SIEMENS

Syva®

pH PERFECT™ Test

See shaded sections:
Updated information from 2018-03 edition.

10869593_E

pH Test

1 Intended Use

The Syva® pH PERFECT™ Test is intended for use in the measurement of pH as an indicator of adulteration in human urine. The 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.

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 that is monitored spectrophotometrically at or about 600 nm.

4 Reagents

REF	Product Description	Volume
3T089UL	**Syva® pH PERFECT™ Test Reagent** aqueous solution of 0.00075% thymol blue (sodium salt), 0.0013% bromcresol green, 0.0010% bromthymol blue, surfactant, and preservative	900 mL

Risk and Safety

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

For forensic/toxicology use only.

Preparation and Storage of Assay Components

The Syva® pH PERFECT™ 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 at 2–8°C (36–46°F), upright 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 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.
- 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 prior to analysis.

6 Procedure

Materials Provided

Syva® pH PERFECT™ Test

Reagent

Materials Required But Not Provided

3T419UL	**Syva® pH PERFECT™ Buffer 4.5**	14 mL
3T449UL	**Syva® pH PERFECT™ Buffer 9.0**	14 mL
3T759UL	**Syva® UR-N-TROL™ Level 3 Control**	100 mL

Automated chemistry analyzer or a spectrophotometer

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 analyzer-specific application sheets.

Analyzers must be capable of maintaining a constant reaction temperature, pipetting samples/reagents and measuring rates 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. 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.

7 Results

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

The assay will measure pH between 4–9. Any measurement obtained that is outside the range of pH 4 to pH 9 should be verified by an alternative method, for example, a pH meter.

8 Limitations

This test measures urinary pH in human urine and has no known interfering substances. Very dilute urine specimens may cause erroneous pH results. Specimens with a creatinine value of less than 20 mg/dL or a specific gravity reading of less than 1.006 should have the pH value verified by an alternative method, for example, a pH meter.

9 Expected Values

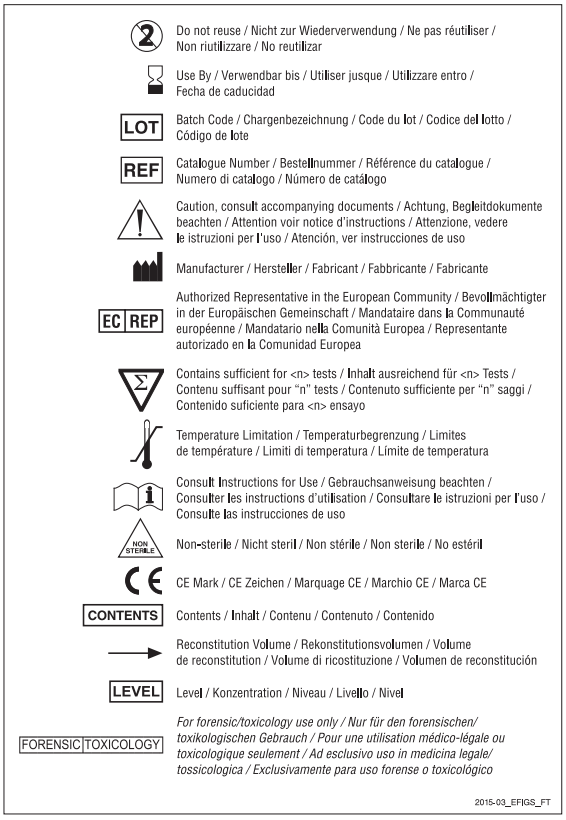
The established cutoff range for pH is ≤3 or ≥11.[1,2]

10 Bibliography

1. *Notice to HHS Certified Laboratories and Inspectors. Subject: Specimen Validity Testing.* Rockville, MD: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services; July 29, 1999. NLCP program documents 35, 37.

2. *MRO Guidance for Interpreting Specimen Validity Test Results.* Washington, DC: Office of the Secretary of Transportation, US Department of Transportation; September 28, 1998. Memorandum.

11 Symbols Key



Notes

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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