# DRI® Creatinine-Detect® Test

Thermo SCIENTIFIC

**IVD** **For In Vitro Diagnostic Use**

**REF** 10015638 (3 x 18 mL)
1797 (500 mL Kit)
100272 Creatinine-Detect Calibrator Kit (2 x 25 mL)
100273 Creatinine-Detect 1.3 mg/dL Control Kit (1 x 25 mL)
100274 Creatinine-Detect 7.5 mg/dL Control Kit (1 x 25 mL)
100275 Creatinine-Detect 23.0 mg/dL Control Kit (1 x 25 mL)

## Intended Use
The DRI Creatinine-Detect® Test is intended for the quantitative determination of creatinine in human urine for the detection of urine adulteration by dilution or substitution with non-urine solution.

## 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.

Creatinine is secreted from muscle into urine daily. In the absence of renal disease, rate of creatinine clearance in an individual is relatively constant. Dilution of urine with water or any other non-urine solution can result in a lower creatinine concentration.

DRI® Creatinine-Detect Test can be performed on automated clinical chemistry analyzers to measure creatinine concentration. This method is based on the Jaffe reaction,[10] whereby creatinine concentration is determined colorimetrically using alkaline picrate to form a reddish Janovski complex according to the following equation:

$$\text{Creatinine} + \text{Picric Acid} \xrightarrow{\text{NaOH}} \text{Janovski Complex (Red)}$$

The color intensity is directly proportional to the creatinine concentration and is measured spectrophotometrically at 505 nm.

## Materials Provided
**Creatinine-Detect Reagent 1:** Contains sodium hydroxide in an aqueous solution.
**Creatinine-Detect Reagent 2:** Contains picric acid in an aqueous solution.

**Calibrators and Controls (sold separately):**
**Creatinine-Detect Calibrator Kit:** Contains 1 x 25 mL of 2.0 mg/dL creatinine and 1 x 25 mL of 20.0 mg/dL creatinine in an aqueous solution.
**Creatinine-Detect 1.3 mg/dL Control Kit:** Contains 1 x 25 mL of 1.3 mg/dL creatinine.
**Creatinine-Detect 7.5 mg/dL Control Kit:** Contains 1 x 25 mL of 7.5 mg/dL creatinine.
**Creatinine-Detect 23.0 mg/dL Control Kit:** Contains 1 x 25 mL of 23.0 mg/dL creatinine.

## ⚠ Precautions and Warning
1. This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagent 1 contains sodium hydroxide, which is caustic. Reagent 2 contains picric acid, which may cause local or generalized allergic reaction. Wear suitable protective clothing, gloves, and eye/face protection.
3. Do not use the reagents beyond their expiration dates.

## Reagent Preparation and Storage
The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly, are stable until the expiration date indicated on the label. The Creatinine-Detect Reagents should be stored at room temperature while the calibrators and controls should be stored at 2-8°C.

## 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.[11]

## Assay Procedure
Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 505 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.

## Quality Control and Calibration
Use the 2.0 and 20.0 mg/dL Creatinine Calibrators to calibrate the test. Good laboratory practice suggests the use of control specimens to validate the calibration and to ensure proper assay performance. Creatinine Controls 1.3 mg/dL, 7.5 mg/dL and 23.0 mg/dL are available from Thermo Fisher Scientific for this purpose. Ensure that control results are within the established range. Recalibrate the system when new reagents are used or when the control values are outside the established range. All quality control requirements should be performed in conformance with local,state and/or federal regulations or accreditation requirements.

## Results and Data Interpretation
A linear calibration curve is generated to calibrate the assay. The sample creatinine concentration 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 creatinine concentration values automatically with no additional requirement of data manipulation. The 2.0 mg/dL calibrator is used to determine if the urine sample is substituted and the 20.0 mg/dL calibrator is used to determine if the sample is diluted.

## Expected Values
Creatinine concentration in normal urine samples range from 80-200 mg/dL. Urine samples with < 20 mg/dL creatinine are considered to be adulterated. Adulteration of urine by substitution of urine sample with non-urine solution will give creatinine concentration < 2 mg/dL.

## Limitations
This assay is optimized for the quantitative determination of creatinine in human urine for adulteration purposes only.

## Typical Performance Characteristics
The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer:

**Precision:**

| Control | Within-run Precision (n=60) | | Total Precision (n=60) | |
|---|---|---|---|---|
| | Mean ± SD (mg/dL) | % CV | Mean ± SD (mg/dL) | % CV |
| 1.3 | 1.2 ± 0.04 | 3.2 | 1.2 ± 0.04 | 3.5 |
| 7.5 | 7.4 ± 0.10 | 1.3 | 7.4 ± 0.12 | 1.7 |
| 23.0 | 23.6 ± 0.30 | 1.4 | 23.6 ± 0.40 | 1.5 |

## Linearity
The assay is linear from 0.78 mg/dL to 420 mg/dL. Assay linearity was determined by testing serial dilutions of a 600 mg/dL creatinine sample. A correlation of 1.000 was obtained when the observed creatinine concentration of each solution was plotted against its corresponding expected creatinine concentration.

## Interference by Endogenous Substances
Interference of endogenous substances in urine was studied. No interference was observed when urine samples were spiked with endogenous substances up to the concentration indicated.

| Compound | Concentration |
|---|---|
| Albumin | 500 mg/dL |
| Ascorbic Acid | 20 mg/mL |
| Galactose | 10 mg/dL |
| Glucose | 3000 mg/dL |
| Hemoglobin | 300 mg/dL |
| Riboflavin | 7.5 mg/dL |
| Urea | 6000 mg/dL |

## Accuracy and Correlation
Eighty urine samples were tested using the previous by available calibrators, 5 and 20 mg/dL, (x) and new calibrators 2.0 and 20.0 mg/dL calibrators (y). Correlation analysis yielded a linear regression equation of $y = 0.990x+1$ and a correlation coefficient of 1.000.

**Bibliography**


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