

**SYNCHRON System(s)
Chemistry Information Sheet**

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**GLUCm
Glucose**
REF 472500

For *In Vitro* Diagnostic Use
Rx Only
ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE
INTENDED USE

GLUCm reagent, when used in conjunction with UniCel DxC 600/800 System(s) and SYNCHRON Systems AQUA CAL 1 and 2, 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.

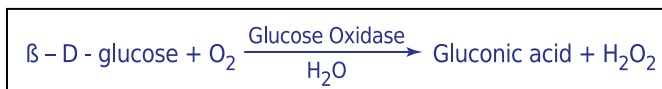
METHODOLOGY

The SYNCHRON System(s) determines GLUCm concentration by an oxygen rate method employing a Beckman Coulter Oxygen electrode.^{1,2}

A precise volume of sample (10 microliters) is injected in a reaction cup containing a glucose oxidase solution. The ratio used is one part sample to 76 parts reagent. The peak rate of oxygen consumption is directly proportional to the concentration of GLUCm in the sample.³

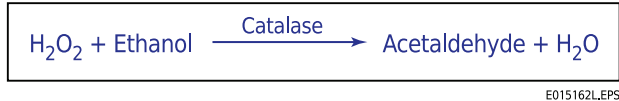
CHEMICAL REACTION SCHEME

Oxygen is consumed at the same rate as glucose reacts to form gluconic acid.

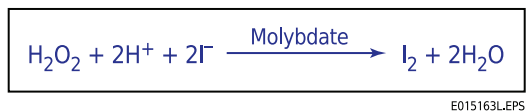


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Because oxygen consumption rather than peroxide formation is measured, the only requirement for peroxide is that it must be destroyed by a path not leading back to oxygen. The addition of ethanol to the reagent causes peroxide to be destroyed in the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



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



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 should be kept in the refrigerator or on ice during the timed period. No preservative is required.⁶
4. CSF specimens should be centrifuged and analyzed without delay.

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 primary sample tube volumes in primary tube samples 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 Glucose Reagent Bottles (2 x 2 L)

VOLUMES PER TEST

Sample Volume	10 µL
ORDAC Sample Volume	5 µL
Total Reagent Volume	765 µL

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Glucose Oxidase	150 U/mL
Denatured Ethanol	5%
Potassium Iodide	0.04 mol/L
Ammonium Molybdate	0.03 mol/L

Also non-reactive chemicals necessary for optimal system performance.

GHS HAZARD CLASSIFICATION

Glucose Reagent (Glucose Oxidase) DANGER



H226	Flammable liquid and vapour.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
P210	Keep away from heat, hot surfaces, and sparks. No smoking.
P261	Avoid breathing vapours.
P284	In case of inadequate ventilation, wear respiratory protection.
P304+P340	IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
	Glucose Oxidase 0.1 - 1%
	Ethyl Alcohol 1 - 10%

SDS

Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON Systems AQUA CAL 1 and 2
At least two levels of control material
Saline

REAGENT PREPARATION

Prior to use, allow the glucose reagent to equilibrate to room temperature for at least 8 hours. A +25°C water bath may be used to warm reagent. Invert reagent 5 times to mix.

Inspect for crystals and if present, see instructions for frozen reagent in Reagent Storage and Stability.

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

GLUCm reagent stored unopened at +2°C to +8°C is stable until the expiration date indicated on each bottle. The reagent is stable on instrument 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 Systems AQUA CAL 1 and 2

CALIBRATOR PREPARATION

No preparation is required.

CALIBRATOR STORAGE AND STABILITY

1. If unopened, the 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:

CALIBRATION INFORMATION

1. The system must have a valid calibration in memory before controls or patient samples can be run.

- Under typical operating conditions the GLUCm assay must be calibrated every 48 hours or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 Systems *Instructions for Use* (IFU) manual. Calibration may be required if the system is powered down for more than five minutes.
- For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
- 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 System *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 bottle of reagent, 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.

NOTICE
Do not use controls containing diethylamine HCl.

Table 1.0 Quality Control Material

CONTROL NAME	SAMPLE TYPE	STORAGE

TESTING PROCEDURE(S)

- If necessary prepare reagent as defined in the Reagent Preparation section of this chemistry information sheet and load the reagent onto the system.
- After reagent load is completed, calibration is required.
- Program samples and controls for analysis.
- After loading samples and controls onto the system, follow the protocols for system operations.

CALCULATIONS

The 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

Equivalency between the SYNCHRON LX and UniCel DxC 600/800 Systems has been established. Chemistry results between these systems are in agreement and data from representative systems may be shown.

REFERENCE INTERVALS

Each laboratory should establish its own reference intervals based upon its patient population. The reference intervals listed below were taken from literature and a study performed on SYNCHRON Systems.⁷

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 ^a	1 – 15 mg/dL	0.06 – 0.83 mmol/L
	Urine (timed) ^a	< 0.5 g/24 hrs	< 2.8 mmol/24 hrs
	CSF	40 – 70 mg/dL	2.2 – 3.9 mmol/L
SYNCHRON	Serum or Plasma	74 – 118 mg/dL	4.1 – 6.6 mmol/L

a In a healthy patient, the normal urine glucose value is zero.

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

ANTICOAGULANT TEST RESULTS

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

Table 3.0 Compatible Anticoagulants

ANTICOAGULANT	LEVEL TESTED FOR IN VITRO INTERFERENCE	AVERAGE PLASMA-SERUM BIAS (mg/dL)
Ammonium Heparin	14 Units/mL	NSI ^a
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	NSI

a NSI = No significant Interference (within ± 4.0 mg/dL or 4%).

LIMITATIONS

1. If sodium fluoride is used as a preservative, a decrease of 9 mg/dL is seen during the first 2 hours.⁷
2. 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.
3. Freshly prepared D-glucose solutions or commercial controls spiked with D-glucose must be allowed to mutarotate before analysis for accurate results.
4. Oxygenated samples will cause low results. Dilute samples 1:1 with saline or use the hexokinase cartridge method.

INTERFERENCES

1. The following substances were tested for interference with this methodology:

Table 4.0 Interferences

SUBSTANCE	SOURCE	LEVEL TESTED	OBSERVED EFFECT
Bilirubin (unconjugated)	Bovine	30 mg/dL	NSI ^a
Hemoglobin	RBC hemolysate	500 mg/dL	NSI
Lipemia	Intralipid ^b	500 mg/dL	NSI

a NSI = No significant Interference (within ± 4.0 mg/dL or 4%).

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

2. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >8, should be ultracentrifuged 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 System(s) method for the determination of this analyte provides the following analytical ranges:

Table 5.0 Analytical Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS
Serum/Plasma/Urine/CSF	10 – 600 mg/dL	0.56 – 33.3 mmol/L
Serum/Plasma/Urine/CSF (ORDAC)	300 – 1200 mg/dL	16.7 – 66.7 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 6.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

SENSITIVITY

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for GLUCm determination is 10 mg/dL (0.56 mmol/L).

EQUIVALENCY

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

Serum or Plasma (in the range of 10 to 571 mg/dL):

Y (UniCel DxC Systems)	= 1.005X - 0.165
N	= 187
MEAN (UniCel DxC Systems)	= 119.3
MEAN (SYNCHRON LX Systems)	= 118.8
Correlation Coefficient (r)	= 1.000

Urine (in the range of 10 to 628 mg/dL):

Y (UniCel DxC Systems)	= 1.014X + 0.385
N	= 96
MEAN (UniCel DxC Systems)	= 211.0
MEAN (SYNCHRON LX Systems)	= 208.5
Correlation Coefficient (r)	= 1.000

CSF (in the range of 22 to 552 mg/dL):

Y (UniCel DxC Systems)	= 0.982X + 0.43
N	= 93
MEAN (UniCel DxC Systems)	= 215
MEAN (SYNCHRON LX Systems)	= 219
Correlation Coefficient (r)	= 1.000

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

PRECISION

A properly operating SYNCHRON System(s) 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 7.0 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 a SYNCHRON LX 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 8.0 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	43.7	1.3	2.9
	Serum	Control 2	1	80	397.1	1.7	0.4
	Urine	Control 1	1	80	37.1	1.0	2.8
	Urine	Control 2	1	80	289.7	1.8	0.6
	CSF	Control 1	1	80	35.6	0.8	2.2
	CSF	Control 2	1	80	111.4	1.1	1.0
Total	Serum	Control 1	1	80	43.7	1.7	3.9
	Serum	Control 2	1	80	397.1	4.7	1.2
	Urine	Control 1	1	80	37.1	1.5	4.0
	Urine	Control 2	1	80	289.7	8.2	2.8
	CSF	Control 1	1	80	35.6	1.3	3.6
	CSF	Control 2	1	80	111.4	1.9	1.7

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 SYNCHRON LX System and are not intended to represent the performance specifications for this reagent.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

May be covered by one or more pat. -see www.beckmancoulter.com/patents.

SHIPPING DAMAGE

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

REVISION HISTORY

Revision AF

Updated corporate address; updated European Hazard Classification and removed EDTA as an Acceptable Anticoagulant claim.

Revision AG

Revised Equivalency examples, and changed sensitivity and low end of analytical range to 10 mg/dL.

Revision AH

Added Revision History

Revision AJ

Added new language requirement: Czech, and Korean.

Revision AK

Removed references to CX and LX systems as they are discontinued effective 12/2013.

Added Beckman Coulter trademark statement and disclaimer.

Revision AL

Revised Interferences section.

Revision AM

Added GHS Classification information

Revision AN

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

Revision AP















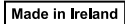

Additional changes to comply with requirements per Beckman Coulter Global Labeling Policy.

Revision AR

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

SYMBOLS KEY

Table 9.0

	Catalogue Number		In Vitro Diagnostic
	Contents		Temperature limit
	Manufacturer		Expiration Date
	Batch code		Safety Data Sheet
	CE Mark		Date of Manufacture
	Authorized Representative in the European Community		Consult Instructions for Use
	Do Not Freeze		DANGER
	Made in Ireland		Serial Number

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