06) or two bottles (7F51-07) containing 125 ml of 20 times working strength Glycine/Borate Wash Fluid. Contains 0.2% Bronidox® preservative.

Add one volume of Wash Fluid concentrate to 19 volumes of distilled or deionised water to give the required volume or dilute the entire contents of one bottle of Wash Fluid to a final volume of 2500 ml. Crystals may be observed in the Wash Fluid Concentrate but these crystals will dissolve when the Wash Fluid is diluted to working strength. When diluted the Wash Fluid contains 0.01% Bronidox® preservative.

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

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 analytes as shown in **Table 2** below.

Table 2

Component	Reactive for	Non-reactive for
Negative Control	N/A	antibodies to HCV, HIV (types 1 and 2), and HBsAg
Positive Control	antibodies to HCV	HBsAg and antibodies to HIV (types 1 and 2)

All reactive serum used has 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.

Information for European customers: For product not classified as dangerous per European Directive 1999/45/EC - Safety Data Sheet available for professional user on request.

1. Potentially contaminated materials should be disposed of safely according to local requirement.
2. Spillage of potentially infectious material should be removed immediately with absorbent paper tissue and the contaminated area swabbed with, for example, 1.0% sodium hypochlorite before work is continued[9]. 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 biohazardous waste. Do not autoclave materials containing sodium hypochlorite.
3. Neutralised 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 ensure effective decontamination.
4. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.
5. The following reagents contain low concentrations of harmful substances:
   a) The Sample Diluent contains saponin and detergents.
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 come into contact with the skin or eyes, wash thoroughly with water.
7. If any of the reagents come into contact with the skin or eyes, wash the area extensively 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 other lots unless the reagent is stipulated as interchangeable. Do not reduce any of the recommended incubation times.
3. Allow all reagents and samples to come to 18 to 30˚C before use. Immediately after use return all reagents to the recommended storage temperature.
4. Any glassware to be used with the reagents should be thoroughly washed with 2M hydrochloric acid and then rinsed with distilled water or high quality deionised water.
5. Avoid the use of self-defrosting freezers for the storage of reagents and samples.
6. Do not expose reagents to strong light or hypochlorite fumes during storage or during incubation steps.
7. Do not allow wells to become dry during the assay procedure.
8. Do not cross-contaminate reagents. Dedicate a pipette for use with the Substrate Solution of Murex assays. A pipette should also be dedicated for use with the Conjugate.
9. Do not touch or splash the rim of the well with Conjugate. Do not blow out from micropipettes; reverse pipetting is recommended wherever possible.
10. 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.
11. Do not contaminate microwells with dust from disposable gloves.
12. When using fully automated microplate processors:
    i) It is not necessary to use plate lids and to tap dry the wells.
    ii) Do not allow system fluids from fully automated microplate processors to contaminate the samples or reagents.
    iii) The possibility of cross contamination between assays needs to be excluded when validating assays on fully automated processors.
13. Cross contamination between assays needs to be considered when validating assays protocols on automated microplate processors.
14. Ensure the assay is run within the temperature limits defined in the assay protocol.
15. Do not use CO_2 Incubators.
16. Do not store the Stop Solution in a shallow dish nor return it to a stock bottle after use.
17. It is important that samples and controls are thoroughly mixed with the Sample Diluent. Failure to do this may cause erroneous results. Adequate mixing can be achieved by:
    a) Manual mixing by pipetting up and down at least four times when adding samples or controls.
    b) Placing the plate on a microplate shaker at a speed of 800 rpm for 30 seconds.

    Users of automatic sample dispensers may find it convenient to add 90 µl of Sample Diluent to the wells, followed by 20 µl of Sample then the remaining 90 µl of Sample Diluent. This procedure will ensure adequate mixing.
18. The possibility of cross contamination between assays needs to be excluded when validating assay protocols on instrumentation.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

SPECIMEN COLLECTION

Serum, EDTA plasma, citrate plasma or heparin plasma samples may be used. Blood collected by venepuncture should be allowed to clot naturally. 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-coagulant e.g. citrate plasma, the dilution effect should be considered.

SPECIMEN TRANSPORT AND STORAGE

Store samples at 2 to 8˚C. Samples not required for assay within seven days should be removed from the clot or cell pellet and stored frozen (-15˚C or colder). Avoid multiple freeze-thaw cycles. After thawing, ensure samples are thoroughly mixed before testing.

PROCEDURE

MATERIALS REQUIRED BUT NOT PROVIDED

1. **Stop Solution (0.5M to 2M Sulphuric Acid)** e.g. add between 3 ml (for 0.5M) and to 11 ml (for 2.0M) of analytical grade concentrated sulphuric acid (18.0 M) 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 N0164).
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. **Micropipettes and Multichannel micropipettes** of appropriate volume.
4. **Incubator** capable of maintaining the temperature limits defined in the assay protocol.
5. **Moulded Heating Block** (code 5F09-02). For use in laboratory incubators. The moulded heating 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. I**nstrumentation**
    a) Automated microplate strip washer.
    b) Microplate reader.

    or

    c) Fully automated microplate processor.

    All instruments must be validated before use.

    Please contact your representative for details of recommended systems, software protocols for instrumentation and validation procedures.
7. **Disposable Reagent Troughs**. (Code No. 5F24-01).
8. **Sodium hypochlorite** for decontamination. **(Refer to Health and Safety Information)**.

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 plate for the following colours.

Sample Diluent is green/brown in colour. On addition of the Sample or Control the colour will change to blue/green. The colour change may vary from sample to sample but some change should always be visible.

Conjugate is brown in colour.

Substrate Solution is initially pink with any positive wells becoming purple. On addition of **Stop Solution** the purple colour of the positives will change to orange, whilst the negatives remain pink.

The addition of sample or reagent can be confirmed using a microplate reader as follows: Sample Diluent plus Sample read at 620 nm or 570 nm with a reference at 690 nm, Conjugate at 410 nm with a reference at 690 nm, Substrate Solution at 490 nm (no reference).

SEMI AUTOMATED PROCESSING

Step 1	**Reconstitute** the Conjugate with **Conjugate Diluent** and prepare the **Substrate Solution** and dilute the **Wash Fluid**.	
Step 2	Use only the **number of strips** required for the test.	
Step 3	**Add** 180 µl of **Sample Diluent** to each well.	**180 µl**
Step 4	**Add** 20 µl of **Samples** or **Controls** to the wells. If using two strips or less pipette one Negative Control to well A1 and one Positive Control to well B1. If using more than two strips it is recommended that two wells of Negative Control are used for additional security. Add the Controls to the designated wells on each plate after dispensing the samples. The use of a white background will aid visualisation of sample addition. Samples and Controls must be thoroughly mixed with the Sample Diluent.	**20 µl**
Step 5	Cover the wells with the lid and **incubate** for 1 hour at 37˚C ± 1˚C.	**1 hour**
Step 6	At the end of the incubation period **wash** the **plate** as described under **Wash Procedures**.	
Step 7	Immediately after washing the plate, **add** 100 µl of **Conjugate** to each well.	**100 µl**
Step 8	Cover the wells with the lid and **incubate** for 30 minutes at 37˚C ± 1˚C.	**30 mins**
Step 9	At the end of the incubation period wash the plate as described under **Wash Procedures**.	
Step 10	Immediately after washing the plate, **add** 100 µl of **Substrate Solution** to each well.	**100 µl**
Step 11	Cover the wells with a lid and **incubate** for exactly 30 minutes at 37˚C ± 1˚C while colour develops. Keep away from direct sunlight. A purple colour should develop in wells containing positive samples.	**30 mins**
Step 12	**Add** 50 µl of **Stop Solution** (0.5M to 2M sulphuric acid) to each well.	**50 µl**
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).	**450 nm**

WASH PROCEDURES

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

a) **Protocol for automated microplate stripwasher**

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

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

(ii) The dispense 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/soak 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 water at the end of the test to avoid blockage and corrosion.

FULLY AUTOMATED MICROPLATE PROCESSORS

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

1. For the first incubation, incubation times between 60 and 70 minutes (or 65 ± 5 minutes) may be programmed.
2. For the 30 minute incubations, incubation times between 30 and 35 minutes (or 32.5 ± 2.5 minutes) may be programmed.
3. Ensure all **'Analytical Precautions'** are followed. Protocols written following these guidelines must be fully validated prior to use according to local procedure.

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

If using duplicate Negative Controls calculate the mean.

Example:

Well 1 = 0.086, Well 2 = 0.094,
Total = 0.180
Mean = 0.180/2 = 0.090

Discard any Negative Control value which is >0.25.

Cut-off Value

Calculate the Cut-off value by adding 0.6 either to the Negative Control or to the mean of the Negative Control replicates (see above).

Example:

Mean Negative Control = 0.090
Cut-off value = 0.090 + 0.600 = 0.690

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 0.25.

Positive Control

The absorbance 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 THE RESULTS

Non-Reactive Results

Samples giving an absorbance less than the Cut-off value are considered negative in the assay.

Reactive Results

Samples giving an absorbance equal to or greater than the Cut-off value are considered initially reactive in the assay. Such samples must be retested in duplicate using the original source. Samples that are reactive in at least one of the duplicate retests are considered repeatedly reactive and are presumed to contain antibody to HCV antigens. Unless local procedures state otherwise these samples must be further investigated.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of Murex anti-HCV (version 4.0) has been determined by testing samples from random blood donors, patients with known antibody to HCV, patients with diseases related to HCV and patients with diseases unrelated to HCV.

In addition, its performance on commercially available seroconversion panels has been evaluated.

1. **Donor Samples**

   A total of 8835 routine donor samples were screened with Murex anti-HCV (version 4.0) in Europe and Australia.

   In the study, 99.82% (8819/8835) of samples were non-reactive, 0.18% (16/8835) were initially reactive and 0.12% (11/8835) were repeatedly reactive. None of the repeatedly reactive samples have been confirmed as positive for the presence of antibody to HCV.

   The specificity of Murex anti-HCV (version 4.0) on this population of presumed negative samples is estimated to be 99.88% (8824/8835) with a 95% confidence interval of 99.77% (8815/8835) to 99.94% (8830/8835) by the binomial distribution.

2. **Clinical Samples**

   A total of 69 samples with antibody to HCV, confirmed with an alternative immunoassay, Ortho RIBA3 and/or Western blot, were reactive with Murex anti-HCV (version 4.0).

   A total of 27 commercially available HCV seroconversion panels were also tested with Murex anti-HCV (version 4.0). Comparison with an alternative commercially available immunoassay for the detection of antibody to HCV showed that Murex anti-HCV (version 4.0) detected antibody two bleeds earlier in four panels, one bleed earlier in three panels, one bleed later in three panels and at the same bleed in 17 panels.

   In addition, 873 potentially cross-reactive samples from patients with conditions unrelated to HCV infection, including other acute viral infections, antenatal, lipaemic, icteric and haemolysed samples, were tested with Murex anti-HCV (version 4.0). A total of 869 of these samples were non-reactive with Murex anti-HCV (version 4.0), the remaining four samples included two which gave indeterminate results with Ortho RIBA3.

3. **Assay Reproducibility**

   Five replicates of each of four samples were tested on ten separate occasions with two separate batches to ascertain the reproducibility of Murex anti-HCV (version 4.0). The results of the study are summarised in Table 3 and Table 4

Table 3
Murex anti-HCV (version 4.0) - Assay Reproducibility (Batch 1)

Specimen	Number of Assays	Mean Absorbance/ Cut-off Value	Intra-assay %CV	Inter-assay %CV
1	10	4.03	2.9	3.9
2	10	3.9	4.6	5.2
3	10	2.33	3.1	6.9
4	10	0.14	3.9	10.2

Table 4
Murex anti-HCV (version 4.0) - Assay Reproducibility (Batch 2)

Specimen	Number of assays	Mean Absorbance/ Cut-off value	Intra-assay % CV	Inter-assay % CV
1	10	3.22	6.5	9.1
2	10	3.14	7.2	9.2
3	10	1.69	5.2	9.5
4	10	0.13	4.0	8.4

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 (unpooled) serum, EDTA plasma, heparin plasma or citrate plasma samples.
3. A negative result with an antibody detection test does not preclude the possibility of infection.
4. Non-repeatable reactive results may be obtained with any EIA procedure.
5. The most common sources of error are:
   a) Imprecise delivery of Sample, Conjugate or Substrate into the wells.
   b) Contamination of Substrate with Conjugate.
   c) Contamination with conjugates from other assays.
   d) Blocked 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 or use of an incorrect reference wavelength.
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.

See also **'Analytical Precautions'.**

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