Bioway Chemistry Reagent Series
Immunoglobulin A Test Kit

Detection of Immunoglobulin A in Human Serum on Chemistry Analyzers

Cat. No. R036K11 ***IgA Test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

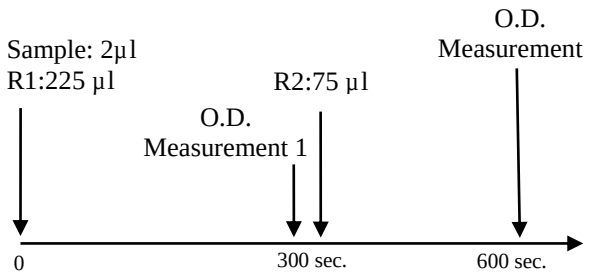

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	600 nm	Sample volume	2 µl
Test method	2 point end	R1 volume	225 µl
Reaction temperature	37℃	R2 volume	75 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **IgA Reagent Kit** (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of immunoglobulin A in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Immunoglobulin A (IgA) accounts for 10 to 15% of serum immunoglobulin. IgA plays a critical role in muscosal immunity and is found to be at high levels in the gastrointestinal system, genitourinary system and respiratory system. IgA measurement is used to diagnose diseases of the respiratory tract, monitor IgA myeloma and evaluate IgA immunity. Increase in IgA levels can be due to recurrent infections, anaphylactic transfusion reactions, chronic liver disease, chronic infections, neoplasia of the lower GI tract, and inflammatory bowel disease. Decreased levels of IgA may be found in isolated genetic deficiency, combined immunodeficiency disorders, non-IgA multiple myeloma or macroglobulinemia.

TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the IgA level in human serum. During the test, IgA in the sample binds with the specific anti-IgA antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry analyzer. The change in absorbance is proportional to the level of IgA in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1%
R2	anti-IgA antibodies, Tris buffer, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. IgA calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Reagents contain less than 0.1% sodium azide as preservative; avoid contact with skin and eyes, flush with copious amounts of water when disposing.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2- 4° C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: 6 level calibrator set available for purchase. Recommend using Bioway calibrators for optimal results. Use multi-point non-linear calibration method.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 2 µl of sample and 225 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Take optical density measurement OD 1 just before addition of R2.
3. Add 75 µl of R2, mix well and incubate at 37℃.
4. Take optical density measurement OD 2 at 600 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The IgA value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

72 - 429 mg/dL.
It is recommended for each laboratory to establish its own expected values.

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QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 550 mg/dL (R≥0.995)

Precision: Within Run: CV≤6%;
Run-to-Run: CV≤10%

Interference: no interference detected for: Bilirubin (60 mg/dL), and hemoglobin (10 g/L).

Reagent Blank Absorbance: at 600 nm wavelength and 10 mm optical diameter, O.D. ≤ 0.10

REFERENCES

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2. Junqueira, Luiz C.; Jose Carneiro (2003). *Basic Histology*. McGraw-Hill.
3. S Fagarasan and T Honjo (2003). "Intestinal IgA Synthesis: Regulation of Front-line Body Defenses". *Nat. Rev. Immunology* 3 (1): 63–72.
4. Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Co; 355–357; 1995.

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com