Hipro Biotechnology Co.,Ltd

EN
ENGLISH

# IgG

Immunoglobulin G Test Kit
(Rate Scattering Turbidimetric Method)

## Instructions for Use

Version: A/6

REF HP-IgG-25

**Manufacturer**

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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## Product Name

General Name：Immunoglobulin G Test Kit
(Rate Scattering Turbidimetric Method)

## Specification

Package Specification
25 Tests/ Kit.

## Intended Use

This product is used to determine the content of Immunoglobulin G (IgG) in human serum, it is mainly used for the evaluation of immune function and auxiliary diagnosis of immune diseases.

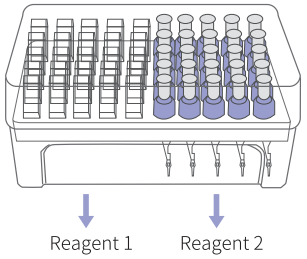
## Test Principle

The immunoglobulin G in the sample specifically binds to the corresponding anti-IgG antibody in the reagent to form the antigen-antibody complexs.. The complexes will produce the phenomenon of light scattering which is proportional to the intensity of scattered light and samples of IgG levels Using specific protein analyzer to measure the intensity of scattered light, the concentration of IgG is determined by comparing the turbidity of samples to the standard concentration.

## Component

The IgG test kit consists of two reagents R1 and R2, as shown on Figure 1.

**Figure 1**




| Name | Content | Quantity |
|---|---|---|
| Reagent 1 (R1) | Phosphate buffer | 50mmol/L |
| | Polyethylene glycol 6000 | 5% |
| Reagent 2 (R2) | Sheep anti human immunoglobulin E antibody | >15mg/mL |
| IC card (optional) | / | 1 |

Do not mix different batches of reagents.

## Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened.

Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

## Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,

HP-083/4-II POCT Immunoassay System,

HP-AFS/1 Automatic Immunoassay System,

HP-AFS/3 Automatic Immunoassay System.

## Specimen type

Plasma, avoid hemolysis. Fasting blood collection and separation of serum as soon as possible. The sample store at 2-8°C for 34 hours, -20°C for 1 month. Avoid repeated freezing. Before test, ensure fully mixed.

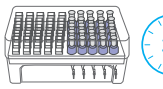
## Procedures

### HP-083/4-I&HP-083/4-II POCT Immunoassay System

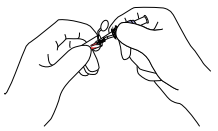
**Note:**

- Please read user manual of HP-083/4-I and HP-083/4-II before use;
- The analyzer will finish self check after start-up;
- Insert the IC card of IgG test kit to let analyzer read the parameter;
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

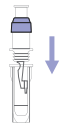
**Step 1 Sample Preparation**




1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

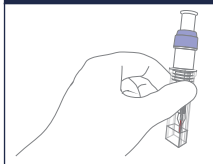


1c Insert the R2 into R1.

**Note:**

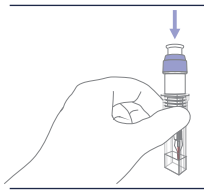
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

**Step 2 Testing**



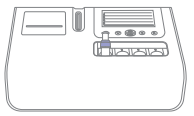
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

**Note:**Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



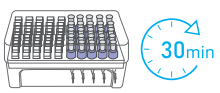
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

### HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

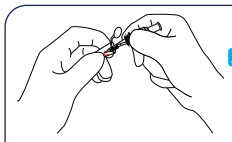
**Note:**

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use;
- The analyzer will finish the self check after start-up;
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

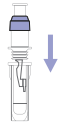
**Step 1 Sample Preparation**




3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

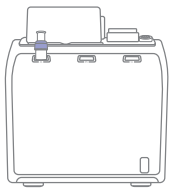


3c Insert the R2 into R1.

**Note:**

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

**Step 2 Testing**



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

### Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

### Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

## Reference Value

7g/L ～ 16g/L recommended that each laboratory establish its own reference range.

## Interpretation

IgG increases: ①IgG, IgA and IgM play an important role in the defense of the body. If IgG, IgA and IgM different immunoglobulin increased as the increase of polyclonal, found in a variety of infections, especially chronic infections, autoimmune diseases such as systemic lupus erythematosus (SLE), lymphoma, tuberculosis, liver diseases and parasitic diseases, etc.;
②The increase of single immunoglobulin, also known as monoclonal increase, mainly in immune proliferative diseases, such as multiple myeloma.
IgG reduction: it can be seen in various congenital or acquired humoral immune deficiency diseases, combined immunodeficiency diseases, etc.
The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.
All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

## Limitations

Hemoglobin>5g/L, triglyceride>10mmol/L, bilirubin>300μmol/L will affect the test result.

## Performance Characteristics

1. Linearity range: 2.0g/L ～ 40.0g/L.
2. Detection limit: ⩽1.2g/L.

   The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data ( Blank table, 1+2SD, within-run precision, n=21).
3. Precision

   Test the control material by Immunoglobulin G Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

| HP-083/4-II POCT Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean g/L | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 7.0 | 0.47 | 6.7 | 0.41 | 5.8 |
| Control 2 | 15.8 | 0.92 | 5.8 | 0.88 | 5.6 |

b.

| HP-AFS/3 Automatic Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean g/L | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 7.1 | 0.45 | 6.3 | 0.46 | 6.5 |
| Control 2 | 16.0 | 0.78 | 4.9 | 0.84 | 5.3 |

c.

| HP-AFS/1 Automatic Immunoassay System | | | | | |
|---|---|---|---|---|---|
| Sample | Mean g/L | Within-Run | | Between-Run | |
| | | S.D. | %C.V. | S.D. | %C.V. |
| Control 1 | 6.9 | 0.49 | 7.1 | 0.46 | 6.7 |
| Control 2 | 16.2 | 0.75 | 4.6 | 0.84 | 5.2 |

### 4.Methodology comparison

Compared to IgG TIA(x) by test the same sample, the relative data as below:

| HP-AFS/3 Automatic Immunoassay System | | | | |
|---|---|---|---|---|
| Site No. | Sample Type | No.of Assays | Regression Line | Coefficient correlation |
| 1 | Serum | 50 | Y= 0.96X+0.18 | 0.97 |

The concentration of sample is about 2.0g/L ～ 40.0g/L.

## Precautions

⚠ **Attention:**

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ **Warning:**

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

## SYMBOLS USED ON LABELS

| Symbol | Usage | Symbol | Usage |
|---|---|---|---|
| | Use-By date | | Do not freeze |
| LOT | Batch code | | Biological risks |
| | Manufacturer | | Do Not Reuse |
| | Temperature Limit | | |
| | Contains sufficient for <n> tests | | |
| | Do not use if package is damaged | | |
| | Consult Instructions for use | | |
| | Keep Away from Sunlight | | |
| IVD | In Vitro Diagnostic Medical device | | |
| EC REP | Authorized Representative in the European Community | | |

## References

He Suqiong. Clinical study on hepatitis B virus immunoglobulin blocking mother-to-child transmission of hepatitis B virus[J]. Chinese Maternal and Child Health, 2007, 22:2664-2665.

## Approval Date&Revision Date

Approval Date: Sept 9,2015
Revision Date: May 6,2016
Revision Date: May 1, 2017
Revision Date: Jan 1, 2021
Revision Date: Apr 1, 2021
Revision Date: Jan 1, 2023
Revision Date: Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折