SIEMENS

Syva®

Oxidant Validity Test

See shaded sections:
Updated information from 2019-08 version.

10869761_E

Oxidant Test

1 Intended Use

The Syva® Oxidant Validity Test is intended for use in the qualitative determination of oxidants as an indicator of adulteration in human urine. This test is for forensic/toxicology use only.

2 Summary and Explanation of the Test

The Syva® Oxidant Validity Test detects elevated amounts of oxidants in urine specimens submitted for drugs of abuse testing on automated analyzers.

Oxidizing agents such as hydrogen peroxide, pyridinium chlorochromate, bleach, nitrites, and the oxidant in Stealth are not found in normal human urine. Therefore, any urine sample containing elevated levels of oxidants may be suspected of adulteration.[1]

3 Principle

When a sample of urine containing oxidizing agents reacts with a substituted benzene compound in the Syva® Oxidant Validity Test reagent, the resulting reaction forms a color complex. The color change can be measured spectrophotometrically at or about 660 nm.

4 Reagents

REF	Product Description	Volume
3T579UL/ 3T079UL	**Syva® Oxidant Validity Test Reagent** 0.03% 2,2'-azino-bis(3-ethylbenzthiazoline-6-sulfonic acid) diammonium salt, 0.01% Sodium dodecylsulfate, 16% Tris HCl	100 mL/ 900 mL

For forensic/toxicology use only.

Precautions

The reagent may irritate the eyes, skin, and mucous membranes and may be harmful if swallowed. Avoid contact with eyes, skin, or clothing. Do not ingest or pipette by mouth. Wash hands thoroughly after handling.

Preparation and Storage of Assay Components

The Syva® Oxidant Validity Test reagent is provided ready to use and may be used directly from the refrigerator. No reconstitution is required. Close the reagent bottle when not in use.

When not in use, store the reagent bottle upright at 2–8°C (36–46°F) with the screw cap tightly closed. If stored as directed, the reagent is stable until the expiration date printed on the label. Do not freeze. Avoid prolonged exposure to temperatures above 30°C. **Improper storage of the reagent can affect assay performance.**

5 Specimen Collection and Preparation

- Human urine samples should be handled and treated as if they were potentially infectious.
- Specimens with high turbidity or particulates should be centrifuged before analysis.
- If not analyzed immediately, samples may be stored unrefrigerated for up to 7 days following collection. After 7 days, samples should be stored frozen.
- Frozen samples must be thawed and mixed thoroughly before analysis.
- The use of preservatives is not recommended.

6 Procedure

Materials Provided

Syva® Oxidant Validity Test
Reagent

Materials Required but Not Provided

3T129UL	**Syva® Validity Negative Calibrator/Control**	14 mL
3T339UL	**Syva® Chromium (VI) Validity Calibrator 50**	14 mL
3T349UL	**Syva® Chromium (VI) Validity Calibrator/Control 100**	14 mL

Automated chemistry analyzer or spectrophotometer

Instruments

Siemens Healthcare Diagnostics provides instructions for using this assay on a number of chemistry analyzers. Contact the Technical Assistance Center or your local Siemens representative for application sheets.

Analyzers must be capable of maintaining a constant reaction temperature, pipetting samples/reagents and measuring absorbance with precision, timing the reaction accurately, and mixing reagents thoroughly.

Calibration

Recalibrate whenever a new lot of reagents is used or as indicated by control results (see Quality Control, below). If a new set of reagents with the same lot number is used, validate the system by assaying controls. Daily calibration is recommended.

Quality Control

Good laboratory practices include the use of high and low quality control materials in a true or synthetic urine matrix to ensure test performance. Controls should be assayed with every run, and customers must establish their own control limits. If any control result is not within its established limits, rerun that control. If the repeat result is then within the established limits, calibration is verified; run patient samples. If the repeat result is not within established limits, recalibrate. If, after recalibration, the control result is not within its established limits, call the Technical Assistance Center or your local Siemens representative.

7 Results

Results are calculated automatically by the analyzers. To run the assay, see the instrument operator's manual and the application sheet from Siemens.

Siemens has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Application Sheets or these instructions for use.

8 Limitations

- Results may be affected by variations in urinary buffer concentrations or urinary constituents.
- Some oxidizing agents are not stable in urine; their levels may diminish over time.
- Urine specimens from individuals who take herbal supplements containing concentrated cranberry extract may test positive with the Syva® Oxidant Validity Test.
- Ascorbic acid is an antioxidant and interferes with the Syva® Oxidant Validity Test.

9 Expected Values

An oxidant concentration assayed at >50 µg/mL is not normally observed in human urine; such samples should be suspected of adulteration.

10 Specific Performance Characteristics

The data appearing in this section were collected using the Syva® Oxidant Validity Test on the Hitachi 717 Analyzer.

Precision

Within-run precision was calculated according to NCCLS Guideline EP5-A by running 2 replicates of each control level twice a day for 10 days (N=40). Total precision was also calculated from these data. The table below summarizes the results.

Table 1 — Summary of Precision Results

	Mean (µg/mL)	SD (µg/mL)	CV (%)
Within-Run			
Level 1	37.4	0.22	0.58
Level 2	50.2	0.38	0.77
Level 3	61.9	0.32	0.51
Level 4	97.2	0.61	0.62
Total			
Level 1	37.4	0.42	1.12
Level 2	50.2	0.63	1.25
Level 3	61.9	0.76	1.23
Level 4	97.2	1.37	1.41

Specificity

The Syva® Oxidant Validity Test detects oxidants in human urine. The following compounds at the stated concentrations yield a positive result relative to a 50 µg/mL Chromium (VI) cutoff.

Pyridinium Chlorochromate	220 µg/mL
Bleach	11 mg/dL
Nitrite	40 µg/mL
Iodine	180 mg/dL
Periodate	300 mg/dL
Iodate	750 mg/dL
Iodic Acid	600 mg/dL

Sensitivity

The sensitivity level of the Syva® Oxidant Validity Test is 1.0 µg/mL sodium dichromate. This level represents the lowest concentration of an oxidant that can be distinguished from 0 µg/mL with a confidence level of 95%.

Method Comparison

Sixty (60) negative urine specimens were spiked with sodium dichromate. The spikes were analyzed using the Syva® Oxidant Validity Test and an alternative colorimetric method. Specimens having results greater than 50 µg/mL sodium dichromate by the Syva® Oxidant Validity Test and greater than 50 µg/mL oxidant by the alternative method were considered positive. Results are shown in the figure below.

		Alternative Method +	Alternative Method −
Syva® Oxidant Validity Test	+	19	5
	−	0	36

% Agreement = 91.7%

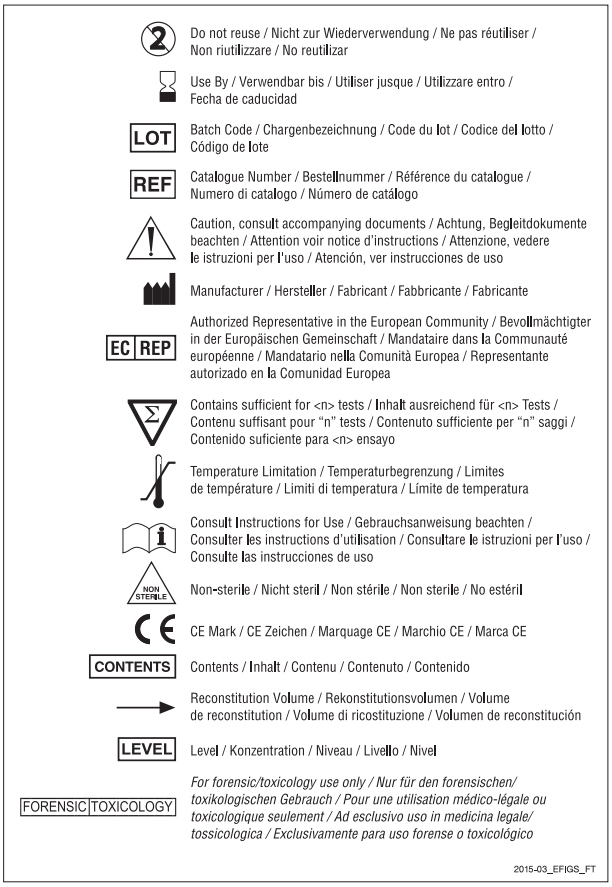
11 Risk and Safety

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare

12 Bibliography

1. U.S. Department of Health & Human Services, Public Health Service Notice-NLCP-Program Document 035; September 28, 1998.
2. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, "Mandatory Guidelines for Federal Workplace Drug Testing Programs", Federal Register, April 13, 3004, Volume 69, Number 71 p. 19644–19673.
3. European Laboratory Guidelines for Legally Defensible Workplace Drug Testing, European Workplace Drug Testing Society, Version 1.0.
4. United Kingdom Laboratory Guidelines for Legally Defensible Drug Testing, Version 1.0, March 2001.

13 Symbols Key



For technical assistance, call Siemens Healthcare Diagnostics:
1-800-227-8994 in the USA
1-800-264-0083 in Canada
Outside the USA and Canada, call your local Siemens representative.

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