SPECIFIC GRAVITY REAGENT KIT
MD-101107

Intended Use
For the determination of the specific gravity of urine specimens. NOT FOR USE IN UNPROFESSIONAL SETTINGS.

Summary and Principle
MISSION Specific Gravity Reagent Kit is for use on automatic Analyzers to determine the specific gravity (SPGR) of urine specimens.
Importance of Measuring Urine Specific Gravity:
Hydration Status: indicates how concentrated the urine is. High SPGR suggests dehydration (concentrated urine). Low SPGR suggests overhydration or inability to concentrate urine.
Kidney Function: Helps detect problems like acute kidney injury, chronic kidney disease, or tubular dysfunction.
Diagnosis of Health Conditions: Assists in diagnosing diabetes insipidus, urinary tract infections, ALS[1], and other metabolic disorders.
Monitoring Therapy: Useful for tracking fluid therapy, especially in hospitalized or critically ill patients.
MISSION Specific Gravity Reagent Kit contains indicators which react with the specimen to yield a colored complex reflecting the ionic strength (specific gravity) of the sample at 600 nm. Normal urine may range in specific gravity from 1.005 to 1.018[2]. Abnormal values should be checked by an alternate (refractometer) method.

Reagents
R1 reagent provided ready to use. No preparation is required.
MISSION Specific Gravity Reagent Kit contains color indicators, buffers and surfactants.

Reagent Stability and Storage
MISSION Specific Gravity Reagent Kit are 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.
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 uncapped on-board the analyzer may be affected in that environment.

Cautions
Avoid contact of specimens with skin and eyes. Should contact occur, wash affected area with plenty of water.
DO NOT PIPETTE SPECIMENS BY MOUTH.

Instrumentation
MISSION Specific Gravity Reagent 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
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 Guidelines[3]:

MD-101207.01 – Specific Gravity Calibrator 1.001
MD-101207.02 – Specific Gravity Calibrator 1.020

Specificity, Limitations, and Interferences
MISSION 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 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 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

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 (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 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.

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:	negative
Units	SG units
DOM wavelength	578
SUB wavelength	800
Sample volume	2.2
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.

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