DRI® Gravity-Detect® Test

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use**

REF 10018532 (6 x 18 mL Kit)
1194 (2 x 500 mL Kit)
1754 Low Gravity Calibrator
1755 High Gravity Calibrator
1756 Level 1 Gravity Control
1757 Level 2 Gravity Control

Intended Use
The DRI® Gravity-Detect® Test is intended for the quantitative determination of human urine specific gravity.

Summary and Explanation of the Test
A complete urine drug of abuse testing program normally involves specimen collection, initial screening with an immunoassay, followed by a confirmation test, such as gas chromatography/mass spectrometry (GC/MS), for positive samples.[1] Many drug users attempt to evade detection by adulterating their specimen in order to produce false negative results during the initial immunoassay screening. Adulteration methods include dilution with water, substitution with a drug free liquid, addition of readily available household materials (e.g., vinegar, baking soda, liquid drain opener, detergent, etc.) or tampering with certain chemicals (e.g., Urine-Aid, which contains glutaraldehyde, or Klear, which contains potassium nitrite).

Several methods have been used to detect urine adulteration. These methods include measuring the temperature, pH, specific gravity and creatinine concentration of the sample. Fresh normal urine should have the following typical characteristics: temperature between 32.5-37.7°C or 90.5-99.8°F,[1] pH within 4.7-7.8,[2,3] specific gravity within a range of 1.003-1.035 g/mL[2,4,5] and creatinine concentration of 80-200 mg/dL.[5-9] If any of these urine parameters is outside the specified range, there should be reason to believe that the urine sample has been adulterated.

Urine specific gravity measurement as well as other methods, such as measuring the concentration of creatinine, pH and appearance, are useful adjuncts to drugs of abuse testing in determining possible adulteration. Densitometer measurement, dipsticks or other manual methods can determine urine specific gravity. An end-point colorimetric measuring technique based on ionic strength measurement can also be used.

The DRI Gravity-Detect Test can be performed on automated clinical chemistry analyzers. This method is based on a linear relationship between the urine chloride ion concentration and the specific gravity.[9] The chloride ion concentration is determined colorimetrically using ferric perchlorate according to the following equation:

$$Cl^- + Fe^{3+} \longleftrightarrow FeCl^{2+}$$

Chloride ion and ferric perchlorate in an acidic medium form a $FeCl^2$ complex with an absorbance maximum at 340 nm. The absorbance at 340 nm is directly proportional to the urine chloride concentration. A linear two-point calibration curve can be established and the sample urine specific gravity value can be extrapolated from the calibration curve using the corresponding absorbance result.

Reagents
Gravity-Detect Reagent: Contains ferric perchlorate in an aqueous acidic solution.

Additional Materials Required (sold separately):
Low Specific Gravity Calibrator: Contains an aqueous sodium chloride solution with a specific gravity of 1.010 g/mL.
High Specific Gravity Calibrator: Contains an aqueous sodium chloride solution with a specific gravity of 1.025 g/mL.
Level 1 Specific Gravity Control: Contains an aqueous sodium chloride solution with a specific gravity of 1.015 g/mL.
Level 2 Specific Gravity Control: Contains an aqueous sodium chloride solution with a specific gravity of 1.030 g/mL.

⚠ Precautions and Warning
This test is for in vitro diagnostic use only. The reagents are harmful if swallowed. Avoid contact with eyes and skin.


The reagent contains ferric perchlorate in an aqueous acidic solution. Wear suitable protective clothing, gloves, and eye/face protection.


Danger. Causes (severe) eye burns. Causes skin irritation.


Oxidizer: contact with other material may cause fire. It is recommended this product be handled in a fume hood.

Keep the solution away from direct sunlight.

Reagent Preparation and Storage
The reagents are ready-to-use, no additional preparation is required. All assay components, opened or unopened, are stable, until the expiration date indicated on their respective labels when stored at room temperature. Do not use the reagents beyond their expiration dates.

In the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, state, and country regulations.

In the case of damaged packaging on arrival, contact your technical support representative (contact details listed at the end of this package insert).

Specimen Collection and Handling
Collect urine specimens in plastic or glass containers. Fresh urine specimens should be used. *"The Mandatory Guidelines for Federal Workplace Drug Testing Programs: Final Guidelines: Notice"* recommends that specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units. Handle all urine specimens as if they were potentially infectious.[10]

Assay Procedure
Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 340 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the appropriate analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration
Good laboratory practice suggests the use of control specimens to validate the calibration and to ensure proper assay performance. The 1.015 g/mL and 1.030 g/mL specific gravity controls are available from Microgenics for this purpose. Ensure that control results are within established ranges as determined by your laboratory. Recalibrate the system when new reagents are used or when the control values are outside established ranges. Use both low and high specific gravity calibrators to generate the calibration curve. A typical calibration curve with a Hitachi 717 analyzer is as follows:

Calibrator	Absorbance (mA/min)
1.010	892
1.025	1208

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Results and Data Interpretation
The specific gravity values of the calibrators and controls used in the Gravity-Detect Test are established and verified by a conventional gravimetric method. The sample specific gravity is extrapolated from the calibration curve using the absorbance value of the sample. Most clinical chemistry analyzers have built-in curve-fit software that can calculate the sample specific gravity values automatically with no additional requirement of data manipulation.

Expected Values
The range of urine specific gravity of apparently healthy individuals has been determined to be 1.003 g/mL to 1.035 g/mL.[2,3] However, it is recommended that each laboratory establish its own normal urine specific gravity range. Urine samples with a low specific gravity may indicate dilution of the specimen. Urine samples with a high specific gravity may suggest the addition of salt or other adulterants.

Limitations
This assay is optimized for the quantitative determination of specific gravity in human urine only. The reportable range is 1.000 g/mL to 1.040 g/mL. It is recommended that specific gravity values less than 1.000 g/mL be reported as "<1.000" and specific gravity values greater than 1.040 g/mL be reported as ">1.040".

Typical Performance Characteristics

The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer:

Precision

Within-run and run-to-run precision were evaluated using clinical urine samples at various specific gravity levels. The following results were obtained:

Within-run (n=20)		Run-to-run (n=10)	
Mean (g/mL)	%CV	Mean (g/mL)	%CV
1.015	0.04	1.010	0.00
1.032	0.06	1.030	0.04
1.016	0.02	1.020	0.03
1.009	0.03	1.010	0.04
1.020	0.12	1.020	0.00

Interference by Urine pH

Potential interference of the assay due to the variation of pH was investigated. Specific gravity did not vary more than ± 0.003 g/mL over a pH range of 3 to 11.

Interference by Endogenous Substances

Interference by endogenous substances in urine was studied. No interference was observed when urine samples were spiked with endogenous substances up to the concentration indicated in the table below.

Interferant	Concentration	Interferant	Concentration
Albumin	500 mg/dL	Urea	6 mg/dL
Creatinine	500 mg/dL	Glucose	3 mg/dL
Galactose	10 mg/dL	Riboflavin	7.5 mg/dL
Hemoglobin	300 mg/dL	Ascorbic Acid	20 mg/dL

For information on substances or conditions that may affect the specific gravity values in vivo, refer to publications[11,12] in the Bibliography section.

Linearity

Solutions containing specific gravity levels at 1.006, 1.010, 1.015, 1.020, 1.025 and 1.030 g/mL were prepared and assayed with the test. A correlation coefficient of 0.999 was obtained when the absorbance value of each solution was plotted against its corresponding specific gravity value.

Accuracy and Correlation

The expected specific gravity of a series of urine samples was determined using the traditional weight by volume method. They were compared to the specific gravity determined by the Gravity-Detect Test. A recovery range of 99.6% to 100.3% was observed. Specific gravity of sixty-five clinical urine samples was determined with both Gravity-Detect and a commercially available method. The following linear regression analysis was observed: (y) = 0.98(x) + 0.02, with a correlation coefficient (r) of 0.983. The sample mean specific gravity for the Gravity-Detect Test was 1.028 g/mL with a range of 1.004 to 1.062 g/mL. The sample mean specific gravity for the commercial method was 1.026 g/mL with a range of 1.004 to 1.048 g/mL.

Bibliography

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1208-7-EN
2015 01

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