CRP WR TURBIDIMETRIC
C-REACTIVE PROTEIN WR

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.

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Pack</th>
<th>Ref No</th>
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<th>Ref No</th>
<th>Pack</th>
<th>Ref No</th>
<th>Pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>TW101N</td>
<td>500 mL</td>
<td>RAB100</td>
<td>1705 Tests</td>
<td>MAB100</td>
<td>2333 Tests</td>
<td>8A101</td>
<td>4682 Tests</td>
</tr>
<tr>
<td>TW102N</td>
<td>250 mL</td>
<td>RAB101</td>
<td>568 Tests</td>
<td>MAB101</td>
<td>1100 Tests</td>
<td>8A102</td>
<td>3020 Tests</td>
</tr>
<tr>
<td>TW103N</td>
<td>125 mL</td>
<td>DMT100</td>
<td>840 Tests</td>
<td>M4B100</td>
<td>2394 Tests</td>
<td>KAB100</td>
<td>4444 Tests</td>
</tr>
<tr>
<td>TA103</td>
<td>125 mL</td>
<td>DMT101</td>
<td>855 Tests</td>
<td>M4B101</td>
<td>1195 Tests</td>
<td>KAB101</td>
<td>2222 Tests</td>
</tr>
<tr>
<td>TW104</td>
<td>50 mL</td>
<td>BY101</td>
<td>4880 Tests</td>
<td>PS2350</td>
<td>470 Tests</td>
<td>ER20</td>
<td>2250 Tests</td>
</tr>
<tr>
<td>TBAB100</td>
<td>250 mL</td>
<td>BY102</td>
<td>3166 Tests</td>
<td>LAB100</td>
<td>3068 Tests</td>
<td>RD103A</td>
<td>600 Tests</td>
</tr>
<tr>
<td>TBAB101</td>
<td>150 mL</td>
<td>SAB10</td>
<td>1176 Tests</td>
<td>LAB101</td>
<td>1364 Tests</td>
<td>LM211</td>
<td>1364 Tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>At101</td>
<td>2190 Tests</td>
<td></td>
<td></td>
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</tbody>
</table>

INTENDED USE

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

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

TEST PARAMETERS

<table>
<thead>
<tr>
<th>Method</th>
<th>: Immunoturbidimetric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wavelength</td>
<td>: 340 nm</td>
</tr>
<tr>
<td>Temperature</td>
<td>: 37 °C</td>
</tr>
<tr>
<td>Sample</td>
<td>: Serum / Plasma</td>
</tr>
<tr>
<td>Linearity</td>
<td>: 2.0 mg/L - 350 mg/L (0.2-35 mg/dL)</td>
</tr>
</tbody>
</table>

REAGENT COMPOSITION

<table>
<thead>
<tr>
<th>Reagent 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffer</td>
</tr>
<tr>
<td>Stabilizer</td>
</tr>
<tr>
<td>Sodium azide</td>
</tr>
<tr>
<td>pH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reagent 2:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-CRP antibody, Sodium azide</td>
</tr>
</tbody>
</table>

Once opened vials, R1 and R2 are stable 30 days minimum at 2-8°C. There is a strong relation between on board stability and analyzers specifications.


Testing of CRP antigens used in the preparation of the standard is resulted as negative for the presence of antibodies anti-HIV and anti-HCV, beside for HBs antigen. Because of the possibility of being infectious, standards should be used cautiously.

REAGENT PREPARATION

Reagents are ready to use, liquid.

REAGENT STABILITY AND STORAGE

Once opened vials are stable 30 days (720 hours) at 2-8°C at optimum conditions. There is a strong relation between on board stability and auto analysers cooling specification.
and carry-over values.

Reagents are stable till the expiry date stated on the label when they stored in closed vials and avoiding contamination during their usage.

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

Calibrator: Presence of moisture.

**SAMPLE**

Serum is collected by standard procedures.
CRP proteins in serum are stable for 5 days at 20 - 25°C, 15 days at 2-8°C and 1 year at -20°C. (Criteria %90 recovery)

For reagents which are related antigen antibody interaction, do not shake the sample, R2, control and calibrator; just gently mix by up-down movement.

**TEST PROCEDURE**

**Sample Start**
In case of request, ready application procedures dedicated to different kind of photometers and ready manual working procedures can be supplied.

In case of request, ready application procedures dedicated to different of biochemistry auto analyzers can be supplied.

**CALCULATIONS**

The C-reactive protein concentration in the sample is calculated using the following general formula:

\[
\frac{A_2 - A_1}{A_2 - A_1} \times C \text{ Standard} = C \text{ Sample} 
\]

**Unit Conversion**

CRP mg/dL*10=CRP mg/L

**REFERENCE INTERVALS (NORMAL VALUES)**

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

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

**QUALITY CONTROL**

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

Rheumatoid Control Level I
Cat.No. RCN01

Rheumatoid Control Level II
Cat.No. RCN05

Liquid Rheumatoid Control Level I
Cat.No. RCN06

Liquid Rheumatoid Control Level II
Cat.No. RCN07

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 Calibrator (Standard) *Ref. No. TA102S-4

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%) 2 mg/L CRP.

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

**Precision Studies (Based on CLSI EP05A3):**

<table>
<thead>
<tr>
<th>Mean conc.</th>
<th>SD</th>
<th>CV %</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5 mg/L</td>
<td>0.18</td>
<td>3.3 %</td>
<td>20</td>
</tr>
<tr>
<td>20.3 mg/L</td>
<td>0.27</td>
<td>1.34 %</td>
<td>20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean conc.</th>
<th>SD</th>
<th>CV %</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.0 mg/L</td>
<td>0.72</td>
<td>3.8 %</td>
<td>88</td>
</tr>
<tr>
<td>54.2 mg/L</td>
<td>1.9</td>
<td>3.5 %</td>
<td>80</td>
</tr>
</tbody>
</table>

**Sensitivity (LOD):** 0.7 mg/L.

**Trueness:** No systematic differences seen in results obtained with this reagent when compared with reference reagents. It’s available to get details of comparison experiments in case of requirement.

**Prozone effect:** If CRP is present in the sample at a concentration higher than 1600 mg/L, it will be resulted in obtaining falsely low values. Concentrations over 1800 mg/L have not tested.
Interferences:
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.

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

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

REFERENCES

<table>
<thead>
<tr>
<th>SYMBOLS</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot number</td>
</tr>
<tr>
<td>R1</td>
<td>Reagent 1</td>
</tr>
<tr>
<td>R2</td>
<td>Reagent 2</td>
</tr>
<tr>
<td>GTIN</td>
<td>Global Trade Item Number</td>
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<tr>
<td>REF</td>
<td>Reference Number</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practices</td>
</tr>
</tbody>
</table>

FOR USE WITH

- Product of Turkey
- Manufacturer
- Expiration date
- Temperature limitation
- Consult instructions for use
- Caution
- Sufficient for

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