**Alinity c CRP Vario (CRP)-12**

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**BIENNIAL REVIEW:**

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**SUPERSEDES: Procedure titled** _____

# INTENDED USE

The Alinity c CRP Vario assay is used for the quantitative immunoturbidimetric determination of C-reactive protein in human serum or plasma with variable assay ranges [CRP HS and CRP WR] on the Alinity c analyzer.

# SUMMARY AND EXPLANATION OF THE TEST

C-reactive protein (CRP) is an acute phase protein whose concentration rises non-specifically in response to inflammation. CRP is seen to increase as a result of the inflammatory process, most notably in response to pneumococcal (bacterial) infection, histolytic disease, and a

variety of other disease states. Intraindividual variation is a major limitation of the assay when the assay is used for directing therapies. Intraindividual variations of the CRP levels are from 30% to 60%. Serial measurement may be required to estimate true mean of CRP depending on the intended use in any specific individual. CRP is used as a marker or general diagnostic indicator of infections and inflammation, in addition to serving as a monitor of patient response to pharmacological therapy and surgery.

# PRINCIPLES OF THE PROCEDURE

Alinity c CRP Vario is a latex immunoassay developed to accurately and reproducibly measure blood CRP levels in serum and plasma. When an antigen-antibody reaction occurs between CRP in a sample and anti-CRP antibody, which has been adsorbed to latex particles, agglutination results. This agglutination is detected as an absorbance change (572 nm), with the rate of change being proportional to the quantity of CRP in the sample. Two different methods (High Sensitivity [CRP HS] and Wide Range [CRP WR]) are available to cover a wide analytical measurement range.

**Methodology: Turbidimetric/Immunoturbidimetric**

For additional information on system and assay technology, **refer to the Alinity ci-series Operations Manual, Section 3.**

# REAGENTS

## Kit Contents

Alinity c CRP Vario Reagent Kit 07P56

Volumes (mL) listed in the table below indicate the volume per cartridge.

| REF | **07P5621** |
|---|---|
| Tests per cartridge | 350 (High Sensitivity)<br>290 (Wide Range) |
| Number of cartridges per kit | 10 |
| Tests per kit | 3500 (High Sensitivity)<br>2900 (Wide Range) |
| R1 | 43.6 mL |
| R2 | 43.2 mL |

R1 Active ingredient: Glycine buffer (pH 7.0) (1.28%). Inactive ingredient: bovine albumin (≤ 1%). Preservative: sodium azide (< 0.1%).

R2 Active ingredient: Anti-CRP polyclonal antibodies (rabbit) adsorbed on latex particles (0.2%). Inactive ingredient: bovine albumin (≤ 0.1%). Preservative: sodium azide (< 0.1%).

### Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

## Safety Precautions

**CAUTION:** This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1], [2], [3], [4]

| The following warnings and precautions apply to: R1 and R2 | |
|---|---|
| Contains sodium azide. | |
| EUH032 | Contact with acids liberates very toxic gas. |
| P501 | Dispose of contents / container in accordance with local regulations. |

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 8.**

## Reagent Handling

- Reagents are shipped on wet ice.
- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Prior to running, gently invert cartridges 5 times.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, **refer to the Alinity ci-series Operations Manual, Section 7.**

### Reagent Storage

| | Storage Temperature | Maximum Storage Time | Additional Storage Instructions |
|---|---|---|---|
| **Unopened** | 2 to 8°C | Until expiration date | Store in upright position. |
| **Onboard** | System Temperature | 60 days | |

### Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when:

- a calibration error occurs
- a control value is out of the specified range

Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10**.

## INSTRUMENT PROCEDURE

The Alinity c CRP Vario assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 2.**

For information on printing assay parameters, **refer to the Alinity ci-series Operations Manual, Section 5.**

For a detailed description of system procedures, refer to the **Alinity ci-series Operations Manual.**

### Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) =
(Concentration in Alternate result unit)

| Default Result Unit | Conversion Factor | Alternate Result Unit |
|---|---|---|
| **mg/dL** | 10 | mg/L |

# SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

## Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

| Specimen Type | Collection Vessel | Special Conditions |
|---|---|---|
| Serum | Serum tubes (with or without gel barrier) | Glass tubes were not tested. |
| Plasma | Collection tubes<br>Acceptable anticoagulants are:<br>Lithium heparin (with or without gel barrier)<br>Sodium heparin | Glass tubes were not tested. |

## Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

## Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

## Specimen Storage

| Specimen Type | Temperature | Maximum Storage Time |
|---|---|---|
| Serum/Plasma | 20 to 25°C | 15 days |

| Specimen Type | Temperature | Maximum Storage Time |
|---|---|---|
| | 2 to 8°C | 2 months |
| | -20°C | 1 year[5] |

Avoid multiple freeze/thaw cycles.

If analysis will not be completed within the maximum storage recommendations, the separated serum/plasma should be frozen at or below -20 °C. For additional information on sample handling and processing, refer to CLSI GP44-A4.[6] Repeated freeze/thaw cycles should be avoided to minimize potential analyte degradation. The storage information provided here is based on references or data maintained by the manufacturer.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

### Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

## PROCEDURE

### Materials Provided

07P56 Alinity c CRP Vario Reagent Kit

### Materials Required but not Provided

- Alinity c CRP Vario assay file
- 07P5603 Alinity c CRP Vario Wide Range Calibrator Kit
- 07P5604 Alinity c CRP Vario High Sensitivity Calibrator Kit
- 07P5612 Alinity c CRP Vario HS Control Kit or other commercially available controls
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, **refer to the Alinity ci-series Operations Manual, Section 1.**

For information on materials required for maintenance procedures, **refer to the Alinity ci-series Operations Manual, Section 9.**

### Assay Procedure

For a detailed description of how to run an assay, **refer to the Alinity ci-series Operations Manual, Section 5.**

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

- Minimum sample volume requirements:
    - Sample volume for single test**: 4.0 µL** (High Sensitivity); **2.0 µL** (Wide Range).

      NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. **For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.**
- Refer to the Alinity c CRP Vario High Sensitivity Calibrator Kit package insert, Alinity c CRP Vario Wide Range Calibrator Kit package insert, and Alinity c CRP Vario HS Control Kit package insert for preparation and usage.
- For general operating procedures, **refer to the Alinity ci-series Operations Manual, Section 5.**
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, **Section 9. Perform maintenance more frequently when required by laboratory procedures.**

## Sample Dilution Procedures

Samples with CRP values exceeding 16.00 mg/dL (160.00 mg/L) for the High Sensitivity application are flagged with the code "> 16.00 mg/dL" (> 160.00 mg/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Samples with CRP values exceeding **48.00 mg/dL** (480.0 mg/L) for the Wide Range application are flagged with the code "> 48.00 mg/dL " (> 480.0 mg/L) and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

### Automated Dilution Protocol

The system performs a 1:10 dilution of the sample when using the High Sensitivity application and automatically calculates the concentration by multiplying the result by the dilution factor.

The system performs a **1:5** dilution of the sample when using the Wide Range application and automatically calculates the concentration by multiplying the result by the dilution factor.

### Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the analytical measuring interval of 0.03 mg/dL (0.30 mg/L) for the High Sensitivity application, do not report the result. Rerun using an appropriate dilution. If a diluted sample result is less than the lower value of the analytical measuring interval of 0.10 mg/dL (1.0 mg/L) for the Wide Range application, do not report the result. Rerun using an appropriate dilution.

NOTE: The default Low Linearity value of the assay file corresponds to the reportable interval limit of 0.02 mg/dL (0.20 mg/L) for the High Sensitivity method. To flag values

using the analytical measuring interval limit of 0.03 mg/dL (0.30 mg/L), the operator must edit the Low Linearity value of the assay parameters to 0.03 mg/dL (0.30 mg/L). The default Low Linearity value of the assay file corresponds to the reportable interval limit of **0.04** mg/dL (0.4 mg/L) for the Wide Range method. To flag values using the analytical measuring interval limit of **0.10 mg/dL** (1.0 mg/L), the operator must edit the Low Linearity value of the assay parameters to 0.10 mg/dL (1.0 mg/L). For detailed information on editing the result settings of assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

## Calibration

For instructions on performing a calibration, **refer to the Alinity ci-series Operations Manual, Section 5.**

### High Sensitivity

Calibration is stable for approximately **15 days (360 hours),** but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the laboratory quality control procedure. If control results fall outside acceptable ranges, recalibration may be necessary.

### Wide Range

Calibration is stable for approximately **15 days (360 hours)**, but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to to the laboratory quality control procedure. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

## Quality Control Procedures

- Two levels of controls (normal and abnormal) are to be run every day testing performed.
- If quality control results do not meet the acceptance criteria defined by laboratory quality controls procedure, sample results may be suspect. Follow the established quality control procedures to troubleshoot. Recalibration may be necessary. For troubleshooting information, **refer to the Alinity ci-series Operations Manual, Section 10.**
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

### Quality Control Guidance

Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[7]

### Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

# RESULTS

## Calculation

The Alinity c CRP Vario assay utilizes the Spline data reduction method to generate a calibration and results.

For information on alternate result units, refer to the INSTRUMENT PROCEDURE, Alternate Result Units section of this package insert.

## Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, **refer to the Alinity ci-series Operations Manual, Section 5**.

## Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[8]

**High Sensitivity**

| | mg/dL | mg/L |
|---|---|---|
| Analytical Measuring Interval (AMI)[a] | 0.03 - 16.00 | 0.30 - 160.00 |
| Extended Measuring Interval (EMI)[b] | 16.00 - 160.00 | 160.00 - 1600.00 |
| Reportable Interval [c] | 0.02 - 160.00 | 0.20 - 1600.00 |

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (mg/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × dilution factor. The value reflects a 1:10 dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval.

**Wide Range**

| | mg/dL | mg/L |
|---|---|---|
| Analytical Measuring Interval (AMI)[a] | **0.10 - 48.00** | 1.0 - 480.0 |
| Extended Measuring Interval (EMI)[b] | 48.00 - 240.00 | 480.0 - 2400.0 |

| | mg/dL | mg/L |
|---|---|---|
| Reportable Interval [c] | **0.04 - 240.00** | 0.4 - 2400.0 |

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/dL (mg/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × dilution factor. The value reflects a 1:5 dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval.

# LIMITATIONS OF THE PROCEDURE

Specimens collected in EDTA collection tubes are not acceptable for use. The following are limitations on the use of the High Sensitivity CRP per CDC/AHA recommendations.[9]

- Screening the entire adult population is not recommended.
- CRP is not a substitute for traditional cardiovascular risk factors.
- Acute coronary syndrome management should not depend on CRP measurements.
- Patients with persistently unexplained CRP levels above 1.0 mg/dL (10 mg/L) should be evaluated for noncardiovascular etiologies.
- Secondary prevention measures should not depend on CRP.
- Serial measurements of CRP should not be used to monitor treatment.
- The average of two CRP results, repeated optimally two weeks apart, should be used on metabolically stable patients.

In very rare cases gammopathy, particularly of the monoclonal IgM type (e.g., Waldenström macroglobulinemia), may cause unreliable results.

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

# EXPECTED VALUES

Manufacturer provided reference range will be used and effort made to verify in house.

**Reference Range**

| | Range (mg/dL) | Range (mg/L) |
|---|---|---|
| Serum and plasma[10] | ≤ 0.5 | ≤ 5 |

Schlebusch et al.[11] have published pediatric reference ranges. CRP is an acute phase protein whose concentration rises non-specifically in response to inflammation. CRP values should not be interpreted without a complete clinical evaluation. Follow-up testing of patients with elevated values is recommended in order to help rule out a recent response to undetected

infection or tissue injury. For diagnostic purposes, the patient's medical history and all other clinical findings should be considered when evaluating CRP results.

# SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

## Precision

Within-Laboratory Precision

### High Sensitivity

A study was performed based on guidance from CLSI EP05-A3.*12* Testing was conducted using 1 lot of the Alinity c CRP Vario Reagent Kit, 1 lot of the Alinity c CRP Vario High Sensitivity Calibrator Kit, and 1 lot of commercially available controls and 1 instrument. Four controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

| | | | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| **Sample** | **n** | **Mean (mg/dL)** | **SD** | **%CV** | **SD** | **%CV** |
| Control Level 1 | 120 | 0.05 | 0.004 | 8.6 | 0.005 | 9.4 |
| Control Level 2 | 120 | 0.33 | 0.007 | 2.0 | 0.008 | 2.6 |
| Control Level 3 | 120 | 0.90 | 0.016 | 1.8 | 0.018 | 2.0 |
| Control Level 4 | 120 | 3.10 | 0.024 | 0.8 | 0.034 | 1.1 |

[a] Includes within-run, between-run, and between-day variability.

| | | | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| **Sample** | **n** | **Mean (mg/L)** | **SD** | **%CV** | **SD** | **%CV** |
| Control Level 1 | 120 | 0.52 | 0.045 | 8.6 | 0.049 | 9.4 |
| Control Level 2 | 120 | 3.26 | 0.066 | 2.0 | 0.084 | 2.6 |
| Control Level 3 | 120 | 9.00 | 0.163 | 1.8 | 0.177 | 2.0 |
| Control Level 4 | 120 | 31.00 | 0.236 | 0.8 | 0.338 | 1.1 |

[a] Includes within-run, between-run, and between-day variability.

**Wide Range**

A study was performed based on guidance from CLSI EP05-A3.[12] Testing was conducted using 1 lot of the Alinity c CRP Vario Reagent Kit, 1 lot of the Alinity c CRP Vario Wide Range Calibrator Kit, and 1 lot of commercially available controls and 1 instrument. Three controls and 1 human serum panel were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.

| | | | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| **Sample** | **n** | **Mean (mg/dL)** | **SD** | **%CV** | **SD** | **%CV** |
| Control Level 1 | 120 | 0.40 | 0.012 | 2.9 | 0.012 | 3.1 |
| Control Level 2 | 120 | 1.33 | 0.024 | 1.8 | 0.026 | 1.9 |
| Control Level 3 | 120 | 13.02 | 0.107 | 0.8 | 0.109 | 0.8 |
| Panel | 120 | 27.21 | 0.300 | 1.1 | 0.317 | 1.2 |

[a] Includes within-run, between-run, and between-day variability.

| | | | Within-Run (Repeatability) | | Within-Laboratory (Total)[a] | |
|---|---|---|---|---|---|---|
| **Sample** | **n** | **Mean (mg/L)** | **SD** | **%CV** | **SD** | **%CV** |
| Control Level 1 | 120 | 4.0 | 0.12 | 2.9 | 0.12 | 3.1 |
| Control Level 2 | 120 | 13.3 | 0.24 | 1.8 | 0.26 | 1.9 |
| Control Level 3 | 120 | 130.2 | 1.07 | 0.8 | 1.09 | 0.8 |
| Panel | 120 | 272.1 | 3.00 | 1.1 | 3.17 | 1.2 |

[a] Includes within-run, between-run, and between-day variability.

## Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[13] Testing was conducted using 3 lots of the Alinity c CRP Vario Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below.

**High Sensitivity**

| | **mg/dL** | **mg/L** |
|---|---|---|
| LoB[a] | 0.01 | 0.10 |
| LoD[b] | 0.02 | 0.20 |

| | mg/dL | mg/L |
|---|---|---|
| LoQ[c] | 0.03 | 0.30 |

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

**Wide Range**

| | mg/dL | mg/L |
|---|---|---|
| LoB[a] | 0.02 | 0.2 |
| LoD[b] | 0.04 | 0.4 |
| LoQ[c] | **0.10** | 1.0 |

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

## Linearity

A study was performed based on guidance from CLSI EP06-A.*14*

**High Sensitivity**

This assay is linear across the analytical measuring interval of 0.03 to 16.00 mg/dL (0.30 to 160.00 mg/L).

**Wide Range**

This assay is linear across the analytical measuring interval of **0.10 to 48.00** mg/dL (1.0 to 480.0 mg/L).

## Interference

This study was performed on the ARCHITECT c System.

Potentially Interfering Substances

Interference studies were conducted using acceptance criteria of ± 5% or 0.05 mg/dL deviation, whichever is greater, from the target value. No interference was observed at the concentrations below.

| Potentially Interfering Substance | Interferent Level | |
|---|---|---|
| | Default Units | Alternate Units |

| Potentially Interfering Substance | Interferent Level | |
|---|---|---|
| | Default Units | Alternate Units |
| Bilirubin, conjugated and unconjugated | 66 mg/dL | 1129 µmol/L |
| Hemoglobin | 500 mg/dL | 5 g/L |
| Intralipid | 1500 mg/dL | 15 g/L |
| Rheumatoid factor | 550 IU/mL | 550 kU/L |

### Method Comparison

Studies were performed based on guidance from CLSI EP09-A3*15* using the Passing-Bablok regression method. For the high sensitivity method, one study included specimens across the AMI. A separate study included specimens at the low end of the AMI, between 0.03 and 1.00 mg/dL (0.30 - 10.00 mg/L).

**High Sensitivity**

**Alinity c CRP Vario vs ARCHITECT CRP Vario**

| | Units | N | Correlation Coefficient | Intercept | Slope | Concentration Range |
|---|---|---|---|---|---|---|
| Serum | mg/dL | 130 | 1.00 | 0.14 | 0.98 | 0.05 - 15.66 |
| | mg/L | 130 | 1.00 | 1.36 | 0.98 | 0.50 - 156.55 |
| Serum | mg/dL | 108 | 1.00 | 0.00 | 0.97 | 0.03 - 0.97 |
| | mg/L | 108 | 1.00 | 0.01 | 0.97 | 0.30 - 9.70 |

**Wide Range**

**Alinity c CRP Vario vs ARCHITECT CRP Vario**

| | Units | N | Correlation Coefficient | Intercept | Slope | Concentration Range |
|---|---|---|---|---|---|---|
| Serum | mg/dL | 120 | 1.00 | -0.01 | 1.01 | 0.32 - 45.66 |
| | mg/L | 120 | 1.00 | -0.13 | 1.01 | 3.2 - 456.6 |

# BIBLIOGRAPHY


1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne pathogens.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. 5th ed. Washington, DC: US Government Printing Office; December 2009.

3. World Health Organization. *Laboratory Biosafety Manual*. 3rd ed. Geneva: World Health Organization; 2004.
4. Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition.* CLSI Document M29-A4. Wayne, PA: CLSI; 2014.
5. Jansen E, Beekhof P, Viezeliene D, et al. Long-term stability of cancer biomarkers in human serum: biomarkers of oxidative stress and redox status, homocysteine, CRP and the enzymes ALT and GGT. *Biomark Med* 2015;9(5):425-432.
6. Clinical and Laboratory Standards Institute (CLSI). *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.* CLSI Document GP44-A4. Wayne, PA: CLSI; 2010.
7. Westgard JO. *Basic QC Practices.* 3rd ed. Madison, WI: Westgard Quality Corporation; 2010.
8. Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.
9. Pearson TA, Mensah GA, Alexander RW, et al. Markers of inflammation and cardiovascular disease: application to clinical and public health practice: A statement for healthcare professionals from the Centers for Disease Control and Prevention and the American Heart Association. *Circulation* 2003;107(3):499–511.
10. Dati F, Johnson AM, Whicher JT. The existing interim consensus reference ranges and the future approach. *Clin Chem Lab Med* 2001;39(11):1134-1136.
11. Schlebusch H, Liappis N, Kalina E, et al. High sensitive CRP and creatinine: reference intervals from infancy to childhood. *J Lab Med* 2002;26(5/6):341-346.
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. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.* CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.
14. Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.
15. Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition.* CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.