

Wide Range C-Reactive Protein (wrCRP)

Current Revision and Date ^a	Rev. 02, 2019-10
Product Name	Atellica CH Wide Range C-Reactive Protein (wrCRP) REF 11097645 (2000 tests)
Abbreviated Product Name	Atellica CH wrCRP
Test Name/ID	wrCRP
Systems	Atellica CH Analyzer
Materials Required but Not Provided	Atellica CH wrCRP CAL REF 11097646
Specimen Types	Human serum, plasma (lithium heparin)
Sample Volume	10 µL
Measuring Interval	0.050–15.600 mg/dL (0.50–156.00 mg/L)

^a A vertical bar in the page margin indicates technical content that differs from the previous version.



Intended Use

The Atellica® CH Wide Range C-Reactive Protein (wrCRP) assay is for *in vitro* diagnostic use in the quantitative determination of the concentration of C-reactive protein in human serum and plasma (lithium heparin) using the Atellica® CH Analyzer. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.¹⁻⁴

Summary and Explanation

The Atellica CH Wide Range C-Reactive Protein (wrCRP) assay measures CRP in serum and plasma by a latex-enhanced immunoturbidimetric assay. It is based on the principle that the analyte concentration is a function of the intensity of scattered light caused by the latex aggregates. The latex particles coated with anti-CRP rapidly agglutinate in the presence of C-reactive protein-forming aggregates.

Principles of the Procedure

The Atellica CH wrCRP assay latex reagent is a suspension of uniform polystyrene latex particles coated with anti-CRP antibody. When serum or plasma containing CRP is mixed with the latex reagent, agglutination takes place resulting in an increase in the turbidity. This turbidity is measured at 571 nm. The CRP concentration in serum or plasma is determined from a calibration curve that is generated with the calibrators.

Reagents

Material Description	Storage	Stability ^a
Atellica CH wrCRP	Unopened at 2–8°C	Until expiration date on product
Pack 1 (P1)	Onboard per well	51 days
Well 1 (W1) Reagent 1 (R1) 17.8 mL Glycine (170 mmol/L); sodium chloride (100 mmol/L); EDTA disodium salt dihydrate (50 mmol/L); sodium azide (0.09% w/v)		
Well 2 (W2) Reagent 1 (R1) 17.8 mL Glycine (170 mmol/L); sodium chloride (100 mmol/L); EDTA disodium salt dihydrate (50 mmol/L); sodium azide (0.09% w/v)		
Pack 2 (P2)		
Well 1 (W1) Reagent 2 (R2) 17.8 mL CRP antibody synthetic latex (rabbit) (variable by lot); sodium azide (0.09% w/v)		
Well 2 (W2) Reagent 2 (R2) 17.8 mL CRP antibody synthetic latex (rabbit) (variable by lot); sodium azide (0.09% w/v)		

^a Refer to *Storage and Stability*.

Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on [siemens.com/healthineers](https://www.siemens.com/healthineers).

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 51 days per well. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (lithium heparin) are the recommended sample types for this assay.

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.⁵
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.⁶
- Follow the instructions provided with your specimen collection device for use and processing.⁷
- Allow blood specimens to clot completely before centrifugation.⁸
- Keep tubes capped at all times.⁸

Storing the Specimen

Specimens are stable for up to 13 days when stored at 2–8°C⁹ and for up to 6 months when stored at -20°C.¹⁰

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 10 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.⁸

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
11097645	Pack 1 (P1) Well 1 (W1) 17.8 mL of Atellica CH wrCRP Reagent 1 Well 2 (W2) 17.8 mL of Atellica CH wrCRP Reagent 1 Pack 2 (P2) Well 1 (W1) 17.8 mL of Atellica CH wrCRP Reagent 2 Well 2 (W2) 17.8 mL of Atellica CH wrCRP Reagent 2	4 x 500

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

REF	Description
Atellica CH Analyzer ^a	
11097646	Atellica CH wrCRP CAL (calibrator) 1 x 1.0 mL calibrator level 1 CAL 1 1 x 1.0 mL calibrator level 2 CAL 2 1 x 1.0 mL calibrator level 3 CAL 3 1 x 1.0 mL calibrator level 4 CAL 4 1 x 1.0 mL calibrator level 5 CAL 5 1 x 1.0 mL calibrator level 6 CAL 6 Calibrator lot-specific value sheet CAL LOT VAL
Commercially available quality control materials	

^a Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 50 µL of primary sample and 200 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 50 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 10 µL of pre-diluted sample into a reaction cuvette.
4. Dispenses 50 µL of Reagent 2 into a reaction cuvette.
5. Mixes and incubates the mixture at 37°C.
6. Measures the absorbance after Reagent 2 addition.
7. Reports results.

Test Duration: 8 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

Performing Calibration

For calibration of the Atellica CH wrCRP assay, use Atellica CH wrCRP CAL. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	61
Pack Calibration	51
Reagent Onboard Stability	51

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

Performing Quality Control

For quality control of the Atellica CH wrCRP assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in mg/dL (common units) or mg/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: $\text{mg/dL} \times 10 = \text{mg/L}$

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Limitations

The Atellica CH wrCRP assay is limited to the detection of concentration of C-reactive protein in human serum and plasma (lithium heparin).

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.¹¹

The reference interval for C-reactive protein is 0.000–0.500 mg/dL (0.00–5.00 mg/L) for adults.¹²

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.¹¹

Performance Characteristics

Measuring Interval

The Atellica CH wrCRP assay provides results from 0.050–15.600 mg/dL (0.50–156.00 mg/L). The system flags all values that are outside the specified measuring interval.

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 62.400 mg/dL (624.00 mg/L) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.¹³ The assay is designed to have a limit of blank (LoB) $\leq$ limit of detection (LoD), a LoD $\leq$ 0.050 mg/dL (0.50 mg/L), and a limit of quantitation (LoQ) $\leq$ 0.050 mg/dL (0.50 mg/L).

The LoD corresponds to the lowest concentration of serum and plasma (lithium heparin) that can be detected with a probability of 95%. The LoD for the Atellica CH wrCRP assay is 0.030 mg/dL (0.30 mg/L), and was determined using 480 determinations, with 240 blank and 240 low level replicates, and a LoB of 0.000 mg/dL (0.00 mg/L).

The LoQ is the lowest amount of C-reactive protein that can be determined quantitatively at $\leq 20\%$ CV, which corresponds to a value of 0.050 mg/dL (0.50 mg/L) for the Atellica CH wrCRP assay.

Assay results obtained at individual laboratories may vary from the data presented.

Precision

Precision was determined in accordance with CLSI Document EP05-A3.¹⁴ Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days ($N \geq 80$ for each sample). The following results were obtained:

Sample Type	N	Mean mg/dL (mg/L)	Repeatability		Designed to be $\leq$		Within-Lab Precision		Designed to be $\leq$	
			SD ^a mg/dL (mg/L)	CV ^b (%)	CV (%)		SD mg/dL (mg/L)	CV (%)	CV (%)	
Plasma Pool	80	0.087 (0.87)	0.0032 (0.032)	3.7	7.0		0.0034 (0.034)	3.9	9.0	
Serum Pool	80	0.562 (5.62)	0.0044 (0.044)	0.8	6.0		0.0074 (0.074)	1.3	8.0	
QC Pool	80	1.344 (13.44)	0.0063 (0.063)	0.5	5.0		0.0100 (0.100)	0.7	7.0	
Serum Pool	80	5.318 (53.18)	0.0225 (0.225)	0.4	4.0		0.0434 (0.434)	0.8	6.0	
Serum Pool	80	12.762 (127.62)	0.0711 (0.711)	0.6	3.0		0.1321 (1.321)	1.0	5.0	

^a Standard deviation.

^b Coefficient of variation.

Assay results obtained at individual laboratories may vary from the data presented.

Assay Comparison

The Atellica CH wrCRP assay is designed to have a correlation coefficient of > 0.950 and a slope of 1.00 ± 0.10 compared to BN ProSpec[®] CardioPhase[®] hsCRP. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.¹⁵ The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N ^a	r ^b
Serum	BN ProSpec CardioPhase hsCRP	$y = 1.08x - 0.030$ mg/dL ($y = 1.08x - 0.30$ mg/L)	0.078–13.2 mg/dL (0.78–132 mg/L)	127	0.997

^a Number of samples tested.

^b Correlation coefficient.

The agreement of the assay may vary depending on the study design, comparative assay, and sample population. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.¹⁵ The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N ^a	r ^b
Plasma (Lithium Heparin)	Atellica CH wrCRP Serum	$y = 1.03x - 0.012 \text{ mg/dL}$ ($y = 1.03x - 0.12 \text{ mg/L}$)	0.052–14.091 mg/dL (0.52–140.91 mg/L)	69	0.998

^a Number of samples tested.

^b Correlation coefficient.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH wrCRP assay is designed to have $\leq 10\%$ interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07-A2 using the Atellica CH wrCRP assay.¹⁶

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias $> 10\%$ is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (mg/L)	Percent Bias
Hemoglobin	500 mg/dL (0.310 mmol/L)	1.003 (10.03)	-3.6
	500 mg/dL (0.310 mmol/L)	4.457 (44.57)	-3.1
Bilirubin, conjugated	30 mg/dL (513 $\mu\text{mol/L}$)	0.992 (9.92)	-3.6
	30 mg/dL (513 $\mu\text{mol/L}$)	4.446 (44.46)	0.2
Bilirubin, unconjugated	30 mg/dL (513 $\mu\text{mol/L}$)	1.026 (10.26)	-0.9
	30 mg/dL (513 $\mu\text{mol/L}$)	4.417 (44.17)	0.7
Lipemia (Intralipid®)	500 mg/dL (5.6 mmol/L)	1.016 (10.16)	-1.6
	500 mg/dL (5.6 mmol/L)	4.410 (44.10)	-2.0

Assay results obtained at individual laboratories may vary from the data presented.

Non-Interfering Substances

The following substances do not interfere with the Atellica CH wrCRP assay when present in serum and plasma (lithium heparin) at the concentrations indicated in the table below. Bias due to these substances is $\leq 10\%$ at the analyte concentrations listed in the table below.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (mg/L)	Percent Bias
Acetaminophen	20 mg/dL (1.3 mmol/L)	1.097 (10.97)	-1.1
	20 mg/dL (1.3 mmol/L)	4.247 (42.47)	0.7
Acetylsalicylic Acid	50 mg/dL (2.8 mmol/L)	1.086 (10.86)	0.1
	50 mg/dL (2.8 mmol/L)	4.276 (42.76)	-0.7
Ibuprofen	50 mg/dL (2.4 mmol/L)	1.082 (10.82)	0.8
	50 mg/dL (2.4 mmol/L)	4.208 (42.08)	-0.5

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (mg/L)	Percent Bias
Methotrexate	100 µmol/L	0.980 (9.80)	-0.8
	100 µmol/L	4.249 (42.49)	0.4
Rheumatoid Factor (RF)	1000 IU/mL	1.114 (11.14)	0.4
	1000 IU/mL	4.322 (43.22)	0.5
Salicylic Acid	50 mg/dL (3.6 mmol/L)	1.076 (10.76)	-0.9
	50 mg/dL (3.6 mmol/L)	4.221 (42.21)	-2.4
Triglyceride-rich Lipoproteins	500 mg/dL (5000 mg/L)	1.087 (10.87)	-0.6
	500 mg/dL (5000 mg/L)	4.217 (42.17)	3.0

Human anti-mouse antibodies (HAMA) interference was assessed by spiking known amounts of C-reactive protein into commercially characterized and purchased HAMA I and HAMA II samples. The spikes were targeted at 1.000 mg/dL (10.00 mg/L) and 4.000 mg/dL (40.00 mg/L) C-reactive protein.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration mg/dL (mg/L)	Percent Bias
Human Anti-mouse Antibodies (HAMA) I	N/A ^a	1.140 (11.40)	-1.4
	N/A	4.157 (41.57)	5.5
Human Anti-mouse Antibodies (HAMA) II	N/A	0.867 (8.67)	-7.9
	N/A	4.242 (42.42)	1.9

^a Not applicable

Assay results obtained at individual laboratories may vary from the data presented.

High-Dose Hook Effect

High C-reactive protein levels can cause a paradoxical decrease in signal as a result of the high-dose hook effect. In the Atellica CH wrCRP assay, C-reactive protein levels as high as 95.000 mg/dL (950.00 mg/L) will read > 15.600 mg/dL (> 156.00 mg/L).

Standardization

The Atellica CH wrCRP assay is traceable to the Institute for Reference Materials and Measurements (IRMM) reference material ERM-DA474/IFCC from the International Federation of Clinical Chemistry (IFCC).

Assigned values for calibrators are traceable to this standardization.⁹

Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens.com/healthineers

References

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15. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	

Symbol	Symbol Title and Description
Rev. REVISION	Revision
	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable
	Oxidizing
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.

Symbol	Symbol Title and Description
	Handheld barcode scanner
	<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
	Mixing of substances Mix product before use.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
	Authorized Representative in the European Community
	Use-by date Use by the designated date.
	Batch code
	Catalog number
	Recycle
	Printed with soy ink
	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
	Common Units

Symbol	Symbol Title and Description
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

Legal Information

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