SIEMENS Healthineers

Syva®

EMIT® II Plus 6-Acetylmorphine Assay Application Sheet

Shading indicates technical content that differs from the previous version.

Emit® II Plus 6-Acetylmorphine Assay 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.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The parameters defined in this application sheet have been developed by Siemens Healthineers 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/Controls listed below only. Other material may be used, however, for quality control purposes.

Emit II Plus 6-Acetylmorphine Assay	Catalog Number
28 mL Kit	9R039UL
115 mL Kit	9R029UL
1000 mL Kit	9R129UL

Calibrator/Control	Catalog Number
Emit Calibrator/Control Level 0	9A509UL
Emit II Plus 6-AM/Ecstasy Calibrator/Control Level 1	9R529UL
Emit II Plus 6-AM/Ecstasy Calibrator/Control Level 2	9R549UL
Emit II Plus 6-AM/Ecstasy Calibrator/Control Level 3	9R569UL
Emit II Plus 6-AM/Ecstasy Calibrator/Control Level 4	9R589UL

Preparation, Storage and Stability of Reagent 2

R2–9R039UL: Add 13 mL of distilled or deionized water

R2–9R029UL: Add 45 mL of distilled or deionized water

R2–9R129UL: Add 450 mL of distilled or deionized water

After preparation, allow reagent to equilibrate on the analyzer for 1 hour.

Table 1 – Preparation, Storage and Stability of Reagent 2

Component	Storage Temperature	Reconstitution Volume	Unopened Stability	Reagent Stability After Reconstitution
Reagent 2 9R039UL	2–8°C	13 mL	Exp. date	30 days
Reagent 2 9R029UL	2–8°C	45 mL	Exp. date	30 days
Reagent 2 9R129UL	2–8°C	450 mL	Exp. date	30 days

Storage

Reagents which are in use may be stored on board the analyzer for up to 4 weeks.

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Qualitative

Calibration

Calibrate by running the Level for the cutoff listed in Table 2. Recalibrate with each new hydration. Select the appropriate Option to use based on how results should be flagged (see Results section below).

Run a reagent blank (blue rack) and place the appropriate calibrator in a white rack for Option 1 or in its assigned position in a yellow rack for Option 2 or 3. Recalibrate as indicated by control results.

Results

Results are reported based on the Option chosen.

Option

1. Results are printed as OD values. Positive samples ***are NOT flagged***. Operator must compare the sample response to the cutoff calibrator response and determine if the sample is positive or negative.
2. The cutoff is normalized to 100. Positive samples are ≥ 100 and are flagged with a (P).
3. The cutoff is normalized to 0. Positive samples are ≥ 0 and are flagged with a (P).

Table 2

Assay	Level 2 ng/mL
6-Acetylmorphine	10

Instrument Settings

See page 2.

Qualitative

Instrument Settings

General Screen

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

Test Name: Test # . User Defined | < | > | Type: Urine | Operation: Yes

Sample Volume: 7.5 uL | Dilution: 0 uL | OD Limit
Pre-Dilution Rate: 1 | Min OD: -2.0000 | Max OD: 2.5000

Reagent Volume: R1(R1-1) 80 uL | Dilution: 0 uL | Reagent OD limit
First Low: -2.0000 | High: 2.5000
Last Low: -2.0000 | High: 2.5000

R2(R2-2) 40 uL | Dilution: 0 uL

Dynamic Range: Low: User Def | High: User Def

Common Reagent: Type | Name | Correlation Factor: A: 1 | B: †

Wave Length: Pri. 340 nm | Sec. 410 nm | Factor for Maker: A | B

Method: FIXED

Reaction Slope: +

Onboard Stability Period: User Defined Day | User Defined Hour

Measuring Point-1: First 13 | Last 15

Measuring Point-2: First | Last

Linearity Limit: %

Lag Time Check

† – **Correlation Factor B:** For Results Option 1 enter 0; for Option 2 enter 0; for Option 3 enter -100

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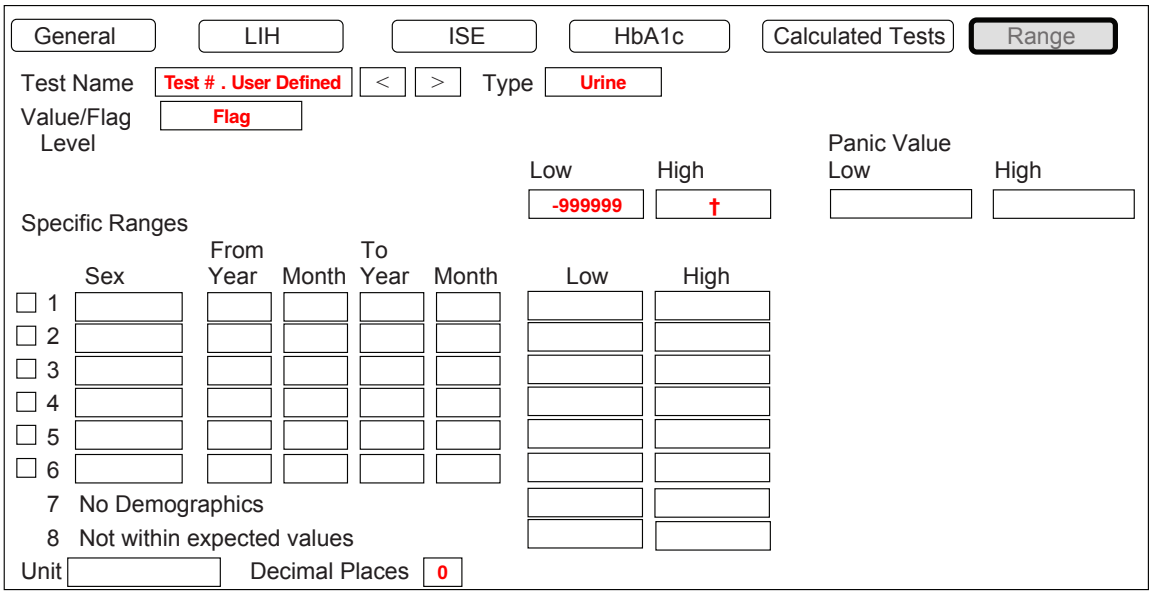
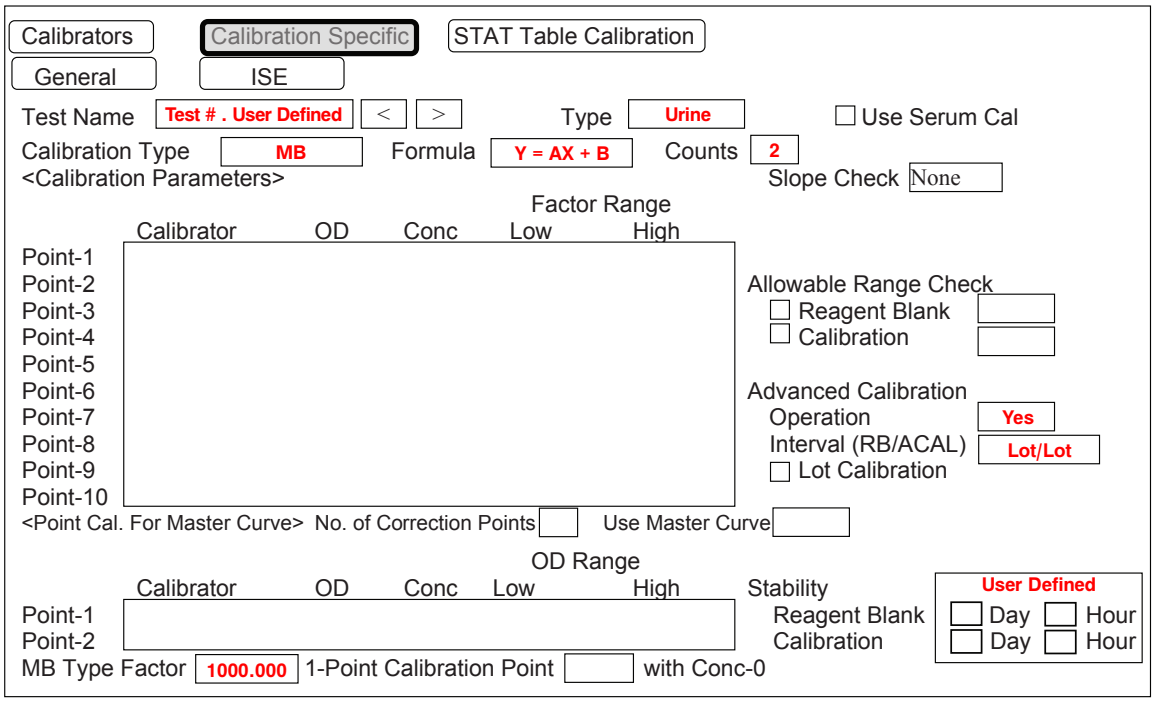
Range Screen



† – **Level High:** For Results Option 1 enter 999999; for Option 2 enter 100; for Option 3 enter 0

Calibration Specific Screen – Results Option 1



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Calibration Specific Screen – Results Option 2 or 3

Calibrators | Calibration Specific | STAT Table Calibration
General | ISE

Test Name: Test # . User Defined < > Type: Urine ☐ Use Serum Cal
Calibration Type: AB Formula: Y = AX + B Counts: 2
<Calibration Parameters> Slope Check: None

Factor Range

	Calibrator	OD	Conc	Low	High
Point-1	Cal # . User Defined		100	-999999	999999
Point-2					
Point-3					
Point-4					
Point-5					
Point-6					
Point-7					
Point-8					
Point-9					
Point-10					

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration Operation: Yes
Interval (RB/ACAL): Lot/Lot
☐ Lot Calibration

<Point Cal. For Master Curve> No. of Correction Points: Use Master Curve:

OD Range

	Calibrator	OD	Conc	Low	High
Point-1					
Point-2					

Stability — User Defined
Reagent Blank: ☐ Day ☐ Hour
Calibration: ☐ Day ☐ Hour

MB Type Factor: 1-Point Calibration Point: with Conc-0

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Semi-Quantitative

Calibration

Prepare a calibration curve by running the Calibrator/ Controls in the order listed in Table 3. After each hydration run controls. Recalibrate as indicated by control results. Run a reagent blank (blue rack) daily to ensure consistent day to day control results.

Table 3

Assay	Level 1 ng/mL	Level 2 ng/mL	Level 3 ng/mL	Level 4 ng/mL
6-Acetylmorphine	5	10	15	20

Results

Results are reported as ng/mL.

Instrument Settings

General Screen

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

Test Name: Test # . User Defined | < | > | Type: Urine | Operation: Yes

Sample Volume: 7.5 uL | Dilution: 0 uL | OD Limit
Pre-Dilution Rate: | Min OD: -2.0000 | Max OD: 2.5000

Reagent Volume: R1(R1-1): 80 uL | Dilution: 0 uL | Reagent OD limit
First Low: -2.0000 | High: 2.5000
Last Low: -2.0000 | High: 2.5000

R2(R2-2): 40 uL | Dilution: 0 uL

Dynamic Range: Low 2.9 | High 20

Common Reagent: Type | Name | Correlation Factor: A 1 | B 0

Wave Length: Pri. 340 nm | Sec. 410 nm | Factor for Maker: A | B

Method: FIXED

Reaction Slope: +

Onboard Stability Period: User Defined Day | User Defined Hour

Measuring Point-1: First 13 | Last 15

Measuring Point-2: First | Last

Linearity Limit: %

Lag Time Check:

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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	10		

Specific Ranges

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

Unit: ng/mL Decimal Places: 1

Calibration Specific Screen

Calibrators | Calibration Specific | STAT Table Calibration

General | ISE

Test Name: Test # . User Defined < > Type: Urine ☐ Use Serum Cal

Calibration Type: 4AB Formula: † Counts: 2

<Calibration Parameters> Slope Check: +

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	Cal # . User Defined		5	-2.0000	2.5000
Point-2	Cal # . User Defined		10	-2.0000	2.5000
Point-3	Cal # . User Defined		15	-2.0000	2.5000
Point-4	Cal # . User Defined		20	-2.0000	2.5000
Point-5					
Point-6					
Point-7					
Point-8					
Point-9					
Point-10					

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration Operation: Yes

Interval (RB/ACAL): Lot/Lot
☐ Lot Calibration

<Point Cal. For Master Curve> No. of Correction Points Use Master Curve

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1					
Point-2					

Stability: User Defined
Reagent Blank: ☐ Day ☐ Hour
Calibration: ☐ Day ☐ Hour

MB Type Factor 1-Point Calibration Point: None with Conc-0

† – **Formula:** enter EIA Type 1 or Polygonal

Performance

Data was collected on the AU400® analyzer. Performance on the AU400, AU480, and AU5800 series analyzers has been shown to be equivalent.

Method Comparison

Clinical urine specimens were tested using the Emit® II Plus 6-Acetylmorphine Assay on the AU400 analyzer and on the Viva-E® analyzer. The results are listed below along with the percent agreement with the Viva-E® analyzer.

Assay	Positive	Negative	% Agreement
6-Acetylmorphine	50	55	100

Precision

Repeatability was calculated according to CLSI Guideline EP5-A2 by running 2 replicates of a cutoff Calibrator/ Control and positive and negative controls twice a day for 20 days (N=80). Within-lab was also calculated from these data. The following data are presented in mAU/min.

6-Acetylmorphine

	Repeatability			Within-Lab		
	Cutoff	Control 75%	Control 125%	Cutoff	Control 75%	Control 125%
Mean	575	526	590	575	526	590
SD	4.8	4.1	5.4	15.2	17.5	15.3
CV%	0.8	0.8	0.9	2.7	3.3	2.6

Analytical Recovery

Negative human urine specimens were spiked with concentrations of 6-Acetylmorphine.

Qualitative analysis of the specimens spiked with drug concentrations lower than the cutoff concentration were correctly identified as negative 100% of the time. Specimens spiked with drug concentrations greater than the cutoff were correctly identified as positive 100% of the time.

Results from semi-quantitative analysis of the specimens are listed below.

6-Acetylmorphine

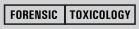
Concentration (ng/mL)	EIA Type 1 Mean (ng/mL)	Polygonal Mean (ng/mL)
5.0	5.6	5.5
7.5	8.2	8.5
12.5	13.5	13.5
15.0	16.3	16.2
17.5	18.9	18.9
20.0	21.2	21.3

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]
	Use-by date	5.1.4[a]
	Catalog number	5.1.6[a]
	Consult Instructions for Use	5.4.3[a]
	Internet URL address to access the electronic instructions for use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]
	Prescription device (US only)	FDA[c]
	CE Marking with Notified Body	EU IVDR[d]
	Temperature limit	5.3.7[a]
	Upper limit of temperature	5.3.6[a]
	Do not re-use	5.4.2[a]

Symbol	Symbol Title	Source
	Authorized representative in the European Community	5.1.2[a]
	Authorized representative in Switzerland	Proprietary
	Batch code	5.1.5[a]
	Contains sufficient for <n> tests	5.5.5[a]
	Version of Instructions for Use	Proprietary
	Revision	Proprietary
	Unique Device Identifier	5.7.10[b]
	CE Marking	EU IVDR[d]
	Keep away from sunlight	5.3.2[a]
	Lower limit of temperature	5.3.5[a]
	Do not freeze	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		International System of Units	Proprietary
	Document face up[f]	1952[e]	YYYY-MM-DD	Date format (year-month-day)	N/A
	Non-sterile	Proprietary	YYYY-MM	Date format (year-month)	N/A
	Reconstitution volume	Proprietary		Contents	Proprietary
	For forensic/toxicology use only	Proprietary		Level	Proprietary
	Dropper	Proprietary		Cassette	Proprietary
	Not for self-testing	EU IVDR[d]		Not for near-patient testing	EU IVDR[d]

[a] International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

[b] ISO 15223-1:2020-04.

[c] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

[d] IVDR REGULATION (EU) 2017/746

[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

[f] Indicates Assay-*e*Note.

For technical assistance:

Beckman Coulter customers, contact the Customer Technical Support Center at 1-800-854-3633 (USA & Canada)

In other countries, please contact your local Beckman Coulter representative.

Siemens Healthineers customers, contact the Technical Solutions Center at 1-800-227-8994 in the USA

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

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