

CRP HS CONTROL LEVEL I - II

EN

REF: 06U45-51

REF: 06U45-52

FOR USE WITH
ARCHITECT

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 CRP HS Control is used for control of CRP HS reagent.

CONTENTS / MATERIALS PROVIDED

CRP HS Control Level 1- Liquid

REF: 06U45-51

Package: 2 x 1.5 mL

CRP HS Control Level 2- Liquid

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Package: 2 x 1.5 mL

Sodium Azide (0.09%) is added as preservative.

CONTROL STORAGE AND STABILITY

1. Unopened CRP HS Control is stable at +2/+8 °C up to the expiration date indicated on the label.
2. Opened control is stable 45 days when stored at +2/+8 °C.

PREPARATION OF CONTROL

It is ready to use because it is liquid.

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.

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.

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. S.Dean Allison, Mark C.Manning, Theodore W.Randolph, Kim Middleton, Ashley Davis, John F.Carpenter. Optimization Of Storage Of Lyophilized Actin Using Combinations Of Disaccharides And Dextran. Journal Of Pharmaceutical Sciences.89/2,199- 214(2000)





TRADEMARKS

Archem CRP HS Control 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
CONTROL	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 Limits
	Consult Instructions for Use
	Caution
	Number of Tests