BECKMAN COULTER CE

SYNCHRON System(s)
Chemistry Information Sheet

GLUH
Glucose
REF B24985

For *In Vitro* Diagnostic Use

Rx Only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

UniCel DxC SYNCHRON Systems Glucose reagent (GLUH), when used in conjunction with UniCel DxC 600/800 SYNCHRON System(s) and SYNCHRON Systems AQUA CAL 1 and 3, is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

CLINICAL SIGNIFICANCE

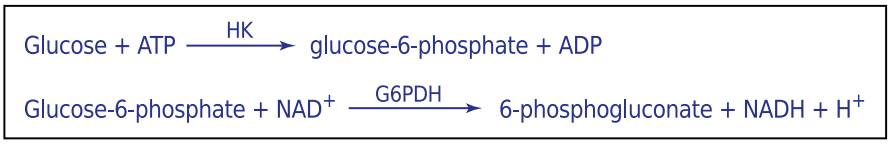
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

METHODOLOGY

GLUH reagent is used to measure glucose concentration by a timed endpoint method.[1] In the reaction, hexokinase (HK) catalyses the transfer of a phosphate group from adenosine triphosphate (ATP) to glucose to form adenosine diphosphate (ADP) and glucose-6-phosphate. The glucose-6-phosphate is then oxidized to 6-phosphogluconate with the concomitant reduction of β-nicotinamide adenine dinucleotide (NAD) to reduced β-nicotinamide adenine dinucleotide (NADH) by the catalytic action of glucose-6-phosphate dehydrogenase (G6PDH).

The UniCel DxC 600/800 SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of glucose in the sample and is used by the system to calculate and express glucose concentration.

CHEMICAL REACTION SCHEME



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SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.[2] Freshly drawn serum, plasma, CSF or properly collected urine (random/timed) are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample. The use of fluoride as a glycolysis inhibitor is recommended.

SPECIMEN STORAGE AND STABILITY

1. Tubes of blood are to be kept closed at all times and in a vertical position. Since glucose in whole blood at room temperature can undergo glycolysis at a rate of approximately 5% per hour, the sample should be centrifuged and removed from the clot or cells as soon as possible.[3] It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.[4]
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C.[4] Glucose in serum or plasma separated from blood cells is stable for up to 2 days at 2° to 8°C . If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.[4]
3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container is to be kept in the refrigerator or on ice during the timed period. If a special preservative is required, it should be added to the container before urine collection begins.[5]
4. CSF specimens should be centrifuged and analyzed without delay. Specimens may be refrigerated or frozen for 7 to 10 days for repeat determinations.[6]

Additional specimen storage and stability conditions as designated by this laboratory:

SAMPLE VOLUME

The optimum volume, when using a 0.5 mL sample cup, is 0.3 mL of sample. For optimum primary sample tube volumes and minimum volumes, refer to the Primary Tube Sample Template for your system.

CRITERIA FOR UNACCEPTABLE SPECIMENS

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Criteria for sample rejection as designated by this laboratory:

PATIENT PREPARATION

Special instructions for patient preparation as designated by this laboratory:

SPECIMEN HANDLING

Special instructions for specimen handling as designated by this laboratory:

REAGENTS

CONTENTS

Each kit contains the following items:

Two GLUH Reagent Cartridges (2 x 300 tests)

VOLUMES PER TEST

Sample Volume	3 µL
Total Reagent Volume	300 µL
Cartridge Volumes	
A	273 µL
B	27 µL
C	– –

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Adenosine Triphosphate	3.8 mmol/L
NAD^+	2.7 mmol/L
Hexokinase	2.0 KIU/L
Glucose-6-phosphate dehydrogenase	3.0 KIU/L

Also non-reactive chemicals necessary for optimal system performance.

Avoid skin contact with reagent. Use water to wash reagent from skin. 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

Glucose Reagent (Compartment A)	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tris(hydroxymethyl)– aminomethane 1 - 5%
Glucose Reagent (Compartment B)	WARNING	
	H316	Causes mild skin irritation.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
		Tris(hydroxymethyl)– aminomethane 1 - 5%

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

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON Systems AQUA CAL 1
SYNCHRON Systems AQUA CAL 3
At least two levels of control material
Saline

REAGENT PREPARATION

No preparation is required.

ACCEPTABLE REAGENT PERFORMANCE

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

REAGENT STORAGE AND STABILITY

GLUH reagent when stored unopened at +2°C to +8°C will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 30 days unless the expiration date is exceeded. DO NOT FREEZE.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

SYNCHRON Systems AQUA CAL 1

SYNCHRON Systems AQUA CAL 3

CALIBRATOR PREPARATION

No preparation is required.

NOTICE

Calibrators must be loaded in non-standard order - first SYNCHRON Systems AQUA CAL 3 (negative) then SYNCHRON Systems AQUA CAL 1 (positive).

CALIBRATOR STORAGE AND STABILITY

If unopened, the SYNCHRON Systems AQUA CAL 1 and 3 should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Opened calibrators stored at room temperature are stable for 1 month unless the expiration date is exceeded.

Calibrator storage location:

CALIBRATION INFORMATION

1. The system must have valid calibration factors in memory before controls or patient samples can be run.
2. Under typical operating conditions the GLUH reagent cartridge must be calibrated every 14 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 SYNCHRON System(s) *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 SYNCHRON System(s) *Instructions For Use* (IFU) manual for information on this feature.
3. For detailed calibration instructions, refer to the UniCel DxC 600/800 SYNCHRON System(s) *Instructions For Use* (IFU) manual.

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

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

At least two levels of control material should be analyzed daily. In addition, these controls should be run with each new calibration, with each new reagent cartridge, and after specific maintenance or troubleshooting procedures as detailed in the appropriate system manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

The following controls should be prepared and used in accordance with the package inserts. Discrepant quality control results should be evaluated by your facility.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

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

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

CALCULATIONS

The UniCel DxC 600/800 SYNCHRON System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

REPORTING RESULTS

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The reference intervals listed below were taken from literature.[6, 7] Serum/plasma and urine were verified on UniCel DxC 600/800 SYNCHRON System(s).

Table 2.0 Reference intervals

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Serum or Plasma	74 – 106 mg/dL	4.1 – 5.9 mmol/L
	Urine	1 – 15 mg/dL	0.06 – 0.83 mmol/L
	Urine (timed)	< 0.5 g/24 hrs	< 2.8 mmol/24 hrs
	CSF	40 – 70 mg/dL	2.2 – 3.9 mmol/L

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Laboratory			

Refer to References (8,6,9) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of at least 60 healthy volunteers[10]:

Table 3.0 Compatible Anticoagulants[a]

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Lithium Heparin	14 Units/mL	≤± 3.2 mg/dL or ± 3.2%
Sodium Heparin	14 Units/mL	≤± 3.2 mg/dL or ± 3.2%
Sodium Fluoride/Potassium Oxalate	2.5/2.0 mg/mL	≤± 3.2 mg/dL or ± 3.2%

a Data shown was collected using UniCel DxC 600/800 SYNCHRON System(s).

2. The following anticoagulants are incompatible with this method: EDTA and Sodium Citrate.

LIMITATIONS

None identified

INTERFERENCES

1. Comparative performance data for a UniCel DxC 600/800 SYNCHRON System(s) evaluated using CLSI EP7-A2 was assessed.[11]

Table 4.0 Low Level Glucose Pool[a]

SUBSTANCE	SOURCE	MAXIMUM LEVEL TESTED	Target (mg/dL)	Recovered (mg/dL)	% Recovery[b]
Hemoglobin	RBC hemolysate	500 mg/dL	45.3	43.7	96.5
Bilirubin	Bovine	24 mg/dL	43.4	42.5	97.9
Lipemia	Human	(3+) Serum Index = 6[c]	46.4	45	97
Ascorbic Acid	NA[d]	6.0 mg/dL	43.6	44.6	102.3
Urea	NA	500 mg/dL	53.7	53.9	98.9
Uric Acid	NA	40 mg/dL	42.9	44.4	103.6
EDTA	NA	16 mg/dL	43.5	44.1	101.4
Creatinine	NA	40 mg/dL	45.2	44.4	98.2

a Data shown was collected using UniCel DxC 600/800 SYNCHRON System(s).
b A properly operating UniCel DxC 600/800 SYNCHRON System(s) should exhibit interference values less than or equal to: ± 6 mg/dL or 10%, crossover value - 60 mg/dL.
c (3+) refers to the visual index of serum interferences on a scale of 1 to 4 and refers to an Intralipid concentration of 200-320 mg/dL.
d NA = Not applicable.

Table 5.0 Mid Level Glucose Pool[a]

SUBSTANCE	SOURCE	MAXIMUM LEVEL TESTED	Target (mg/dL)	Recovered (mg/dL)	% Recovery[b]
Hemoglobin	RBC hemolysate	500 mg/dL	171.5	169.1	98.6
Bilirubin	Bovine	24 mg/dL	169.3	170.7	100.8
Lipemia	Human	(4+) Serum Index = >10[c]	189.6	184.8	97.5
Ascorbic Acid	NA[d]	6.0 mg/dL	167.7	166.4	99.2
Urea	NA	500 mg/dL	207.1	208.9	100.9
Uric Acid	NA	40 mg/dL	170.5	168.6	98.6
EDTA	NA	16 mg/dL	168.9	166.8	98.8
Creatinine	NA	40 mg/dL	172.5	173.2	100.4

a Data shown was collected using UniCel DxC 600/800 SYNCHRON System(s).
b A properly operating UniCel DxC 600/800 SYNCHRON System(s) should exhibit interference values less than or equal to: ± 6 mg/dL or 10%, crossover value - 60 mg/dL.
c (4+) refers to the visual index of serum interferences on a scale of 1 to 4 and refers to an Intralipid concentration of 360-400 mg/dL.
d NA = Not applicable.

Table 6.0 High Level Glucose Pool[a]

SUBSTANCE	SOURCE	MAXIMUM LEVEL TESTED	Target (mg/dL)	Recovered (mg/dL)	% Recovery[b]
Hemoglobin	RBC hemolysate	500 mg/dL	410.7	406.1	98.9
Bilirubin	Bovine	24 mg/dL	407.2	404.8	99.4
Lipemia	Human	(4+) Serum Index = >10[c]	465.5	451.8	97.1
Ascorbic Acid	NA[d]	6.0 mg/dL	396.2	394.6	99.6
Urea	NA	500 mg/dL	454	456.6	100.6
Uric Acid	NA	40 mg/dL	397.1	405	102
EDTA	NA	16 mg/dL	397	400.2	100.8
Creatinine	NA	40 mg/dL	418	414.9	99.3

a Data shown was collected using UniCel DxC 600/800 SYNCHRON System(s).
b A properly operating UniCel DxC 600/800 SYNCHRON System(s) should exhibit interference values less than or equal to: ± 6 mg/dL or 10%, crossover value - 60 mg/dL.
c (4+) refers to the visual index of serum interferences on a scale of 1 to 4 and refers to an Intralipid concentration of 360-400 mg/dL.
d NA = Not applicable.

2. Listings of drugs, diseases and other pre-analytical variables known to affect glucose measurements when analyzing Serum, Urine and CSF are described in References (12, 13, 14). Visually turbid urine specimens should be centrifuged prior to analysis.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

The UniCel DxC 600/800 SYNCHRON System(s) method for the determination of this analyte provides the following analytical ranges, which have been verified using the EP6 standard.[15]

Table 7.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum, Plasma, Urine or CSF	5 – 700 mg/dL	0.3 – 38.8 mmol/L

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

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 8.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

SENSITIVITY

SENSITIVITY/DETECTION LIMIT

Limit of blank (LoB), limit of detection (LoD), and Limit of Quantitation (LoQ) data analysis was performed in accordance with the CLSI EP17-A2 guideline.[16] The LoB corresponds to the concentration below which analyte-free samples are found with 95% confidence. The LoD corresponds to the sample concentration above the LoB which is detectable with 95% confidence. The Limit of Quantitation is defined as the lowest amount of analyte in the sample that can be quantitatively determined with stated acceptable precision and trueness, under stated experimental conditions. A properly operating UniCel DxC Systems should exhibit detection limit values equal to the following:

Detection Limit Claim

LoB	≤ 5 mg/dL
	0.28 mmol/L
LoD	≤ 5 mg/dL
	0.28 mmol/L
LoQ	≤ 5 mg/dL
	0.28 mmol/L

Comparative performance data for a UniCel DxC 600/800 SYNCHRON System(s) evaluated using the CLSI EP17-A2 appears in the table below.

Table 9.0 CLSI EP17-A2 Verification sample mean results

	Serum	CSF	Urine
LoB	0.19 mg/dL	0.17 mg/dL	0.19 mg/dL
	0.011 mmol/L	0.009 mmol/L	0.011 mmol/L
LoD	1.74 mg/dL	1.68 mg/dL	1.78 mg/dL
	0.097 mmol/L	0.093 mmol/L	0.099 mmol/L
LoQ[a]	3.78 mg/dL	3.67 mg/dL	3.69 mg/dL
	0.210 mmol/L	0.204 mmol/L	0.205 mmol/L

a The LoQ data is based on a total error of ≤ 6mg/dL.[17]

EQUIVALENCY

Equivalency was assessed by Deming regression analysis of patient samples to accepted clinical methods.

Serum or Plasma, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 5 – 697 mg/dL)

Y (SYNCHRON UniCel DxC 600 Systems GLUH)	= 0.98x – 1.02
N	= 120
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 118
MEAN X (SYNCHRON UniCel DxC Systems GLU)	= 121
CORRELATION COEFFICIENT (r)	= 1.000

Serum or Plasma, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 5 – 691 mg/dL)

Y (SYNCHRON UniCel DxC 800 Systems GLUH)	= 1.00x – 1.60
N	= 120
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 118
MEAN X (SYNCHRON UniCel DxC Systems GLU)	= 120
CORRELATION COEFFICIENT (r)	= 1.000

CSF, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 9 – 693 mg/dL)

Y (SYNCHRON UniCel DxC 600 Systems GLUH)	= 0.98x + 1.25
N	= 100
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 108
MEAN X (SYNCHRON UniCel DxC Systems GLU)	= 109
CORRELATION COEFFICIENT (r)	= 1.000

CSF, UniCel DxC 600/800 SYNCHRON System(s) GLU (Range 8 – 675 mg/dL)

Y (SYNCHRON UniCel DxC 800 Systems GLUH)	= 1.00x – 0.61
N	= 100
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 108
MEAN X (SYNCHRON UniCel DxC Systems GLU)	= 108
CORRELATION COEFFICIENT (r)	= 1.000

Urine, UniCel DxC 600/800 SYNCHRON System(s) GLUCm (Range 8 – 671 mg/dL)

Y (SYNCHRON UniCel DxC 600 Systems GLUH)	= 1.00x - 0.21
N	= 103
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 218
MEAN X (SYNCHRON UniCel DxC Systems GLUCm)	= 218
CORRELATION COEFFICIENT (r)	= 0.999

Urine, UniCel DxC 600/800 SYNCHRON System(s) GLUCm (Range 9 – 687 mg/dL)

Y (SYNCHRON UniCel DxC 800 Systems GLUH)	=1.00x + 0.46
N	= 98
MEAN Y (SYNCHRON UniCel DxC Systems GLUH)	= 228
MEAN X (SYNCHRON UniCel DxC Systems GLUCm)	= 227
CORRELATION COEFFICIENT (r)	= 1.000

Refer to References (18) for guidelines on performing equivalency testing.

PRECISION

A properly operating UniCel DxC 600/800 SYNCHRON System(s) should exhibit precision values less than or equal to the following:

Table 10.0 Precision Values

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE[a]		% CV
		mg/dL	mmol/L	mg/dL	mmol/L	
Within-run	Serum/Plasma, Urine or CSF	2.0	0.11	100.0	5.5	2.0
Total	Serum/Plasma, Urine or CSF	3.0	0.17	100.0	5.5	3.0

a When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine the acceptability of the precision testing. When the mean of the test precision data is greater than the changeover value, compare the test % CV to the guideline given above to determine acceptability. Changeover value = (SD guideline/CV guideline) x 100.

Comparative performance data for a UniCel DxC 600/800 SYNCHRON System(s) evaluated using the CLSI EP5-A2 appears in the table below.[19] Each laboratory should characterize their own instrument performance for comparison purposes.

Table 11.0 CLSI EP5-A2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points[a]	GLUH GRAND MEAN (mg/dL)	SD	% CV
Within-run (DxC600)	Serum	Control 1	1	80	43	0.7	1.6
	Serum	Control 2	1	80	219	2.3	1.0
	Serum	Control 3	1	80	390	5.7	1.5
	Serum	Pool 1	1	80	9	0.3	3.6
	Serum	Pool 2	1	80	101	1.1	1.1
	Serum	Pool 3	1	80	660	6.4	1.0
	Urine	Pool 1	1	80	10	0.3	3.2
	Urine	Pool 2	1	80	95	0.9	1.0
	Urine	Pool 3	1	80	670	5.2	0.8
	CSF	Pool 1	1	80	11	0.3	3.0
	CSF	Pool 2	1	80	109	1.3	1.2
	CSF	Pool 3	1	80	677	7.0	1.0
Total (DxC600)	Serum	Control 1	1	80	43	0.8	1.9
	Serum	Control 2	1	80	219	2.6	1.2
	Serum	Control 3	1	80	390	6.5	1.7
	Serum	Pool 1	1	80	9	0.6	5.9
	Serum	Pool 2	1	80	101	1.6	1.6

Table 11.0 CLSI EP5-A2 Precision Estimate Method, Continued

TYPE OF IMPRECISION	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points[a]	GLUH GRAND MEAN (mg/dL)	SD	% CV
	Serum	Pool 3	1	80	660	8.4	1.3
	Urine	Pool 1	1	80	10	0.6	5.7
	Urine	Pool 2	1	80	95	1.4	1.5
	Urine	Pool 3	1	80	670	6.1	0.9
	CSF	Pool 1	1	80	11	0.6	5.3
	CSF	Pool 2	1	80	109	1.6	1.5
	CSF	Pool 3	1	80	677	8.6	1.3

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

Table 12.0 CLSI EP5-A2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points[a]	GLUH GRAND MEAN (mg/dL)	SD	% CV
Within-run (DxC800)	Serum	Control 1	1	80	43	0.5	1.2
	Serum	Control 2	1	80	219	2.7	1.2
	Serum	Control 3	1	80	389	6.3	1.6
	Serum	Pool 1	1	80	9	0.3	3.2
	Serum	Pool 2	1	80	101	1.1	1.1
	Serum	Pool 3	1	80	662	7.5	1.1
	Urine	Pool 1	1	80	10	0.3	3.0
	Urine	Pool 2	1	80	94	1.2	1.2
	Urine	Pool 3	1	80	668	7.9	1.2
	CSF	Pool 1	1	80	11	0.3	2.3
	CSF	Pool 2	1	80	108	1.1	1.0
	CSF	Pool 3	1	80	680	6.7	1.0
Total (DxC800)	Serum	Control 1	1	80	43	0.7	1.7
	Serum	Control 2	1	80	219	3.5	1.6
	Serum	Control 3	1	80	389	7.2	1.9
	Serum	Pool 1	1	80	9	0.3	3.6
	Serum	Pool 2	1	80	101	1.2	1.2
	Serum	Pool 3	1	80	662	9.4	1.4
	Urine	Pool 1	1	80	10	0.4	3.7

Table 12.0 CLSI EP5-A2 Precision Estimate Method, Continued

TYPE OF IMPRECISION	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points[a]	GLUH GRAND MEAN (mg/dL)	SD	% CV
	Urine	Pool 2	1	80	94	1.3	1.3
	Urine	Pool 3	1	80	668	8.1	1.2
	CSF	Pool 1	1	80	11	0.4	3.6
	CSF	Pool 2	1	80	108	1.7	1.6
	CSF	Pool 3	1	80	680	8.1	1.2

a The point estimate is based on the pooled data from one system, run for twenty days, two runs per day, two observations per run on an instrument operated and maintained according to the manufacturer's instructions.

NOTICE

These degrees of precision and equivalency were obtained in typical testing procedures on a UniCel DxC 600/800 SYNCHRON System(s) and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC 600/800 SYNCHRON System(s), refer to the appropriate system manual.

SHIPPING DAMAGE

If damaged product is received, notify your Beckman Coulter Clinical Support Center.

REVISION HISTORY

Revision AB

Revised the Intended Use, Specimen Storage and Stability, Sensitivity, CLSI EP17-A2 and EP5-A2 data, and Reference sections.

Revision AC

Revised Urine EQUIVALENCY information, added "RX Only" notice, removed distribution notice, and removed references to NCCLS throughout the document. Revised drug interference reference and turbid sample recommendation.

Revision AD

Added GHS Classification information

Revision AE

Added GHS Classification information

Revision AF

Updated to include Russian.

Revision AG

Updates to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AH

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AJ

Added new language requirement: Bulgarian, Romanian, Serbian, and Vietnamese. Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

SYMBOLS KEY

Table 13.0

REF	Catalogue Number	IVD	In Vitro Diagnostic
CONTENTS	Contents		Temperature limit
	Manufacturer		Expiration Date
LOT	Batch code	SDS	Safety Data Sheet
CE	CE Mark		Consult Instructions for Use
EC REP	Authorized Representative in the European Community		Date of Manufacture
	Caution		Biological risks
WARNING	WARNING		Do Not Freeze
	Do not reuse		
Made in USA of US and Foreign Components		Made in USA of US and Foreign Components	

REFERENCES

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