Specimen Validity Testing

from Siemens Healthineers

siemens-healthineers.com/validitytest

SIEMENS Healthineers

Ensuring the accuracy of drug-testing results is critical. Specimen validity testing is an important part of urine drug testing, verifying the integrity and reliability of drug-testing samples for confidence in results and clinical decision-making.

In addition to an extensive drugs-of-abuse testing menu featuring trusted EMIT technology, Siemens Healthineers offers five specimen validity tests to help you ensure the integrity of drug test results.

– Creatinine
– Nitrites
– Oxidants
– pH
– Specific gravity

Available on the Syva family of instruments and Atellica CI and Atellica CH analyzers.

What is specimen validity testing?

Specimen validity testing (SVT) is performed on a urine specimen to detect substitution, adulteration, dilution, or invalidation of the sample prior to running drug tests for detection of specific substances. SVT provides critical information about the validity of the specimen and helps to validate the accuracy and reliability of subsequent drug test results.

Why test for sample validity?

Drug users often attempt to conceal their drug use from others. SVT checks whether a sample has been tampered with or adulterated to manipulate the test results.

What are the ways in which samples are altered?

Substitution: A specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

Adulteration: Adding a substance to a specimen after it has been collected. The product added is designed to mask the presence of, or chemically destroy, the drug or drug metabolite that the specimen may contain. An adulterant product may be added with the intention of adversely affecting the testing reagents.

Dilution: Result of ingestion of large amounts of water typically just before urine donation or because of physiological conditions or adding water or another liquid to the specimen after collection. If drug/metabolites are diluted to a concentration below the initial test cutoff, diluted urine may result in a false negative.

Invalid: Refers to the result for a urine specimen that contains an unidentified adulterant or unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Who typically performs SVT?

SVT is an integral part of the drug screening process and is commonly performed in criminal justice facilities, pain management centers, treatment and workplace testing sites, and military facilities, as well as clinical laboratories of all sizes.

Specimen validity test	Introduction to urine sample	Method	Mode of action
Creatinine	This substance is normally present in urine within a specific range. Donors may consume large quantities of water or add water to their sample, resulting in diluted creatinine concentrations in the specimen.	In vivo or in vitro	Creatinine is excreted from the body at a constant rate. When large quantities of water are consumed (in vivo dilution) or added (in vitro dilution), the urine becomes diluted and creatinine levels are reduced. A range of 2 mg/dL and/or 20 mg/dL are used in conjunction with specific gravity to classify urine as invalid, dilute, substituted.
Nitrites	Donor adds nitrite salts to the urine collection cup.	In vitro	Nitrites are oxidizing agents, which may interfere with screen and confirmation results for certain drugs—most notably cannabinoids. A nitrite screen cutoff level of ≤200 µg/mL may be used for invalid results and ≤500 µg/mL for adulterated results.
Oxidants	Donor adds oxidizing agents (pyridinium chlorochromate, bleach, nitrite, iodine, periodate, peroxidase, peroxide, iodate iodic acid, and/or chromium VI) to the urine collection cup.	In vitro	Oxidizing agents react with certain drugs or drug metabolites and interfere with detection.
pH	Donor adds a substance which would drastically modify the urine pH. Several common household products, such as bleach, acid, soap, detergent, and vinegar (when added to a urine sample) can alter the pH of the urine sample to a value outside the physiological range.	In vitro	pH levels determine whether the urine sample is acidic or basic. Normal urine pH is slightly acidic, with standard cutoffs with a pH of about 4.5 to 9.0. Extremely low pH of <4 or extremely high pH of >11 is suggestive of sample tampering or adulteration.
Specific gravity	Donor consumes large quantities of water (in vivo) or adds liquid (in vitro) to the urine sample.	In vivo or in vitro	The relationship between specific gravity and creatinine trend in the same direction—any factors which increase the concentration of creatinine in urine would be expected to increase the specific gravity of the sample.

Substance Abuse and Mental Health Services Administration (SAMHSA) Guidelines[1]

The Substance Abuse and Mental Health Services Administration issues guidelines for drug testing programs, particularly for federal employees and workplaces regulated by federal law. These guidelines are designed to ensure accuracy, reliability, and uniformity in drug testing procedures. SAMHSA's guidelines for specimen validity mandate that:

- At a minimum, creatinine and pH must be determined for each specimen.
- Specific gravity must be determined for each specimen with creatinine less than 20 mg/dL.
- One or more tests for oxidizing adulterants must be performed.
- Specimen validity tests must be performed for split specimens (Bottle B) when a laboratory fails to reconfirm a drug analyte reported positive in the primary specimen (Bottle A).
- Labs may order additional specimen validity test when a specimen exhibits abnormal physical characteristics or abnormal drug test results.

European Laboratory Guidelines for Legally Defensible Workplace Drug Testing[2]

The European Laboratory Guidelines for Legally Defensible Workplace Drug Testing provide standards and best practices for accurate, reliable, and ethical drug testing processes. While the exact guidelines may vary slightly by country or organization, the general principles are as follows:

- The validity of the sample must be checked either before or during the screening process.
- Creatinine should always be analyzed (mandatory).
- The laboratory may also test for pH, nitrite, or other adulterants.
- All screen test results must be reviewed with regard to the results of the validity tests performed.

Specimen Validity Tests

For full Instructions for Use and Frequently Asked Questions for all specimen validity tests, visit **siemens-healthineers.com/svt**

Syva Creatinine Validity Test[3,4]	
Intended use	The Syva Creatinine Validity Test is intended for the quantitative determination of creatinine as an indicator of adulteration in human urine. The test is for forensic/toxicology use only.
Chemistry	The test is a modified Jaffe method. Creatinine interacts with alkaline picrate to form a reddish-yellow solution, which is measured photometrically at 505 nm. The color intensity is directly proportional to the concentration of creatinine.
Specimen handling	Urine: Analyze specimens as soon as possible. Creatinine in urine is stable for 1–2 days when stored at 2–10°C. Specimens with high turbidity or particulates should be centrifuged before analysis.
Expected results	Published studies show ranges from 18.1 to 531.7 mg/dL. SAMHSA cutoffs are 2 and/or 20 mg/dL for diluted, substituted, and invalid.
Special precautions	Reagent 1 contains sodium azide (< 0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Waste must be disposed of properly and in accordance with local regulations. Reagent 2 contains low levels of picric acid. Picric acid may react with metals in plumbing to form highly explosive metallic compounds. FLUSH WITH LARGE AMOUNTS OF WATER ON DISPOSAL. Keep reagents tightly capped. Picric acid is a shock-sensitive explosive when dry.
Limitations	The test is linear to 300 mg/dL (low range) and 400 mg/dL (high range). Specimens above the range should be diluted with physiological saline. Many in vivo conditions can affect creatinine levels such as thyroid disorders, hypertension, renal failure/disease, and cancer. Glucose levels >1.0 g/dL interfere at a creatinine concentration of 1.5 mg/dL. Boric acid and sodium fluoride are not recommended as preservatives for samples that will be tested with the Syva Creatinine Validity Test.

Syva Nitrite Validity Test[5,6]	
Intended use	The Syva Nitrite Validity Test is intended for the quantitative determination of nitrite as an indicator of adulteration in human urine. The test is for forensic/toxicology use only.
Chemistry	The test detects high concentrations of potassium or sodium salts of nitrite added to urine. The test contains an aromatic amine that reacts with nitrite to form a diazonium salt that couples with an indicator to yield a colored complex.
Specimen handling	The test is liquid ready to use and may be used directly from the refrigerator. When not in use, the reagent should be stored at 2–8°C (36–46° F) upright and closed. When stored properly, the reagents are stable until the expiration date printed on the label, either opened or unopened. Opened calibrators are stable for 21 days when stored properly.
Expected results	The test provides a quantitative determination of nitrite 5–3,500 µg/mL in human urine. The established cutoff value for nitrite is 500 µg/mL; a urine specimen is reported as invalid when the nitrite concentration is ≥200 µg/mL and adulterated when the nitrite concentration is ≥500 µg/mL.
Limitations	Nitrite is not normally found in random urine specimens. The presence of nitrite levels i.e., 100–300 µg/mL may occur. However, these levels are significantly lower than those seen in adulteration. For specimens with results that yield values beyond the analyzer range, if the analyzer does not dilute and retest automatically, these should be diluted with distilled or deionized water and re-assayed. After diluting the sample, repeat the entire assay sequence and multiply the results by the dilution factors. Ascorbic acid is an antioxidant and interferes with the test. Urine preservatives should not be used.

Syva Oxidant Validity Test[7,8]

Intended use	The Syva Oxidant Validity Test is intended for the qualitative determination of oxidants as an indicator of adulteration in human urine. The test is for forensic/toxicology use only.
Chemistry	The test detects elevated amounts of oxidants added to urine. Oxidizing agents with a substituted benzene compound in the test react to form a colored complex. The color change is measured spectrophotometrically at 660 nm.
Specimen handling	The test is liquid ready to use and may be used directly from the refrigerator. When not in use, the reagent should be stored at 2–8°C (36–46° F) upright and closed. Do not freeze as improper storage of the reagent can affect assay performance. When stored properly, the reagents are stable until the expiration date printed on the label, either opened or unopened.
Expected results	An oxidant concentration assayed at >50 µg/mL is not normally observed in human urine; such samples should be suspected of adulteration.
Limitations	Ascorbic acid is an antioxidant and interferes with the test. Urine specimens from individuals who take herbal supplements containing concentrated cranberry extract may test positive with this test. Results may be affected by variations in urinary buffer concentrations or urinary constituents.

Syva pH Validity Test[9,10]

Intended use	The Syva pH Validity Test is intended for use as a measurement of pH as an indicator of adulteration in human urine. The test is for forensic/toxicology use only.
Chemistry	The test is based on an indicator principle which gives a change in absorbance throughout the urinary pH range of 2.0–12.0. A urine sample is mixed with reagent and depending on the hydrogen ion concentration of the sample the indicator will exhibit a change in color. This color change results in an absorbance change that is measured spectrophotometrically at or about 600 nm.
Specimen handling	The test is liquid ready to use and may be used directly from the refrigerator. No reconstitution required. When not in use, the reagent should be stored at 2–8°C (36–46° F) upright and closed. When stored properly, the reagents are stable until the expiration date printed on the label, either opened or unopened. Opened calibrators are stable for 90 days when stored properly.
Expected results	The Syva pH Validity Test provides a measurement of pH 2.0 to 12.0 in human urine.

SAMHSA classification	pH result
Adulterated	<4.0 or ≥11.0
Invalid	≥4.0 </=4.5 or ≥9.0 and <11.0

Limitations	Very dilute specimens may cause erroneous pH results. Specimens with a creatinine value less than 20 mg/dL or a specific gravity reading less than 1.003 should have the pH value verified by an alternate method such as a pH meter.

Syva Specific Gravity Validity Test[11,12]

Intended use	The Syva Specific Gravity Validity Test is intended for use as a measurement of specific gravity as an indicator of adulteration in human urine. The test is for forensic/toxicology use only.
Chemistry	The test is based on the pKa change of pretreated polyelectrolytes in response to ionic concentration of the sample, which will give a change in absorbance throughout the urinary specific gravity range of 1.0010–1.0250. When sample is mixed with reagent the indicator will change in color, depending on the specific gravity; color change measured at or about 600 nm.
Specimen handling	The test is liquid ready to use and may be used directly from the refrigerator. No reconstitution is required. When not in use, the reagent should be stored at 2 – 8°C (36 – 46° F) upright and closed. When stored properly, the reagents are stable until the expiration date printed on the label, either opened or unopened. Opened calibrators are stable for 21 days when stored properly.
Expected results	The test provides a measurement of 1.0010–1.0250 specific gravity of human urine.
Limitations	Specimens with a pH of <4 may increase the specific gravity value; specimens with a pH >9 may decrease the specific gravity value reported by this test. Specimens with a specific gravity result that is less than 1.0030 or greater than 1.0200 or has a creatinine value <20 mg/dL should be tested on a refractometer to determine suitability for drug screening. Highly buffered urine samples (>0.5M) may affect results. Elevated protein levels ≥100 mg/dL may increase the specific gravity readings obtained with a refractometer to a greater extent than readings obtained with the Syva Specific Gravity Validity Test.

Ordering Information

The Viva Pro-E System, Atellica CH, and Atellica IM Analyzers utilize the same test kits for result correlation between platforms.

Product Description	Kit Size	SMN
Creatinine		
Syva Creatinine Validity Test	100 mL	10445287
Syva Creatinine Validity Test	900 mL	10445265
Syva Validity Negative Calibrator/Control	14 mL	10445268
Syva Creatinine Validity Calibrator 2	14 mL	10445273
Syva Creatinine Validity Calibrator 20	14 mL	10445269
UTAK Level 2 Control	25 mL	10445225
UTAK Level 3 Control	25 mL	10445226
UTAK Level 4 Control	25 mL	10445227
Nitrites		
Syva Nitrite Validity Test	50 mL	10445288
Syva Nitrite Validity Test	500 mL	10445266
Syva Validity Negative Calibrator/Control	14 mL	10445268
Syva Nitrite Validity Calibrator 500	14 mL	10445275
UTAK Level 1 Control	25 mL	10445224
UTAK Level 3 Control	25 mL	10445226
Oxidants		
Syva Oxidant Validity Test	50 mL	10445267
Syva Oxidant Validity Test	500 mL	10445289
Syva Validity Negative Calibrator/ Control	14 mL	10445268
Syva Chromium (VI) Validity Calibrator/Control 50	14 mL	10445277
Syva Chromium (VI) Validity Calibrator/Control 100	14 mL	10445278
UTAK Level 2 Control	25 mL	10445225
UTAK Level 5 Control	25 mL	10445228

Product Description	Kit Size	SMN
pH		
Syva pH Validity Test	100 mL	10445299
Syva pH Validity Test	900 mL	10445274
Syva pH Validity Calibrator 2.0	14 mL	10445279
Syva pH Validity Calibrator 3.0	14 mL	10445280
Syva pH Validity Calibrator 4.0	14 mL	10736632
Syva pH Validity Calibrator 4.5	14 mL	10445286
Syva pH Validity Calibrator 9.0	14 mL	10445285
Syva pH Validity Calibrator 11.0	14 mL	10445283
Syva pH Validity Calibrator 12.0	14 mL	10445284
UTAK Level 1 Control	25 mL	10445224
UTAK Level 2 Control	25 mL	10445225
UTAK Level 3 Control	25 mL	10445226
UTAK Level 4 Control	25 mL	10445227
UTAK Level 5 Control	25 mL	10445228
Specific Gravity		
Syva Specific Gravity Validity Test	100 mL	10445300
Syva Specific Gravity Validity Test	900 mL	10445292
Syva Specific Gravity Calibrator 1.0030	14 mL	10445290
Syva Specific Gravity Calibrator 1.0200	14 mL	10445291
UTAK Level 1 Control	25 mL	10445224
UTAK Level 2 Control	25 mL	10445225
UTAK Level 4 Control	25 mL	10445227

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably. As a leading medical technology company, we want to advance a world in which breakthroughs in healthcare create new possibilities sustainably. We partner with healthcare providers to address their most pressing challenges so that they can deliver high-quality, patient-centered care, efficiently.

We are active in the areas of imaging, diagnostics, cancer care, and minimally invasive therapies, augmented by digital technologies and artificial intelligence. With our unique combination of strengths in Patient Twinning,* Precision Therapy, as well as Healthcare AI, we take on the greatest challenges in healthcare. We help improve access to healthcare for underserved communities worldwide and overcome the most threatening diseases.

We are a team of around 74,000 Healthineers in over 70 countries passionately pushing the boundaries of what is possible in healthcare so that patients can live with hope, not fear of disease.

**Early detection, accurate diagnosis, individualized therapy selection, simulation and planning, continuous monitoring and aftercare.*

References:

1. Medical review officer manual for federal agency workplace drug testing programs. Substance Abuse and Mental Health Services Administration. Available from: https://www.samhsa.gov/sites/default/files/workplace/mro-guidance-manual-oct2017_2.pdf [accessed 1/20/2025]
2. European Laboratory Guidelines for legally defensible workplace drug testing. European Accreditation. Available from: https://european-accreditation.org/wp-content/uploads/2018/10/ewdts-ta.pdf [accessed 1/20/2025]
3. Syva Creatinine Validity Test Instructions for Use 10869664_D. Siemens Healthcare Diagnostics 2019-08.
4. Syva Creatinine Validity Assay Overview and Frequently Asked Questions 11641106, Rev. A. Siemens Healthcare Diagnostics (02 2022).
5. Syva Nitrite Validity Test Instructions for Use 10869649_D. Siemens Healthcare Diagnostics 2019-08.
6. Syva Nitrite Validity Assay Overview and Frequently Asked Questions 11558783, Rev. A. Siemens Healthcare Diagnostics (02 2022).
7. Syva Oxidants Validity Test Instructions for Use 10869761_E. Siemens Healthcare Diagnostics 2020-10.
8. Syva Oxidants Validity Assay Overview and Frequently Asked Questions 11558781, Rev. A. Siemens Healthcare Diagnostics (02 2022).
9. Syva pH Validity Test Instructions for Use 10869621_D. Siemens Healthcare Diagnostics 2019-08.
10. Syva pH Validity Assay Overview and Frequently Asked Questions 11558782, Rev. A. Siemens Healthcare Diagnostics (02 2022).
11. Syva Specific Gravity Test Instructions for Use 10869616_D. Siemens Healthcare Diagnostics 2019-08.
12. Syva Specific Gravity Validity Assay Overview and Frequently Asked Questions 11558780, Rev. A. Siemens Healthcare Diagnostics (02 2022).

Siemens Healthineers Headquarters
Siemens Healthineers AG
Siemensstr. 3
91301 Forchheim, Germany
Phone: +49 9191 18-0
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Specialty Lab Solutions
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000

Published by Siemens Healthcare Diagnostics Inc. · SLS-26-00143-76 · QR700018406 · 07-2026 ·