

INSTRUCTIONS FOR USE

hsCRP

VITROS Chemistry Products hsCRP Reagent

High-Sensitivity C-Reactive Protein

REF 6801739

Intended Use

For *in vitro* diagnostic use only.

VITROS Chemistry Products hsCRP Reagent is used on the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System to quantitatively measure C-reactive protein (CRP) in human serum and plasma. CRP is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with values of CRP that exceed 3 mg/L.

Summary and Explanation of the Test

C-reactive protein is an acute-phase reactant that reflects low-grade systemic inflammation.^{1, 2} Increases in CRP values are non-specific and should not be interpreted without a complete clinical history.² CRP measurements may be performed for early detection of infection in pediatrics and risk assessment of coronary heart disease.^{1, 3, 4, 5, 6} The risk of CHD increases with values of CRP that exceed 3 mg/L.⁵

The VITROS hsCRP assay is classified as a cardiac C-Reactive Protein (cCRP) assay. Cardiac CRP (cCRP) assays are for use as an aid in the identification and stratification of individuals at risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, cCRP may be useful as an independent marker of prognosis for recurring events in patients with stable coronary or acute coronary syndrome.⁷

The Centers for Disease Control and Prevention and the American Heart Association have made the following recommendations concerning the use of high sensitivity C-Reactive Protein (hsCRP) for cardiovascular disease risk assessment⁵:

- Measurement of hsCRP should be done twice (averaging results) optimally two weeks apart, on metabolically stable patients, and should be compared to previous values. Testing should not be performed while there is indication of infection, systemic inflammation, or trauma.
- Follow-up testing of patients with elevated CRP values should be performed. Patients with persistently unexplained hsCRP levels above 10 mg/L after repeated testing should be evaluated for non-cardiovascular sources of infection or inflammation.
- Due to within-individual variability, serial measurements of hsCRP should not be used to monitor effects of treatment.
- Screening the entire adult population for hsCRP is not recommended.
- hsCRP is not a substitute for traditional cardiovascular risk factors.
- Application of management guidelines for acute coronary syndromes should not be dependent on hsCRP levels.
- Application of secondary prevention measures should be based on global risk assessment and not depend on hsCRP measurements.

Principles of the Procedure

The quantitative measurement of C-reactive protein (CRP) is performed using the VITROS Chemistry Products hsCRP Reagent in conjunction with the VITROS Chemistry Products Calibrator Kit 17 and VITROS Chemistry Products FS Calibrator 1 on the VITROS 5,1 FS/4600 Chemistry System and the VITROS 5600 Integrated System. The VITROS Chemistry Products hsCRP Reagent is a dual chambered package containing ready-to-use liquid reagents. Samples, calibrators and controls are mixed with Reagent 1 containing a buffer. Addition of anti-CRP antibodies coupled to latex microparticles (Reagent 2) produces an immunochemical reaction yielding CRP antigen/antibody complexes. The turbidity is measured spectrophotometrically at 660 nm. Once a calibration has been performed for each reagent lot, the CRP concentration in each unknown sample can be determined using the stored calibration curve and the measured absorbance obtained in the assay of the sample.

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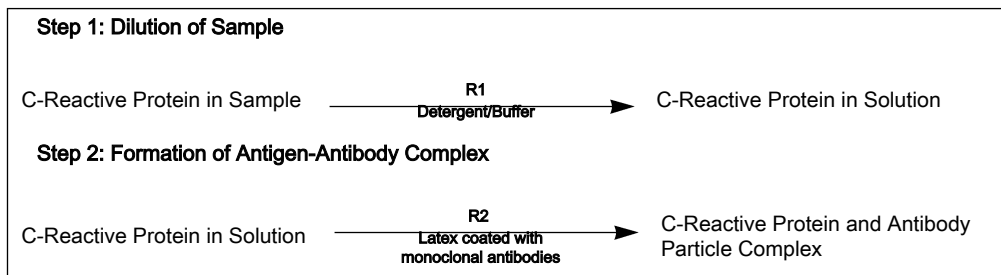
Warnings and Precautions

Test Type and Conditions

Test Type	VITROS System	Approximate Incubation Time	Temperature	Wavelength	Reaction Sample Volume
Two-point Rate	5600, 4600, 5,1 FS	8 minutes	37 °C (98.6 °F)	660 nm	16 µL

Not all products and systems are available in all countries.

Reaction Scheme



Warnings and Precautions

For in vitro diagnostic use only.

WARNING: *This product contains bovine blood components and should be handled using the same precautions as with any other blood or blood-derived product.*

WARNING: *Take care when handling materials and samples of human origin. Since no test method can offer complete assurance that infectious agents are absent, consider all clinical specimens, controls, and calibrators potentially infectious. Handle specimens, solid and liquid waste, and test components in accordance with local regulations and CLSI Document M29⁸ or other published biohazard safety guidelines.*

For specific warnings and precautions for calibrators, quality control materials, and other components, refer to the Instructions for Use for the appropriate VITROS product, or to other manufacturer's product literature.

Reagents

Reactive Ingredients

Reagent 1 (R1): None

Reagent 2 (R2): Latex particles coated with anti-CRP mouse monoclonal antibodies 0.1 % [w/w]

Other Ingredients

Reagent 1 (R1): Buffer, bovine serum albumin, polymer, and preservative

Reagent 2 (R2): Buffer and preservative

Reagent Handling

Caution: Do not use reagent packs with damaged or incompletely sealed packaging.

- Inspect the packaging for signs of damage.
- Be careful when opening the outer packaging with a sharp instrument so as to avoid damage to the individual product packaging.
- The reagents are supplied ready for use.
- Avoid agitation, which may cause foaming or the formation of bubbles.

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Reagent Storage and Stability

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Reagent Preparation

1. Remove from refrigerated storage.
2. Mix thoroughly by gently inverting several times. DO NOT SHAKE.
3. Immediately load into Supply 3.

IMPORTANT: Do not loosen or remove caps prior to loading.

Reagent Storage and Stability

VITROS Chemistry Products hsCRP Reagent is stable until the expiration date on the carton when it is stored and handled as specified. Do not use beyond the expiration date.

Reagent	Storage Condition		Stability
Unopened	Refrigerated	2–8 °C (36–46 °F)	Until expiration date
Opened	On-analyzer	System turned on	≤ 4 weeks
	On-analyzer	System turned off	≤ 30 minutes

Verify performance with quality control materials:

- If the system is turned off for more than 30 minutes.
- After reloading reagents that have been removed from Supply 3 and stored for later use.

Specimen Collection, Preparation and Storage

Specimens Recommended

- Serum
- Plasma: Heparin

IMPORTANT: Certain collection devices have been reported to affect other analytes and tests.⁹ Owing to the variety of specimen collection devices available, Ortho-Clinical Diagnostics is unable to provide a definitive statement on the performance of its products with these devices. Confirm that your collection devices are compatible with this test.

Specimens Not Recommended

Plasma:

- EDTA
- Citrate

Serum and Plasma

Specimen Collection and Preparation

Collect specimens using standard laboratory procedures.^{10, 11}

Note: For details on minimum fill volume requirements, refer to the operating instructions for your system.

Patient Preparation

No special patient preparation is necessary.

Special Precautions

- Refer to “Sample Dilution” for dilution instructions.
- Centrifuge specimens and remove the serum from the cellular material within two hours of collection.¹²

Specimen Handling and Storage

- Handle and store specimens in stoppered containers to avoid contamination and evaporation.
- Mix samples by gentle inversion and bring to room temperature, 18–28 °C (64–82 °F), prior to analysis.

Specimen Storage and Stability¹²

Storage	Temperature	Stability
Original Specimen		
Room temperature	18–28 °C (64–82 °F)	≤ 4 hours
Refrigerated	2–8 °C (36–46 °F)	≤ 3 days
Frozen	≤ -18 °C (≤ 0 °F)	≤ 6 months

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Testing Procedure

Testing Procedure

Materials Provided

VITROS Chemistry Products hsCRP Reagent

Materials Required but Not Provided

- VITROS Chemistry Products Calibrator Kit 17
- VITROS Chemistry Products FS Calibrator 1
- VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) (for calibration only)
- Quality control materials, such as VITROS Chemistry Products hsCRP Performance Verifier I, II and III

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned workload.
- For additional information, refer to the operating instructions for your system.

IMPORTANT: *Bring all fluids and samples to room temperature, 18–28 °C (64–82 °F), prior to analysis.*

Sample Dilution

Do not dilute samples where CRP concentration exceeds the VITROS Chemistry Products hsCRP assay measuring (reportable) range. For these samples, use an alternate method such as VITROS Chemistry Products CRP Slides.

Calibration

Required Calibrators

- VITROS Chemistry Products Calibrator Kit 17
- VITROS Chemistry Products FS Calibrator 1

Calibrator Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Chemistry Products Calibrator Kit 17 and VITROS Chemistry Products FS Calibrator 1.

Calibration Procedure

Refer to the operating instructions for your system.

When to Calibrate

Calibrate:

- When the reagent lot number changes.
- When critical system parts are replaced due to service or maintenance.
- When government regulations require.

For example, in the USA, CLIA regulations require calibration or calibration verification at least once every six months.

The VITROS hsCRP assay may also need to be calibrated:

- If quality control results are consistently outside acceptable range.
- After certain service procedures have been performed.

For additional information, refer to the operating instructions for your system.

Calculations

Absorbance is measured at 660 nm after a fixed incubation time. Once a calibration has been performed for each reagent lot, CRP concentration in the unknown samples can be determined using the stored calibration curve and the measured absorbance obtained in the assay of each sample.

Validity of a Calibration

Calibration parameters are automatically assessed by the system against a set of quality parameters detailed in the Review Assay Data screen (found via Options → Review/Edit Calibrations → Review Assay Data). Failure to meet any of the pre-defined quality parameters results in a failed calibration. The calibration report should be used in conjunction with quality control results to determine the validity of a calibration.

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Quality Control

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Measuring (Reportable) Range

	Conventional and SI Units (mg/L)
Serum	0.10–15.00

For out-of-range samples, refer to "Sample Dilution."

Traceability of Calibration

Values assigned to the VITROS Chemistry Products Calibrator Kit 17 and VITROS Chemistry Products FS Calibrator 1 for C-reactive protein are traceable to ERM-DA470 Reference Material. ¹³

Quality Control

Quality Control Material Selection

IMPORTANT: VITROS Chemistry Products hsCRP Performance Verifiers are recommended for use with the VITROS 5,1 FS/4600 Chemistry and VITROS Integrated Systems. Evaluate the performance of other commercial control fluids for compatibility with this assay before using for quality control.

Control materials other than VITROS Chemistry Products hsCRP Performance Verifiers may show a difference when compared with other hsCRP methods if they:

- Depart from a true human matrix.
- Contain high concentrations of preservatives, stabilizers, or other nonphysiological additives.

Quality Control Procedure Recommendations

- Choose control levels that check the clinically relevant range.
- Analyze quality control materials in the same manner as patient samples, before or during patient sample processing.
- To verify system performance, analyze control materials:
 - After calibration.
 - According to local regulations or at least once each day that the assay is being performed.
 - After specified service procedures are performed. Refer to the operating instructions for your system.
- If control results fall outside your acceptable range, investigate the cause before deciding whether to report patient results.
- For general quality control recommendations, refer to CLSI *Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline—Third Edition* ¹⁴ or other published guidelines.
- For additional information, refer to the operating instructions for your system.

Quality Control Material Preparation, Handling, and Storage

Refer to the Instructions for Use for VITROS Chemistry Products hsCRP Performance Verifiers I, II and III or to other manufacturer's product literature.

Results

Reporting Units and Unit Conversion

The VITROS 5,1 FS/4600 Chemistry and VITROS Integrated Systems may be programmed to report CRP results in conventional, SI, and alternate units.

Conventional and SI Units	Alternate Units
mg/L (mg/dL x 10)	mg/dL (mg/L x 0.1)

Limitations of the Procedure

Known Interferences

None identified.

Other Limitations

- No antigen excess effect was observed for samples with C-reactive protein concentrations up to 360 mg/L.

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Interpretation of Results and Expected Results

- Samples that generate a Sample Integrity T-index flag and are above the measuring (reportable) range should be assayed by an alternative method, such as the VITROS Chemistry Products CRP Slide assay. Refer to the operating instructions for additional information concerning Sample Integrity flags.
- Samples that generate a Sample Integrity T-index flag and are within the measuring (reportable) range will be negatively biased by >15%. These samples may be diluted with equal parts of human serum containing a low concentration of C-reactive protein and retested.
- Certain drugs and clinical conditions are known to alter C-reactive protein concentration *in vivo*. For additional information, refer to one of the published summaries. [15](#), [16](#), [17](#), [18](#), [19](#), [20](#), [21](#)
- Heterophilic, e.g. human anti-mouse, antibodies in the serum or plasma of certain individuals are known to cause interference with immunoassays. [22](#) These antibodies may be present in blood samples from individuals regularly exposed to animals or who have been treated with animal serum products.

Interpretation of Results and Expected Results

Reference Interval

These guidelines have been recommended by the U.S. Centers for Disease Control and Prevention, and the American Heart Association for assessment of risk for cardiovascular disease in adults. [5](#)

Classification for Cardiovascular Disease Risk	Conventional and SI Units (mg/L)
Low	<1.0
Average	1.0–3.0
High	>3.0–10.0
Indeterminant*	>10.0

* May be an indication of another source of inflammation or infection.

As CRP is a non-specific indicator for a wide range of disease processes, and as reference intervals may vary for each population studied, each laboratory should confirm the validity of these intervals for the population it serves.

Increases in CRP values are non-specific and should not be interpreted without a complete clinical history. Recent medical events resulting in tissue injury, infections, or inflammation, which may cause elevated CRP levels, should be considered. Follow-up testing of patients with elevated CRP values should be performed. Patients with persistently unexplained CRP levels above 10 mg/L after repeated testing should be evaluated for non-cardiovascular sources of infection or inflammation.

When using CRP to assess the risk of coronary heart disease, measurement of hsCRP should be done twice (averaging results) optimally two weeks apart, on metabolically stable patients, and should be compared to previous values. Testing should not be performed while there is indication of infection, systemic inflammation, or trauma.

Performance Characteristics

Method Comparison

The plots and table show the results of a comparison of serum samples analyzed on the VITROS 5,1 FS Chemistry System with those analyzed using the comparative method, Dade Behring BN ProSpec Nephelometric Method with CRM 470 Calibration. [23](#)

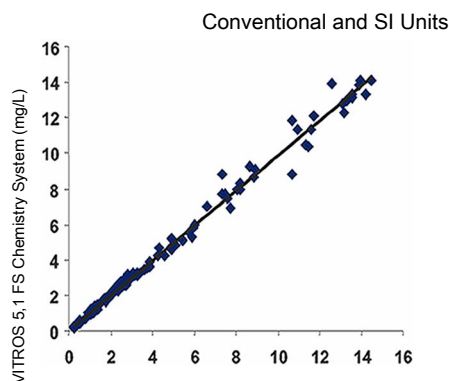
The table also shows the results of comparisons with serum and plasma samples on the VITROS 5600 Integrated System and the VITROS 5,1 FS Chemistry System. Testing followed NCCLS Protocol EP9. [24](#)

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Performance Characteristics

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Comparative Method: Dade Behring BN ProSpec Nephelometric (mg/L)

	n	Slope	Correlation Coefficient	Conventional and SI Units (mg/L)		
				Range of Sample Conc.	Intercept	Sy.x
5,1 FS [†] vs. comparative method	103	0.98	0.995	0.25–14.25	0.049	0.40
5600 vs. 5,1 FS [†]	100	0.98	1.000	0.11–14.68	0.016	0.12

[†] Analytical processing hardware and software algorithms on the VITROS 4600 Chemistry System are designed to the same specifications as those applied to the VITROS 5,1 FS Chemistry System. Assay performance on the VITROS 4600 System has been demonstrated to be comparable to that on the VITROS 5,1 FS System. All performance characteristics for VITROS 5,1 FS System are therefore applicable to the VITROS 4600 System.

Precision

Precision was evaluated with quality control materials on the VITROS 5,1 FS Chemistry System following NCCLS Protocol EP5.²⁵ Precision was also evaluated with quality control materials on the VITROS 5600 Integrated System following NCCLS Protocol EP5.²⁶

These results are guidelines. Variables such as instrument maintenance, environment, reagent storage/handling, control material reconstitution, and sample handling can affect the reproducibility of test results.

	Conventional and SI Units (mg/L)			Within Lab CV% ^{**} No. Observ. No. Days		
	Mean Conc.	Within Day SD [*]	Within Lab SD ^{**}			
5,1 FS [†]	0.60	0.014	0.030	5.0	80	20
	1.84	0.018	0.038	2.1	80	20
	10.64	0.124	0.187	1.8	80	20
5600	0.40	0.014	0.019	4.8	88	22
	1.44	0.018	0.020	1.4	88	22
	8.14	0.046	0.094	1.2	88	22

^{*} Within Day precision was determined using two runs per day with two replications per run.

^{**} Within Lab precision was determined using a single lot of reagents and at least four calibrations.

[†] Analytical processing hardware and software algorithms on the VITROS 4600 Chemistry System are designed to the same specifications as those applied to the VITROS 5,1 FS Chemistry System. Assay performance on the VITROS 4600 System has been demonstrated to be comparable to that on the VITROS 5,1 FS System. All performance characteristics for VITROS 5,1 FS System are therefore applicable to the VITROS 4600 System.

Specificity

Substances that Do Not Interfere

Rheumatoid factor (RF) up to 1200 IU/mL does not interfere.

The substances listed in this table were tested on the VITROS Chemistry Products hsCRP assay at a nominal C-reactive protein concentration of 3 mg/L using protocols based on NCCLS Protocol EP7,²⁷ and found not to interfere, bias <0.28 mg/L, at the concentrations shown.

Compound	Concentration	
Acetaminophen	20 mg/dL	1 mmol/L
N-Acetyl-L-cysteine	100 mg/dL	6.13 mmol/L
Amoxicillin	20 µg/mL	1.15 mmol/L

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Compound	Concentration	
Ascorbic acid	3 mg/dL	171 µmol/L
Bilirubin	50 mg/dL	0.85 mmol/L
Carbamazepine	120 µg/mL	508 µmol/L
Dipyrene	30 mg/dL	0.85 mmol/L
Ethamsylate	3 mg/dL	0.11 mmol/L
Gentamicin sulfate	120 µg/mL	251 µmol/L
Hemoglobin	1000 mg/dL	10 g/L
Ibuprofen	400 µg/mL	2 µmol/L
Lidocaine	60 µg/mL	2.6 µmol/L
Methotrexate	40 µmol/L	40 µmol/L
Procainamide	100 µg/mL	368 µmol/L
Propanolol	5 µg/mL	19 µmol/L
Rantidine	200 µg/mL	637 µmol/L
Salicylic acid	50 mg/dL	4 mmol/L
Simvastatin	16 µg/mL	1.2 mmol/L
Theophylline	25 mg/dL	1 mmol/L
Valproic acid	500 µg/mL	3 mmol/L

References

- Rifai, N. High-sensitivity C-reactive protein: a novel and promising marker of coronary heart disease. *Clin Chem* 47: 403-11; 2001.
- Burtis C, Ashwood, ER (ed). *Tietz Textbook of Clinical Chemistry*, 3rd ed. Philadelphia, PA; WB Saunders Co; 493; 1999.
- Ridker PM. High-sensitivity C-reactive protein: potential adjunct for global risk assessment in the primary prevention of cardiovascular disease. *Circulation* 103: 1813-8; 2001.
- Wasunna A et al. C-reactive protein and bacterial infection in preterm infants. *Eur J Pediatr* 1990; 149: 424-427.
- Pearson, TA 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* 107: 499-511, 2003.
- Nader Rifai, PhD (host), HsCRP: a Novel Marker for Coronary Heart Disease August 1, 2000, <http://www.aacc.org/access/crp/index.stm>
- US Department of Health and Human Services, FDA. Guidance for Industry and FDA Staff: Review Criteria for Assessment of C Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays, <http://www.fda.gov/cdrh/oivd/guidance/1246.pdf>; September 22, 2005.
- CLSI. *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Third Edition*. CLSI document M29-A3 [ISBN 1-56238-567-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2005.
- Calam RR. Specimen Processing Separator Gels: An Update. *J Clin Immunoassay*. 11:86–90; 1988.
- CLSI. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Sixth Edition*. CLSI document H3-A6 [ISBN 1-56238-650-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA; 2007.
- NCCLS. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Fifth Edition*. . NCCLS document H4-A5 [ISBN 1-56238-538-0]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2004.
- Clinical Laboratory Handbook for Patient Preparation and Specimen Handling*. Fascicle VI: Chemistry/Clinical Microscopy. Northfield, IL: College of American Pathologists; 1992.
- European Commission, The Certification of a Matrix Reference Material for Immunochemical Measurement of 15 Serum Proteins, ERM-DA470, Report EUR 15243 EN and 16882 EN, European Communities; 2004.
- CLSI. *Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Third Edition*. . CLSI document C24-A3 [ISBN 1-56238-613-1]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2006.
- Chang CY, Lu JY, Chien TI, Kao JT, Lin MC, Shih PC and Yan SN. Interference caused by the contents of serum separator tubes in the VITROS CRP assay. *Ann Clin Biochem* 2003; 40(Pt 3): 249-51.
- Yu A and Pira U. False increase in serum C-reactive protein caused by monoclonal IgM-lambda: a case report. *Clin Chem Lab Med*. 2001; 39(10): 983-7.
- Benoist JF, Orbach D and Biou D. False increase in C-reactive protein attributable to heterophilic antibodies in two renal transplant patients treated with rabbit antilymphocytic globulin. *Clin Chem* 1998; 44(9): 1980-5.

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Glossary of Symbols


































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18. Yamada K, Yagihashi A, Ishii S, Tanemura K, Kida T, Watanabe N and Niitsu Y. Interference with nephelometric assay of C-reactive protein and antistreptolysin-O by monoclonal IgM-kappa from myeloma patient. *Clin Chem* 1997; 43(12): 2435-7.
19. Young DS. *Effects of Drugs on Clinical Laboratory Tests*. ed. 5. Washington, D.C.: AACC Press; 2000.
20. Friedman RB, Young DS. *Effects of Disease on Clinical Laboratory Tests*. Washington, D.C.: AACC Press; 1990.
21. Tryding N, Tufvesson C, Sonntag O (eds). *Drug Effects in Clinical Chemistry*. Ed. 7 Stockholm: The National Corporation of Swedish Pharmacies, Pharasoft AB, Swedish Society for Clinical Chemistry; 1996.
22. Levinson SS. The Nature of Heterophilic Antibodies and Their Role in Immunoassay Interference. *J Clin Immunoassay*. 15:108-115; 1992.
23. Dati F, et al. Referenzwerte für 18 Plasmaproteine am Behring-Nephelometer-System. *Lab. Med.* 13:87-90; 1989.
24. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition*. NCCLS document EP9-A2 [ISBN 1-56238-472-4]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2002.
25. NCCLS. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*. NCCLS document EP5-A [ISBN 1-56238-368-X]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 1999.
26. NCCLS. *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition*. NCCLS document EP5-A2 [ISBN 1-56238-542-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2004.
27. NCCLS. *Interference Testing In Clinical Chemistry; Approved Guideline*. NCCLS document EP7-A [ISBN 1-56238-480-5]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; 2002.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.

	Do Not Reuse		Upper Limit of Temperature		Range
	Use by or Expiration Date (Year-Month-Day)		Lower Limit of Temperature		Range of Means
	Batch Code or Lot Number		Temperature Limitation		Midpoint
	Serial Number		Consult Instructions for Use		Revised
	Catalog Number or Product Code		Attention: The Instructions for Use (IFU) has been updated		Supersedes
	Caution		For use in Slide Supply 1		Irritant
	Manufacturer		For use in Slide Supply 2		Harmful
	Date of Manufacture		SI Units		Toxic
	Authorized Representative in the European Community		Conventional Units		Corrosive
	Contains Sufficient for "n" Tests		Value		Flammable
	In vitro Diagnostic Medical Device		Der Grüne Punkt (the Green Dot). Manufacturer follows certain packaging material waste disposal management regulations		Estimated within-lab SD

Revision History

Date of Revision	Version	Description of Technical Changes*
2014-09-05	7.0	Glossary of Symbols: added Date of Manufacture
2013-08-20	6.1	Traceability of Calibration: deleted Kit from FS Calibrator 1 product name
2012-02-28	6.0	Glossary of Symbols: updated
2010-11-01	5.0	Added information for the VITROS 4600 Chemistry System

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Revision History

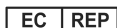
Date of Revision	Version	Description of Technical Changes*
2008-11-06	4.0	<ul style="list-style-type: none"> Added information for the VITROS 5600 Integrated System Test Type and Conditions – Added statement Traceability of Calibration – Reference material name changed Method Comparison – Added information on sample types References – Updated Glossary of Symbols – Updated Minor wording and formatting changes
2006-12-21	3.0	<ul style="list-style-type: none"> Minor formatting updates Summary and Explanation of the Test – Added definition of cCRP assays References – Added FDA cCRP reference; updated M29, H4 and C24.
2005-04-25	2.0	<ul style="list-style-type: none"> Reference Interval – updated values Reporting Units and Unit Conversion – wording update Precision – wording update
2005-01-13	1.1	Method Comparison - Minor Correction
2004-09-15	1.0	First release of document

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

When this Instructions For Use is replaced, sign and date below and retain as specified by local regulations or laboratory policies, as appropriate.

Signature

Obsolete Date



Ortho-Clinical Diagnostics
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