

Emit® II Plus  
Specialty Drug Calibrators/Controls  
Levels 1,2,3, and 4



Specialty Drug Calibrators/Controls  
Levels 1,2,3 and 4

1 Intended Use

The Emit® II Plus Specialty Drug Calibrators/Controls are used in the calibration of the Emit® II Plus Buprenorphine Assay. These products may also be used as quality control materials based on the Buprenorphine Assay cutoff.

2 Description

REF	Product Description	Volume
9S529UL	Emit® II Plus Specialty Drug Calibrator/Control Level 1 Human urine, 2.5 ng/mL buprenorphine, preservative	10 mL
9S549UL	Emit® II Plus Specialty Drug Calibrator/Control Level 2 Human urine, 5 ng/mL buprenorphine, preservative	10 mL
9S569UL	Emit® II Plus Specialty Drug Calibrator/Control Level 3 Human urine, 15 ng/mL buprenorphine, preservative	10 mL
9S589UL	Emit® II Plus Specialty Drug Calibrator/Control Level 4 Human urine, 25 ng/mL buprenorphine, preservative	10 mL

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

Risk and Safety

H412  
P273, P501

Harmful to aquatic life with long lasting effects.

Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations.


Contains: 2-Methyl-4-isothiazolin-3-one

Safety Data Sheets (MSDS/SDS) available on [www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Precautions



Contains human source material. 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 universal precaution and good laboratory practice to avoid skin contact or ingestion.

Preparation

The calibrators/controls are provided ready to use. Remove the cap and mark it to identify it with the original vial.

Storage

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 the calibrators/controls are stable opened or unopened until the expiration date printed on the vial label.

3 Procedure

Refer to the Emit® II Plus Buprenorphine Assay Instructions for Use for additional calibration, quality control and procedure information.

4 Limitations

The Emit® II Plus Specialty Drug Calibrators/Controls are for use with the Emit® II Plus Buprenorphine Assay according to the procedure published by Siemens Healthcare Diagnostics.

	Do not reuse / Nicht zur Wiederverwendung / Ne pas réutiliser / Non riutilizzare / No reutilizar
	Use By / Verwendbar bis / Utiliser jusqu'à / Utilizzare entro / Fecha de caducidad
<b>LOT</b>	Batch Code / Chargenbezeichnung / Code du lot / Codice del lotto / Código de lote
<b>REF</b>	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 / Fabbrikante / Fabricante
<b>EC REP</b>	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 suficiente para <n> ensayos
<b>IVD</b>	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 / Limite 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
<b>CONTENTS</b>	Contents / Inhalt / Contenu / Contenuto / Contenido
	Reconstitution Volume / Rekonstitutionsvolumen / Volume de reconstitution / Volume di ricostituzione / Volumen de reconstitución
<b>LEVEL</b>	Level / Konzentration / Niveau / Livello / Nivel
<b>RxOnly</b>	Prescription Device (US Only) / Verschreibungspflichtiges Medizinprodukt (nur USA) / Dispositif soumis à prescription (États-Unis uniquement) / Dispositivo su prescrizione (solo USA) / Dispositivo de prescripción médica (solo EE. UU.)

2015-10\_EFIGS

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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Printed in USA  
2019-07  
10872303\_B