BECKMAN COULTER CE

SYNCHRON System(s)

Chemistry Information Sheet

HbA1c3

Hemoglobin A1c3

REF B36415

For *In Vitro* Diagnostic Use

Rx Only

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The UniCel DxC Synchron Systems Hemoglobin A1c3 (HbA1c3) Reagent, when used in conjunction with UniCel DxC 600/800 SYNCHRON Systems, UniCel DxC SYNCHRON Systems HbA1c3 Calibrators and HbDIL reagent, is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood.

The A1c3 and Hb3 values generated as part of the HbA1c3 assay are intended for use in the calculation of the A1c3/Hb3 ratio and must not be used individually.

CLINICAL SIGNIFICANCE

Measurement of hemoglobin A1c is accepted as a method to measure long-term glucose control in patients with diabetes mellitus (a chronic disorder associated with disturbances in carbohydrate, fat, and protein metabolism and characterized by hyperglycemia).[1] Determination of hemoglobin A1c provides an important tool for monitoring the efficiency of dietary control and therapy during treatment of diabetes mellitus. Long term treatment of the disease emphasizes control of blood glucose levels in preventing the acute complications of ketosis and hyperglycemia. In addition, long term complications such as retinopathy, neuropathy, and cardiovascular disease can be minimized if blood glucose levels are effectively controlled.[1,2,3]

The process of conversion from hemoglobin A to hemoglobin A1c depends on the blood glucose concentration. Since the average life of a red blood cell is 120 days, measurement of hemoglobin A1c can reflect the mean daily blood glucose concentration over the preceding two to three months and provides a much better indication of glycemic control than blood or urinary glucose determinations.[1,4,5,6]

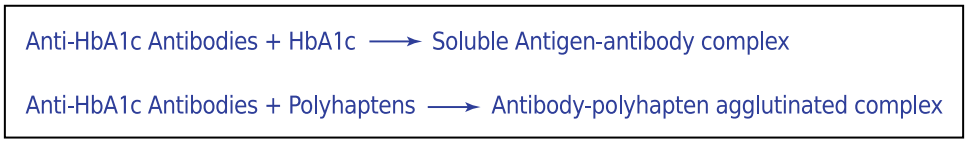
METHODOLOGY

The UniCel DxC Systems utilize two unique cartridges, Hb3 and A1c3, to determine hemoglobin A1c concentration as a ratio of total hemoglobin. Whole blood is treated on-line by preparing a hemolysate at a 1:100 dilution (3 µL of whole blood + 300 µL of HbDIL reagent).

Hb3 reagent is used to measure total hemoglobin concentration by a colorimetric method. The system automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 8.6 parts reagent. The system monitors the change in absorbance at 410 nanometers. This change in absorbance is directly proportional to the concentration of total hemoglobin in the sample and is used by the system to calculate and express total hemoglobin concentration.

A1c3 reagent is used to measure the hemoglobin A1c concentration by a turbidimetric immunoinhibition method. In the reaction, hemoglobin A1c antibodies combine with hemoglobin A1c from the sample to form soluble antigen-antibody complexes. Polyhaptens from the reagent then bind with the excess antibodies and the resulting agglutinated complex is measured turbidimetrically. The system automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 28 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is inversely proportional to the concentration of hemoglobin A1c in the sample and is used by the systems to calculate and express hemoglobin A1c concentration as a ratio of total hemoglobin (refer to the CALCULATIONS section of this chemistry information sheet).

CHEMICAL REACTION SCHEME



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SPECIMEN

TYPE OF SPECIMEN

Freshly drawn blood treated with EDTA is the preferred specimen. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet.

SPECIMEN STORAGE AND STABILITY

1. Whole blood samples are stable for 8 hours at +15°C to +25°C, 7 days at +2°C to +8°C and 3 months at -15°C to -20°C.[7] Whole blood samples are stable for 18 months at -70°C.[8] Frozen samples should be thawed only once.
2. Each laboratory should evaluate sample handling procedures to avoid variable results.

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

SAMPLE PREPARATION

Sample preparation is not required if "BLOOD" or "SERUM" is used as a sample type. Refer to "TESTING PROCEDURES" for details of sample processing.

If manual preparation of the hemolysate is desired, select sample type as "OTHER" and follow the steps below for manual sample preparation.

1. Bring the Hemolyzing Reagent to room temperature prior to use.
2. Pipette exactly 1,000 µL Hemolyzing Reagent into a test tube. DO NOT pipette directly from the reagent bottle (use a disposable tube). Ensure that the entire volume is dispensed from the tip.
3. Thoroughly mix the whole blood sample to ensure a uniform distribution of erythrocytes.
4. Add exactly 10 µL of whole blood sample to the test tube.
5. Rinse the pipette tip in Hemolyzing Reagent by aspirating and dispensing several times. Ensure that the entire volume is dispensed from the tip.
6. Vortex the hemolysate for 5 seconds at medium speed, avoiding the formation of foam.
7. Assay the hemolysate after hemolysis is complete, which is indicated by a color change from red to brown-green (approximately 1-2 minutes).

   Note: All hemolyzed samples should be mixed thoroughly immediately prior to assay. The hemolysate is stable for 4 hours at +15°C to +25°C, or 24 hours at +2°C to +8°C.
8. Select "OTHER" as sample type and process for HbA1c3.

SAMPLE VOLUME

When using a 0.5 mL sample cup for the hemolyzed sample, the optimum volume is 0.3 mL. When using a primary sample tube for the whole blood sample, refer to the Primary Tube Sample Template for the optimum volume.

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 A1c3 Cartridges (125 tests/cartridge)
Two Hb3 Cartridge (125 tests/cartridge)
One Bottle A1c3 Calibrator Level 1 (lyophilized, 2 mL when reconstituted)
One Bottle Hb3/A1c3 Calibrator Level 2 (lyophilized, 2 mL when reconstituted)
One Bottle A1c3 Calibrator Level 3 (lyophilized, 2 mL when reconstituted)
One Bottle A1c3 Calibrator Level 4 (lyophilized, 2 mL when reconstituted)
One Bottle A1c3 Calibrator Level 5 (lyophilized, 2 mL when reconstituted)
One Calibrator Value Assignment Sheet

NOTICE
The components supplied in this kit are intended for use as an integral unit. Do not mix various lots of kit components.

VOLUMES PER TEST

	Hb3	A1c3
Sample (Hemolysate) Volume	25 µL	10 µL
Total Reagent Volume	215 µL	280 µL
Cartridge Volume		
A	215 µL	220 µL
B	– –	60 µL
C	– –	– –

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Antibody Reagent (41 mL) :	
Anti-human HbA1c Antibody (sheep)	≥0.5 mg/mL
MES (2-morpholino-ethanesulfonic acid) Buffer	0.025 mol/L
TRIS (tris(hydroxymethyl)aminomethane) Buffer (pH 6.2)	0.015 mol/L
Polyhapten Reagent (10.6 mL)	
HbA1c Polyhapten	≥8 µg/mL
MES Buffer	0.025 mol/L
TRIS Buffer (pH 6.2)	0.015 mol/L
Hemoglobin Reagent (37 mL):	
Phosphate Buffer (pH 7.4)	0.02 mol/L

Also non-reactive chemicals necessary for optimal system performance.

CALIBRATOR CONSTITUENTS

Hemolysate (human and sheep)

0.9% tetradecyltrimethylammonium bromide

Also non-reactive chemicals necessary for optimal system performance.

GHS HAZARD CLASSIFICATION

A1c CAL L1, L2, L3, L4, L5	DANGER	
		
		
	H314	Causes severe skin burns and eye damage.
	H317	May cause an allergic skin reaction.
	H401	Toxic to aquatic life
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	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.
	P362+P364	Take off contaminated clothing and wash it before use.
		2-Methyl-4-isothiazolin-3-one < 1%
		Tetradecyltrimethylammonium bromide 1 - 10%
Hemoglobin Reagent (Compartment A)	EUH208	May produce an allergic reaction.
		2-Methyl-4-isothiazolin-3-one < 0.1%
Anti-HbA1c (Sheep) (Compartment A)	EUH208	May produce an allergic reaction.
		2-Methyl-4-isothiazolin-3-one < 0.1%
HbA1c-Polyhapten (Compartment B)	EUH208	May produce an allergic reaction.
		2-Methyl-4-isothiazolin-3-one < 0.1%

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

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

UniCel DxC SYNCHRON Systems HbDIL Reagent (Part Number A88469, for use in on-line sample dilution).
SYNCHRON and AU Systems Hemolyzing Reagent (Part Number 472137, for use in manual sample preparation).
At least two levels of control material.
Calibration Diskette P/N B36446 (lot specific)

REAGENT PREPARATION

Gently invert the Hb3 and A1c3 cartridges once before loading on the instrument. Remove bubbles from the cartridge compartments.

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

Hemoglobin A1c3 reagent kit, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the kit label. Once opened, the Hb3 reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. Once opened, the A1c3 reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. DO NOT FREEZE. Once opened, the UniCel DxC SYNCHRON Systems HbDIL reagent is stable for 60 days at +2°C to +8°C unless the expiration date is exceeded. Once opened, the SYNCHRON and AU Systems Hemolyzing Reagent is stable until the expiration date printed on the bottle label when stored and capped at +2°C to +8°C.

Reagent storage location:

CALIBRATION

CALIBRATOR REQUIRED

Hb3 (Single point calibration):

Hb3/A1c3 Calibrator Level 2 (included in HbA1c3 reagent kit)

A1c3 (Multi point calibration):

A1c3 Calibrator Level 1 (included in HbA1c3 reagent kit)
Hb3/A1c3 Calibrator Level 2 (included in HbA1c3 reagent kit)
A1c3 Calibrator Level 3 (included in HbA1c3 reagent kit)
A1c3 Calibrator Level 4 (included in HbA1c3 reagent kit)
A1c3 Calibrator Level 5 (included in HbA1c3 reagent kit)

CALIBRATOR PREPARATION

1. Carefully open calibrator bottles, avoiding loss of lyophilizate.
2. Add exactly 2,000 µL of deionized water to each bottle of calibrator and replace the stopper and cap, matching each to the calibrator bottle.
3. Dissolve the contents for 30 minutes by occasional gentle inversion or by placing on a rocker.
4. Vortex each bottle for 5 seconds at medium speed. Avoid the formation of foam.
5. Record calibrator reconstitution date and time on bottles.

NOTICE

Calibrators are lot-specific and should not be interchanged.

NOTICE

Calibrators DO NOT require pretreatment with the Hemolyzing Reagent prior to assay.

CALIBRATOR STORAGE AND STABILITY

If unopened, the HbA1c3 calibrators should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Reconstituted calibrators are stable for 8 hours stored at +15°C to +25°C or 48 hours stored at +2°C to +8°C unless the expiration date is exceeded. Calibrators that are aliquoted immediately after reconstitution and stored at -15°C to -20°C are stable for 60 days. Frozen calibrators should be thawed only once. After thawing vortex each bottle for 5 seconds at medium speed. Avoid the formation of foam.

⚠ **CAUTION**

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HbsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples to be handled as specified in Centers for Disease Control's Biosafety Level 2 guidelines.[9]

Calibrator storage location:

CALIBRATION INFORMATION

1. Load calibrator diskette. The calibrator values are reagent lot specific.
2. The system must have valid calibration factors in memory before controls or patient samples can be run.
3. Under typical operating conditions the Hb3 reagent cartridge must be calibrated every 15 days and the A1c3 reagent cartridge must be calibrated every 15 days, and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC Synchron Clinical Systems *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC Synchron Clinical Systems *Instructions For Use* (IFU) manual for information on this feature.
4. For detailed calibration instructions, refer to the UniCel DxC Synchron Clinical Systems *Instructions For Use* (IFU) manual.
5. 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 Synchron Clinical Systems *Instructions For Use* (IFU) manual.

CALIBRATOR ASSIGNED VALUES

For calibrator values traceable to IFCC (International Federation of Clinical Chemistry), see the Calibrator Value Assignment Sheet provided in the reagent kit.[10,11]

CALIBRATOR SUMMARY

A one-point linear calibration scheme is used for Hb3 calibration. The calibration generates a slope that is utilized by the system to convert absorbance data to Hb concentration. A five-point non-linear calibration scheme is used for A1c3 calibration. The calibration generates parameters that are utilized by the system to convert absorbance data to A1c concentration.

CALIBRATOR LIMITATIONS

These calibrators should only be used in conjunction with the UniCel DxC SYNCHRON Systems HbA1c3 reagent.

NOTICE
Calibrators are lot-specific and should not be interchanged.

TRACEABILITY

For calibrator value assignment information refer to the calibrator value assignment sheet in the reagent kit.

HbA1c measurand in this calibrator is traceable to the IFCC Reference Method.[10] The traceability process is based on prEN ISO 17511.

The UniCel DxC SYNCHRON Systems Hemoglobin A1c3 assay (HbA1c3) is certified by the National Glycohemoglobin Standardization Program (NGSP). The list of NGSP certified methods can be found at: www.ngsp.org

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.

Whole blood sample is automatically processed when the instructions below are strictly followed.

1. Do not run any other chemistry while processing HbA1c3 samples.
2. Instrument must be in STANDBY and the CTA sample wheel must have no racks loaded before processing HbA1c3 samples.
3. Sample type must be programmed as "BLOOD" or "SERUM".
4. Thoroughly mix the whole blood sample to ensure a uniform distribution of erythrocytes IMMEDIATELY before loading into the rack(s) reserved for HbA1c. Make sure there are no bubbles in the sample.
5. Load a maximum of 2 racks with up to 8 samples per load.
6. Start the run IMMEDIATELY after the racks are loaded on the instrument.
7. For additional HbA1c3 samples, repeat steps 4 to 6 after the previous 2 racks are off loaded.
8. Do not resume sample processing with other chemistries on the system until the last HbA1c3 rack is off loaded.

NOTICE

For pretreated (hemolyzed or lyophilized) control materials and manually prepared samples, select "OTHER" as sample type and process with other routine samples.

CALCULATIONS

Operator defined special calculations may be set up to report HbA1c concentration in IFCC and National Glycohemoglobin Standardization Program (NGSP) units.

For detailed special calculation programming, refer to the Special Calculations Definition section of the UniCel DxC Synchron Clinical Systems *Instructions For Use* (IFU) manual.

IFCC HbA1c special calculation formula:

mmol/mol HbA1c3 = (A1c3/Hb3)*1000

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Hb3 and A1c3 must be selected in the same units.

NGSP HbA1c special calculation formula:

% HbA1c3 (NGSP) = (A1c3/Hb3)*91.48+2.152

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Hb3 and A1c3 must be selected in the same units.

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 and confirmed by internal testing.[12]

Table 2.0 HbA1c Reference Intervals

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS
Literature	Whole Blood	NGSP 4.0 – 6.0%
		IFCC 20 – 42 mmol/mol

INTERVALS	SAMPLE TYPE	CONVENTIONAL UNITS
Laboratory		

Refer to References (13, 14, 15) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

PROCEDURAL NOTES

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with a minimum of 50 paired EDTA whole blood and heparin whole blood samples. Values of K2-EDTA (X) ranging from 4.8% HbA1c NGSP to 16.0% HbA1c NGSP were compared with the values for K3-EDTA and heparin whole blood (Y) yielding the following results.

Table 3.0 Anticoagulant Test Results

ANTICOAGULANT	LEVEL OF ANTICOAGULANT TESTED	DEMING REGRESSION ANALYSIS
K_3-EDTA	1.74 mg/mL	Y =1.012X - 0.043; r = 0.999
Lithium Heparin	15.8 USP units/mL	Y = 1.007X - 0.034; r = 0.999
Sodium Heparin	15.8 USP units/mL	Y = 1.007X - 0.034; r = 0.999

LIMITATIONS

1. **This assay is designed only for the measurement of mmol/mol HbA1c (IFCC) and %HbA1c (NGSP). The individual results for Hb and A1c concentration should not be reported.**
2. Do not use this test for screening or diagnosis of diabetes mellitus. Performance characteristics for this use have not been determined.
3. This assay is not useful in evaluating day-to-day glucose control and should not be used to replace daily home testing of glucose.
4. Caution should be exercised when interpreting the HbA1c results from patients with hemolytic disease or other conditions characterized by shortened erythrocyte survival, acute blood loss, and iron deficiency.[16,17]
5. The HbA1c3 assay running in batch mode from STANDBY requires the cuvette cleaning procedure with Cartridge Chemistry Wash Solution (CCWA, PN 657133) after every 4th batch of HbA1c. This cuvette cleaning procedure is required to minimize the risk of cuvette coating by the HbA1c3 reagent. The cuvette cleaning procedure can be conducted using the automated maintenance procedure #9 "CC Reagent Wash All Cuvettes", or by selecting the "CC Cuvettes" when performing the automated maintenance procedure #10 "Clean Flow Cell, Cups, & CC

Probes/Mixers". If unacceptable drift or imprecision is observed in Quality Control results or calibration failures are observed, additional cuvette cleaning is recommended.

6. Erythrocytes in a whole blood sample will settle out over time. An inaccurate result could be produced from an unmixed whole blood sample.
7. Specimens with elevated Erythrocyte Sedimentation Rate (ESR) may generate inaccurate results. The hemolysate should be manually prepared and assayed for HbA1c3 using "OTHER" as sample type.
8. Samples containing >10% HbF may result in lower than expected HbA1c3 results.[18, 19, 20]

INTERFERENCES

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

Table 4.0 Interferences

SUBSTANCE	SOURCE	LEVEL	OBSERVED EFFECT
Bilirubin (unconjugated)	Bovine	30 mg/dL (0.3 g/L)	NSI[a]
Lipemia	Intralipid	1,000 mg/dL (10 g/L)	NSI
Rheumatoid Factor	Human	2,000 IU/mL (2.0×10^6 IU/L)	NSI
Ascorbic Acid	NA[b]	50 mg/dL (0.5 g/L)	NSI

a NSI = No Significant Interference (within ± 6% mathematical)
b NA = Not applicable.

2. Refer to References (21, 22, 23) for other interferences caused by drugs, disease and preanalytical variables.

SPECIFICITY

The antibody used in this assay shows no cross-reactivity with HbA0, HbA1a, HbA1b, acetylated hemoglobin, carbamylated hemoglobin, and glycated albumin.[7]

No significant effect of HbS, HbD, HbE, HbC, and up to 10% HbF was observed with this assay. Glycated HbF is not detected by the A1c3 assay as it does not contain the glycated β-chain. However, HbF is measured in the Hb3 assay. Samples containing >10% HbF may result in lower than expected HbA1c3 results.[18, 19, 20]

No significant effect of labile glycated hemoglobin (up to 2,000 mg/dL, 5 hours at +37°C) was observed with this assay.

Criteria: Recovery within +/- 7% of control sample for HbS, HbD, HbE and HbC. Recovery within +/- 10% of control sample for HbF and labile glycated hemoglobin.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

Analytic ranges were determined in accordance with the CLSI EP6-A guideline.[24] The UniCel DxC SYNCHRON Systems method for the determination of HbA1c concentration provides the following analytical ranges:

Table 5.0 Analytical Range

ANALYTE	SAMPLE TYPE	UNITS
Hb	Whole Blood	6.0 – 24.0 g/dL (3.72 – 14.88 mmol/L)
A1c	Whole Blood	0.30 to Cal 5 g/dL[a]

Table 5.0 Analytical Range, Continued

ANALYTE	SAMPLE TYPE	UNITS
		(0.186 – Cal 5 mmol/L)
HbA1c (NGSP)	Whole Blood	4.0 – 17.0%
HbA1c (IFCC)	Whole Blood	20 – 162 mmol/mol

a Cal 5 Value is printed on the HbA1c3 calibrator value assignment sheet included in the kit.

This assay is designed only for the measurement of mmol/mol HbA1c (IFCC) and %HbA1c (NGSP). The individual results for Hb and A1c concentration should not be reported.

Samples that are out of the analytic range for Hb3, A1c3 or HbA1c3 should be analyzed by an alternative method.

REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 6.0 Reportable Range

SAMPLE TYPE	CONVENTIONAL UNITS	S.I. UNITS

SENSITIVITY

SENSITIVITY/DETECTION LIMIT

Limit of blank (LoB) and limit of detection (LoD) data analysis was performed in accordance with the CLSI EP17-A2 guideline.[25] 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.

Total Hemoglobin (Hb3)
LoB = 0.5 g/dL (0.31 mmol/L)
LoD = 6 g/dL (3.72 mmol/L)

Hemoglobin A1c (A1c3)
LoB = 0.2 g/dL (0.12 mmol/L)
LoD = 0.3 g/dL (0.19 mmol/L)

EQUIVALENCY

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

Whole Blood (K2-EDTA) in the NGSP range of 4.4 to 16.6% HbA1c:

Y (SYNCHRON UniCel DxC 600 Systems HbA1c3)	= 1.031x – 0.267
N	= 119
MEAN Y (UniCel DxC 600 SYNCHRON Systems HbA1c3)	= 6.84
MEAN X (UniCel DxC 600 SYNCHRON Systems HbA1C-)	= 6.89
CORRELATION COEFFICIENT (r)	= 0.998

Whole Blood (K2-EDTA) in the NGSP range of 4.3 to 15.9% HbA1c:

Y (UniCel DxC 800 SYNCHRON Systems HbA1c3)	= 1.031x - 0.294
N	= 118
MEAN Y (UniCel DxC 800 SYNCHRON Systems HbA1c3)	= 6.82
MEAN X (UniCel DxC 800 SYNCHRON Systems HbA1c-)	= 6.90
CORRELATION COEFFICIENT (r)	= 0.999

Refer to References (26) for guidelines on performing equivalency testing.

PRECISION

Properly operating UniCel DxC Systems should exhibit precision values less than or equal to the following:

Table 7.0 Precision Values (NGSP)

TYPE OF PRECISION	SAMPLE TYPE	< 5%HbA1c NGSP < 0.4 g/dL A1c	≥ 5%HbA1c NGSP ≥ 0.4 g/dL A1c
		HbA1c %CV	HbA1c %CV
Within-run	Whole Blood	5.0	4.0
Total	Whole Blood	7.5	4.0

Comparative performance data for the UniCel DxC Synchron System evaluated using the CLSI Approved Guideline EP5-A2 appears in the table below.[27] Each laboratory should characterize its own instrument performance for comparison purposes. Refer to Reference (27) for guidelines on performing precision testing.

Table 8.0 CLSI EP5-A2 Precision Estimate Method (NGSP)

TYPE OF IMPRECISION	SAMPLE TYPE	No. Systems	No. Data Points	Mean Value (%HbA1c)	EP5-A2 Calculated Point Estimates[a]	
					SD	%CV
Within-run (DxC 600)	Whole Blood Control 1	1	80	5.5	0.07	1.24
	Whole Blood Control 2	1	80	10.0	0.11	1.13
	Human Whole Blood Sample 1	1	80	8.9	0.09	0.96
	Human Whole Blood Sample 2	1	80	6.3	0.08	1.30
	Human Whole Blood Sample 3	1	80	4.8	0.07	1.52
Total (DxC 600)	Whole Blood Control 1	1	80	5.5	0.09	1.56

Table 8.0 CLSI EP5-A2 Precision Estimate Method (NGSP), Continued

TYPE OF IMPRECISION	SAMPLE TYPE	No. Systems	No. Data Points	Mean Value (%HbA1c)	EP5-A2 Calculated Point Estimates[a]	
					SD	%CV
	Whole Blood Control 2	1	80	10.0	0.15	1.46
	Human Whole Blood Sample 1	1	80	8.9	0.14	1.56
	Human Whole Blood Sample 2	1	80	6.3	0.10	1.62
	Human Whole Blood Sample 3	1	80	4.8	0.09	1.93

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 9.0 CLSI EP5-A2 Precision Estimate Method (NGSP)

TYPE OF IMPRECISION	SAMPLE TYPE	No. Systems	No. Data Points	Mean Value (%HbA1c)	EP5-A2 Calculated Point Estimates[a]	
					SD	%CV
Within-run (DxC 800)	Whole Blood Control 1	1	80	5.4	0.06	1.13
	Whole Blood Control 2	1	80	9.9	0.08	0.80
	Human Whole Blood Sample 1	1	80	8.9	0.07	0.81
	Human Whole Blood Sample 2	1	80	6.3	0.07	1.16
	Human Whole Blood Sample 3	1	80	4.6	0.06	1.34
Total (DxC 800)	Whole Blood Control 1	1	80	5.4	0.09	1.61
	Whole Blood Control 2	1	80	9.9	0.13	1.34
	Human Whole Blood Sample 1	1	80	8.9	0.13	1.47
	Human Whole Blood Sample 2	1	80	6.3	0.11	1.72
	Human Whole Blood Sample 3	1	80	4.6	0.09	1.89

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.

ADDITIONAL INFORMATION

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

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 AB

Updates to Reagent Constituents, Limitations, and Performance Characteristics sections and copyright information.

Revision AC

Added GHS Classification information

Revision AD

Added new language requirement: Romanian

Revision AE

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

Revision AF

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

Revision AG

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

Revision AH

Restored GHS HAZARD CLASSIFICATION INFORMATION. Moved Calibration Diskette information from CONTENTS to MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT and revised CALIBRATOR ASSIGNED VALUES to align with content updates.

SYMBOLS KEY

Table 10.0

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
Hb REAGENT	Hb Reagent	CAL DISKETTE	Calibration Diskette
A1c REAGENT	A1c Reagent	VA SHEET	Value Assignment Sheet
CAL 1-5	Calibrator Levels 1 to 5 (after reconstitution)	DANGER	DANGER
	Biological risks		Do not reuse
	Caution	Made in Germany	Made in Germany

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EC REP Beckman Coulter Eurocenter S.A., 22, rue Juste-Olivier. Case Postale 1044, CH - 1260 Nyon 1, Switzerland
Tel: +41 (0)22 365 36 11

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
www.beckmancoulter.com
Manufactured for Beckman Coulter, Inc.