CRP TURBI

Diagnostic reagent for determination of CRP Turbi (C-Reactive Protein Turbi) concentration.
Liquid. Dual Reagents *(Ratio: R1/R2: 4/1)*. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Package	Ref No	Package	Ref No	Package	Ref No	Package
BY101T	675 mL	LAB102	300 mL	RD102	300 mL	TA104N	50 mL
BY102T	450 mL	LM250	675 mL	RD103	150 mL	TAB100	672 mL
DMT100	285 mL	LM251	300 mL	S2232	125 mL	TAB101	350 mL
DMT200	285 mL	M3B105	200 mL	S2233	50 mL	8A101T	675 mL
HN402	300 mL	PL2351	63 mL	TA101N	500 mL	8A102T	450 mL
HN403	225 mL	TA110N	250 mL	TA102N	250 mL		
MDB200	250 mL	TA210N	500 mL	TA103N	125 mL		
S2531	500 mL	S2530	250 mL				

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

INTENDED USE

The test is applied for the quantitative determination of C-Reactive Protein (CRP) in serum.

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5, 6, 7, 8]

After tissue damage or inflammation, liver synthesized C-Reactive Protein is one of the most sensitive acute phase reactants.

CRP tests are used for the detection of systemic inflammatory processes, evaluation of antibiotic treatment of bacterial infections, detection of intrauterine infections with concomitant premature amniorexia, distinguishing between active and inactive forms of diseases that are also infectious, detection of the presence of post-operative complications such as infected wounds, thrombosis and pneumonia at an early stage and distinguishing between infection and bone marrow transplant rejection. Postoperative monitoring of patients' CRP levels can help the detection of unexpected complications (constantly high or increasing levels). Measuring the changes in CRP concentration provides useful diagnostic information about how acute and how serious a disease is. It also allows making decisions about the occurrence of the disease. A persistent high serum CRP concentration is a serious prognostic sign, often indicating the presence of an uncontrollable infection.

The level of CRP in plasma increases dramatically after atherosclerosis, stress, trauma, infection, inflammation, surgery, or neoplastic proliferation. The increase occurs within 24 to 48 hours and the level is 2000 times normal. All tissue-related damage is expected to increase, but the finding is nonspecific.

Serum C-reactive protein causes precipitation of latex particles coated with anti-human C-reactive protein. The precipitation of latex particles is directly proportional to the CRP concentration and can be measured turbidimetrically.

Clinical diagnosis should not be made only with the findings of test results, integration of the laboratory data should be used in clinical diagnosis as well.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Linearity : 120 mg/L

REAGENT COMPONENTS

Reagent 1:
Glycine buffer : ≤ 0.12 mol/L
Sodium azide : ≤ 0.99 g/L
pH : 8.6

Reagent 2:
Suspension of latex particles coated with anti-human CRP antibodies:
Sodium azide : ≤ 0.99 g/L

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE [9]

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Serum is collected according to the standard procedures.

CRP in serum is stable for:
15 days at +20/+25°C,
2 months at +2/+8ºC,
3 years at -20°C.

For reagents which are related to antigen antibody interaction, do not shake the sample, just gently mix.

Unit Conversion:
mg/dL x 10 = mg/L

REFERENCE INTERVAL (NORMAL VALUES) [10]

Serum : < 5.0 mg/L

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

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

Specific Protein Control level I (Rheumatoid Control I) Lyophilized
Ref.No: RCN01
Ref.No: RCN08

Specific Protein Control level II (Rheumatoid Control II) Lyophilized
Ref No: RCN02
Ref.No: RCN09

Specific Protein Control Level I (Rheumatoid Control I) Liquid
Ref.No: RCN06

Specific Protein Control Level II (Rheumatoid Control II) Liquid
Ref.No: RCN07

The assay requires the use of an CRP Standard (Calibrator) Liquid High. We recommend:

CRP Standard (Calibrator) Liquid High
Ref.No: TA101-3

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 15 days.

Traceability is provided by ERM-DA472/IFCC (European Reference Material/International Federation Clinical Chemistry) from IRMM.

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

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 1.0 mg/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤ 20]:[11] 1.9 mg/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 120 mg/dL.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[12]

Repeatibility (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
9.0 mg/L	0.10	1.10	20
19.0 mg/L	0.17	0.89	20

Reproducibility (Run to Run) (Inter-Assay)

Mean Concentration	SD	CV%	n
8.5 mg/L	0.19	2.23	40
19.0 mg/L	0.27	1.42	40

*SD: Standard Deviation

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Prozone Effect: No prozone effect has been observed up to 1000 mg/L value which is tested for CRP Turbi.

Method Comparison:[13, 14]
Correlation with a comparative method is: r= 0.9994
According to Passing-Bablok equation:
Slope: 0.945
Intercept: -0.84

Interference:[15, 16, 17, 18]

No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia, rheumatoid factors up to the interferent concentration given in the table.

Interfering Substance and Concentration	CRP Turbi Target (U/L)	N	Observed Recovery %
Hemoglobin 500 mg/dL	21.0	3	92.0
Bilirubin 60 mg/dL	18.0	3	102.0
Lipemi 3300 mg/dL	21.0	3	97.0

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

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

EUH032 :Releases a very toxic gas if contacts with acid.
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. Greiling H, Gressner AM, eds. Lehrbuch der Klinischen Chemie und Pathobiochemie, 3rd ed. Stuttgart/New York: Schattauer Verlag 1995:234-236.
2. Thomas L. Labor und Diagnose, 7. Auflage, TH-Books Verlagsgesellschaft mbH, Frankfurt/Main 2008;1010-1021.
3. Burtis CA, Ashwood ER, eds. Tietz Fundamentals of Clinical Chemistry, 5th ed. Pa: WB Saunders Co 2001;332-333.
4. Thomas L, Messenger M. Pathobiochemie und Labordiagnostik der Entzündung. Lab med 1993;17:179–194.
5. Young B, Gleeson M, Cripps AW. C-reactive protein: A critical review. Pathology 1991;23:118-124.
6. Wasunna A, Whitelaw A, Gallimore R, et al. C-reactive protein and bacterial infection in preterm infants. Eur J Pediatr 1990 Mar;149(6):424-427.
7. Vergis N. Should CRP be used as a marker of infection in patients with liver cirrhosis? Clin Lab Int 2007;6:12-13.
8. Mackenzie I, Woodhouse J. C-reactive protein concentrations during bacteraemia: a comparison between patients with and without liver dysfunction. Intensive Care Medicine 2006;32:1344-1351.
9. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
10. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
11. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
12. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.
13. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26.783-79.
14. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline.CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
15. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline.CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition.CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)

16. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
17. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
18. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
19. Price CP, Trull AK, Berry D, Gorman EG. Development and validation of a particle-enhanced turbidimetric immunoassay for C-reactive protein. J Immunol Methods 1987; 99: 205-211
20. Otsuji S, Shibata H, Umeda M. Turbidimetric immunoassay of serum C-reactive protein. Clin Chem 1982; 28: 2121-4
21. Tietz Textbook of Clinical Chemistry, 3rd edition. Burtis CA, Ashwood ER. WB Saunders Co. 1999.
22. Young DS. Effects of drugs on clinical laboratory Test, 3th ed. AACC Press, 1997.
23. Friedman and Young. Effects of disease on clinical laboratory Test, 3th ed. AACC Press, 1997.
24. Kindmark C-O. The concentration of C-Reactive Protein in sera from healthy individuals. Scand J Clin Lab Invest 1972; 29: 407-411
25. Grange J, Roch AM, Quash GA. Nephelometric assay of antigens and antibodies with latex particles. J Immunol Methods 1977; 18: 365-375

Archem Sağlık Sanayi ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr **www.archem.com.tr**

CE

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 Practice
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