Bioway Chemistry Reagent Series

Immunoglobulin G Test Kit

Detection of Immunoglobulin G in Human Serum on Chemistry Analyzers

Cat. No. R037K11 ***IgG Test Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

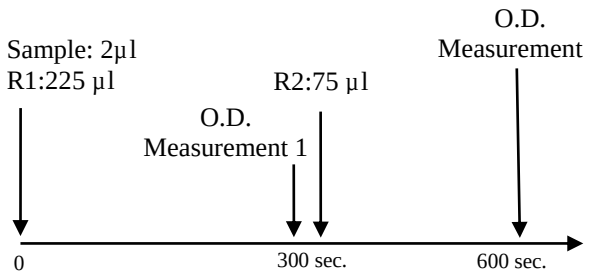

Table 1: Instrument Parameters*

Calibration method	6 point non-linear	Slope of reaction	increase
Wavelength	700 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 **IgG Reagent Kit** (the Kit) is an immunoturbidimetric assay intended for *in vitro* quantitative detection of immunoglobulin G in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Immunoglobulin G (IgG) is the principle immunoglobulin in all extracellular fluids and makes up about 75% of the plasma immunogloulins in adults. IgG provides one of the body's major defence against bacterial infection by eliminating small soluble proteins and enhance the clearance through the reticuloendothelial system. Measurement of IgG levels is used for diagnosis of infectious and inflammatory diseases, diagnosis of malignancies, and detection of soluble antigens and monitoring therapy in myeloma. Deficiency of IgG may be genetic or acquired.

TEST PRINCIPLES

The Kit utilizes immunoturbidimetry to measure the IgG level in human serum. During the test, IgG in the sample binds with the specific anti-IgG 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 IgG 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-IgG antibodies, Tris buffer, sodium azide < 0.1%

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. IgG 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 IgG value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

EXPECTED VALUES

800 - 1700 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 – 3500 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

1. Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA; WB Saunders Co; 509; 1999.
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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.

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