Intended Use
This reagent is intended for *in vitro* quantitative determination of IgG antibodies in serum.
-Nephelomtry Methodology
-Linearity up to 3000 mg/dL
-Ready to use reagents
-No calibration required
-Lower detection Limit is 360 mg/dL

Clinical Significance
IgG is a predominant serum immunoglobulin . The measurement of IgG is important for typing immunodeficiencies and myelomas. Increased levels are found in chronic infections and chronic inflammation. IgG is the only immunoglobulin which crosses the placenta and is therefore of special importance in infants defense against infection.

Principle
Antibodies to IgG are combined with IgG in the patient's serum, forming immune complexes. The immune complexes cause an increase in absorbance which correlate with the concentration of IgG in the serum.

Reagent Composition
IgG Cartridge

Reagent	Well	Description
IgG R1	Well No. 3	Tris(hydroxymethyl) amino methane 100 mmol/L
IgG R2	Well No. 4	Anti-human IgG antiserum
Reagent R3	Well No. 2	Normal Saline

Note: Wells are numbered consecutively from the reaction cell end of the cartridge. (Well No. 1) Refer Figure No. 1

Risk & Safety
Material safety data sheets (MSDS) will be provided on request.

Reagent Preparation
Reagents are ready to use and supplied in prefilled cartridges.
Pipetting, dispensing and mixing are automatically performed by the instrument.

Reagent Storage and Stability
The sealed cartridges are stable up to the expiry date stated on the kit label, when stored at 2- 8^{0}C and protected from light. **DO NOT FREEZE**

Reagent Deterioration
Turbidity or precipitation in any cartridge component indicates deterioration and the cartridge must be discarded. Values outside the recommended acceptable range for the Agappe Protein control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh Cartridge.

Precaution
1. To avoid contamination use clean laboratory wares. Use clean dry disposable pipette tips for dispensing sample.
2. Avoid direct exposure of cartridge to light. **Allow the cartridge to attain room temperature before performing the test.**
3. Avoid reuse of sample from used cartridges.
4. **Before performing the test ensure that reagents are not sticked to the sealing,if so tap the cartridge gently to get it down to the bottom of the well.**
5. Avoid air bubbles in the cartridge before test.
6. **Clean the exterior of the reaction cell (Well No.1) with dry tissue paper before loading in the cartridge carrier.**
7. Ensure the reaction cell is dust free and moisture free.

Note: Used cartridge contain human body fluids, which can be potentially bio hazardous, handle with appropriate care to avoid skin contact and ingestion.

Waste Management
Cartridges must be disposed off in accordance with local regulations.

Sample
Use Fresh serum . Do not use hemolysed or lipemic sample

Interferences
No interference for

Bilirubin up to	20 mg/dL
Haemoglobin up to	1000 mg/dL
Triglycerides up to	2500 mg/dL

Materials Provided
IgG Test Cartridges – 10 nos

IC Card with Calibration Data - 1 no.

Procedure
The test details and the calibration data is provided in the smart card along with the kit.

- Insert the smart card in to card reader slot.
- Select test function from the main screen and allow the carrier to slide out of equipment.
- **Take one pre-filled cartridge of IgG and tap gently before adding the sample to remove air bubbles if any.**
- Add 80 µL of sample to the dedicated well in the cartridge. (Well No. 6) and place in the cartridge carrier. Select the OK button in the equipment.
- Cartridge slides into the equipment, and gets detected for the test. If not detected equipment will make two additional attempts. On successful detection of cartridge the display shows the corresponding test name with calibration details. Select 'Save' button to save the calibration of corresponding test in to the analyzer.
- Select "OK" to conform the calibration data and for entering patient demographic details.
- Enter the patient demographic details and select the 'START' button to run the test. Status updates along with progress bar will be shown during the test.
- After analyzing the sample, the test results will be printed as well as displayed on the screen.
- The equipment will eject the cartridge carrier for removing the used cartridge. Remove the cartridge, press "EXIT" and select "Ok" to proceed further for next test or select 'HOME' for the main menu.

Note: Once the calibration of particular test is saved in to analyzer, test can be performed without inserting smart card in to the analyzer, until and unless calibration in the analyzer expires or no more test left in the saved card.

Quality Control
It is recommended to use Agappe Protein Control (51614006) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values.
The following value may be used as guide line.

new born (4 days)	: 700 -1480 mg/dL
1 -3 years	: 453 -916 mg/dL
4 -12 years	: 504 -1560 mg/dL
Adults	: 700 -1600 mg/dL
Adults (>60yrs)	: 600 -1560 mg/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance Characteristics
1. Linearity
The reagent is linear up to 3000 mg/dL. If the concentration is greater than linearity, dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.98 and a regression equation of y = 0.999x.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADS/IFU/IgG/I3/R01

CE ISO 9001 : 2015
EN ISO 13485 : 2016

3. Precision

	Intra Run		Inter Run	
Control	**Level 1**	**Level 3**	**Level 1**	**Level 3**
n	20	20	20	20
Mean (mg/dL)	788.26	1916.0	770.71	1898.98
SD	37.97	37.42	40.23	60.94
CV(%)	4.82	1.95	5.22	3.21

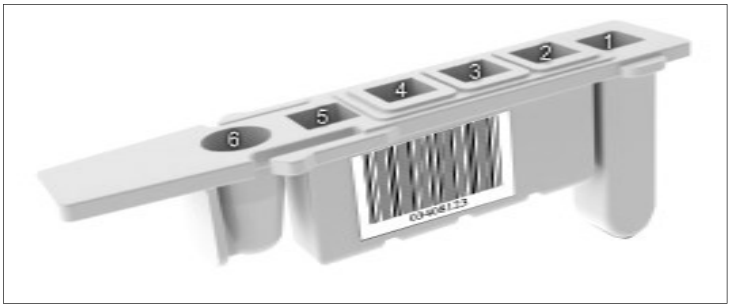
Accuracy (mg/dL)		
Control	**Expected Value**	**Measured Value**
Control Level 1	735 ± 130	739.0
Control Level 3	1893 ± 365	1894

4. Sensitivity

Lower detection Limit is 360 mg/dL

Bibliography

1. Otani,H. :Medical Technology,14, 965(1986)
2. Rinsho Kensa Guide 1992, 269-274, BUNKOOD Co. Ltd.
3. Kanai's Manual of Clinical Laboratory Medicine, 30th ed. 868-874, KANEHARA&CO.
4. TIETZ Text book of Clinical chemistry and Molecular diagnostic 4th Edition.



Cartridge Image (Figure No. 1)

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