## **SIEMENS**

### Syva®

# $Emit^{ ext{ iny Calibrators/Controls}}$ Levels 0, 1, 2, 3, 4, and 5

See shaded sections: Updated information from 2017-10 version.



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#### Calibrators/Controls

#### 1 Intended Use

The Emit® Calibrators/Controls are used in the calibration of the Emit® II Plus Amphetamines, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Ecstasy, Methadone, Methaqualone, Monoclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine, and Propoxyphene Assays. These standards may also be used as quality control materials based upon specified assay cutoff levels for the Emit® II Plus drugs-of-abuse assays.

#### 2 Description

REF	Product Description	Volume
9A509UL	Emit <sup>®</sup> Calibrator/Control Level 0 human urine, preservative	14 mL
9A529UL	Emit <sup>®</sup> Calibrator/Control Level 1 human urine, D-methamphetamine, morphine, preservative	14 mL
9A549UL	Emit® Calibrator/Control Level 2 human urine, benzoylecgonine, lormetazepam, methadone, D-methamphetamine, methaqualone, morphine, 11-nor-∆9-THC-9-COOH, phencyclidine, propoxyphene, secobarbital, preservative	14 mL
9A569UL	Emit <sup>®</sup> Calibrator/Control Level 3 (Contents listed above in Level 2)	14 mL
9A589UL	Emit® Calibrator/Control Level 4 (Contents listed above in Level 2, excluding D-methamphetamine and morphine)	14 mL
9A609UL	Emit® Calibrator/Control Level 5 (Contents listed above in Level 2) (See Table 1 for drug concentrations in each level)	14 mL

Note: The calibrators are shipped ready to use. No reconstitution is necessary.

The calibrators/controls contain the following stated drug concentrations:

Table 1a — Drug Concentrations in Emit® Calibrators/Controls Levels 0-2

Drug	Calibrator/Control Level 0 (drug-free)	Calibrator/Control Level 1 (ng/mL)	Calibrator/Control Level 2 (ng/mL)
Benzoylecgonine			150
Lormetazepam			100
Methadone			150
D-Methamphetamine		300	500
Methaqualone			150
Morphine		300	1000
11-nor-Δ <sup>9</sup> -THC-9-COOH			20
Phencyclidine			12.5
Propoxyphene			150
Secobarbital			100

Table 1b — Drug Concentrations in Emit® Calibrators/Controls Levels 3-5

Drug	Calibrator/Control Level 3 (ng/mL)	Calibrator/Control Level 4 (ng/mL)	Calibrator/Control Level 5 (ng/mL)
Benzoylecgonine	300	500	1000
Lormetazepam	200	300	1000
Methadone	300	500	1000
D-Methamphetamine	1000		2000
Methaqualone	300	500	1000
Morphine	2000		4000
11-nor-∆9-THC-9-COOH	50	100	200
Phencyclidine	25	75	100
Propoxyphene	300	500	1000
Secobarbital	200	300	800

#### Risk and Safety

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

For in vitro diagnostic use.

#### **Precautions**

Human urine used in the preparation of this product was not tested by licensed reagents for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2), for hepatitis B surface antigen (HbsAg), or for hepatitis C virus (anti-HCV). This material should be handled using good laboratory practice to avoid skin contact or ingestion.

#### **Preparation and Storage**

The calibrators/controls are provided ready to use. Remove the cap and mark it to identify it with the original vial. Always store the calibrators/controls refrigerated at 2–8°C (36–46°F) when not in use. Store upright. Do not freeze or expose to temperatures above 32°C (90°F).

#### Stability

When stored refrigerated at 2–8°C,  $Emit^{\oplus}$  Calibrators/Controls are stable unopened until the expiration date printed on the vial label.

Once opened, the Emit® Calibrators/Controls are stable for 5 weeks when recapped and stored at 2–8°C when not in use.

#### 3 Procedure

For procedures, refer to the appropriate Emit® II Plus drugs-of-abuse assay instructions for use.

#### 4 Limitations

The Emit® Calibrators/Controls are for use with the Emit® II Plus Amphetamines, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Ecstasy, Methadone, Methaqualone, Monoclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine, and Propoxyphene Assays according to the procedures published by Siemens Healthcare Diagnostics.

5 Symbols Key



Do not reuse / Nicht zur Wiederverwendung / Ne pas réutiliser / Non riutilizzare / No reutilizar



Use By / Verwendbar bis / Utiliser jusque / Utilizzare entro / Fecha de caducidad



Batch Code / Chargenbezeichnung / Code du lot / Codice del lotto / Código de lote



Catalogue Number / Bestellnummer / Référence du catalogue / Numero di catalogo / Número de catálogo



Caution, consult accompanying documents / Achtung, Begleitdokumente beachten / Attention voir notice d'instructions / Attenzione, vedere le istruzioni per l'uso / Atención, ver instrucciones de uso



Manufacturer / Hersteller / Fabricant / Fabbricante / Fabricante



Authorized Representative in the European Community / Bevollmächtigter in der Europäischen Gemeinschaft / Mandataire dans la Communauté européenne / Mandatario nella Comunità Europea / Representante autorizado en la Comunidad Europea



Contains sufficient for <n> tests / Inhalt ausreichend für <n> Tests / Contenu suffisant pour "n" tests / Contenuto sufficiente per "n" saggi / Contenido sufficiente para <n> ensayos



In Vitro Diagnostic Medical Device / In-Vitro-Diagnostikum / Dispositif médical de diagnostic in vitro / Dispositivo medico-diagnostico in vitro / Producto sanitario para diagnóstico in vitro



Temperature Limitation / Temperaturbegrenzung / Limites de température / Limiti di temperatura / Límite de temperatura



Consult Instructions for Use / Gebrauchsanweisung beachten / Consulter les instructions d'utilisation / Consultare le istruzioni per l'uso / Consulte las instrucciones de uso



Non-sterile / Nicht steril / Non stérile / Non sterile / No estéril



CE Mark / CE Zeichen / Marquage CE / Marchio CE / Marca CE



Contents / Inhalt / Contenu / Contenuto / Contenido



Reconstitution Volume / Rekonstitutionsvolumen / Volume de reconstitution / Volume di ricostituzione / Volumen de reconstitución



Level / Konzentration / Niveau / Livello / Nivel

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#### 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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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

