

SYNCHRON CX[®]3 DELTA System Chemistry Information Sheet

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GLU
Glucose
REF 443355

For *In Vitro* Diagnostic Use

ANNUAL REVIEW

Reviewed by:	Date	Reviewed by:	Date

PRINCIPLE

INTENDED USE

GLU reagent, when used in conjunction with SYNCHRON CX[®]3 DELTA System and SYNCHRON CX[®] Calibrators 1, 2 and 3, is intended for the quantitative determination of glucose (GLU) concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

CLINICAL SIGNIFICANCE

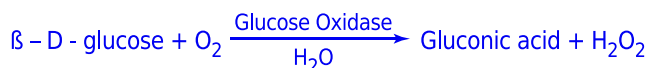
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

METHODOLOGY

The SYNCHRON CX[®]3 DELTA System determines GLU concentration by an oxygen rate method employing a Beckman Coulter Oxygen electrode.^{1,2}

A precise volume of sample (10 microliters) is injected into a reaction cup containing a glucose oxidase solution. The ratio used is one part sample to 100 parts reagent. Electronic circuits determine the rate of oxygen consumption, which is directly proportional to the concentration of glucose in the sample.³

CHEMICAL REACTION SCHEME



E015161L.EPS

Because oxygen consumption rather than peroxide formation is measured, the only requirement for peroxide is that it must be destroyed by a path not leading back to oxygen. The addition of ethanol to the reagent causes peroxide to be destroyed in the presence of catalase without yielding oxygen, according to the following reaction:



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To ensure complete destruction of the peroxide, iodide and molybdate are added to the enzyme reagent, causing the following reaction:



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The reaction is effective even after the catalase activity has diminished with length of storage.

SPECIMEN

TYPE OF SPECIMEN

Biological fluid samples should be collected in the same manner routinely used for any laboratory test.⁴ 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. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.⁵
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. 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.⁵
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.⁶
4. CSF specimens not analyzed upon receipt should be refrigerated at +2°C to +8°C. Samples may be frozen.⁷

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

SAMPLE VOLUME

A filled 0.5 mL sample cup is the optimum volume. For optimum volume in primary tube samples, or if urine specimens are sampled from test tubes, refer to Primary Sample Tube Chart Template (P/N 248511) for minimum volume requirements.

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:

One Glucose Reagent Bottle (500 mL)

VOLUMES PER TEST

Sample Volume	10 µL
ORDAC Sample Volume	5 µL
Total Reagent Volume	1.00 mL
Component Volume	
Glucose Oxidase	0.22 mL
Wash Solution	0.88 mL

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS	CONCENTRATION
Glucose Oxidase	590 U/mL
Denatured Ethanol	10%
Potassium Iodide	0.04 mol/L

Also non-reactive chemicals necessary for optimal system performance.

EUROPEAN HAZARD CLASSIFICATION

Glucose Reagent R10 Flammable.

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON CX Wash Solution

SYNCHRON CX[®] Calibrators 1, 2 and 3

At least two levels of control material. Do not use controls containing diethylamine HCl on Ca ISE configured systems.
Saline

REAGENT PREPARATION

Prior to use, allow the GLU reagent to equilibrate to room temperature. A +25°C water bath may be used to warm reagent. The Wash Solution, packaged separately, requires reconstitution. Follow directions included in package insert. Allow 24 hours for the reconstituted Wash Solution to outgas prior to use.

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

GLU reagent stored unopened at +2°C to +8°C is stable until the expiration date indicated on each bottle. The reagent is stable for 30 days when stored at room temperature or until the expiration date, if sooner. The reconstituted Wash Solution is stable for 30 days or until the expiration date, if sooner.

If reagent is frozen in transit, thaw completely, warm to room temperature and mix thoroughly by gently inverting bottle a least 10 times.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

SYNCHRON CX[®] Calibrators 1, 2 and 3

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

1. Unopened calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, the calibrators are stable at room temperature for 30 days.
2. Repetitive refrigeration of the aqueous calibrators may facilitate crystal formation. Once removed from refrigerated storage, these calibrators should remain at room temperature.

Calibrator storage location:

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CALIBRATION INFORMATION

1. The system must have a valid calibration in memory before controls or patient samples can be run.
2. Under typical operating conditions the GLU assay must be calibrated every 24 hours or with each new bottle of reagent or wash solution and also with certain parts replacements or maintenance procedures, as defined in the *Maintenance, Diagnostics and Troubleshooting* manual.
3. For detailed calibration instructions, refer to the SYNCHRON CX3 Delta *Operating Instructions* 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 print out with error codes and the system will alert the operator of the failure. An explanation of these error codes can be found in the *Maintenance, Diagnostics and Troubleshooting* manual.

TRACEABILITY

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

At least two levels of control material, normal and abnormal, should be analyzed daily. In addition, these controls should be run with each new calibration, with each new bottle of reagent, and after specific maintenance or troubleshooting procedures as detailed in the *Maintenance, Diagnostics and Troubleshooting* manual. More frequent use of controls or the use of additional controls is left to the discretion of the user based on work load and work flow.

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 as directed in Section 6 of the SYNCHRON CX3 Delta *Operating Instructions* manual.
2. After reagent load is completed, calibration is required. Refer to Section 6 of the SYNCHRON CX3 Delta *Operating Instructions* manual for details of the calibration procedure.

3. Program samples and controls for analysis as directed in Section 6 of the SYNCHRON CX3 Delta *Operating Instructions* manual.
4. After loading samples and controls onto the system, follow the protocols for system operation as directed in Section 6 of the SYNCHRON CX3 Delta *Operating Instructions* manual.

CALCULATIONS

The system performs calculations internally, including ORDAC, to produce the final reported result. SYNCHRON CX3 DELTA Systems will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming. For information on timed urine calculations, refer to Appendix Timed Urine Results in the Synchron CX3 Delta *Operating Instructions* manual.

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.⁷

Table 2.0 Reference Range

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Literature	Serum or Plasma	70 – 105 mg/dL	3.9 – 5.8 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 (8,9,10) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

LIMITATIONS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method:

Table 3.0 Acceptable Anticoagulants

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Ammonium Heparin	29 Units/mL	NSI ^a
EDTA	3.0 mg/mL	NSI
Lithium Heparin	29 Units/mL	NSI
Potassium Oxalate/Sodium Fluoride	4.0 / 5.0 mg/mL	NSI
Sodium Heparin	29 Units/mL	NSI

a NSI = No Significant Interference (within $\pm$ 4 mg/dL or 4%)

- The following anticoagulants were found to be incompatible with this method:

Table 4.0 Incompatible Anticoagulants

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL) ^a
Sodium Citrate	6.6 mg/mL	-19.0

a Bias is based on worst case instead of average. Plus (+) or minus (-) signs in this column signify positive or negative bias.

- If urine or CSF samples are cloudy or turbid or if CSF samples are visibly contaminated with blood, it is recommended that they be centrifuged before transfer to a sample cup.
- Freshly prepared D-glucose solutions or commercial controls spiked with D-glucose must be allowed to mutarotate before analysis for accurate results.

INTERFERENCES

- Common chemical substances were tested for possible interference with the SYNCHRON CX3 DELTA GLU method. Substances which were tested include endogenous metabolites, antibiotics, stimulants, depressants, barbiturates, hypnotics, anticoagulants and preservatives. Those materials which demonstrated any clinically significant interferences are listed below:

Table 5.0 Interferences

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT ^a
Cysteine	Cysteine	20 mmol/L	$\leq$ +11 mg/dL
Glutathione	Glutathione	5 mmol/L	$\leq$ +28 mg/dL
Hydroxyethyl Starch	Corn starch	5 mg/dL	$\leq$ +3.0 mg/dL
Penicillin G	Penicillin G potassium	250,000 U/mL	NSI ^b
n-Acetylcysteine	n-Acetylcysteine	20 mmol/L	$\leq$ +7.0 mg/dL
Hemoglobin	RBC hemolysate	500 mg/dL	NSI
Lipemia	Intralipid ^c	1000 mg/dL	NSI
Bilirubin	Bilirubin	30 mg/dL	NSI

a Plus (+) or minus (-) signs in this column signify positive or negative bias.

b NSI = No Significant Interference (within $\pm$ 4 mg/dL or 4%).

c Intralipid is a registered trademark of KabiVitrum, Inc., Clayton, NC 27250.

- Lipemic samples >3+ should be ultra-centrifuged and the analysis performed on the infranate.

3. Refer to References (11,12,13) for other interferences caused by drugs, disease and preanalytical variables.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

The SYNCHRON CX®3 DELTA System method for the determination of this analyte provides the following analytical ranges:

Table 6.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum/Plasma/Urine/CSF	0 – 450 mg/dL	0 – 25.0 mmol/L
Serum/Plasma/Urine/CSF (ORDAC)	450 – 900 mg/dL	25.0 – 50.0 mmol/L

Printed or displayed glucose values obtained in the non auto-ORDAC mode between 451 mg/dL and 475 mg/dL must be diluted with deionized water or normal saline and reanalyzed. Printed or displayed glucose values obtained in the ORDAC mode between 901 mg/dL and 950 mg/dL must also be diluted and reanalyzed.

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 7.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

EQUIVALENCY

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

Serum or Plasma:

Y (SYNCHRON CX3 DELTA)	= 1.033X - 3.89
N	= 82
MEAN (SYNCHRON CX3 DELTA)	= 151.5
MEAN (SYNCHRON CX3)	= 150.5
CORRELATION COEFFICIENT (r)	= 0.9992

Urine:

Y (SYNCHRON CX3 DELTA)	= 1.012X - 4.89
N	= 73
MEAN (SYNCHRON CX3 DELTA)	= 108.3
MEAN (SYNCHRON CX3)	= 111.8
CORRELATION COEFFICIENT (r)	= 0.9994

CSF:

Y (SYNCHRON CX3 DELTA)	= 1.062X - 5.65
N	= 60
MEAN (SYNCHRON CX3 DELTA)	= 93.3
MEAN (SYNCHRON CX3)	= 93.2
CORRELATION COEFFICIENT (r)	= 0.9980

Refer to References (14) for guidelines on performing equivalency testing.

PRECISION

A properly operating SYNCHRON CX[®]3 DELTA System should exhibit imprecision values less than or equal to the maximum performance limits in the table below. Maximum performance limits were derived by an examination of the imprecision of various methods, proficiency test summaries, and literature sources.

Table 8.0 Maximum Performance Limits

TYPE OF PRECISION	SAMPLE TYPE	1 SD		CHANGEOVER VALUE ^a		% CV
		mg/dL	mmol/L	mg/dL	mmol/L	
Within-run	Serum/Plasma/Urine/CSF	2.0	0.1	100.0	5.6	2.0
Total	Serum/Plasma/Urine/CSF	3.0	0.2	100.0	5.6	3.0
Within-run	Serum/Plasma/Urine/CSF (ORDAC)	NA ^b	NA	NA	NA	5.0
Total	Serum/Plasma/Urine/CSF (ORDAC)	NA	NA	NA	NA	7.5

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.

b NA = Not applicable.

Comparative performance data for the SYNCHRON CX[®]3 DELTA System evaluated using the NCCLS Proposed Guideline EP5-T2 appears in the table below.¹⁵ Each laboratory should characterize their own instrument performance for comparison purposes.

Table 9.0 NCCLS EP5-T2 Precision Estimate Method

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points ^a	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Within-run	Serum	Control 1	1	80	42.2	1.4	3.3
	Serum	Control 2	1	80	199.5	1.6	0.8
	Serum	Control 3	1	80	345.3	3.8	1.1
	Urine	Control 1	1	80	9.4	1.2	12.3
	Urine	Control 2	1	80	301.8	2.4	0.8
	CSF	Control 1	1	80	111.7	1.3	1.1
	CSF	Control 2	1	80	53.6	1.1	2.1

Table 9.0 NCCLS EP5-T2 Precision Estimate Method, Continued

TYPE OF IMPRECISION	SAMPLE TYPE		No. Systems	No. Data Points ^a	Test Mean Value (mg/dL)	EP5-T2 Calculated Point Estimates	
						SD	%CV
Total	Serum	Control 1	1	80	42.2	1.6	3.9
	Serum	Control 2	1	80	199.5	3.1	1.6
	Serum	Control 3	1	80	345.3	6.1	1.8
	Urine	Control 1	1	80	9.4	1.7	19.1
	Urine	Control 2	1	80	301.8	5.7	1.9
	CSF	Control 1	1	80	111.7	2.2	2.0
	CSF	Control 2	1	80	53.6	1.8	3.4

a The serum/plasma, urine, and CSF point estimate is based on the pooled data from 1 system, each run for 20 days, 2 runs per day, 2 observations per run on instruments operated and maintained according to the manufacturers instructions.

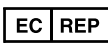
ADDITIONAL INFORMATION

SHIPPING DAMAGE

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

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 Beckman Coulter Ireland Inc., Mervue Business Park, Mervue, Galway, Ireland (353 91 774068)



Beckman Coulter, Inc., 250 South Kraemer Blvd., Brea, CA 92821