SIEMENS

Syva®

Specific Gravity Validity Test — Application Sheet

Specific Gravity Validity Test Application Sheet

For the AU480® and AU5800® Clinical Chemistry Systems

Refer to the appropriate Instructions for Use for information regarding these reagents. Also refer to the instrument manual for additional instructions.

The parameters defined in this application sheet have been developed by Siemens Healthcare Diagnostics to optimize product performance. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results.

Reagents

These reagents are qualified for use with the Calibrators listed below only. Other material may be used for quality control purposes.

Test	Catalog Number	
	Small	Large
Syva® Specific Gravity Validity Test	3T899UL	3T699UL

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

Storage

Reagents which are in use may be stored on board the analyzer for up to 4 weeks or as long as the control results fall within acceptable limits.

Instrument

Calibration

Calibrate by running the Syva® Specific Gravity Calibrators listed in Table 1 in the calibration rack (yellow rack). Run a reagent blank (blue rack). Recalibrate whenever a new lot of reagent is used or as indicated by control results.

Table 1

Test	Calibrators	
Specific Gravity	1.0030	1.0200

Instrument Settings

See page 2.

Results

Results are reported in specific gravity units.

Note: Specimen results <1.0010 should be reported as <1.0010.

SIEMENS

Syva®

Specific Gravity Validity Test — Application Sheet

Instrument Settings

General Screen

General | LIH | ISE | HbA1c | Calculated Tests | Range

Test Name: User Defined < > Type: Urine Operation: Yes

Sample Volume: 3.2 uL Dilution: 0 uL OD Limit

Pre-Dilution Rate: 1 Min OD: -2.0000 Max OD: 2.5000

Reagent Volume R1(R1-1): 157 uL Dilution: 0 uL Reagent OD limit

First Low: -2.0000 High: 2.5000

Last Low: -2.0000 High: 2.5000

R2(R2-2): 0 uL Dilution: 0 uL

Dynamic Range Low: 1.0010 High: 1.0250

Common Reagent Type: Name: Correlation Factor A: 1.0000 B: 0.0000

Wave Length Pri.: 600 nm Sec.: nm Factor for Maker A: B:

Method: END1

Reaction Slope: +

Onboard Stability Period: User Defined Day User Defined Hour

Measuring Point-1 First: 0 Last: 18

Measuring Point-2 First: Last:

Linearity Limit: %

Lag Time Check:

Range Screen

General | LIH | ISE | HbA1c | Calculated Tests | Range

Test Name: Test # . User Defined < > Type: Urine

Value/Flag Level: Value

	Low	High	Panic Value Low	Panic Value High
	User Defined	User Defined	User Defined	User Defined

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1							
☐ 2							
☐ 3							
☐ 4							
☐ 5							
☐ 6							
7	No Demographics					-99999	99999
8	Not within expected values						

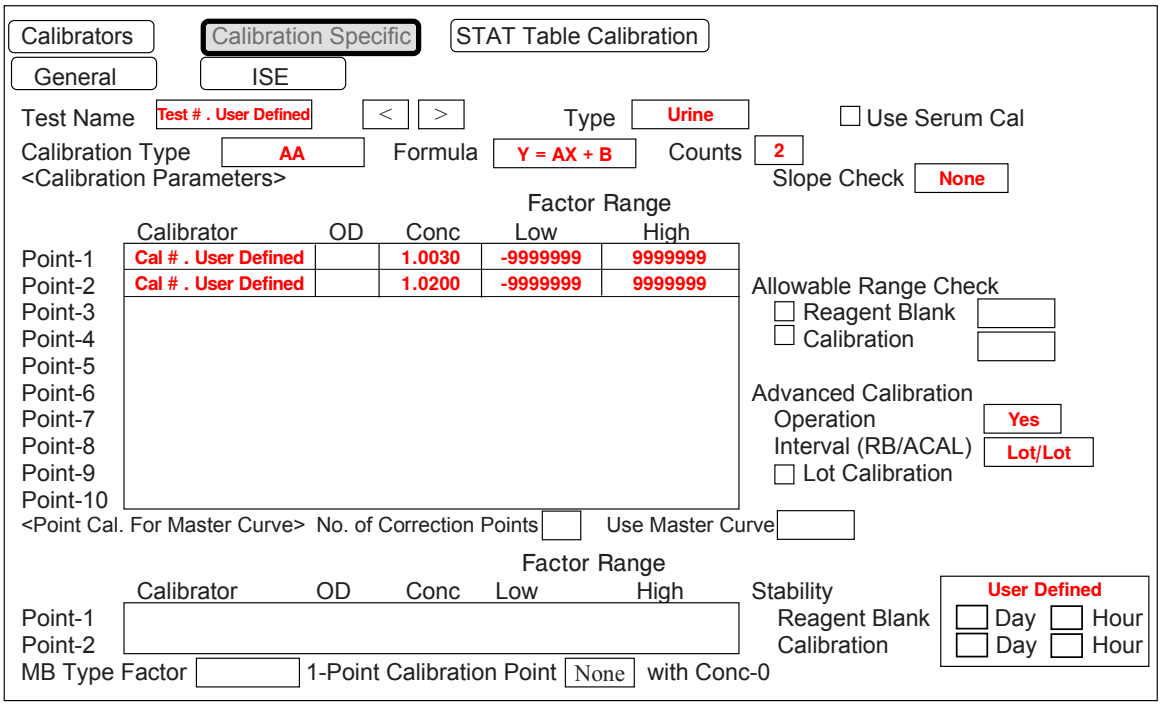
Unit: Decimal Places: 4

SIEMENS

Syva®

Specific Gravity Validity Test — Application Sheet

Calibration Parameters



Performance

Method Comparison

Sixty-five (65) human urine specimens were analyzed using the Specific Gravity Validity Test on the AU600® and the Hitachi 717 analyzers. Results are shown in the tables below.

Test	≥1.0030	<1.0030	% Agreement
SG 1.0030 Cutoff	47	16	96.9

Test	≥1.0200	<1.0200	% Agreement
SG 1.0200 Cutoff	16	49	100

Precision

Within run precision was calculated according to NCCLS Guideline EP5–A by running 2 replicates of each urine sample twice a day for 10 days (N=40). Total precision was also calculated from these data. The following data are presented in specific gravity units.

	Within Run Precision			
	Level 1	Level 2	Level 3	Level 4
Mean	1.0005	1.0028	1.0204	1.0245
SD	0.0003	0.0003	0.0002	0.0004
% CV	0.03	0.03	0.02	0.04

	Total Precision			
	Level 1	Level 2	Level 3	Level 4
Mean	1.0005	1.0028	1.0204	1.0245
SD	0.0005	0.0003	0.0006	0.0007
% CV	0.05	0.03	0.05	0.07

SIEMENS

Syva®

Specific Gravity Validity Test — Application Sheet

Linearity

Linearity was tested for the Syva® Specific Gravity Validity Test by preparing 8 samples throughout the assay range. Five replicates of each sample were analyzed on the AU600® analyzer. Linearity was acceptable across the assay range. Results are shown below.

Refractometer	AU600®
1.0000	0.9988
1.0010	1.0007
1.0020	1.0019
1.0030	1.0026
1.0040	1.0034
1.0150	1.0157
1.0200	1.0206
1.0250	1.0250

NOTE: Performance on the AU480®, AU5800® and AU600® series analyzers has been shown to be equivalent.

For technical assistance, call Siemens Healthcare Diagnostics:
1-800-227-8994 in the USA

Rev. AU4SPGR.4

Siemens Healthcare Diagnostics Inc.
500 GBC Drive
Newark, DE 19714 USA

Global Siemens Headquarters
Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters
Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare

Global Division
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens.com/healthcare

2021-12 msw: 936q-US

FOR DISTRIBUTION WITHIN THE US ONLY