DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

CRP 5+1

Diagnostic reagent for the quantitative in vitro determination of CRP (C-Reactive Protein) in human serum by turbidimetric assay.

Ref.No.	Kit Size	Content
DIA020010	60 ml	2x25 ml R1 + 1x10 ml R2
DIA020011	120 ml	4x25 ml R1 + 1x20 ml R2
DIA020012	6 x 25 ml	5x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040020	1 x 1 mL	**CRP Calibrator High**
DIA030040	1 x 1 mL	**CRP Control High**
DIA030090	1 x 1 mL	**Triple Control (ASO, CRP, RF)**

GENERAL INFORMATION

Method	Immunoturbidimetric
Reaction	Nonlinear, endpoint
Wavelength	340 nm
Assay Temperature	18 – 37 °C
Sample	Serum
Measuring Range	approx. 0 – 22 mg/dL
Sensitivity	0.6 mg/dL (Hitachi 911)
Hook Effect	No risk

Automated Test Procedure
Instrument dependent – please ask for applications

REAGENT COMPOSITION

COMPONENTS	FINAL CONCENTRATION
CRP Antibody Reagent	
Polyclonal goat anti-h CRP antibody	variable
Sodium azide	0.095 %
PEG4 Buffer	
Phosphate buffered saline, pH 7.4	
PEG	4 %
Sodium azide	0.095 %

REAGENT PREPARATION

The reagents are liquid and ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light. Close immediately after use.

Stability: at 2 – 8 °C up to the expiration date
at 18 – 25 °C 1 month

Do not freeze!
Incompetent handling will release Diagnostica from any responsibility.

SAMPLE STABILITY AND STORAGE

Stability: at 2 – 8 °C 48 hours
at – 20 °C 3 months

Freeze only once!

TEST PRINCIPLE

The assay of CRP is based on turbidimetric measurement. Turbidity is caused by the formation of antigen-antibody insoluble immuno complexes. The formation of the complexes is accelerated and enhanced by PEG.

REFERENCE RANGE

0 – 1 mg/dL

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

MANUAL TEST PROCEDURE

Test Procedure without Sample Dilution:
Samples/Controls: ready to use
Calibration curve: Use CRP Calibrator High to generate a calibration curve by making 1:2 serial dilutions of the calibrator with 0.9% saline as diluent or use the 5 level calibrator series. Use 0.9% saline as zero point.

Pipette into test tubes:	Calibrators	Samples/Controls
Buffer	1000 µL	1000 µL
Cal./Ctrls/Samples	64 µL	64 µL
Mix. Read A1 of calibrators and samples/controls at 340 nm. Then add:		
Antibody Reagent	200 µL	200 µL
Mix. Incubate 5 minutes at assay temperature. Read A2 of calibrators and samples/controls at 340 nm. Calculate: ΔA = (A2 – A1)		

CALCULATION

Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and control(s) and read values in mg/dL on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

DIAGNOSTIC IMPLICATIONS

C-Reactive Protein (CRP) is an acute marker of inflammatory processes. In case of an acute inflammation the concentration of CRP increases and decreases more rapidly than the red cell sedimentation rate. The increase of CRP occurs in a non-specific way in different kinds of tissular aggression, as for example in infectious states, rheumatoid arthritis, myocardial infarction, malignant tumor, etc.

PERFORMANCE CHARACTERISTICS

SENSITIVITY
0.6 mg/dL (Hitachi 911)

ACCURACY

Control	Assigned Value (mg/dL)	Measured (mg/dL)
CRP Control	1.00 (0.85 – 1.15)	0.9
CRP Control	2.02 (1.72 – 2.32)	1.92
CRP Control	2.78 (2.21 – 4.35)	3.5
CRP Control	11.9 (10.12 – 13.69)	11.8

PRECISION

Intra-Assay Precision
3 Serum Samples were consecutively measured 20 times on the Hitachi 911 and the variation coefficient was calculated.

Expected Value	n	Mean mg/dL	S.D.	C.V. %
Low	20	1.15	0.051	4.46
Medium	20	6.61	0.059	0.89
High	20	11.63	0.087	0.75

Inter-Assay Precision
Diagnostica CRP Control serum was measured daily on the Hitachi 911 during one month after calibration. Furthermore a serum with a high CRP level was divided in aliquots and stored at -20 °C. After calibration it was measured on 6 occasional days on the Hitachi 911.

Analyzer	n	Mean mg/dL	S.D.	C.V. %
Hitachi 911	20	1.42	0.05	4.2
Hitachi 911	20	11.4	0.4	3.42

INTERFERING SUBSTANCES

No interference up to:

Triglycerides	2500 mg/dL	**Hemoglobin**	1000 mg/dL
Bilirubin	20 mg/dL	**Sodium Citrate**	1000 mg/dL
Heparin	50 mg/dL		

QUALITY CONTROL

All Control sera with CRP values measured by this method may be used. We recommend the Diagnostica CRP Control High, the Protein Control and the Triple Control.

CALIBRATION

The assay requires the use of CRP serum Calibrators. We recom-

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mend the Diagnostica CRP Calibrator High.
The use of other commercially available CRP calibrators is not recommended. It is sufficient to perform calibration once a month.

AUTOMATION

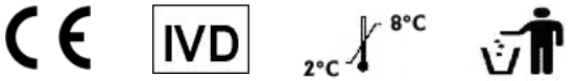
Applications for automated systems are available upon request.

WARNINGS AND PRECAUTIONS

1. The CRP reagents are intended for in vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV antibodies, as well as for Hepatitis B surface antigen, using a method approved by the FDA
4. Avoid eyes and skin contact. If contact, flush with a large amount of water. If irritation persists, consult a physician

WASTE MANAGEMENT

Please refer to local requirements.



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