

IgE Turbidimetric Control Set

En

REF 01R98-01

FOR USE WITH
ARCHITECT

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

IgE Turbidimetric Control Set are for use in the control of the IgE reagent on the Architect cSystems.

IgE Turbidimetric Control Set

REF: 01R98-01

Package: 2 x 2 mL **Liquid**

For use with;

IgE Turbidimetric Assays

REF: *01R89-21

01R89-31

*01R89-41

CONTENTS / MATERIALS PROVIDED

IgE Turbidimetric Control Set (REF: 01R98-01) doesn't contains the human serum.
Sodium Azide (0.09 %) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

- IgE Turbidimetric Assays
REF: *01R89-21
01R89-31
*01R89-41

STANDARDIZATION

The traceability of the method is verified using 75/502 following an international collaborative study and WHO International Standard Immunoglobulin E (IgE), human serum that comes from NIBSC code: 11/234.

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.
Animal/Plasma Cell sourced material.

Control 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.

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

- Unopened IgE Turbidimetric Control Set are stable until the expiration date when stored +2 to +8 °C.
- Opened controls are stable **60 days** when stored tightly capped in a dark place +2 to +8°C and kept free of contamination.

PREPARATION OF CONTROL

Liquid, ready to use. No need for preparation.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

- Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis , MO, Elsevier Saunders; 2006:2263.
- Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001; 17:260–273.
- Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.
- Tietz, N. W. (1983) Clinical guide to Laboratory Tests, p384 W.B. Saunders Co., Philadelphia.

TRADEMARKS

IgE Turbidimetric Control Set is a trademark of ARCHEM Diagnostic A.Ş. In various jurisdictions. The ARCHITECT c System family of instruments consists of c4000, c8000 and c16000 instruments. ARCHITECT, c4000, c8000, c16000, c System are trademark of Abbott Laboratories in various jurisdictions All trademarks are property of their respective owner(s)

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Customer Service:
Contact Archem Diagnostics Industry A.Ş.



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SYMBOLS

IVD

In Vitro Diagnostic Medical Device

LOT

Lot number

CON

Control

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

