

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 ASO (Anti-Streptolysin O) antibodies in human serum on Beckman Coulter analysers.

SUMMARY AND EXPLANATION

Reference^{1,2}

Group A streptococcus is one of the most common causes of human bacterial infections, causing diseases such as acute rheumatic fever, acute glomerulonephritis, acute pharyngitis, sinusitis, pneumonia, septic scarlet fever, gangrene, and lymphangitis. Streptolysin O is a haemolysin produced by group A streptococci. In an infected individual streptolysin O acts as a protein antigen to which the patient mounts an antibody response. Titres rise as early as 1 week and peak 3 – 6 weeks after infection. In the absence of complications or re-infection, the ASO titre will usually fall to pre-infection levels within 6 – 12 months.

METHODOLOGY

When a sample is mixed with R1 buffer and R2 latex solution, Anti-Streptolysin O antibodies react specifically with Streptolysin-O coated latex to yield insoluble aggregates. The absorbance of these aggregates is proportional to the ASO concentration in the sample.

SPECIMEN**SPECIMEN STORAGE AND STABILITY**

Serum: Stable for 8 days when stored at 2...8°C and 2 days when stored at 15...25°C.³

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:

Phosphate buffer (pH 7.0)	40 mmol/L
Streptolysin-O coated latex	<0.2% w/v
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

Not classified as hazardous



Safety Data Sheet is available at techdocs.beckmancoulter.com

REAGENT PREPARATION

R1 is ready for use and can be placed directly on board the instrument. R2 should be mixed by inversion 5 – 10 times before placing on board the instrument and at weekly intervals thereafter.

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 60 days.

Do not use if there are visible signs of microbial growth, turbidity of precipitate, or any change in reagent colour.

CALIBRATION

CALIBRATOR REQUIRED

This assay may be calibrated using multi-point calibration or single point calibration assay. For multi-point calibration use Serum Protein Multi-Calibrator Cat. No.: ODR3021. For single point calibration Serum Protein Multi-Calibrator Cat. No.: ODR3021, Calibrator 4 may be used.

Please refer to User Guide/Instructions For Use (IFU) for further instructions.

Calibrator ASO values are traceable to the WHO NIBSC 1st International standard for Anti- Streptolysin O, AST.^{4, 5}

Recalibrate the assay 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 for acceptability, on the Beckman Coulter analyser, using the software options to access the Calibration Monitor. 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 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.

CALCULATIONS

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

REPORTING RESULTS

REFERENCE INTERVALS

Reference¹

Adults ≤ 200 IU/mL

Children ≤ 150 IU/mL

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

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 5% up to 40 mg/dL or 684 µmol/L bilirubin

Haemolysis: Interference less than 3% up to 5 g/L haemoglobin

Lipemia: Interference less than 5% up to 1,000 mg/dL Intralipid.

Refer to Young⁶ 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 100 – 1000 IU/mL.

SENSITIVITY

The lowest detectable level in serum on an AU400 analyser was calculated as 7 IU/mL.

The lowest detectable level represents the lowest measurable level of Anti-Streptolysin O 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 ASO OSR6194 assay on the AU2700 against another commercially available ASO method. Results of linear regression analysis were as follows:

$y = 1.031x - 16.575$	$r = 0.992$	$n = 102$	Sample range = 106 – 941 IU/mL
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PRECISION

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

n = 80	Within-run		Total	
	SD	CV%	SD	CV%
Mean (IU/mL)				
152	2.50	1.65	3.77	2.49
318	3.84	1.21	7.74	2.43
644	7.61	1.18	16.90	2.63

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
ASO1N	ASO (Serum) 5 point Calibration
ASO2N	ASO (Serum) 1 point Calibration

Setting Sheet Footnotes

User defined

† For multi-point calibration use Serum Protein Multi-Calibrator Cat. No.: ODR3021.

For single-point calibration use Serum Protein Multi-Calibrator ODR3021 (Cal. No. 4), with calibration type "AB". * Set the factor range at 0 to 99999.9 when using calibration type "AB".

DxC 700 AU: † For multi-point calibration ASO1N use Serum Protein Multi-Calibrator Cat. No.: ODR3021. For single-point ASO2N calibration use Serum Protein Multi-Calibrator ODR3021 (Cal. No. 4), with calibration type "AB" * Set the factor range at 0 to 99999.9 when using calibration type "AB"

* Values set for working in IU/mL

REVISION HISTORY

IFU updated to add Vietnamese language.

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

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2. Tietz NW, ed. Clinical guide to laboratory tests, 3rd ed. Philadelphia: WB Saunders Company, 1995:919pp.
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.2:22pp.
4. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem Lab Med 2001;39:1110-1122.
5. Spaun J, Bentzon MW, Olesen Larsen S, Hewitt LF. International standard for anti-streptolysin-O. Bull Wld Hlth Org 1961;24:271-79.
6. Young DS. Effects of drugs on clinical laboratory tests, 5thed. AACCC Press, 2000.



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