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. 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 nitrate).

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, pH within 4.7-7.8, specific gravity within a range of 1.003-1.030 g/mL and creatinine concentration of 80-200 mg/dL. 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. The chloride ion concentration is determined colorimetrically using ferric perchlorate according to the following equation:

\[ Cl^- + Fe^{3+} \rightarrow FeCl_3 \]

Chloride ion and ferric perchlorate in an acidic medium form a FeCl₃ 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 value.

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 1.025 g/mL.

Precautions and Warning
DANGER: Gravity-Detect Test contains ≤4.0% perchloric acid and ≤2.0% iron (III) perchlorate. H317 - Causes skin irritation. H315 - Causes eye irritation. H272 - May intensify fire, oxidizer.

Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep/Store away from clothing/combustible materials. Take any precaution to avoid mixing with combustibles. Wash hands thoroughly after handling. Wear protective glasses/eye protection/face protection. Specific treatment (see First Aid Information on Product label and/or Section 4 of the SDS). If on skin: Wash with plenty of soap and water. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a Poison Center or doctor/physician. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. In case of fire: Use water spray [fog], foam, dry powder or carbon dioxide for extinction. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

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

Keep the solution away from direct sunlight.
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:

<table>
<thead>
<tr>
<th></th>
<th>Within-run (n=20)</th>
<th>Run-to-run (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (g/mL)</td>
<td>%CV</td>
</tr>
<tr>
<td>1.015</td>
<td>0.04</td>
<td>1.010</td>
</tr>
<tr>
<td>1.032</td>
<td>0.06</td>
<td>1.030</td>
</tr>
<tr>
<td>1.016</td>
<td>0.02</td>
<td>1.020</td>
</tr>
<tr>
<td>1.009</td>
<td>0.03</td>
<td>1.010</td>
</tr>
<tr>
<td>1.020</td>
<td>0.12</td>
<td>1.020</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Interferant</th>
<th>Concentration</th>
<th>Interferant</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>500 mg/dL</td>
<td>Urea</td>
<td>6 mg/dL</td>
</tr>
<tr>
<td>Creatinine</td>
<td>500 mg/dL</td>
<td>Glucose</td>
<td>3 mg/dL</td>
</tr>
<tr>
<td>Galactose</td>
<td>10 mg/dL</td>
<td>Riboflavin</td>
<td>7.5 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>300 mg/dL</td>
<td>Ascorbic Acid</td>
<td>20 mg/dL</td>
</tr>
</tbody>
</table>

For information on substances or conditions that may affect the specific gravity values in vivo, refer to publications11,12 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**