BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access Folate

REF A98032

FOR PROFESSIONAL USE ONLY

For *in vitro* diagnostic use

Rx Only

For use on DxI Access Immunoassay Analyzers

PRINCIPLE

INTENDED USE

The Access Folate assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of folic acid levels in human serum, lithium heparin plasma, and red blood cells using the Access Immunoassay Systems. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia.

Folate levels in serum, lithium heparin plasma, and red blood cells are used to assess folate status. The serum folate levels is an indicator of recent folate intake. A low RBC folate value can indicate a prolonged folate deficiency.

SUMMARY AND EXPLANATION

Folate is an essential vitamin vital to normal cell growth and DNA synthesis. It is present in a wide variety of foods such as dark, leafy vegetables, citrus fruits, yeast, beans, eggs, and milk. It is absorbed by the small intestine and stored in the liver. A folate deficiency can lead to megaloblastic anemia and ultimately to severe neurological problems.[1,2,3]

Folate deficiency can be caused by insufficient dietary intake, malabsorption or excessive folate utilization. Excessive utilization occurs very commonly during pregnancy. Alcoholism, hepatitis, or other liver-damaging diseases can also cause excessive folate utilization.[1,2,3] Folate levels in both serum and red blood cells are used to assess folate status. The serum folate level is an indicator of recent folate intake. Red blood cell (RBC) folate is the best indicator of long term folate stores. A low RBC folate value can indicate a prolonged folate deficiency.

Folate and vitamin B_{12} are linked by the reaction pathway for methionine synthesis. A deficiency in either leads to a disruption of this pathway and to similar clinical symptoms.[1,3] Another consequence of this common metabolic pathway is that a B_{12} deficiency disrupts the uptake of folate into red blood cells. This leads to a low RBC folate value even with adequate folate intake. For the above reasons, it is often necessary to measure both vitamins in a clinical workup. The treatment depends on which vitamin is deficient.

METHODOLOGY

Assay type: two-step, competitive

The Access Folate assay is a competitive binding receptor assay. For the assay of folate in serum or plasma (heparin), no pre-treatment is required. For the assay of folate in red blood cells, a whole blood sample is first treated off-line with a lysing agent composed of ascorbic acid. This pre-treatment hemolyzes the red blood cells and converts the folate polyglutamic acid forms present in red cells to the monoglutamic acid form predominant in serum.[4] The sample from the pre-treatment of whole blood is defined as a hemolysate.

A serum, plasma (heparin), or hemolysate sample is treated to release folate from endogenous binding proteins. Folate binding protein, mouse anti-folate binding protein, folic acid-alkaline phosphatase conjugate, and goat anti-mouse capture antibody coupled to paramagnetic particles are added to the reaction vessel. Folate in the sample competes with the folic acid-alkaline phosphatase conjugate for binding sites on a limited amount of folate binding protein. Resulting complexes bind to the solid phase via mouse anti-folate binding protein.

After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is inversely proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

SPECIMEN

SPECIMEN COLLECTION AND PREPARATION

Serum or Plasma (Heparin) Folate

1. Serum and plasma (heparin) folate from fasting individuals are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples:[5]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation.
   - Keep tubes stoppered at all times.
   - Physically separate serum or plasma from contact with cells as soon as possible.
   - If the assay will not be completed immediately, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C or colder.[6]
   - Beckman Coulter, Inc. recommends that frozen specimens can be stored up to six months before testing.
   - Thaw samples only once.
   - Studies have shown that degradation of folate due to fluorescent light up to one week after blood collection is small and unlikely to affect accuracy of results.[7]
3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter have been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Do not use hemolyzed samples. The folate level in the red cells is much greater than that of the serum or plasma (heparin), leading to spuriously high results.

Red Blood Cell Folate

1. Collect whole blood specimens in tubes containing EDTA or heparin. Determine and record the hematocrit for use in the calculations. The specimen may be stored at 2 to 8°C for up to 4 hours before preparing the hemolysate.
2. Reconstitute the vial of Access Red Blood Cell Folate Lysing Agent (Cat. No. A14206) with 100 mL of deionized water. Allow to stand until completely dissolved, a minimum of 40 minutes. Swirl gently to mix before use. The solution may be stored at 2 to 8°C for up to 2 weeks. Allow the solution to come to room temperature before each use.
3. Gently invert the whole blood sample several times to insure that it is well mixed and combine 50 µL of the whole blood with 1 mL of the lysing agent.

4. Gently invert the mixture several times and allow it to stand at room temperature for a minimum of 90 minutes. After 90 minutes, either test the hemolysate within 1.5 hours or freeze it at -70°C or colder for storage or shipment. The hemolysate may be stored at -70°C or colder for up to 30 days. Alternatively, the hemolysate may be stored at -20°C or colder for up to 30 days; however, there may be some reduction (typically less than 10%) in the RBC folate hemolysate result.
5. To assay frozen hemolysates, thaw and allow sample to come to room temperature. Mix the sample by inverting the tube several times. Assay the sample within 1.5 hours.

REAGENTS

CONTENTS

Access Folate Reagent Pack

Ref. No. A98032: 100 determinations, 2 packs, 50 tests/pack

The same reagent formulation is used on all Access Immunoassay Systems.

- All antisera are polyclonal unless otherwise indicated.

Well	Contents	Ingredients
R1a:	3.25 mL	Mouse monoclonal anti-folate binding protein, paramagnetic particles coated with goat anti-mouse IgG, buffer, human serum albumin (HSA) and 0.1% ProClin* 300.
R1b:	13.5 mL	1.0M Ascorbate, 0.05N HCl, pH 5.5.
R1c:	9.86 mL	Milk folate binding protein (bovine) in buffer, HSA and 0.1% ProClin 300.
R1d:	3.1 mL	Folic acid alkaline phosphatase (bovine) conjugate in buffer, HSA and 0.1% ProClin 300.
R1e:	3.1 mL	0.6M K_3PO_4.

*ProClin is a trademark of LANXESS Corp.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[8]
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

> ⚠ **CAUTION**
>
> **Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).**
> **To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

GHS HAZARD CLASSIFICATION

Folate PMP (Compartment R1a)	DANGER	
		
		
	H317	May cause an allergic skin reaction.
	H360	May damage fertility or the unborn child.
	H412	Harmful to aquatic life with long lasting effects.
	P201	Obtain special instructions before use.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		Sodium Borate Decahydrate 1 - 2%
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Folate Binding Protein (Compartment R1c)	DANGER	
		
		
	H317	May cause an allergic skin reaction.
	H360	May damage fertility or the unborn child.

	H412	Harmful to aquatic life with long lasting effects.
	P201	Obtain special instructions before use.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		Sodium Borate Decahydrate 1 - 2%
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Folate Conjugate (Compartment R1d)	EUH208	May produce an allergic reaction.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Folate Phosphate (Compartment R1e)	DANGER	
		
	H314	Causes severe skin burns and eye damage.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER or doctor/physician.
		Potassium Phosphate, Tribasic 10 - 15%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access Folate Calibrators
   Provided at zero and approximately 1.2, 3.1, 6.2, 12.4, and 24.8 ng/mL (2.8, 7.0, 14.0, 28.1, and 56.2 nmol/L).
   Ref. No. A98033
2. Quality Control (QC) materials: commercial control material.

3. Lumi-Phos PRO
   Ref. No. B96000
4. UniCel DxI Wash Buffer II
   Ref. No. A16793
5. Access Red Blood Cell Folate Lysing Agent
   Ref. No. A14206
6. Optional materials for dilution:
   - Access Wash Buffer II
     Ref. No. A16792
   - Access Folate Calibrator S0
     Ref. No. A99250

REAGENT PREPARATION

Provided ready to use.

REAGENT STORAGE AND STABILITY

Stability	
Unopened at 2 to 10°C	Up to stated expiration date
After opening at 2 to 10°C	14 days

- Store upright.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., broken elastomer), discard the pack.

CALIBRATION

CALIBRATION INFORMATION

An active calibration is required for all tests. Calibration is required every 28 days. See calibrator Instructions For Use (IFU) for additional calibration information. Refer to the appropriate system manuals and/or Help system for information on calibration method, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Quality control materials are essential for monitoring the system performance. Quality controls with varying concentration ranges should be run individually at least once every 24 hours when the assay is being performed.[9] Quality control ranges should be determined by each laboratory's individual requirements. Follow applicable regulations and guidelines for quality control.

TESTING PROCEDURE(S)

PROCEDURE

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.

2. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.
3. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
4. Use 55 µL of sample for each determination in addition to the sample container and system dead volumes. Use 105 µL of sample in addition to the sample container and system dead volumes for each determination run with the automated dilution feature. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
5. The system default unit of measure for sample results is ng/mL. To change sample reporting units to the International System of Units (SI units), nmol/L, refer to the appropriate system manuals and/or Help system. To manually convert concentrations to the International System, multiply ng/mL by multiplication factor 2.266.[10]

LIMITATIONS

1. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce human anti-animal antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other antibodies such as human anti-goat antibodies may be present in patient samples.[11,12] Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
2. Other potential interferences in the sample could be present and may cause erroneous results in immunoassays. Some examples that have been documented in literature include rheumatoid factor, fibrin, endogenous alkaline phosphatase, exogenous alkaline phosphatase (e.g. asfotase alfa, Strensiq), and proteins capable of binding to alkaline phosphatase. Carefully evaluate results if the sample is suspected of having these types of interferences.[13,14]
3. The results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.

RESULTS INTERPRETATION

Test results are determined automatically by the system software. Test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

Use the following procedure to calculate RBC folate results:[6]

1. Multiply the RBC folate hemolysate result by 21 to correct for the 1:21 dilution that was made during preparation of the hemolysate.
2. Divide this result by the patient's hematocrit.

$$\text{RBC Folate (ng/mL)} = \frac{\text{hemolysate folate x 21}}{\text{(hematocrit/100)}}$$

Example:

Hemolysate folate value = 3.5 ng/mL
Hematocrit = 40%

$$\text{RBC Folate (ng/mL)} = \frac{\text{3.5 ng/mL x 21}}{\text{(40/100)}} = \frac{73.5}{0.4}$$

$$\text{RBC Folate (ng/mL)} = \text{184 ng/mL packed RBC}$$

The previous calculation assumes that the serum or plasma (heparin) folate value is low relative to the RBC folate value. Occasionally, this is not the case. Use the following calculation when the serum or plasma (heparin) folate is elevated and the RBC folate is low:

$$\text{RBC Folate (ng/mL)} = \frac{\text{(hemolysate folate x 21) - [serum folate x (1 - hematocrit/100)]}}{\text{(hematocrit/100)}}$$

Example:

Hemolysate folate value = 3.5 ng/mL
Serum or plasma (heparin) folate value = 18 ng/mL
Hematocrit = 40%

$$\text{RBC Folate (ng/mL)} = \frac{\text{(3.5 x 21) - [18 x (1 - 40/100)]}}{\text{(40/100)}} = \frac{62.7}{0.4}$$

RBC Folate (ng/mL) = 157 ng/mL packed RBC

REPORTING RESULTS

MEASURING INTERVAL

Approximately 2.0 - 24.8 ng/mL (4.53 - 56.2 nmol/L)

Automated dilution: Up to approximately 49.6 ng/mL (112.4 nmol/L)

Samples can be accurately measured within the measuring interval defined as the lower Limit of Quantitation (LoQ) 2.0 ng/mL [4.53 nmol/L] and the highest calibrator lot-specific stated value or 24.8 ng/mL (56.2 nmol/L), whichever value is lower.

1. If a sample contains less than the lower limit for the assay, report the result as less than that value (i.e. < 2.0 ng/mL [4.53 nmol/L]).
2. If a sample contains more than the calibrator lot-specific stated value of the highest calibrator, report the result as greater than that value (maximum reportable value is > 24.8 ng/mL [56.2 nmol/L]). Alternatively, the sample may be diluted to obtain a result.
   - For automated dilutions, the system dilutes one volume of sample with one volumes of Wash Buffer II. Refer to the appropriate system manuals and/or Help system for instructions.
   - For manual dilutions, dilute one volume of sample with one volumes of Wash Buffer II or Access Folate Calibrator S0 which is also available as Access Folate Calibrator S0, Ref. No. A99250. Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.
3. Red Blood Cell Folate
   - If a red blood cell hemolysate result is greater than the stated value of the highest calibrator, calculate the minimum value to report by multiplying the result by 21 to correct for the 1:21 dilution that was made during preparation of the hemolysate. Report the result as greater than this calculated value. Alternatively, dilute one volume of red blood cell hemolysate with one volume Access Red Blood Cell Folate Lysing Agent (Ref. No. A14206). After assaying the diluted hemolysate, multiply the calculated value by the dilution factor two or refer to the appropriate system manuals and/or Help system for detailed instructions on processing pre-diluted samples. Use the corrected value to recalculate ng/mL packed RBC using the equation in the RESULTS INTERPRETATION section.

EXPECTED VALUES

1. Each laboratory should validate or establish its own reference intervals to assure proper representation of specific populations.

2. Reference intervals from several populations have shown increased folate levels as compared to historical data due to folic acid fortification of foods.[15,16,17,18]

3. **Serum Folate:** Sera from 171 normal subjects from the United States were assayed to establish expected ranges. The normal values ranged from 2.3 to greater than 24.8 ng/mL (5.2 to > 56.2 nmol/L). The two-sided, non-parametric 90% reference range of this study is:

Units	Reference Range
ng/mL	5.9 to > 24.8
nmol/L	13.4 to > 56.2

The WHO Technical Consultation on folate and vitamin B_{12} deficiencies has determined that deficient folate concentrations are considered to be less than 4 ng/mL (10 nmol/L).[19]

4. **Red Blood Cell Folate:** Whole blood samples from 144 normal subjects from the United States were assayed to establish an expected range. The normal values ranged from 215 to greater than 1,356 ng/mL (487 to > 3,073 nmol/L) packed red blood cells (RBCs). The two-sided, non-parametric 90% reference range of this study is:

Units	Reference Range
ng/mL	366 to > 1,356
nmol/L	829 to > 3,073

Note: The folate and RBC folate expected values should only be considered as guidelines. Data was obtained on normal subjects in the United States and may not apply to countries/populations where folic acid fortification of foods does not occur.

PERFORMANCE CHARACTERISTICS

ASSAY CRITERIA AND REPRESENTATIVE DATA

Representative data is provided for illustration only. Performance obtained in individual laboratories may vary.

METHODS COMPARISON

A study based on CLSI EP09c, 3rd Edition[20] using Passing-Bablok regression and Pearson's correlation compared the Access 2 Immunoassay System and the DxI 9000 Access Immunoassay Analyzer.

Serum Folate

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
123	1.4 - 25	1.04	1.01 - 1.07	0.081	-0.074 - 0.19	0.99

RBC Folate Hemolysate

N	Concentration Range* (ng/mL)	Slope	Slope 95% CI	Intercept	Intercept 95% CI	Correlation Coefficient R
52	4.9 - 24	1.03	0.98 - 1.08	0.41	-0.17 - 0.93	0.99

*Range is Access 2 values

LINEARITY

A study based on CLSI EP06-Ed2[21] performed on the DxI 9000 Access Immunoassay Analyzer determined the assay demonstrated linearity across the measuring interval.

IMPRECISION

The assay was designed to have within-laboratory imprecision as listed below:

- ≤ 0.30 ng/mL (0.68 nmol/L) SD at concentrations ≤ 2.0 ng/mL (4.5 nmol/L)
- ≤ 15.0% CV at concentrations > 2.0 ng/mL (4.5 nmol/L)

The assay was designed to have repeatability (within-run) imprecision as listed below:

- ≤ 0.18 ng/mL (0.41 nmol/L) SD at concentrations ≤ 2.0 ng/mL (4.5 nmol/L)
- ≤ 9.0% CV at concentrations > 2.0 ng/mL (4.5 nmol/L)

A study based on CLSI EP05-A3[22] performed on the DxI 9000 Access Immunoassay Analyzer tested multiple samples in duplicate in 2 runs per day for a minimum of 20 days.

Serum Folate (ng/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	88	1.7	0.09	5.3	0.10	6.1	0.16	9.7	0.21	12.6
Sample 2	88	4.7	0.10	2.1	0.07	1.4	0.17	3.6	0.21	4.4
Sample 3	88	9.2	0.25	2.7	0.00	0.0	0.27	2.9	0.36	3.9
Sample 4	88	16	0.3	2.0	0.2	1.2	0.4	2.7	0.6	3.6
Sample 5	88	21	0.4	2.1	0.3	1.3	0.6	2.7	0.8	3.7

Hemolysate Folate (ng/mL)			Repeatability (Within-Run)		Between-Run		Between-Day		Within-Laboratory	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	80	5.0	0.21	4.3	0.00	0.004	0.00	0.001	0.21	4.3
Sample 2	80	11	0.3	2.8	0.3	2.8	0.0	0.02	0.5	4.0
Sample 3	80	11	0.5	4.4	0.0	0.02	0.2	2.2	0.5	4.9
Sample 4	80	13	0.2	1.9	0.1	0.5	0.0	0.002	0.3	1.9
Sample 5	80	18	0.4	2.2	0.3	1.8	0.3	1.4	0.6	3.1
Sample 6	80	22	0.4	1.8	0.3	1.2	0.0	0.003	0.5	2.1

ANALYTICAL SPECIFICITY / INTERFERENCES

Samples containing up to 10 mg/dL (171 µmol/L) bilirubin, 300 IU/mL rheumatoid factor, and lipemic samples containing up to 1,800 mg/dL (20.32 mmol/L) triglycerides do not affect the concentration of folate assayed.

In addition, samples with 5 g/dL (50 g/L) paraprotein (as human serum albumin) added to the endogenous albumin in the samples do not affect the concentration of folate assayed. The following table describes the cross-reactivity of the assay with substances that are similar in structure to folate. The analytes were spiked into serum samples. Values for cross-reactivity were calculated as described in CLSI EP7-A2.[23]

Substance	Analyte Added	Cross-Reactivity (%)
Aminopterin	500 ng/mL	0.3
Phenytoin	100 µg/mL	< 0.1
Methotrexate	100 ng/mL	4.0
Folinic Acid (Leucovorin)	100 ng/mL	0.3

DETECTION CAPABILITY

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were conducted on the DxI 9000 Access Immunoassay Analyzer following CLSI guideline EP17-A2.[24] The LoB study included multiple reagent lots and 3 instruments over a minimum of 3 days. The LoD and LoQ studies included multiple reagent lots and 3 instruments over a minimum of 5 days.

The serum folate assay and the RBC folate assay have an LoB of 0.80 ng/mL (1.81 nmol/L), LoD of 1.0 ng/mL (2.27 nmol/L) and ≤ 20% within-lab CV LoQ of 2.0 ng/mL (4.53 nmol/L).

ADDITIONAL INFORMATION

REVISION HISTORY

Revision A

New release of DxI Access Immunoassay Analyzer reagent IFU.

Revision B

Updated Limitations, Measuring Interval, Methods Comparison and Detection Capability sections.

Revision C

Updated ProClin trademark statement.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

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