C-REACTIVE PROTEIN-WIDE RANGE
(CRP TURBI WR)

En

REF DMT102
REF 8A11T
REF At103

Diagnostic reagent for determination of Low CRP concentration with higher sensitivity.
Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze.
DMT102, 8A11T and At103 products are produced specifically for Siemens Advia, Siemens Atellica and Siemens Dimension Analyzer Series.

INTENDED USE[1,5,8,9]

The test is applied for the quantitative determination of CRP in 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. CRP activates the classical complement pathway as a response to the inflammatory reaction.

CRP levels in plasma can rise dramatically 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. An elevation can be expected in virtually all diseases involving tissue damages so the finding is nonspecific.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE[3,10,11,12]

Serum C-reactive protein (CRP) causes agglutination of the latex particles coated with anti- human C-reactive protein. The agglutination of the latex particles is proportional to the CRP concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method	: Turbidimetric
Wavelength	: 570 nm
Temperature	: 37°C
Sample	: Serum
Linearity	: 1 mg/L - 350 mg/L (for Advia and Atellica)
	: 2,0 mg/L - 200 mg/L (for Dimension)

REAGENT COMPOSITION

Reagent1:
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.

CRP Standard (Calibrator): Human serum. C-reactive protein concentration is stated on the vial label.
Concentration value is traceable to the Standard Reference Material ERM-DA472/IFCC (Institute for Reference Materials and Measurements, IRMM).
Human serum used in the preparation of the controls have been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the controls should be handled cautiously as potentially infectious.

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

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

On board stability:
Once the vials are open they are stable at least 30 days at +2/+8°C in optimum conditions.
Once opened vials are stable 30 days at +2/+8°C at optimum conditions. There is a strong relation between on board stability and auto analyzer's cooling specification and the carry-over percentage.
For reagents which are related to antigen antibody reaction, do not shake the R2, sample, control and calibrator; just gently mix them.

Indications of deterioration:
Reagents: Absorbance of the blank over 0.900 at 570 nm.
Standard (Calibrator): Presence of moisture.

SAMPLE

Serum:
Sample is collected by standard procedures.

CRP in serum is stable for:

15 days at +20 /+25°C,
2 months at +2/+8ºC
and 3 years at -20°C.

Samples should preferably be analyzed on the day of collection.
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 Turbi WR Turbidimetric,
REF DMT102,
REF 8A11T,
REF At103.

Materials required but not provided

- Archem CRP Turbi WR Calibrator 5 Levels
  REF: TA104S (Advia and Atellica CH)
- Archem CRP Turbi WR Calibrator 4 Levels
  REF: TA104D (Dimension)

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

REFERENCE INTERVALS (NORMAL VALUES) (Based on CLSI EP28A3/Transference) [18]

Serum Adults:	0-5 mg/L (0-0.5 mg/dL) [17]
Neonatal (0-30 days):	0-10 mg/L (0-1 mg/dL)

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

Unit Conversion
CRP mg/dL*10=CRP mg/L

QUALITY CONTROL

Commercially available control material with established values determined by the same method of Archem CRP WR Turbidimetric. We highly recommend:

Specific Protein Control Level I**: REF No: RCN01**

Specific Protein Control Level II: **REF No: RCN05**

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

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CALIBRATION

The assay requires the use of an Archem Standard (Calibrator). We recommend:
Archem CRP Turbi WR Calibrator 5 Levels
(For Advia and Atellica CH)
Archem CRP Turbi WR Calibrator 4 Levels
(For Dimension Series)

Calibration Stability: Calibration stability is 30 days.
Calibration is not recommended if QC values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity (LoQ):
Values are based on CLSI Standard EP17A and LoQ CV% values ≤ 20%:
1 mg/L (For Advia and Atellica)
2.0 mg/L (For Dimension)

Sensitivity (LoD):
Limit of detection is 0.5 mg/L (For Advia and Atellica)
Limit of detection is 1 mg/L (For Dimension Series)

High Linearity

350 mg/L (35 mg/dL) for Advia and and Atellica CH
200 mg/L (20 mg/dL) for Dimension Series

For higher concentrations over linearity range dilute sample 1/5 with distilled water or dilute with analyser predefined automated dilution mode and repeat measurement

Precision Studies (Based on CLSI EP05A3.):
Repeatability (within run) (intra-assay) Within-run reproducibility was established by assaying two levels of control serum 20 runs.

Mean (mg/L)	Std. Dev.	CV%	N
20.4	0.30	1.42	40
122.3	1.14	0.93	40

Repeatability (Run to run) (inter-assay) Run-to-run reproducibility was established by assaying two levels of control serum for 20 runs.

Mean (mg/L)	Std.Dev.	CV%	N
20.9	0.34	1.65	40
122.2	1.27	1.04	40

* An Advia 1800 has been used to obtain these performance characteristics.

Method Comparison and Correlation:
Correlation with a reference reagent is r=0.999
Regression analysis according to Passing-Bablok Fit**:**
Slope: 0.99
Intercept: -0.18

Prozone effect: Falsely low values are obtained when CRP is present in the sample with a concentration higher than 1000 mg/L.

Interferences: [6, 15, 16]
The acceptable interference limit is set 10% below the highest interferent concentration that is within ±10% recovery of the target.
No significant interaction was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferant concentration given in the table. Other drugs and substances may interfere.
Reference observed results in the table below.[10, 11]

Interferent and Concentration	CRP Turbi WR Target (mg/L)	N	Observed Recovery %
Bilirubin (Conjugated) 54 mg/dL	17.6	3	91%
	132.6	3	91%
Triglycerides 1035 mg/dL	18.5	3	91%
	132.5	3	91%
Hemoglobin 540 mg/dL	21.0	3	90%
	145.0	3	93%

The effect of interfering substances has only been evaluated for those listed in this table.
An analyzer (Advia 1800) has been used to obtain these performance characteristics. Usage of different analyzer or a manual procedure may cause the variance in results.
Intralipid has been used for Triglycerides interferences studies.

NOTES

1. For in vitro diagnostic use only. Mouth pipetting is prohibited. Avoid contact with skin and mucous membranes.
2. All the calibrators and controls must be considered as human or animal-sourced substances and thus they are potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet (SDS) will be provided upon request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. Caps of the reagents bottles cannot 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
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