

Intended Use

Mission's Glucose Reagent is for the quantitative measurement of glucose in urine.

For Research Use Only. Site validation required for Lab Developed Test (LDT), 510K approval pending.

Summary and Principle

Urine glucose testing (glucosuria detection) is a simple, non-invasive method used to screen for and monitor conditions affecting glucose metabolism and kidney function. Glucose appears in urine when blood glucose exceeds the renal threshold (~180 mg/dL) and is useful as an initial screening tool for undiagnosed diabetes.¹ Monitoring of known diabetics helps assess glycemic control,² especially when blood glucose monitoring isn't available. May indicate poorly controlled diabetes if glucose is persistently present in urine. In renal glucosuria, glucose appears in urine despite normal blood glucose levels due to defective tubular reabsorption.³ Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). G-6-P is then oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) in the presence of nicotinamide adenine dinucleotide (NAD) producing 6-phosphogluconate and NADH. The formation of NADH causes an increase in absorbance at 340 nm which is directly proportional to the concentration of glucose in the sample.

Reagents

Glucose Reagent: A buffered solution containing 2 mmol/L nicotinamide adenine dinucleotide, 4 mmol/L adenosine triphosphate, 2 mmol/L magnesium, > 2000 U/L hexokinase (yeast), > 4000 U/L glucose-6-phosphate dehydrogenase (microbial), stabilizers, and preservatives.

Reagents Stability and Storage

Reagents are ready for use. Supplied reagent is stable at 2-8°C until expiry date. Stability claims are based on real-time studies. Manufacturer studies have shown that the reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

Cautions

May be harmful if inhaled or swallowed. Avoid contact with skin and eyes. In case of contact, flush affected area with water. Seek immediate medical attention for eyes.

Instrumentation

Mission Glucose Reagent Kits are for use on Mission CA200¹ and Beckman AU680 analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific analyzer.

¹ Also known as Zybion EXC200 Analyzer

Specimen Collection and Handling

Proper collection and storage of urine are essential for accurate urine glucose testing, as glucose can degrade over time or under improper conditions. Collection: use a clean, dry, sterile container (plastic or glass). Storage: Room temperature (20-25°C) stable for <2 hours due to bacterial glycolysis. Refrigerated at 2-8°C samples are stable for up to 24 hours.

Quality Control

Store and handle reagents properly before and during use. Every laboratory should establish its own test requirements using controls and calibrators. Mission Diagnostics provides quality calibrators to meet your program needs and which conform to NLCP Guidelines⁴:

MD-101210 Glucose Calibrator

Specificity, Limitations, and Interferences

High specific gravity urine samples due to patient dehydration may falsely elevate results. If the sample is not tested promptly or refrigerated, bacteria can consume glucose, leading to false negative results. Fanconi syndrome, or certain medications (e.g., SGLT2 inhibitors) can cause urine glucose without diabetes.

Typical Performance Characteristics

The following performance data was obtained using the Mission CA200 and Beckman AU680 analyzers. Other instruments may yield different performance data.

Linearity

The following results were obtained on Mission CA200 and Beckman AU680 analyzers using the Mission Glucose Reagent Kit on samples containing 10, 50, 100, 200, 400, 600, 800, and 1000 mg/dL glucose. The table below includes mean, standard deviation (SD) and coefficient of variation (CV) for each value.

Mean (mg/dL)	SD	CV%
10.7	0.06	0.6
52.2	0.34	0.6
103.4	0.53	0.5
204.4	1.06	0.5
409.9	3.27	0.8
613.7	2.26	0.4
807.5	5.58	0.7
1010.0	2.39	0.2

Precision

Studies were performed on Mission CA200 and Beckman AU680 analyzers. The precision of the assay was evaluated following a modification of NCCLS protocol EPT-T2. The within-run precision data was obtained by running two samples in replicates of 20 on the same day. The run-to-run data was obtained from QC data over a 25-day period.

Within-Run			Run-to-Run		
Mean (mg/dL)	SD	CV%	Mean (mg/dL)	SD	CV%
64.7	1.0	1.6	64.6	1.2	1.9
418.3	4.6	1.1	418.9	8.7	2.1

Analytical Specificity

Cross contamination studies have not been performed. Certain reagent/instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Test Conditions

For the data presented in this insert, studies using this reagent were performed on Mission CA200 and Beckman AU680 analyzers using the parameters listed below.

Limitations

A sample with a glucose concentration exceeding the analytical measuring range should be diluted with deionized water and reanalyzed incorporating the dilution factor in the calculation of the value.

The limit of quantification (LOQ) must be determined by each laboratory according to their SOP.

Calibration

Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used. If control results are found to be out of range, the test may need to be re-calibrated.

Method Parameters

Analyzer Specific Settings

Method type:	Endpoint
Slope:	positive
Units	mg/dL
DOM wavelength	340
SUB wavelength	380
Sample volume	2
Reagent volume	200
Blank rxn read (cycles)	7 - 9
Sample rxn read (cycles)	22 - 26

Calibration Settings

Calibration Type	Linear
Reagent Blank required	Yes
Calibrator 1 (water)	0
Calibrator 2	100

Analytical Measuring Range (AMR)

Range: (low)	LOQ
Range: (high)	1000

BIBLIOGRAPHY

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