(IgA)

Kit for the quantitative determination of IgA in human serum

- Immunoturbidimetric method-

REF			
SPE22			INTERMEDICAL

PRINCIPLE OF THE TEST

The additionally, in a precise ratio, the serum containing IgA (antigen) to a solution that contains the corresponding antiserum (antibody), determines a turbidity that allows, from the OD value, to easily determine the concentration of antigen present in the sample.

SAMPLES

Fresh serum

If you cannot run the test in the day, the sample can be stored for 48 hours at 2-8 ° C or longer if frozen.

REAGENTS

Reagents: liquid and ready to use

Essential that the reagents, when in use, are at room temperature.

REAGENT PREPARATION

R1: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, PEG, Sodium azide 0.1%, detergents and stabilizers.

R2: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, anti-human IgA antibody (Goat), Sodium azide 0.1%, detergents and stabilizers.

PRECAUTIONS

Every time infectious agents, chemical reagents, human or animal reagents, blood or other body fluids, it is advisable to follow the common recommendations and take all the necessary hygiene precautions such as the use of disposable gloves.

STORAGE AND STABILITY 'PRODUCT

Store the kit at 2 - 8 ° C.

The reagents, if used and maintained in accordance with good laboratory practice, are stable until expiry date stated on the label.

Once the instrument stability, if the reagents do not show contamination, is a maximum of 4 weeks (not freeze)

CALCULATION

The Spectra 8P performs automatic calculation of results at the end of the incubation.

NOTE

A diagnosis can not be based on the outcome of a single test; but it must always be supplemented and confirmed by clinical information and any other tests.

SIZING

The reagents in the kit have already been calibrated. The calibration values are stored in the smart card in the kit and are only valid for the lot on this' label of the Smart Card. Each kit should be used with its Smart Card supplied.

PRELIMINARY OPERATION: insert the blank cuvette into positions thermostat at least 5 minutes before the test; dilute the serum sample 1:10 with saline (100 µl serum + 900 µl saline). Invert and agitate.

PREPARE THE WORKING REAGENT mixing in a CUVETTE 330 µl of REAGENT R1 and 65 µl of REAGENT R2.

HYDRA PROCEDURE

1)Pre-heat the cuvette containing the Working Reagent.
2)Add 40 µl of sample and stir gently to a few seconds.
3)Insert the cuvette into the reading cell and wait for the end the incubation period for the result.

REFERENCE VALUES

Men **70 - 406 mg / dl (IFCC)**

Women **60-374 mg / dl**

Recommended that each laboratory should determine its own reference values.

PRECISION:

determined on 20 samples of two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	104.9±2.2	1.0
Human2	221.3±7.9	1.8

PRECISION BETWEEN THE SERIES:

determined for 5 days on 20 samples per day for two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	104.6±5.3	2.5
Human2	222.8±8.8	2.0

Accuracy: a group of 20 sera was tested with this procedure and using a similar commercially available reagent. The comparison yielded the following results:

Linear regression 0.9798x + y = 3

Correlation coefficient r = 0.9975 n = 20

INTERFERENCE

see Bibliography point 2.

Policy of interference tests: Recovery ± 30% of the value initial.

Not interference are observed on samples with:

- Total bilirubin up to 20 mg / dL;
- Hemoglobin up to 600 mg / dL;
- Lipemia [Intralipid ®] up to 250 mg / dL;
- Ascorbic acid up to 50 mg / dL.

WASTE DISPOSAL

The product is to be used in professional laboratories. For proper disposal of waste refer to local regulations and data sheets on safety.

INTERVAL MEASURING

4-600 mg / dl

Samples with concentrations higher than that of the highest calibrator should be diluted 1: 2 with Physiologic solution and reviewed by multiplying the result by 2.

SENSITIVITY '

4 mg / dl

HOOK EFFECT> 6000 mg / dl

BIBLIOGRAPHY

1.Textbook of Clinical Chemistry, Ed. By NW Tietz, WB Saunders Co., Philadelphia (1999).

2.Young DS, Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).

3.CLSI (NCCLS) C49-A / H56-A: Collection, Handling, Transport and Storage for Body Fluids. Quick Guide.

Manufacturer

INTERMEDICAL Ltd.
Via A. Genovesi, 13
80010 Villaricca (Na) -ITALY

CE

(IgG)

Kit for the quantitative determination of IgG in human serum

- Immunoturbidimetric method-

REF			
SPE22			INTERMEDICAL

PRINCIPLE OF THE TEST

The addition, in a precise ratio, the serum containing IgG (antigen) to a solution that contains the corresponding antiserum (antibody), determines a turbidity that allows, from the OD value, to easily determine the concentration of antigen present in the sample .

SAMPLES

Fresh serum

If you cannot run the test in the day, the sample can be stored for 48 hours at 2-8 ° C or longer if frozen.

REAGENTS

Reagents: liquid and ready to use

Essential that the reagents, when in use, are at room temperature.

REAGENT PREPARATION

R1: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, PEG, Sodium azide 0.1%, detergents and stabilizers.

R2: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, anti-human IgG antibody (Goat), Sodium azide 0.1%, detergents and stabilizers.

PRECAUTIONS

Every time infectious agents, chemical reagents, human or animal reagents, blood or other body fluids, it is advisable to follow the common recommendations and take all the necessary hygiene precautions such as the use of disposable gloves.

STORAGE AND STABILITY 'PRODUCT

Store the kit at 2 - 8 ° C.

The reagents, if used and maintained in accordance with good laboratory practice, are stable until expiry date stated on the label.

Once the instrument stability, if the reagents do not show contamination, it is a maximum of 4 weeks (not freeze).

CALCULATION

The Spectra 8P performs automatic calculation of results at the end of the incubation.

NOTE

A diagnosis can not be based on the outcome of a single test; but it must always be supplemented and confirmed by clinical information and any other tests.

SIZING

The reagents in the kit have already been calibrated. The calibration values are stored in the smart card in the kit and are only valid for the lot on this' label of the Smart Card. Each kit should be used with its Smart Card supplied.

PRELIMINARY OPERATION: insert the blank cuvette into positions thermostat at least 5 minutes before the test; dilute the serum sample 1:10 with saline (100 µl serum + 900 µl saline). Invert and agitate.

PREPARE THE WORKING REAGENT mixing in a CUVETTE 330 µl of REAGENT R1 and 70 µl of REAGENT R2.

HYDRA PROCEDURE

1) Pre-heat the cuvette containing the Working Reagent.
2) Add 20 µl of sample and stir gently to a few seconds.
3) Insert the cuvette into the reading cell and wait for the end of the incubation period for the result.

REFERENCE VALUES

565 - 1765 mg / dl (IFCC)

Recommended that each laboratory should determine its own reference values.

PRECISION:

determined on 20 samples of two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	1036±36	1.7
Human2	1823± 146	4.0

PRECISION BETWEEN THE SERIES:

determined for 5 days on 20 samples per day for two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	1035±31	1.5
Human2	1885±120	3.2

Accuracy: a group of 20 sera was tested with this procedure and using a similar commercially available reagent. The comparison yielded the following results:

Linear regression y = + 91 0.9483x

Correlation coefficient r = 0.9939 n = 20

INTERFERENCE

see Bibliography point 2.

Policy of interference tests: Recovery ± 30% of the value initial.

Not interference are observed on samples with:

- Total bilirubin up to 20 mg / dL;
- Hemoglobin up to 600 mg / dL;
- Lipemia [Intralipid ®] up to 500 mg / dL;
- Ascorbic acid up to 50 mg / dL.

WASTE DISPOSAL

The product is to be used in professional laboratories. For proper disposal of waste refer to local regulations and data sheets on safety.

INTERVAL MEASURING

80-2700 mg / dl

Samples with concentrations higher than that of the highest calibrator should be diluted 1: 5 with Physiologic solution and reviewed by multiplying the result by 5.

SENSITIVITY '

0.00014 ABS units / concentration unit

HOOK EFFECT> 10000 mg / dl

BIBLIOGRAPHY

1.Textbook of Clinical Chemistry, Ed. By NW Tietz, WB Saunders Co., Philadelphia (1999).

2.Young DS, Effect of drugs on Clinical Lab. Test, 5th Ed. AACC Press (2000).

3.CLSI (NCCLS) C49-A / H56-A: Collection, Handling, Transport and Storage for Body Fluids. Quick Guide.

Manufacturer

INTERMEDICAL Ltd.
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CE

(IgM)

Kit for the quantitative determination of IgG in human serum

- Immunoturbidimetric method-

REF			
SPE22			

PRINCIPLE OF THE TEST

The addition, in a precise ratio, the serum containing IgM (antigen) to a solution that contains the corresponding antiserum (antibody), determines a turbidity that allows, from the OD value, to easily determine the concentration of antigen present in the sample.

SAMPLES

Fresh serum

If you cannot run the test in the day, the sample can be stored for 48 hours at 2-8 ° C or longer if frozen.

REAGENTS

Reagents: liquid and ready to use

Essential that the reagents, when in use, are at room temperature.

REAGENT PREPARATION

R1: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, PEG, Sodium azide 0.1%, detergents and stabilizers.

R2: Tris buffer 100 mmol / l, Sodium chloride 150 mmol / l, anti-human IgM antibody (Goat), Sodium azide 0.1%, detergents and stabilizers.

PRECAUTIONS

Every time infectious agents, chemical reagents, human or animal reagents, blood or other body fluids, it is advisable to follow the common recommendations and take all the necessary hygiene precautions such as the use of disposable gloves.

STORAGE AND STABILITY 'PRODUCT

Store the kit at 2 - 8 ° C.

The reagents, if used and maintained in accordance with good laboratory practice, are stable until expiry date stated on the label.

Once the instrument stability, if the reagents do not show contamination, it is a maximum of 4 weeks (not freeze).

CALCULATION

The Spectra 8P performs automatic calculation of results at the end of the incubation.

NOTE

A diagnosis cannot be based on the outcome of a single test; but it must always be supplemented and confirmed by clinical information and any other tests.

SIZING

The reagents in the kit have already been calibrated. The calibration values are stored in the smart card in the kit and are only valid for the lot on this' label of the Smart Card. Each kit should be used with its Smart Card supplied.

PRELIMINARY OPERATION: insert the blank cuvette into positions thermostat at least 5 minutes before the test; dilute the serum sample 1:10 with saline (100 µl serum + 900 µl saline). Invert and agitate.

PREPARE THE WORKING REAGENT mixing in a CUVETTE 330 µl of REAGENT R1 and 65 µl of REAGENT R2.

HYDRA PROCEDURE

1) Pre-heat the cuvette containing the Working Reagent.
2) Add 65 µl of sample and stir gently to a few seconds.
3) Insert the cuvette into the reading cell and wait for the end of the incubation period for the result.

REFERENCE VALUES

Men **34-230 mg / dl (IFCC)**

Women **40-230 mg / dl**

Recommended that each laboratory should determine its own reference values.

PRECISION:

determined on 20 samples of two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	77.9±8.3	5.3
Human2	164.7± 11.6	3.5

PRECISION BETWEEN THE SERIES:

determined for 5 days on 20 samples per day for two samples. The results obtained are the following:

Sample	Average(Mg / dL)±2s	CV%
Human1	79.2±9.7	6.1
Human2	161.7±13.1	4.0

Accuracy: a group of 20 sera was tested with this procedure and using a similar commercially available reagent. The comparison yielded the following results:

Linear regression y = 0.9805x - 7

Correlation coefficient r = 0.9921 n = 20

INTERFERENCE

see Bibliography point 2.

Policy of interference tests: Recovery ± 30% of the value initial.

Not interference are observed on samples with:

- Total bilirubin up to 20 mg / dL;
- Hemoglobin up to 300 mg / dL;
- Ascorbic acid up to 50 mg / dL.

WASTE DISPOSAL

The product is to be used in professional laboratories. For proper disposal of waste refer to local regulations and data sheets on safety.

INTERVAL MEASURING

0 - 500 mg / dl

Samples with concentrations higher than that of the highest calibrator should be diluted 1: 2 with Physiologic solution and reviewed by multiplying the result by 2.

SENSITIVITY '

3 mg / dL

HOOK EFFECT> 6500 mg / dl

BIBLIOGRAPHY

1.Textbook of Clinical Chemistry, Ed. By NW Tietz, WB Saunders Co., Philadelphia (1999).

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