DXC 800 (CRP) C-REACTIVE PROTEIN

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☐ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for the quantitative determination of C-Reactive Protein on the DXC 800.

PRINCIPLE

CRP reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems CAL 5 Plus, is intended for quantitative determination of C-Reactive Protein concentration in human serum or plasma.

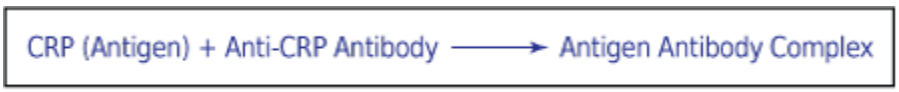
BACKGROUND

Clinical Significance

C-reactive protein measurements are useful in the clinical evaluation of stress, trauma, infection, inflammation, and surgery.

Methodology

CRP reagent is used to measure the C-Reactive Protein concentration by a turbidimetric method. In the reaction, C-Reactive Protein combines with specific antibody to form insoluble antigen-antibody complexes.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 26 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is proportional to the concentration of C-reactive protein in the sample and is used by the System to calculate and express C-reactive protein concentration based upon a single-point adjusted, pre-determined calibration curve.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
J-F-CH-0826	DXC 800 Calibrators
J-F-CH-1940	DXC 800 Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • Frozen 3 months

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two CRP Reagent Cartridges (2 x 200 tests)
One lot-specific Parameter Card

Volume per Test	
Sample Volume	10 uL
ORDAC Sample Volume	4 uL
Total Reagent Volume	260 uL
Cartridge, Volumes	A 250 uL and C 10 uL

Reactive Ingredients	
Polyclonal anti-CRP Antibody(Goat)	3.5mL
Reaction Buffer	63.4mL

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

CRP reagent when stored unopened at +2°C to +8°C, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 60 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE

CALIBRATION

Calibrator Required

SYNCHRON® Systems CAL 5 Plus

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems CAL 5 Plus is stable until the expiration date printed on the calibrator bottle if stored capped in the original container at +2°C to +8°C.

Calibrator Information

1. The system must have a lot-specific parameter card and a valid calibration adjustment in memory before controls or patient samples can be run.

2. Under typical operating conditions the CRP reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual for information on this feature.
3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls

STEPS

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program samples and controls for analysis.
4. After loading samples and controls onto the system, follow the protocols for system operation.

For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with 50 paired human serum and plasma samples. Values of serum (X) ranging from 0.7 mg/dL to 14.9 mg/dL were compared with the values for plasma (Y) yielding the following results.

Anticoagulant	Level Tested for In Vitro Interference
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL

PERFORMANCE CHARACTERISTICS

Reference Range

0 -1.5 mg/dL

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	0.5 – 20 mg/dL
Serum or Plasma(ORDAC)	15 – 48.8 mg/dL

Due to CRP turbidimetric method limitation the Neonate results will have the following amended comment.

"**This CRP tubidimetric method should not be used as the sole diagnostic marker of infection in neonates due to reports of suboptimal sensitivity**."

Samples with concentrations exceeding the high end of the analytical range should be diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of detection	0.5 mg/dL	Results below 0.5 report < 0.5mg/dL
Upper limit of detection(ORDAC)	48.8 mg/dL	Results > 48.8 should be with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >97.6 are reported as >97.6 mg/dL.

Lipemic specimens >=2 Index Level or "**SUPPRESSED"** result due to **RXN ERROR** should be sent to PAML. "**Results Suppressed**, **Blank Rate-High**" should NOT be diluted and should be sent to PAML.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CRP determination is 0.5 mg/dL (5.0 mg/L).

LIMITATIONS

Neonatal samples should not be tested using the SYNCHRON CRP turbidimetric assay.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	No Significant Interference (within +/- 0.4 mg/dL or 10%)
Bilirubin	Porcine	30 mg/dL INDEX of 20	No Significant Interference (within +/- 0.4 mg/dL or 10%)
Lipemia	Human	1+ INDEX of 2	No Significant Interference (within +/- 1.4 mg/dL or 10%)
Rheumatoid Factor	Human	400 IU/mL	No Significant Interference (within +/- 1.4 mg/dL or 10%)

2. Lipemic specimens >=2 Index Level or "SUPPRESSED" result due to RXN ERROR should be sent to PAML. "Results Suppressed, Blank Rate-High" should NOT be diluted and should be sent to PAML.

3. Refer to References for other interferences caused by drugs, disease and preanalytical variables.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Change in formatting. Removed EDTA as specimen type. Added max dilutions.			
☒ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☐ Date: ☒ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 9/25/15