

## Instructions For Use

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OSR61171 4 x 14 mL R1, 4 x 11 mL R2

IgA  
IgA

**For *in vitro* diagnostic use only.**

### ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

## PRINCIPLE

### INTENDED USE

Immuno-turbidimetric test for the quantitative determination of immunoglobulin A (IgA) in human serum and plasma on Beckman Coulter analysers.

### SUMMARY AND EXPLANATION

Reference<sup>1,2</sup>

Immunoglobulin classes IgG, IgA, IgM, IgD and IgE are present in descending order of concentration in the serum of healthy people. IgA antibodies occur as serum IgA and as secretory IgA. Unlike secretory IgA the specific role of serum IgA is unclear. IgA does not cross the placenta, therefore it is not present in fetal blood. Secretory IgA consists of a dimer connected by a J-chain and has a secretory component that protects the molecule from proteolytic enzymes. Secretory IgA is the predominant immunoglobulin of body secretions such as saliva, tears, colostrum, nasal secretions, tracheobronchial mucus and gastrointestinal secretions. Essential functions of secretory IgA are the binding of microorganisms on mucous membranes, the activation of the alternative complement pathway and activation of inflammatory reactions, it particularly plays a major role in the protection of the respiratory, genitourinary, and gastrointestinal tracts against infection.

Changes in serum immunoglobulin concentrations can be classified as follows:

Hypogammaglobulinemias, individuals with secretory IgA deficiency are found to suffer more commonly from mucosal infections, atopy, and autoimmune diseases. Individuals with absent IgA have a higher than expected incidence of rheumatic disorders and lymphoma.

Polyclonal gammopathies, increased levels occur in chronic liver disease; chronic infections, especially of the GI and respiratory tracts; neoplasia of the lower GI tract; inflammatory bowel disease; some immunodeficiency states such as Wiskott-Aldrich syndrome and rheumatoid arthritis.

Monoclonal gammopathies, e.g. in IgA type multiple myeloma.

## METHODOLOGY

When a sample is mixed with R1 buffer and R2 antiserum solution, human IgA reacts specifically with anti-human IgA antibodies to yield insoluble aggregates. The absorbance of these aggregates is proportional to the IgA concentration in the sample.

## SPECIMEN

### TYPE OF SPECIMEN

Serum and EDTA or heparinised plasma

### SPECIMEN STORAGE AND STABILITY

Stable in serum and plasma for 8 months when stored at 2...25°C.<sup>3</sup>

Strongly lipemic samples should be avoided.

## REAGENTS

### WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

### REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Tris buffer (pH 7.2)	50 mmol/L
Polyethylene glycol 6000	3.5%
Goat anti-IgA antibodies	Dependent on titre
Preservative	

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

 **CAUTION**

**Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).**

**To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

## GHS HAZARD CLASSIFICATION

IgA-R1

**WARNING**

H316

Causes mild skin irritation.

P332+P313

If skin irritation occurs: Get medical advice/attention.

Tris(hydroxymethyl)- aminomethane 1 - 5%

<b>SDS</b>	Safety Data Sheet is available at <a href="http://techdocs.beckmancoulter.com">techdocs.beckmancoulter.com</a>
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## REAGENT PREPARATION

The reagents are ready for use and can be placed directly on board the instrument

## REAGENT STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2...8°C. Once open, reagents stored on board the instrument are stable for 90 days.

## CALIBRATION

### CALIBRATOR REQUIRED

Serum Protein Multi-Calibrator Cat. No. ODR3021.

The calibrator IgA values are traceable to IFCC (International Federation of Clinical Chemistry) standard CRM 470.

Recalibrate the assay every 90 days or when the following occur:

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyser or a critical part was replaced

Following calibration, the resulting curve should be visually reviewed, on the Beckman Coulter analyser, for acceptability using the software options - Routine, Calibration Monitor, Calibration Curve. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

## QUALITY CONTROL

ITA Control Sera ODC0014, ODC0015 and ODC0016 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

## TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement. The paediatric application is suitable for use with small volume serum/plasma samples.

Data check parameters are required, see setting sheets for specific instrument details.

## CALCULATIONS

The Beckman Coulter analysers automatically compute the IgA concentration of each sample.

## REPORTING RESULTS

### REFERENCE INTERVALS

Reference<sup>4</sup>

Adults 0.7 – 4.0 g/L (70 – 400 mg/dL)

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

## PROCEDURAL NOTES

### LIMITATIONS

The IgA assay has been optimised to reduce the risk of prozone occurrence in the presence of abnormally high immunoglobulin concentrations.

However, as a precaution samples from patients with suspected paraproteinaemia should also be tested by electrophoresis.

Samples with very high IgA concentrations (> 100 g/L polyclonal) can generate false low results without appropriate "Z" flags due to excess antigen in the sample.

AU5800: Samples with very high IgA concentrations (> 90 g/L polyclonal) can generate false low results without appropriate "Z" flags due to excess antigen in the sample.

When running elevated samples on any of the AU system analysers, "F" flags or a combination of "F" and "Z" flags may be obtained. Such samples should be diluted using physiological saline so as to recover close to the middle of the measuring range.

Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results.

### INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 3% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 5% up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% up to 1,000 mg/dL Intralipid
RF:	Interference less than 10% up to 600 IU/mL

Refer to Young<sup>5</sup> for further information on interfering substances.

## PERFORMANCE CHARACTERISTICS

### PERFORMANCE CHARACTERISTICS

Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

#### LINEARITY

The test is linear within a concentration range of 0.1 – 7.0 g/L (10 – 700 mg/dL).

#### SENSITIVITY

The lowest detectable level in serum on an AU640 analyser was estimated at 0.01 g/L.

The lowest detectable level represents the lowest measurable level of IgA immunoglobulins that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

#### METHODS COMPARISON

Patient serum samples were used to compare this IgA assay on the AU2700 against another commercially available IgA assay. Results of linear regression analysis were as follows:

$y = 0.923x + 0.151$	$r = 0.999$	$n = 111$	Sample range = 0.32 – 6.84 g/L
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#### PRECISION

The following data was obtained on an AU640 analyser using 3 serum pools analysed over 20 days.

n = 80 Mean g/L	Within-run		Total	
	SD	CV%	SD	CV%
1.02	0.01	1.41	0.03	3.39
2.40	0.04	1.52	0.09	3.85
4.79	0.10	2.18	0.19	4.01

## ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
IGA1G	Immunoglobulin A (Serum)
IGA1GP	Immunoglobulin A (Serum Paediatric)

### **Setting Sheet Footnotes**

# User defined

† Beckman Coulter Serum Protein Multi-Calibrator Cat. No: ODR3021

\* Values set for working in SI units (g/L). To work in mg/dL multiply by 100.

### **REVISION HISTORY**

IFU updated to add Vietnamese language.

Revised GHS section

Updated Additional Information section

#### **Preceding version revision history**

Added Revision History

DxC 700 AU updates

Updated Warning and Precautions section

Revised GHS section

Updated Calibration section

## REFERENCES

1. Thomas L. Immunoglobulins (Ig). In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:667-678.
2. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company, 1995:354-357.
3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples. WHO/DIL/LAB/99.1 Rev.2:35pp.
4. Baudner S, Dati F. Standardization of the measurement of 14 proteins in human serum based on the new IFCC/BCR/CAP International reference material CRM 470. J Lab Med 1996;20:145-152.
5. Young DS. Effects of drugs on clinical laboratory tests, 5<sup>th</sup>ed. AACC Press, 2000.

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