

ASO Turbidimetric Calibrator

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE

ASO Turbidimetric Calibrator is for use in the calibration of the ASO Turbidimetric assay on the Architect cSystems.

ASO Turbidimetric Calibrator

REF: 01R90-01

Package: 5x1 mL **Lyophilized**

For use with;

ASO Turbidimetric reagent

REF: 01R86-21

01R86-31

CONTENTS / MATERIALS PROVIDED

ASO Turbidimetric Calibrator (REF: 01R90-01) contains human serum.

Sodium Azide (0.09 %) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric pipette for delivery of 1.0 mL
2. Distilled or deionized water meeting specifications equivalent to USP purified water
3. ASO Turbidimetric reagent

REF: 01R86-21

01R86-31

STANDARDIZATION

The traceability of the method is verified using NIBSC 97/662 for ASO Calibrator values.¹

PRECAUTIONS (General and Users)

IVD

For *in Vitro* Diagnostic Use.

Do not use components beyond the expiration date.

Contains sodium azide.

EUH032 Contact with acids liberates very toxic gas.

Do not mix materials from different kit lot numbers.

Human source material.

Calibrator can contain preservatives (as Sodium Azide or others) which total concentration is lower than the limits mentioned in Directive 67/548/ CEE and 88/379 CEE.



Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA-approved

method and found nonreactive for the presence of HBsAg, HCV, HIV-Ag and antibody to HIV 1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions. Safety Data Sheets are available at www.archem.com.tr or contact your local representative. Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish:(114) (24 hours/7 days). Please contact with Archem for information in English: +(90) 212 444 0 892 (Turkey) (8:30-18:30/ except Sundays)

STORAGE AND STABILITY

1. Unopened ASO Turbidimetric Calibrator is stable until the expiration date when stored +2 to +8 °C.
2. Opened calibrators are stable **3 days** when stored in a dark place +2 to +8°C.
3. ASO Turbidimetric Calibrator is stable 30 days when stored -20°C. Reconstitute and store tightly capped in a dark place, kept free of contamination and FROZEN. (Freeze and thaw once only)

PREPARATION OF CALIBRATOR

Lyophilized serum calibrator should be reconstituted by adding 1.0 mL of distilled or deionized water. Close the vial and let stand for 20 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

1. 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.
2. Thomas L. Immunochemical technics. In: Thomas L, ed. Clinical Laboratory Diagnostics. Use and Assesment of Clinical Laboratory Results. 1st Edition. TH-Books, Frankfurt/Main, Germany, 1998.
3. Thomas L. Streptococcus pyogenes infection. In: Thomas L, ed. Clinical Laboratory Diagnostics. Use and Assesment of Clinical Laboratory Results. 1st Edition.

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REF 01R90-01

FOR USE WITH
ARCHITECT

TH-Books, Frankfurt/Main, Germany, 1998.

TRADEMARKS

ASO Turbidimetric Calibrator is a trademark of Archem Diagnostic A.Ş. In various jurisdictions.

The ARCHITECT c System family of instruments consists of c 4000, c8000 and c 16000 instruments.

ARCHITECT, c4000, c8000, c16000, c System are trademark of Abbott Laboratories in various jurisdictions

All trademarks are property of their respective owner(s)

Customer Service:







Contact Archem Diagnostics Industry A.Ş.



Archem Sağlık Sanayi ve Tic. A.Ş.
 Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
 Bağcılar/Istanbul/Turkey
 Tel: + 90 212 444 08 92
 Fax: +90 212 629 98 89
info@archem.com.tr www.archem.com.tr



SYMBOLS

| | |
|---|---|
| IVD | In Vitro Diagnostic Medical Device |
| LOT | Lot number |
| CAL | Calibrator |
| GTIN | Global Trade Item Number |
| REF | Reference Number |
| FOR USE WITH | Identifies products to be used together |
| PRODUCT OF TURKEY | Product of Turkey |
|  | Manufacturer |
|  | Expiration date |
|  | Temperature limitation |
|  | Consult instructions for use |
|  | Caution |
|  | Sufficient for |