

IgE Calibrator Set

En

REF: IGCL06 IgE Calibrator Set 5 x 1 mL

Changes made in the instructions for use are marked as grey.

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

Archem IgE Calibrator Set is for calibration of the IgE Liquid assay.

CONTENTS / MATERIALS PROVIDED

Archem IgE Calibrator Set

REF: IGCL06

Package: 5 x 1 mL **Liquid**

For use with:

Archem IgE Liquid Reagents
 Archem IgE Control

IGCL06 does not contain the human serum.

Sodium Azide (0,09 %) is added as preservative.

Materials Required But Not Provided:

1. Class A volumetric pipette for liquid transfer
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.

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.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at +2/+8°C	Expiry date on the vial.
Opened and stored at +2/+8°C	60 days

PREPARATION OF CALIBRATOR

Calibrator is ready for use.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

PRECAUTIONS



Human source material. Treat as potentially infectious material. Each plasma donor used in the preparation of this product has been tested by an FDA-approved method and found negative for the presence of HIV 1/2 HBsAg, HCV, HIV-Ag antibodies. However, none of the known testing methods can offer complete assurance that the hepatitis B virus, Human Immunodeficiency Virus (HIV) or infectious agents are not present. All human-based products should be handled in accordance with Good Laboratory Practice (GLP) principles using appropriate precautions. Safety data sheets are available at www.archem.com.tr or you may contact your local representative.

WARNINGS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.

P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

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Intervention

- P302+P352 :Wash with plenty of water and soap if it contacts with skin.
- P333+P313 :Seek medical help if it irritates your skin or develops rash.
- P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

- P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th 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

Archem IgE Calibrator Set is a trademark of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



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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 Limits



Consult Instructions for Use



Caution



Number of Tests