

DRI[®] General Oxidant-Detect[®] Test

IVD For In Vitro Diagnostic Use

Rx Only

REF 10018528 (6 x 18 mL Kit)
10009958 (2 x 500 mL Kit)
10009971 General Oxidant-Detect Calibrator Kit (2 x 25 mL)
10009972 General Oxidant-Detect Control Kit (2 x 25 mL)

Intended Use

The DRI[®] General Oxidant-Detect[®] Test is intended for the detection of urine adulteration by oxidizing compounds.

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 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 or Klear, which contains potassium nitrite). Additionally, drug users may alter their urine pH (acidity or alkalinity) to facilitate faster drug (e.g., phencyclidine, amphetamines) elimination.

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.⁵⁻⁸ If any of the urine parameters are outside the specified range, there is reason to believe that the urine sample has been adulterated.

Several oxidizing adulterants are being sold with a claim to clear all positive drug test results. The most commonly used oxidizing adulterants are Nitrite (Klear[™]), Chromate (Urine Luck[™]), Iodine, Bleach and Horse Radish Peroxidase/H₂O₂ (Stealth[™]). When added to urine, there is no significant change to the appearance, pH, specific gravity or creatinine concentration. Marijuana samples adulterated with oxidants can produce a positive result, during initial screening by immunoassay, notably the marijuana metabolite (THC). However, they can not be confirmed by GC/MS.^{9,10}

The General Oxidant-Detect Test can be performed on any automated clinical chemistry analyzer to detect oxidants. The method is based on the reaction between the substrate Tetramethylbenzidine (TMB) and the oxidant in the sample producing color that can be measured at 660 nm.

Material Provided

General Oxidant-Detect Reagent: Contains 2 x 500 mL of 3,3',5,5' tetramethylbenzidine in an acidic solution.

Additional Materials Required (sold separately):

General Oxidant-Detect Calibrator Kit: Contains 1 x 25 mL of negative calibrator and 1 x 25 mL of 200 µg/mL nitrite in an aqueous solution.

General Oxidant-Detect Control Kit: Contains 1 x 25 mL of Negative Control (100 µg/mL nitrite) and 1 x 25 mL of Positive Control (300 µg/mL nitrite) in an aqueous solution.

⚠️ Precautions and Warning

This test is for in vitro diagnostic use only. The reagents are harmful if swallowed.

WARNING: DRI General Oxidant-Detect Test contains <0.2% Citric acid.

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

Do not use the reagent, calibrators and controls beyond the expiration date.

Reagent color might change over long-term storage.

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 2-8° C. 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. Specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units.¹² Repeated freezing and thawing of the sample should be avoided.

Handle all urine specimens as if they were potentially infectious.¹³

Assay Procedure

Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring absorbance at 660 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 100 µg/mL and 300 µg/mL Nitrite Controls are available from Microgenics for this purpose. Ensure that control results are within established ranges. Recalibrate the system when new reagents are used or when the control values are outside established ranges. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Use the Negative and 200 µg/mL Calibrators to generate the calibration curve.

Results

A linear calibration is generated to calibrate the assay. Most clinical chemistry analyzers have built-in software that can calculate the oxidant concentrations automatically with no additional requirement of data manipulation.

Expected Values

Some oxidants such as nitrite may be generated in the human body and excreted into urine through an enzymatic oxidation by the enzyme Nitric Oxide Synthase (NOS). However, most nitrite formed is oxidized to nitrate. Therefore, nitrate concentration in human urine from NOS activity is much greater than the nitrite concentration. Moshage et. al.¹⁴ conducted a study with healthy volunteers and reported an average urine concentration of 61 µg/mL for nitrate and 0.2 µg/mL for nitrite.

Patients with urinary tract infection or pathological conditions may have urine nitrite as high as 100-150 µg/mL.¹⁵ Urine samples to which Klear was added were found to contain between 1900 and 15,000 µg/mL nitrite.¹⁵ Therefore, a urinary nitrite concentration of 200 µg/mL or greater is a scientifically valid and forensically defensible proof of adulteration of the specimen with a nitrite-containing substance.

Chromate is also present in human body at very low concentration. The normal urinary chromium concentrations range from 0.04 - 1.0 µg/mL.

Limitations

This assay is optimized for the quantitative determination of oxidants such as nitrite, chromate and stealth oxidants in human urine. Sodium azide may cause interference with the assay and should not be used as a preservative for the urine sample.

Typical Performance Characteristics

The following typical performance data were generated with a Hitachi 717 clinical chemistry analyzer:¹⁶

Precision

The within-run and total-run precision was evaluated using modified NCCLS method with the following results.

Calibrator or Control	Within-run (n = 120)		Total Precision (n=120)	
	Mean ± SD (µg/mL)	% CV	Mean ± SD (µg/mL)	% CV
100 µg/mL	84.8 ± 2.1	2.4	84.8 ± 2.7	3.2
200 µg/mL	199.3 ± 2.9	1.5	199.3 ± 3.6	1.8
300 µg/mL	322.1 ± 3.8	1.2	322.1 ± 5.8	1.8

Sensitivity

Sensitivity, defined as the lowest concentration of nitrite that can be differentiated from the negative calibrator with 95% confidence, is 2.65 µg/mL.

Specificity

Specificity is defined as the minimum concentration of an oxidant that produces a result greater than or equal to 200 µg/mL nitrite. The following table provides a list of oxidants and concentrations that produce a positive result in the assay.

Oxidant	Concentration
Chromium	50 µg/mL
Bleach	2%
Iodine	0.2 %
Peroxidase	50 U/mL

Interference

Interference of the following substances in urine was studied. No interference was observed when urine samples were spiked with these substances up to the concentrations indicated.

Compound	Concentration
Albumin	500 mg/dL
Ascorbic Acid	5 mg/dL
Creatinine	250 mg/dL
Galactose	10 mg/dL
Glucose	3000 mg/dL
Hemoglobin*	300 mg/dL
Riboflavin**	7.5 mg/dL
Urea	6000 mg/dL

* Hemoglobin interferes in the assay at 100 mg/dL in the presence of bleach and iodine.

** Riboflavin interferes in the assay at 5 mg/dL in the presence of bleach.

Accuracy and Correlation

A total of 93 samples adulterated with oxidants were tested with DRI General Oxidant-Detect Test and a commercially available method as reference. Method comparison results showed >95% agreement with reference method.

Reference

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16. Data on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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