

# IgE Turbidimetric Calibrator Set

# En

REF: 01R99-01

**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 Calibrator Set are for use in the control of the IgE reagent on the Architect cSystems.

### IgE Turbidimetric Calibrator

REF: 01R99-01

Package: 5 x 1 mL **Liquid**

### For use with;

IgE Turbidimetric Assays

REF: 01R89-21

01R89-31

01R89-41

## CONTENTS / MATERIALS PROVIDED

IgE Turbidimetric Calibrator Set (REF: 01R99-01) doesn't contains the human serum.

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

## MATERIALS REQUIRED BUT NOT PROVIDED

1. 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](http://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 IgE Turbidimetric Calibrator Set are stable until the expiration date when stored +2 to +8 °C.
2. Opened calibrators 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

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

## TRADEMARKS

IgE Turbidimetric Calibrator 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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## SYMBOLS

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



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