DRI® pH-Detect® Test, Calibrators and Controls

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use**

REF 10015654 (6 x 18 mL)
100054 (2 x 500 mL Kit)
100283 pH 3.0 and pH 11.0 Calibrator Sets (2 x 25 mL)
100282 pH 3.6 Control (25 mL)
100284 pH 7.0 Control (25 mL)
100285 pH 10.0 Control (25 mL)
100281 pH 11.5 Control (25 mL)

Intended Use
The DRI® pH-Detect Test® is intended for the determination of urine pH.

Summary and Explanation of the Test
A urine drug of abuse testing program typically involves specimen collection, initial screening with an immunoassay, followed by a confirmation test, such as gas chromatography/mass spectrometry (GC/MS), for the positive samples.[1] Many drug users will attempt to evade detection by adulterating the 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).

Several methods have been used to detect urine adulteration. These methods include measuring the temperature, pH, specific gravity and creatinine concentration of the sample. 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[2,4,5] and creatinine concentration of 80.0-200.0 mg/dL.[5-8] If any of the urine parameters is outside the specified range, there should be reason to believe that the urine sample has been adulterated.

Urine pH®, as well as other markers of adulteration, are useful for indicating specimen validity for drugs of abuse testing. Most urine pH determination is performed with pH paper or by a pH meter.

pH-Detect Test is an end point colorimetric method which can be performed with automated clinical chemistry analyzers for urine pH measurement. The method is based on the property of acid-base indicator dyes, which produce color depending on the pH of the urine sample. The color change can be measured as an absorbance change spectrophotometrically. A linear two-point calibration curve can be established using the pH 3.0 and pH 11.0 calibrators.

Materials Provided

Reagent

pH-Detect Reagent: Contains pH indicator dyes in an aqueous solution.

Calibrators and Controls (sold separately):

pH-Detect Calibrator Kit: Contains 1 x 25 mL of pH 3.0 acetate buffer and 1 x 25 mL pH 11.0 carbonate buffer.
pH-Detect 3.6 Control Kit: Contains 1 x 25 mL of pH 3.6 acetate buffer.
pH-Detect 7.0 Control Kit: Contains 1 x 25 mL of pH 7.0 phosphate buffer.
pH-Detect 10.0 Control Kit: Contains 1 x 25 mL of pH 10.0 carbonate buffer.
pH-Detect 11.5 Control Kit: Contains 1 x 25 mL of pH 11.5 carbonate buffer.

⚠ Precautions and Warning
1. This test is for specimen validity testing only. The components are harmful if swallowed.
2. Do not use the reagent and calibrators beyond their expiration dates.
3. Do not expose reagent to direct sunlight.
4. Avoid contact with eyes and skin. Wear suitable protective clothing.
5. pH-Detect 3.0 Calibrator, pH-Detect 3.6 Control, pH-Detect 10.0 Control, pH-Detect 11.0 Calibrator and pH-Detect 11.5 Control can be irritating to eyes,respiratory system and skin.
6. pH-Detect 3.0 Calibrator and pH-Detect 3.6 Control contains acid which can cause burns.

DANGER:
DRI pH-Detect Test pH 3.0 Calibrator Kit and pH 3.6 Control Kit contain ≤10.5% Acetic acid (low pH).
H314 - Causes severe skin burns and eye damage.
H318 - Causes serious eye damage.

DRI pH-Detect Test pH 11.5 Control Kit contains high pH.
H314 - Causes severe skin burns and eye damage.

Do not breathe mist/vapors/spray. Wash hands thoroughly after handling. Wear protective gloves/eye protection/face protection. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. If on skin or hair: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. 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. Specific treatment (see First Aid information on product label and/or Section 4 of the SDS). Wash contaminated clothing before reuse. Store locked up. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Reagent Preparation and Storage
The reagent and calibrators are ready for use. No reagent preparation is required. All assay components, when stored properly at 2°C to 8°C, are stable until the expiration date indicated on the label.

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. Repeated freezing and thawing of the sample should be avoided. **Handle all urine specimens as if they were potentially infectious.**[9]

Assay Procedure
Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 600 nm and timing the reaction accurately can be used to perform this assay.

Before performing the assay, refer to the 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 pH 3.6, pH 7.0, pH 10.0 and pH 11.5 controls from Microgenics should be used 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 pH 3.0 and pH 11.0 calibrators to generate the calibration curve. All quality control requirements should be performed in conformance with local,state and/or federal regulations or accreditation requirements.

Results
A linear calibration is generated to calibrate the assay. The sample pH concentration is extrapolated from the calibration using the absorbance value of the sample. Most clinical chemistry analyzers have built-in software that can calculate the pH concentration automatically with no additional requirement of data manipulation.

Expected Values
The normal range of urine pH values of apparently healthy individuals has been determined to be 4.7 to 7.8.[2,3]

Limitations
This assay is optimized for the quantitative determination of human urine pH only. The assay range for urine pH is 3.0 to 11.0. It is recommended that samples with pH values < 3.0 and > 11.5 are confirmed by an alternate method such as a pH meter. Urine samples suspected of bacterial contamination (samples stored at 2-8°C for several weeks and urinary tract infections) will produce inaccurate results by pH-Detect Test.

Typical Performance Characteristics
The following typical performance data was generated with a Hitachi 717 clinical chemistry analyzer.

Precision
The within-run and total precision were evaluated with three levels of pH control samples at various pH values with the following results:

	Within-run Precision (n=60)		Total Precision (n=60)	
Control	Mean ± SD	% CV	Mean ± SD	% CV
3.6	3.4 ± 0.1	3.6	3.4 ± 0.2	4.5
7.0	7.1 ± 0.1	1.2	7.1 ± 0.1	2.0
10.0	10.6 ± 0.1	1.0	10.6 ± 0.1	1.1
11.5	11.5 ± 0.1	1.0	11.5 ± 0.2	1.4

Linearity
A series of pH buffers ranging from 3.0-11.5 were tested. A correlation coefficient of 0.998 was obtained when the observed values were plotted against the corresponding expected pH values.

Interference
Interference from endogenous substances and urine adulterants (For example: Urine Luck™ and Klear) was studied. These compounds were added to urine at different concentrations and the pH was determined using the pH-Detect Test. The pH values were within the normal range (4.7-7.8) at the concentrations listed in the table.

Interferant	Concentration
Acetone	1000 mg/dL
Albumin	500 mg/dL
Ammonium Phosphate	600 mg/dL
Ascorbic Acid	100 mg/dL
Bilirubin	5 mg/dL
Chromate (Urine Luck™)	1000 µg/mL
Creatinine	500 mg/dL
Ethanol	300 mg/dL
Galactose	10 mg/dL
Glucose	2000 mg/dL
Hemoglobin	50 mg/dL
Nitrite (Klear)	2000 µg/dL
Oxalic Acid	100 mg/dL
Riboflavin	7.5 mg/dL
Sodium Chloride	6000 mg/dL
Urea	3000 mg/dL
Uric Acid	70 mg/dL

Accuracy and Correlation
A total of 78 random urine samples and 13 adulterated samples were tested by the pH-Detect Test. The results were compared with the pH meter. Correlation analysis yielded a linear regression equation of y=0.990x+1 and a correlation coefficient of 0.933.

References

1. *Mandatory Guidelines for Federal Workplace Drug Testing Programs*.National Institute On Drug Abuse. Federal Register Vol. 73, No. 228, 2008:71877.
2. Schumann GB, and Schweitzer SC, 1989, *Examination of Urine*. In Clinical Chemistry: Theory, Analysis and Correlation, 2nd Edition, Kaplan LA, and Pesce AJ (Eds.) pp 820-849.
3. Cody GT. *Specimen Adulteration in Drug Urinalysis*. Forensic Science Review. 2, 63 (1990).
4. Tiez, NW, ed. *Clinical Guide to Laboratory Test*. Philadelphia: WB Sanders, 514 (1990).
5. Edwards C, Fyfe MJ, Liu RH and Walia AS. *Evaluation of Common Urine Specimen Adulteration Indicators*. J Anal Toxicol 17, 251 (1993).
6. Murray RL, 1989. Creatinine. In Clinical Chemistry: Theory, Analysis and Correlation, 2nd Edition, Kaplan LA and Pesce AJ (Eds.) pp 1015-1020.
7. Newkirk RE and Rawnsley HM, *Creatinine Clearance*, ASCP Check Sample Clinical Chemistry, No. CC-110, Chicago, 1978, American Society of Clinical Pathologists.
8. Faulkner WR and King JW, Renal Function. In Tietz NW, Ed. Fundamentals of Clinical Chemistry, 2nd Edition, Philadelphia, 1976, WB Saunders Co, pp 975-1014.
9. Centers for Disease Control/National Institutes of Health Manual *"Biosafety in Microbiological and Biomedical Laboratories"*. 2009

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10009578-7-EN
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