For In Vitro Diagnostic Use

Rx Only

ANNUAL REVIEW

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PRINCIPLE

INTENDED USE

The Hemoglobin A1c-reagent, when used in conjunction with UniCel® DxC 600/800 SYNCHRON® Systems, UniCel® DxC SYNCHRON® Systems HbA1c-Calibrators and SYNCHRON® and AU® Systems Hemolyzing Reagent, is intended for the quantitative determination of hemoglobin A1c concentration in human whole blood.

The A1c- and Hb- values generated as part of the HbA1c- assay are intended for use in the calculation of the A1c-/Hb-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, Hb- and A1c-, to determine hemoglobin A1c concentration as a ratio of total hemoglobin.
Hb- 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.

A1c- 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

\[
\text{Anti-HbA1c Antibodies + HbA1c} \rightarrow \text{Soluble Antigen-antibody complex}
\]

\[
\text{Anti-HbA1c Antibodies + Polyhaptens} \rightarrow \text{Antibody-polyhapten agglutinated complex}
\]

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. Whole blood samples are stable for 18 months at -70°C. 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

1. Bring the Hemolyzing Reagent to room temperature prior to use.

2. Pipette exactly 1000 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.

**SAMPLE VOLUME**

When using a 0.5 mL sample cup, the optimum volume is 0.3 mL of sample.

**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 A1c- Cartridges (200 tests/cartridge)
- One Hb- Cartridge (400 tests/cartridge)
- One Bottle A1c- Calibrator Level 1 (lyophilized, 2 mL when reconstituted)
- One Bottle Hb-/A1c- Calibrator Level 2 (lyophilized, 2 mL when reconstituted)
- One Bottle A1c- Calibrator Level 3 (lyophilized, 2 mL when reconstituted)
- One Bottle A1c- Calibrator Level 4 (lyophilized, 2 mL when reconstituted)
One Bottle A1c- Calibrator Level 5 (lyophilized, 2 mL when reconstituted)
One Calibrator Diskette
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

<table>
<thead>
<tr>
<th></th>
<th>Hb-</th>
<th>A1c-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Volume</td>
<td>25 µL</td>
<td>10 µL</td>
</tr>
<tr>
<td>Total Reagent Volume</td>
<td>215 µL</td>
<td>280 µL</td>
</tr>
<tr>
<td>Cartridge Volume</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>215 µL</td>
<td>220 µL</td>
</tr>
<tr>
<td>B</td>
<td>--</td>
<td>60 µL</td>
</tr>
<tr>
<td>C</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

REACTIVE INGREDIENTS

REAGENT CONSTITUENTS

Antibody Reagent (64 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 (16.9 mL):
- HbA1c Polyhapten ≥8 µg/mL
- MES Buffer 0.025 mol/L
- TRIS Buffer (pH 6.2) 0.015 mol/L

Hemoglobin Reagent (103 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
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%

Anti-HbA1c (Sheep) (Compartment A)  EUH208 May produce an allergic reaction.

HbA1c-Polyhapten (Compartment B)  EUH208 May produce an allergic reaction.

2-Methyl-4-isothiazolin-3-one < 0.1%

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

EUROPEAN HAZARD CLASSIFICATION

A1c CAL L1, L2, L3, L4, L5  Xi;R36/38
R36/38 Irritating to eyes and skin.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

SYNCHRON and AU Systems Hemolyzing Reagent (for use in sample preparation).
At least two levels of control material.

REAGENT PREPARATION

Gently invert the 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 A1c- 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 Hb- reagent cartridge is stable for 30 days at +2°C to +8°C unless the expiration date is exceeded. Once opened, the A1c- 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 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

Hb- (Single point calibration):
Hb-/A1c- Calibrator Level 2 (included in HbA1c- reagent kit)

A1c- (Multi point calibration):
A1c- Calibrator Level 1 (included in HbA1c- reagent kit)
Hb-/A1c- Calibrator Level 2 (included in HbA1c- reagent kit)
A1c- Calibrator Level 3 (included in HbA1c- reagent kit)
A1c- Calibrator Level 4 (included in HbA1c- reagent kit)
A1c- Calibrator Level 5 (included in HbA1c- reagent kit)

CALIBRATOR PREPARATION

1. Carefully open calibrator bottles, avoiding loss of lyophilizate.
2. Add exactly 2000 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 HbA1c- 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.³

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 Hb- reagent cartridge must be calibrated every 7 days and the A1c- reagent cartridge must be calibrated every 7 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. The calibrator diskette is supplied with each reagent kit and contains the calibrator values for that specific lot of reagent.\(^{10,11}\)

**CALIBRATOR SUMMARY**

A one-point linear calibration scheme is used for Hb- calibration. The calibration generates slope that is utilized by the system to convert absorbance data to Hb concentration. A five-point non-linear calibration scheme is used for A1c- 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 HbA1c- reagent.

\[
\text{NOTICE}
\]

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 A1c- (HbA1c-) assay is certified by the National Glycohemoglobin Standardization Program (NGSP). The list of NGSP certified methods can be found at: [www.ngsp.org](http://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

<table>
<thead>
<tr>
<th>CONTROL NAME</th>
<th>SAMPLE TYPE</th>
<th>STORAGE</th>
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</table>

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 Synchron Clinical System Instructions For Use (IFU) manual.

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:

\[ \text{mmol/mol HbA1c-} = (A1c- / Hb-)*1000 \]

Hb- and A1c- must be selected in the same units.

NGSP HbA1c special calculation formula:

\[ \% \text{HbA1c- (NGSP)} = (A1c- / Hb-)*91.48+2.152 \]

Hb- and A1c- 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.\(^ \text{12} \)
Table 2.0 HbA1c Reference Intervals

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature</td>
<td>Whole Blood Hemolysate</td>
<td>NGSP 4.0 – 6.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IFCC 20 – 42 mmol/mol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INTERVALS</th>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory</td>
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Refer to References (13, 14, 15) for guidelines on establishing laboratory-specific reference intervals.

Additional reporting information as designated by this laboratory:

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 4.7% HbA1c NGSP to 16.8% 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

<table>
<thead>
<tr>
<th>ANTICOAGULANT</th>
<th>LEVEL OF ANTICOAGULANT TESTED</th>
<th>DEMING REGRESSION ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>K3-EDTA</td>
<td>1.74 mg/mL</td>
<td>Y = 0.993X + 0.028; r = 0.999</td>
</tr>
<tr>
<td>Lithium Heparin</td>
<td>15.8 USP units/mL</td>
<td>Y = 0.996X + 0.006; r = 0.998</td>
</tr>
<tr>
<td>Sodium Heparin</td>
<td>15.8 USP units/mL</td>
<td>Y = 0.993X + 0.025; r = 0.999</td>
</tr>
</tbody>
</table>

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 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. If running the HbA1c assay in random access, cuvette cleaning procedure with Cartridge Chemistry Wash Solution (CCWA, PN 657133) is recommended weekly. The cuvette cleaning procedure can be conducted by selecting the "CC Cuvettes" when performing the automated maintenance procedure #10 "Clean Flow Cell, Cups, & CC Probes/Mixers". If running the HbA1c assay in batch mode from standby, the automated maintenance procedure #9 "CC Reagent Wash All Cuvettes" is recommended after every 4th batch of HbA1c. This cuvette cleaning procedure is required to minimize the risk of cuvette coating by the HbA1c reagent. If unacceptable drift or imprecision is observed in Quality Control results or calibration failures are observed, additional cuvette cleaning
is recommended. Additional cuvette cleaning can be conducted using procedure #10 as described above or by choosing the automated maintenance procedure #9 "CC Reagent Wash All Cuvettes".

INTERFERENCES

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

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>SOURCE</th>
<th>LEVEL</th>
<th>OBSERVED EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilirubin (unconjugated)</td>
<td>Bovine</td>
<td>30 mg/dL (0.3 g/L)</td>
<td>NSI^a</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Intralipid^b</td>
<td>1000 mg/dL (10 g/L)</td>
<td>NSI</td>
</tr>
<tr>
<td>Rheumatoid Factor</td>
<td>Human</td>
<td>2000 IU/mL (2.0 x 10^6 IU/L)</td>
<td>NSI</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>NA^c</td>
<td>50 mg/dL (0.5 g/L)</td>
<td>NSI</td>
</tr>
</tbody>
</table>

^a NSI = No Significant Interference (within ± 6% mathematical)
^b Company and product names are the property of their respective owners.
^c NA = Not applicable.

2. Refer to References (18, 19, 20) 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 HbF up to 10% was observed with this assay. Glycated HbF is not detected by the A1c- assay as it does not contain the glycated β-chain. However, HbF is measured in the Hb- assay. Samples containing >10% HbF may result in lower than expected HbA1c- results.\(^21, 22, 23\)

No significant effect of labile glycated hemoglobin (up to 2000 mg/dL, 5 hours at +37°C) was observed with this assay.

Criterion: Recovery within +/- 10% of control sample.

PERFORMANCE CHARACTERISTICS

ANALYTIC RANGE

The UniCel DxC SYNCHRON Systems method for the determination of HbA1c concentration provides the following analytical ranges:

<table>
<thead>
<tr>
<th>ANALYTE</th>
<th>SAMPLE TYPE</th>
<th>UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb</td>
<td>Whole Blood Hemolysate</td>
<td>6 – 24 g/dL</td>
</tr>
<tr>
<td>A1c</td>
<td>Whole Blood Hemolysate</td>
<td>0.3 to Cal 5 g/dL^a</td>
</tr>
<tr>
<td>HbA1c (NGSP)</td>
<td>Whole Blood Hemolysate</td>
<td>4 – 17%</td>
</tr>
<tr>
<td>HbA1c (IFCC)</td>
<td>Whole Blood Hemolysate</td>
<td>20 – 162 mmol/mol</td>
</tr>
</tbody>
</table>

^a Cal 5 Value is printed on the HbA1c- 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.
REPORTABLE RANGE (AS DETERMINED ON SITE):

Table 6.0 Reportable Range

<table>
<thead>
<tr>
<th>SAMPLE TYPE</th>
<th>CONVENTIONAL UNITS</th>
<th>S.I. UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

SENSITIVITY

Limit of blank (LoB) and limit of detection (LoD) data analysis was performed in accordance with the CLSI EP17-A guideline.24 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 (Hb-)
LoB = 0.5 g/dL (0.31 mmol/L)
LoD = 6 g/dL (3.72 mmol/L)

Hemoglobin A1c (A1c-)
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 Hemolysate (K2-EDTA) in the NGSP range of 4.4 to 14.6% HbA1c:

\[
\begin{align*}
Y \text{ (UniCel DxC SYNCHRON Systems HbA1c-)} &= 1.041x - 0.286 \\
N &= 118 \\
\text{MEAN Y (UniCel DxC SYNCHRON Systems HbA1c-)} &= 7.16 \\
\text{MEAN X (SYNCHRON Systems HbA1c)} &= 7.16 \\
\text{CORRELATION COEFFICIENT (r)} &= 0.997
\end{align*}
\]

Refer to References (25) 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)

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>&lt; 5 %HbA1c NGSP &lt; 0.4 g/dL A1c</th>
<th>≥ 5 %HbA1c NGSP ≥ 0.4 g/dL A1c</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HbA1c %CV</td>
<td>HbA1c %CV</td>
</tr>
<tr>
<td>Within-run</td>
<td>Whole Blood Hemolysate</td>
<td>5.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Total</td>
<td>Whole Blood Hemolysate</td>
<td>7.5</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Comparative performance data for the UniCel DxC Synchron System evaluated using the CLSI Approved Guideline EP5-A2 appears in the table below.26 Each laboratory should characterize its own instrument performance for comparison purposes. Refer to Reference (26) for guidelines on performing precision testing.
### Table 8.0 CLSI EP5-A2 Precision Estimate Method (NGSP)

<table>
<thead>
<tr>
<th>TYPE OF IMPRECISION</th>
<th>SAMPLE TYPE</th>
<th>No. Systems</th>
<th>No. Data Points</th>
<th>Mean Value (%HbA1c)</th>
<th>SD</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-run</td>
<td>Control 1</td>
<td>1</td>
<td>80</td>
<td>5.3</td>
<td>0.05</td>
<td>1.04</td>
</tr>
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* 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.

### SHIPPING DAMAGE

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

### REVISION HISTORY

**Revision AB**

Revised the Specificity section.

**Revision AC**

Added new language requirement: Czech, and Korean.

**Revision AD**

Added GHS Classification information

**Revision AE**

Added new language requirement: Romanian
REFERENCES


7. Data on file at Beckman Coulter, Inc.


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EC REP

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