

CRP HS CALIBRATOR SET

(1-2 Levels)

En

Ref 06U45-50

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

Archem CRP HS Calibrator Set is for calibration of the Archem CRP HS assay.

CONTENTS / MATERIALS PROVIDED

CRP HS Calibrator Set (1-2 Levels)

REF: 06U454-50

Package: 2 x 1.5 mL + 2 x 1.5 mL Liquid

STANDARDIZATION

The traceability of the method is verified using NIBSC 85/506 for CRP HS Calibrator values.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at +2/+8°C	Expiry date on the vial.
Opened and stored at +2/+8°C	45 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 calibrators.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

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 OHSAS 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.

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



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SEMBOLLER

IVD	In Vitro Diagnostik Medikal Cihaz
LOT	Lot Numarası
CAL	Kalibratör
GTIN	Küresel Ticari Ürün Numarası
REF	Referans Numarası
FOR USE WITH	Birlikte Kullanılacak Ürünleri Tanımlar
PRODUCT OF TURKEY	Türkiye Ürünü
	Üretici
	Son Kullanma Tarihi
	Sıcaklık Sınırlaması (Saklama Şartları)
	Kullanım Kılavuzuna Bakınız
	Dikkat
	Test Sayısı