SIEMENS

Syva®

pH Validity Test

See shaded sections:
Updated information from 2018-10 version.

10869621_D

pH Test

1 Intended Use

The Syva® pH Validity Test is intended for use as a measurement of pH as an indicator of adulteration in human urine. This test is for forensic/toxicology use only.

2 Summary and Explanation of the Test

The analysis is based on an indicator principle which gives a change in absorbance throughout the urinary pH range of 2.0 to 12.0.

SAMHSA Guidelines: The analysis is based on an indicator principle which gives a change in absorbance throughout the urinary pH range of 3.0 to 12.0.

3 Principle

A sample of urine is mixed with the reagent and, depending on the hydrogen ion concentration of the urine, 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.

4 Reagents

REF	Product Description	Volume
3T889UL/ 3T289UL	**Syva® pH Validity Test Reagent** Aqueous solution of thymol blue (2.8 µg/mL), bromphenol blue (4.1 µg/mL), bromcresol purple (3.0 µg/mL), *m*-cresol purple (2.9 µg/mL), methanol, preservatives	100 mL/ 900 mL

Risk and Safety

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

For forensic/toxicology use only.

Precautions

The reagents must not be pipetted by mouth. Avoid contact with eyes, skin, or clothing. Wash hands thoroughly after handling.

Preparation and Storage of Assay Components

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

When not in use, store the reagent upright at 2–8°C (36–46°F) and with 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

- Specimens with high turbidity or particulates should be centrifuged before analysis.
- Human urine samples should be handled and treated as if they were potentially infectious.
- Frozen samples must be thawed and mixed thoroughly before analysis.
- The use of preservatives is not recommended.

6 Procedure

Materials Provided

Syva® pH Validity Test

Reagent

Materials Required But Not Provided

3T389UL	**Syva® pH Validity Calibrator 2.0**	14 mL
3T399UL	**Syva® pH Validity Calibrator 3.0**	14 mL
10736632	**Syva® pH Validity Calibrator 4.0**	14 mL
3T499UL	**Syva® pH Validity Calibrator 4.5**	14 mL
3T489UL	**Syva® pH Validity Calibrator 9.0**	14 mL
3T459UL	**Syva® pH Validity Calibrator 11.0**	14 mL
3T479UL	**Syva® pH Validity Calibrator 12.0**	14 mL

Instruments

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

Analyzer 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

Prepare a calibration curve by using the Calibrators listed in Table 1 or Table 2. 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.

Measuring intervals are dependent on the calibration scheme chosen.

Table 1 – Standard Calibration Scheme

pH Validity Calibrator Level (pH)					
2.0	3.0	4.5	9.0	11.0	12.0

Table 2 – SAMHSA Calibration Scheme

pH Validity Calibrator Level (pH)					
3.0	4.0	4.5	9.0	11.0	12.0

Quality Control

Validate the calibration curve by assaying commercial controls. Ensure that control results fall within acceptable limits as described by your laboratory. Once the calibration curve is validated, run urine specimens.

Note: Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

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

- The assay is designed for use only with human urine.
- Very dilute urine 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.
- Boric acid and sodium fluoride are not recommended as preservatives.

9 Expected Values

- The Syva® pH Validity Test provides a measurement of pH 2.0 to 12.0 in human urine.
- The specimen will be characterized as adulterated if the pH is less than 3.0 or greater than or equal to 11.0.[1,2,3] The specimen will be characterized as invalid if the pH is greater than or equal to 3.0 and less than 4.5 or greater than or equal to 9.0 and less than 11.0.[1]

SAMHSA Guidelines:

- The Syva pH Validity Test provides a measurement of pH 3.0 to 12.0 in human urine.
- The specimen will be characterized as adulterated if the pH is less than 4.0 or greater than or equal to 11.0.[1,2,3] The specimen will be characterized as invalid if the pH is greater than or equal to 4.0 and less than 4.5 or greater than or equal to 9.0 and less than 11.0.[1]

10 Specific Performance Characteristics

The data appearing in this section were collected using the Syva® pH Validity Test on the SYVA®-30R or Viva-E® analyzer.

Method Comparison

One hundred sixty nine (169) samples were analyzed by the Syva® pH Validity Test and compared to the pH meter as the reference method. Comparisons were made with specimens considered adulterated or invalid following the established cutoff ranges[1] and compared to the pH meter. These are presented in Tables 3–6 below along with the percent agreement.

Table 3 — pH 4.0 Cutoff

		pH Meter	
		<4.0	≥4.0
Viva-E®	<4.0	28	0
	≥4.0	9	132

Percent agreement 95%

Table 4 — pH 4.5 Cutoff

		pH Meter	
		<4.5	≥4.5
Viva-E®	<4.5	39	0
	≥4.5	5	125

Percent agreement 97%

Table 5 — pH 9.0 Cutoff

		pH Meter	
		<9.0	≥9.0
Viva-E®	<9.0	111	0
	≥9.0	0	58

Percent agreement 100%

Table 6 — pH 11.0 Cutoff

		pH Meter	
		<11.0	≥11.0
Viva-E®	<11.0	144	0
	≥11.0	0	25

Percent agreement 100%

Precision

Within run precision was tested on the SYVA®-30R and calculated according to NCCLS Guideline EP5-A by running 2 replicates of the indicated samples twice a day for 20 days (N=80). Total precision was also calculated from these data. The following data are presented in pH units.

Precision: Standard Scheme

	Mean (pH)	SD (pH)	% CV
Within-Run			
pH 3.0	3.0	0.05	1.55
pH 4.5	4.5	0.07	1.49
pH 7.0	8.0	0.06	0.81
pH 9.0	9.0	0.13	1.39
pH 11.0	11.1	0.07	0.61
Total			
pH 3.0	3.0	0.08	2.61
pH 4.5	4.5	0.07	1.62
pH 7.0	8.0	0.15	1.93
pH 9.0	9.0	0.13	1.49
pH 11.0	11.1	0.14	1.22

An additional precision study was performed on the Viva-E® analyzer. Repeatability precision was calculated according to CLSI EP15-A3 by running 5 replicates of the indicated samples once a day for 5 days (N=25).[4] Within-Laboratory precision was also calculated from this data. The following data are presented in pH units.

Precision: SAMHSA Scheme

	Mean (pH)	SD (pH)	% CV
Repeatability			
pH 4.0	4.3	0.04	0.9
pH 4.5	4.8	0.02	0.4
pH 7.0	7.9	0.04	0.6
pH 9.0	8.8	0.25	2.8
pH 11.0	10.2	0.15	1.4
Within-Lab			
pH 4.0	4.3	0.25	5.8
pH 4.5	4.8	0.13	2.7
pH 7.0	7.9	0.07	0.9
pH 9.0	8.8	0.25	2.8
pH 11.0	10.2	0.22	2.1

Linearity

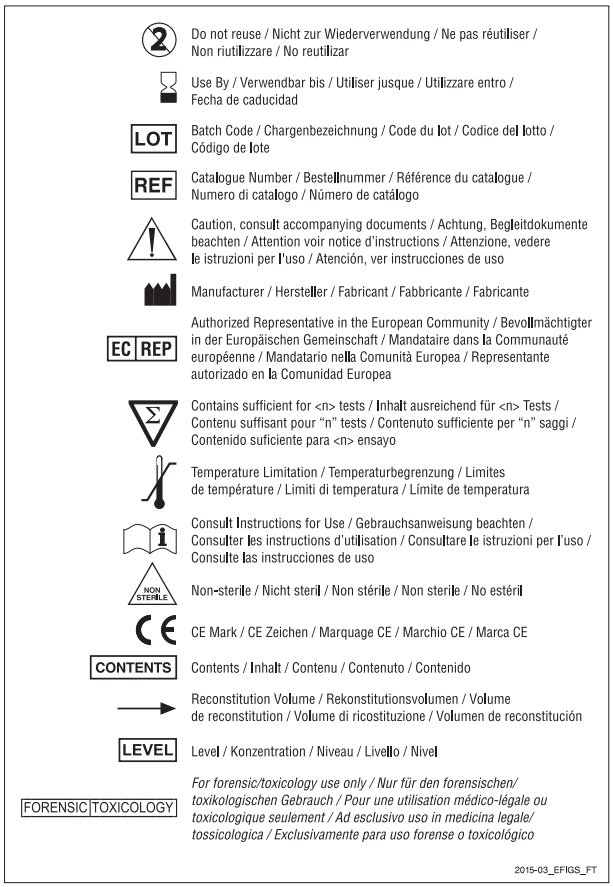
Linearity was tested for the Syva® pH Validity Test by preparing 11 samples equally spaced throughout the assay range. Five replicates of each sample were analyzed on the SYVA®-30R analyzer. Linearity was acceptable across the assay range. Results are shown below.

pH Meter	SYVA®-30R
2.0	2.0
3.0	3.0
4.0	4.0
5.0	5.1
6.0	6.4
7.0	7.5
8.0	8.0
9.0	8.7
10.0	10.2
11.0	11.0
12.0	11.9

11 Bibliography

1. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, “Mandatory Guidelines for Federal Workplace Drug Testing Programs”, Federal Register, January 23, 2017, Volume 82, Number 13 p. 7920-7970.
2. European Laboratory Guidelines for Legally Defensible Workplace Drug Testing, European Workplace Drug Testing Society, Version 1.0.
3. United Kingdom Laboratory Guidelines for Legally Defensible Drug Testing, Version 1.0, March 2001.
4. Clinical and Laboratory Standards Institute/NCCLS. User Verification of Precision and Estimation of Bias; Approved Guideline-3rd Edition. CLSI document EP15-A3 [ISBN 1-56238-965-3]. CLSI, Wayne, PA, USA, 2014.

12 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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