SIEMENS Healthineers

Syva®

EMIT® II Plus Buprenorphine Assay — Alliance Application Sheet

Emit® II Plus Buprenorphine Assay Application Sheet

For the Atellica® CH Analyzer

Refer to the appropriate Instructions for Use for information regarding these reagents. Also refer to the online help for instructions on filling and loading empty CH reagent packs.

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 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.

Materials

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

These reagents are for human urine use only.

Emit® II Plus Buprenorphine Assay	REF	Catalog Number
28 mL	10720048	9S039UL
EMPTY reagent pack* (4 x Empty P1s and 4 x Empty P2s)	11097534	N/A**
EMPTY1 reagent pack* (8 x Empty P1s)	11538114	N/A**
EMPTY2 reagent pack* (8 x Empty P2s)	11538115	N/A**

**Materials required but not provided.*

***Not Applicable.*

Emit® Calibrator/Control	REF	Catalog Number
Level 0	10445406	9A509UL

Emit® II Plus Specialty Drug Calibrators/Controls	REF	Catalog Number
Level 1 (2.5 ng/mL)	10720049	9S529UL
Level 2 (5 ng/mL)	10720050	9S549UL
Level 3 (15 ng/mL)	10720051	9S569UL
Level 4 (25 ng/mL)	10720052	9S589UL

Emit® II Plus Specialty Drug Control	REF	Catalog Number
Negative (3 ng/mL)	10718700	9S609UL
Positive (7 ng/mL)	10718701	9S619UL

Syva Reagent Preparation, Storage, and Stability

Note For reagent preparation, storage information, and full product details, refer to the Syva Instructions for Use.

Atellica Reagent Preparation, Storage, and Stability

Preparation Instructions

Assay reagents are provided as liquid and are ready to use. See reagent IFU for storage instructions of original reagent containers when not in use.

Transfer the appropriate reagent volume to Empty reagent packs (refer to Table 1).

Manually fill the Empty reagent packs with R1 and R2 (refer to Table 1).

Table 1

Contents	Number of Tests
Pack 1 Well 1 (W1) 14.0 mL of Bupn* Well 2 (W2) Empty **Pack 2** Well 1 (W1) 7.0 mL of Bupn* Well 2 (W2) Empty	2 x 100

**Do not exceed required fill volume.*

Refer to the online help for instructions on filling and loading empty CH reagent packs.

Assay parameters have been predetermined in the instrument software. The reagent pack must be manually loaded on the Atellica® CH Analyzer.

Important Information

For performance characteristics, intended use, limitations and a detailed description how to perform this method, refer to the Emit® II Plus Buprenorphine Assay Instructions for Use.

Calibration and Stability

Table 2

Pack Calibration	Onboard Stability
8 days	28 days

Qualitative

Results

Results are reported as positive or negative.

Semi-Quantitative

Calibration

Prepare a calibration curve by running the calibrators/controls listed below. Recalibrate whenever a new lot of reagents are used or as indicated by control results.

Table 3

Assay	Level 0 ng/mL	Level 1 ng/mL	Level 2 ng/mL	Level 3 ng/mL	Level 4 ng/mL
Bupn	0	2.5	5	15	25

An automatic repeat condition for this assay extends the measuring interval to 100 ng/mL for urine. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat.**

Results

Results are reported as ng/mL.

Table 4

Assay	TDEF Code	Time to First Result
Bupn	8049	6 minutes

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EMIT® II Plus Buprenorphine Assay

Alliance Application Sheet

Symbols Key

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For technical assistance, call Siemens Healthcare Diagnostics:
1-877-229-3711 in the USA and Canada

In other countries, please contact your local representative.

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