CRP WR TURBIDIMETRIC En

REF 02R04-31 2809 Tests
REF 02R04-21 1489 Tests

FOR USE WITH
ARCHITECT

Test for the quantitative immunological determination of C-reactive protein in human serum.
Liquid. Dual reagents. Store at 2°C - 8°C. Do not freeze. For in Vitro Diagnostic Use.

02R04-31 / 02R04-21 Ref Number Products are Produced Specifically for Abbott Architect Chemistry Analyzer Series.
Note: REF 02R04-21 is not available in Poland.

INTENDED USE [1,5,8,9]

Test for the quantitative immunological determination of C-reactive protein in human serum.
C-Reactive Protein (CRP), which is synthesized in the liver, is one of the most sensitive acute phase reactants after tissue damage or inflammation. The classical complement pathway is activated by CRP as a response to the inflammatory reaction.

A dramatical rise can be observed in CRP levels in serum after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation.

The increase occurs within 24 to 48 hours and the level may be 2000 times normal. Finding of CRP rising is nonspecific to (any) infection because of the possibility of being an elevation in virtually all diseases involving tissue damages.

Not only the findings of a single test result but also an integration of both clinical and laboratory data should be used in clinical diagnosis.

TEST PRINCIPLE [3,10,11,12]

CRP antigens in the sample react with specific antiserum to form a precipitate which is measured turbidimetrically at 340nm.

TEST PARAMETERS

Method	: Immunoturbidimetric
Wavelength	: 340 nm
Temperature	: 37 ºC
Sample	: Serum.
Linearity	: 1.0 mg/L - 350 mg/L (0.1-35 mg/dL)

REAGENT COMPOSITION

Reagent 1:

Buffer	≤ 5 g/L
Stabilizer	≤ 1 g/L
Sodium azide	≤ 0.1 g/L
pH	8.6 +10%

Reagent 2:

Anti-CRP antibody, Sodium azide	< 0.1 g/L.

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

On board stability:
Once opened vials are stable 30 days (720 hours) at 2-8ºC at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and carry-over values.
Store at 2-8ºC.
Reagents are stable until the expiry date stated on the label when stored in closed vials and avoiding contamination during their usage.

Indications of deterioration:
Reagents: absorbance of the blank over 0.3 at 340 nm.

SAMPLE

Serum:
Serum is collected by standard procedures.
CRP in serum is stable for 5 days at 20 - 25°C, 1 month at 2-8ºC and 1 year at -20°C.[13]
Use fresh serum samples. Clot formation must be completed prior to centrifugation. Also after centrifugation red blood cells must be separated from serum immediately.

PROCEDURE

Materials Provided

CRP WR Turbidimetric, REF 02R04-31 or REF 02R04-21

Materials Required but not Provided

- Archem CRP WR Turbidimetric Calibrator
  REF**:** 01R91-01

Assay Procedure and Specimen Dilution Procedures:
For higher samples run the dilution within the ARCHITECT application.

REFERENCE INTERVALS (NORMAL VALUES)

Serum Adults: Up to 5 mg/L. (0.5 mg/dL) [17]

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

QUALITY CONTROL

Commercially available control material with established values determined by this method may be used. We recommend:

Specific Protein Control Level I **REF: 04R42-01**

Specific Protein Control Level II **REF: 04R43-01**

Quality control is recommended every day.
Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

CALIBRATION

Calibrator:
We recommend: ARCHEM CRP WR Turbidimetric (Standard) **REF: 01R91-01**

Calibration:
Calibration stability is 30 days in ARCHITECT c Systems.

Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity (LOQ) (LOQ values are based on CV% ≤ 20%) 1 mg/L CRP.

High linearity: The method is linear up to 350 mg/L (35 mg/dL) CRP.

Precision Studies (Based on CLSI EP05A3):

Repeatability (within run) (Intra-assay)

Mean conc.	SD	CV	N
5.5 mg/L	0.18	3.3 %	20
20.3 mg/L	0.27	1.34 %	20

Reproducibility (day to day) (Inter-assay)

Mean conc.	SD	CV	N
19.0 mg/L	0.72	3.8 %	88
54.2 mg/L	1.9	3.5 %	80

Correlation: Correlation with a reference reagent is: r=0.99 (Range 1.48 mg/L to 362 mg/L)
According to Passing-Bablok Fit:
Slope: 0.98
Intercept: -0.49

Sensitivity (LOD): 0.7 mg/L.

Prozone effect: If CRP is present in the sample at a concentration higher than 450 mg/L, it will result in obtaining falsely low values.

Interferences: [6, 15, 16]
The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.

Hemoglobin up to 3.6 g/L, bilirubin up to 54 mg/dL, lipemia (Triglycerides) up to 2970 mg/dL do not interfere. Other drugs and substances may interfere. Significant interference may be observed with hemolyzed samples. Reference observed results in the table below. [10, 11]

Interferent and Concentration	CRP WR Target (mg/L)	N	Observed Recovery %
Bilirubin Total 60 mg/dL	17.6	3	101
	132.6	3	95
Triglyceride 3810 mg/dL	18.7	3	99
Triglyceride 3300 mg/dL	132.1	3	99
Hemoglobin 4 g/L	20.9	3	92
Hemoglobin 7 g/L	143.6	3	96

The effect of interfering substances has only been evaluated for those listed in this labeling.
An analyzer has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles can not be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general GLP guidelines.
R32: Contact with acids liberates very toxic gas.
EUH032: Contact with acids liberates very toxic gas.
H300: Fatal if swallowed
H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long lasting effects.
Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI	: Clinical and Laboratory Standards Institute
CRP	: C - reactive protein
CV%	: Coefficient of Variation Percentage
EP	: Evaluation Protocols
GLP	: Good Laboratory Practice
mL	: milliliter
QC	: Quality Control
mg	: milligram
L	: liter
g	: gram
IU	: International unit
dL	: deciliter

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
R1	Reagent 1
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
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

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