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IMMUNOGLOBULIN G

STABLE LIQUID REAGENT

CE

Cat. No.: 31470 (4x25 ml (4x20 ml+ 4x5ml)) 31472 (10x25 ml (10x20 ml+ 10x5ml))

Reagent kit for immuno-turbidimetric determination of Immunoglobulin G (IgG) in human serum.

Principle
Measurement of antingen/antibody reaction by the endpoint method.

Reference values

Serum: 680- 1445 mg/dl
It is recommended that each laboratory should assign its own normal range.

Reagents
1. Reagent 1 (R1)
buffer
sodium-azide (0,95 g/l)
2. Reagent 2 (R2)
antiserum
sodium-azide (0,95 g/l)

Precaution
Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers,...).
The reagents contain sodium azide. To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

Sample
Use fresh serum. The serum can be stored at 2-8 °C for 48 hours. If stored for a longer period, the sample should be frozen.

PROCEDURE

The reagents are ready for use.

Assay conditions

Wavelength:	340 nm
Temperature:	37 °C
Cuvette:	1 cm light path
Read against:	sample blank
Method:	endpoint (increasing)

Pipette into cuvette

	Blank	Standard	Sample
1. reagent (R1)	360 µl	360 µl	360 µl
Standard	3 µl or 3 µl	3 µl	
Sample			3 µl

Mix, wait 20 seconds then add:

2. reagent (R2)		90 µl	90 µl

Mix and after a 4-minute incubation read the absorbance against the sample blank.

Calibration
5 level (at the least 3) standard set for calibration is necessary.

S1: Distilled water or physiological salt solution
S2-S6: 5 level standard set

New calibration is recommended:
- after reagent lot change,
- as required following quality control procedures.

Calculation
Based on the calibration curve.

Quality control
A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus AU600 and Advia 1650 analysers (37°C).

Linearity
The test is linear up to 3000 mg/dl (30 g/l).

Sensitivity
It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used.
The estimated value of limit of detection (LOD) is 3,7 mg/dl.

Precision

	Reproducibility		
	Average concentration (g/l)	SD	CV %
sample I	10,17	0,53	5,23
sample II	9,05	0,63	7,01

	Repeatability		
Sample	Average concentration (g/l)	SD	CV%
sample I.	18,74	0,27	1,45
sample II.	11,51	0,04	0,31
sample III.	6,40	0,05	0,77

Correlation
Comparative studies were done to compare our reagent with another commercial IgG reagent. The results from these studies are detailed below.
Correlation coefficient: r=0,9947
Linear regression: y (g/l)= 0,995x + 0,535
(x= other commercial reagent, y= own reagent).

Specificity
Bilirubin 20 mg/dl, triglycerides 1000 mg/dl, hemoglobin 1000 mg/dl don't interfere with the assay up to the given levels.

NOTE
Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For *in vitro* diagnostic use only.

The following symbols are used on labels

IVD For in vitro diagnostic use

Use by (last day of the month)

Temperature limitation

LOT Batch Code

REF Code

Bibliography

Dati, F. et al., Lab. Med. 13, 87 (1989)