IgA (2nd generation)
Turbidimetric Immunoassay

REF : 521 001 (2 X 10 ml) + 0.5 ml High calibrator **(40 test)**
REF : 521 002 (2 X 25 ml) + 0.5 ml High calibrator **(100 test)**

Intended Use
For the quantitative determination of IgA in human serum by turbidimetric immunoassay for manual and automated chemistry analyzers.

Background
The measurement of IgA is important for typing immune-deficiencies and myelomas. Furthermore it plays a role in acute and chronic infections as first line of defence. Increased levels may be found in acute infectious hepatitis, chronic aggressive hepatitis, posthepatic/ cryptogenic cirrhosis, active alcoholic cirrhosis. chronic infection, rheumatoid arthritis, poly-dermatomyositis and mixed connective tissue disease.

Method
Antigen-antibody reaction using endpoint method.

Reagent (R)
1. Polyclonal goat anti-human IgA stabilised in saline supplemented with accelerator.
2. Sodium azide (0.95 g/L).

Reagents required but not supplied
1. Saline (9 g/L)
2. Calibrators and Controls

Reagent Preparation, Storage and Stability
The reagent is stable until expiry date when kept at 2-8°C. Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.

Specimen Collection and Preservation
Use fresh serum. If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Procedure
Sample/Control: dilute 1:10 in saline (9 g/L NaCl).
Reference curve: generate a reference curve by diluting the standard high level 1:10, 1:20, 1:40, 1:80 and 1:160 with saline (9 g/L NaCl). Use saline (9 g/L NaCl)as zero point.

Test:

	Diluted Samples	Diluted Standards	Diluted Controls
Samples	5 µl	.....	.....
Standards	.....	5 µl	.....
Controls	.....	.....	5 µl
Reagent	500 µl	500 µl	500 µl

Mix and incubate for 5 minutes at room temperature.
Read optical density (OD) of samples, standards and control(s) at 340 nm. Plot a standard curve and read the concentration of controls and samples.

Reference Values
Men: 83 - 406 mg/dL
Women: 70 - 374 mg/dL
These values are for reference only. Each laboratory should establish its own reference values.

Performance Characteristics
1-Dynamic Range
0 - 654 mg/dL

2-Detection Limit
20 mg/dL

3-Hookeffect
> 13080 mg/dL

4-Sensitivity:
0.00045 ABS units/concentration unit

5-Specificity
Monospecific

6-Interferences:
No interference for: Haemoglobin (1000 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Triglyceride (2500 mg/dL), EDTA (5mg/dL). Turbidity (> 2.5%) and Bilirubin (> 5mg/dL) interfere with the test.

7-Precision (CV%)

	Low	Medium	High
Intra run	**1.56**	**2.43**	**1.71**
Inter run	**3.28**	**3.05**	**1.67**

8- Methods Comparison
A comparison between Spectrum Diagnostics IgA reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.993 was obtained.

Precautions and warnings
1. For In vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Flush drains with water thoroughly after disposing of fluids containing sodium azide.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA.

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

Egyptian Company for Biotechnology(S.A.E)
Obour city industrial area.block 20008 piece 19 A.
Cairo. Egypt.
Tel: +20244892248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com