Glucose Reagent Kit
MD-101110

Intended Use
For the in vitro quantitative measurement of glucose in urine.
NOT FOR USE IN UNPROFESSIONAL SETTINGS.

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
MISSION Glucose Kit is For Laboratory Use Only. May be harmful if inhaled or swallowed. Do not pipette by mouth. Avoid contact with skin and eyes. In case of contact, flush area with water. Seek immediate medical attention for eyes.

Instrumentation
MISSION Glucose Kit are for use on Mission Diagnostics Affirm C200 [1]and Beckman AU680 Analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific 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 Guidelines[4]:

MD-101213 – Glucose Calibrator

Specificity, Limitations, and Interferences
Elderly or pregnant patients may have a lower renal threshold, leading to false positives (glucose in urine without hyperglycemia). Dehydration or concentration 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 Affirm C200 and Beckman AU680 Analyzers. Other instruments may yield different performance data.

[1] Also known as Zybio EXC200 Analyzer

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Linearity
The following results were obtained on an Affirm C200 and Beckman AU680 Analyzers using the MISSION Glucose Kit on samples containing 42.3, 84.5, 169.0, 388.0, 676.1 mg/dL glucose. The table below includes mean, standard deviation (SD) and Coefficient of Variation (CV) for each value.

Mean (mg/dL)	SD	CV%
42.936	0.121	0.3
83.962	0.565	0.7
167.382	1.232	0.7
331.050	2.080	0.6
651.030	8.287	1.3

Precision
Studies performed on Affirm C200 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 by running two samples in replicates over a five-day period.

Within-Run			Run-to-Run		
Mean (mg/dL)	SD	CV%	Mean (mg/dL)	SD	CV%
155.9	1.8	1.1	10.286	0.487	4.7
523.1	3.4	0.7	552.770	13.029	2.4

Analytical Specificity
Cross contamination studies have not been performed on Affirm C200 and Beckman AU680 Analyzers. 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 Affirm C200 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.

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. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Method Parameters

Analyzer Specific Settings

Method type:	Endpoint
Slope:	positive
Units	mg/dL
DOM wavelength	340
SUB wavelength	405
Sample volume	2
Reagent volume	225
Blank rxn read (cycles)	7 - 9
Sample rxn read (cycles)	22 - 26

Calibration Settings

Calibration Type	Linear
Reagent Blank required	Yes
Calibrator 1	0
Calibrator 2	180

Analytical Measuring Range (AMR)

Range: (low)	0
Range: (high)	500

BIBLIOGRAPHY
1. WHO. Package of Essential Noncommunicable (PEN) Disease Interventions for Primary Health Care.
2. O'Kane MJ et al., "Urine glucose testing: is it still a useful tool?" *Diabetes Care*..
3. Medscape: *Renal Glucosuria. https://emedicine.medscape.com/article/983678-overview*
4. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November, 2002.

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