

Intended Use

Mission's Specific Gravity Reagent is for the determination of the specific gravity of urine specimens.

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

Summary and Principle

Measuring urine specific gravity (SPGR) provides hydration status of the patient. High SPGR suggests dehydration (concentrated urine) while low SPGR suggests overhydration or inability to concentrate urine.

Measuring urine SPGR assists in detection of problems like acute kidney injury, chronic kidney disease, or tubular dysfunction. Urine SPGR also is useful in diagnosing diabetes insipidus, urinary tract infections, ALS¹, and other metabolic disorders.

Mission's Specific Gravity Reagent Kit contains indicators which react with the specimen to yield a colored complex reflecting the ionic strength (correlates with specific gravity) of the sample at 600 nm. Normal urine may range in specific gravity from 1.005 to 1.018². Abnormal values should be checked by an alternate (refractometer) method.

Reagents

SPGR reagent provided ready-to-use. No preparation is required.

Mission's Specific Gravity Reagent Kit contains color indicators and surfactants.

Reagent Stability and Storage

Unopened and opened reagents are stable until expiration date when stored tightly capped at room temperature. Reagents may also be stored tightly capped at 2-10°C. The stability of reagents stored on the analyzer 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's Specific Gravity Reagent Kit is for use on Mission CA200¹ and Beckman AU680 analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific analyzer.

Specimen Collection and Handling

Use clean plastic or glass containers to collect urine specimens. Protect the sample from heat and light. Testing may be performed on samples at room temperature and samples may be stored refrigerated at 2-10°C. Handle all urine samples as if potentially infectious.

Quality Control

Standard practice for quality control should be applied to this procedure. Store and handle reagents properly before and during use. Every laboratory should establish its own test requirements using controls and calibrators. Mission Diagnostics provides calibrators to meet your program needs and which conform to NLCP Guidelines³:

MD-101207.01 – Specific Gravity Calibrator 1.001

MD-101207.02 – Specific Gravity Calibrator 1.020

Specificity, Limitations, and Interferences

Mission's Specific Gravity Reagent Kit is for the detection of specific gravity of urine specimens. Erroneous results may result from improperly stored samples and bacterial growth. Urine samples with abnormal pH values may affect test results. Highly alkaline urines may lower specific gravity results, while urines with abnormally acidic pH values may increase specific gravity results.

Typical Performance Characteristics

The following performance data was obtained using 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 Specific Gravity Reagent Kit on samples having SPGR values: 1.001, 1.005, 1.010, 1.020 and 1.030. The table below includes mean, standard deviation (SD) and coefficient of variation (CV) for each value.

Mean (SG Units)	SD	CV%
1.0010	0.0000	0.0
1.0062	0.0004	0.0
1.0108	0.0004	0.0
1.0212	0.0004	0.0
1.0292	0.0004	0.0

¹ Also known as Zybion EXC200 Analyzer

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 by running two samples in replicates over a five-day period.

Within-Run			Run-to-Run		
Mean (SG Units)	SD	CV%	Mean (SG Units)	SD	CV%
1.0218	0.0004	0.0	1.0209	0.0008	0.1
1.0118	0.0004	0.0	1.0112	0.0005	0.1

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.

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:	negative
Units	SG units
DOM wavelength	578
SUB wavelength	800
Sample volume	2
Reagent volume	150
Blank rxn read (cycles)	7 - 9
Sample rxn read (cycles)	16 - 20

Calibration Settings

Calibration Type	Linear
Reagent Blank required	No
Calibrator 1	1.001
Calibrator 2	1.020

Analytical Measuring Range (AMR)

Range: (low)	1.001
Range: (high)	1.030

BIBLIOGRAPHY

1. Urine specific gravity to identify and predict hydration need in ALS. doi: 10.1080/21678421.2021.2013894.
2. Burtis, C.A. and E.R. Ashwood, Eds: Tietz Textbook of Clinical Chemistry, 2nd ed., Philadelphia, Saunders, 1994.
3. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November 2002.