SIEMENS

Syva®

Specific Gravity Validity Test

See shaded sections:
Updated information from 2018-02 version.

10869616_D

Specific Gravity Test

1 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. This test is for forensic/toxicology use only.

2 Summary and Explanation of the Test

This test is based on the pKa change of pretreated polyelectrolytes in response to ionic concentration of the test sample, which will give a change in absorbance throughout the urinary specific gravity range of 1.0010–1.0250.

3 Principle

A sample of urine is mixed with the reagent and the indicator will exhibit a change in color, depending on the specific gravity (ionic strength) of the urine. The reaction produces a color change that is measured spectrophotometrically at or about 600 nm.

4 Reagents

REF	Product Description	Volume
3T899UL/ 3T699UL	**Syva® Specific Gravity Validity Test Reagent** Poly (methyl vinyl ether-*alt*-maleic acid) (2 mg/mL), isopropyl alcohol, Brij-35, sodium dodecyl sulfate, *m*-cresol purple (0.025 µg/mL), sodium hydroxide	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® Specific Gravity 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 at 2–8°C (36–46°F), upright and with screw caps 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.
- 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.
- The use of preservatives is not recommended.

6 Procedure

Materials Provided

Syva® Specific Gravity Validity Test

Reagent

Materials Required But Not Provided

3T619UL	Syva® Specific Gravity Validity Calibrator 1.0030
3T629UL	Syva® Specific Gravity Validity Calibrator 1.0200

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.

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

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 analyzer. To run the assay, see the instrument operator's manual and the analyzer-specific 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.
- Highly buffered urine samples (> 0.5 M) 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.
- Urine 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 the Syva® Specific Gravity Validity Test.
- Any specimen 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 in order to determine suitability for drug screening.[1]

9 Expected Values

- The Syva® Specific Gravity Validity Test provides a measurement of 1.0010–1.0250 specific gravity of human urine.
- The Syva® Specific Gravity Validity Test can be used as an aid to identify normal specific gravity levels in human urine.

10 Specific Performance Characteristics

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

Method Comparison

One hundred twenty-seven (127) samples were analyzed by the Syva® Specific Gravity Validity Test and compared to a refractometer as the reference method. Comparisons were made at each cutoff. These are presented in Tables 1 and 2 below along with the percent agreement.

Table 1 — 1.0030 Cutoff

		Refractometer	
		< 1.0030	≥ 1.0030
Hitachi 717	< 1.0030	30	0
	≥ 1.0030	0	97

Percent agreement 100%

Table 2 — 1.0200 Cutoff

		Refractometer	
		< 1.0200	≥ 1.0200
Hitachi 717	< 1.0200	99	3
	≥ 1.0200	7	18

Percent agreement 92.1%

	Discrepants	
Hitachi 717	**Refractometer**	**Difference**
1.0165	1.0227	-0.0062
1.0177	1.0200	-0.0023
1.0197	1.0209	-0.0012
1.0203	1.0179	0.0024
1.0205	1.0175	0.0030
1.0205	1.0196	0.0009
1.0209	1.0197	0.0012
1.0210	1.0195	0.0015
1.0212	1.0195	0.0017
1.0217	1.0167	0.0050

Precision

Within run precision was 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 units of specific gravity.

Table 3 — Precision

Within-Run	Mean (SG)	SD (SG)	%CV
1.0010	1.0011	0.0004	0.04
1.0030	1.0031	0.0003	0.03
1.0200	1.0205	0.0003	0.03
1.0250	1.0241	0.0003	0.03
Total			
1.0010	1.0011	0.0004	0.04
1.0030	1.0031	0.0004	0.04
1.0200	1.0205	0.0004	0.04
1.0250	1.0241	0.0004	0.04

Linearity

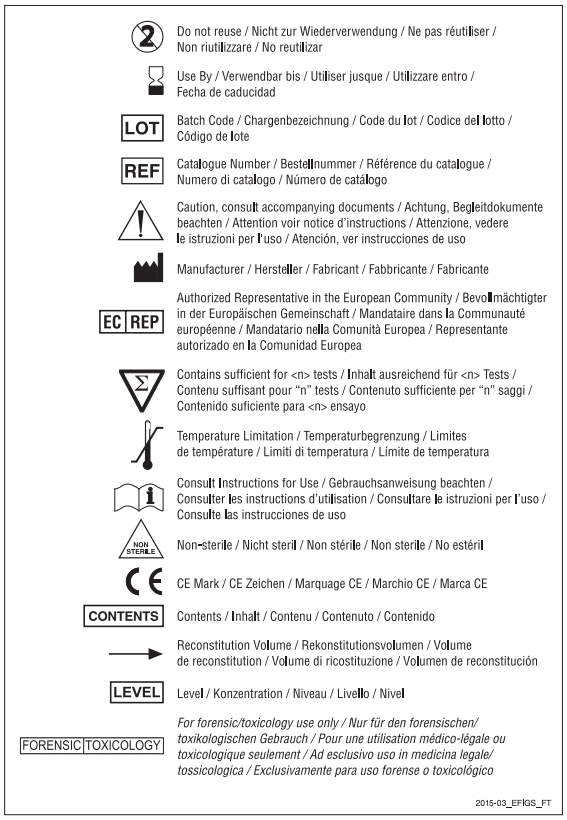
Linearity was tested for the Syva® Specific Gravity Validity Test by preparing 13 samples spaced throughout the assay range. Five replicates of each sample were analyzed on the Hitachi 717 analyzer. Linearity was acceptable across the assay range. Results are shown below.

Refractometer	Hitachi 717
1.0000	1.0006
1.0010	1.0015
1.0020	1.0024
1.0030	1.0030
1.0040	1.0046
1.0060	1.0057
1.0090	1.0087
1.0120	1.0119
1.0150	1.0152
1.0175	1.0178
1.0200	1.0207
1.0225	1.0222
1.0250	1.0229

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, April 13, 2004, Volume 69, Number 71 p. 19644–19673.
2. European Laboratory Guidelines for Legally Defensible Workplace Drug Testing, European Workplace Testing Society, Version 1.0.
3. United Kingdom Laboratory Guidelines for Legally Defensible Drug Testing, Version 1.0, March 2001.

12 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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