

Portex[®] Dry Heparin Arterial Blood Sampling Kits

Technical Summary Sheet

Device Classification

Class IIa per MDD 93/42/EEC
IVD 98/79/EC

GMDN

Code Number: 31336
Term: Blood Sampling Kit, Arterial

CE Mark

CE 0473 93/43/EEC and/or
CE 98/79/EC

Device Description

The Dry Heparin Arterial Blood Sampling Kit is a single-use, in-vitro diagnostic device designed for the drawing of arterial blood. This product is not for injection. It is provided sterile and non-pyrogenic.

The material used to manufacture this arterial blood sampling kit is not made with natural rubber latex.

Indications*

The arterial blood sampling syringe with Calcium Neutralized Dry Lithium Heparin is intended for sampling of arterial blood for the measurement of pO₂, pCO₂, pH, CO-oximetry, electrolytes (Ca⁺⁺, Na⁺, K⁺, Cl⁻, and Mg⁺⁺), Total Magnesium, and

the metabolites Glucose and Lactate. Dry Lithium Heparin is neutralized for Ionic Calcium. The syringe is heparinized for anticoagulant effect.

Precautions*

Follow the standard infection control procedures as specified by the CDC and OSHA standards (USA) or local equivalent. Do not reuse. Procedure should be performed by a trained and properly qualified person.

Mixing and Sample Analysis*

After sample collection, sample should be mixed by holding syringe in hand and rotating wrist back and forth for 20 to 30 seconds. Sample should be analyzed within 30 minutes. Follow NCCLS guidelines or health care facility protocol.

*Note: Please see the Instructions For Use provided with the device for a complete listing of indications, contraindications, warnings and precautions.



Device Components

ProVent® Syringe

Each Portex® Pro-Vent® dry heparin arterial blood sampling kit consists of a heparinized syringe, a Filter-Pro® air bubble removal device and may include a needle, needle stopper and needle protection device.

LineDraw Syringe

Each Portex® LineDraw dry heparin arterial blood sampling kit consists of a heparinized syringe and a Filter-Pro® air bubble removal device.

Pulsator® Syringe

Each Portex® Pulsator® dry heparin arterial blood sampling kit consists of a heparinized syringe, a Filter-Pro® air bubble removal device and may include a needle, needle stopper or a needle protection device.

Component Composition

- **Syringe:** Polypropylene
- **Plunger Gasket:** Butyl Rubber Compound
- **Heparin Type:** Porcine intestinal mucosa based, neutralized for ionic Ca++
- **Heparin Volume:** Approximately 23.5 I.U. per mL
- **Low Heparin (LH) Volume:** Approximately 7.0 I.U. per mL
- **Needle Hub:** Polypropylene
- **Needle:** Stainless Steel
- **Sheath:** Polypropylene
- **Lubricants:** Silicone
- **Needle Stopper:** PVC
- **Filter Pro:** Acrylic and polyethylene filter
- **Needle Protection:** Polypropylene
- **Needle-Pro® EDGE™:** Polypropylene, Stainless Steel, Acrylic Adhesive

Manufacturing Site Name and Address

Smiths Medical ASD, Inc.
10 Bowman Drive, Keene, NH, USA

Country of Origin

USA

Sterilization Method

Smiths Medical uses a validated sterilization cycle to sterilize this product. Validation and routine operation is performed based upon the guidelines set forth in ISO 11135-1 for the products that are ethylene oxide (EO) sterilized or ISO 17665 for the products that use steam sterilization. The products are for single-use only and they cannot be re-sterilized.

Shelf-Life

Sterile Devices

A 3-year expiration date is assigned to the product as long as the packaging is undamaged and unopened, based on accelerated aging stability shelf-life testing followed by real time aging.

Labeling and Packaging

One (1) ABS unit is packaged in a flexible, peel-open blister or in a polyethylene bag with product specific information. Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged. Cases are packed as two hundred (200) units. PG-suffix products are packaged in four (4) shelf boxes of fifty (50). All others are packaged as four (4) bags of fifty (50) units. The lot number and expiration date are located on the pack. The manufacturing date is located on the shipper box.

Product Codes: 4648PE, 4558PE, 4618PE, 4619PE, 4628PE, 4629PE, 4645PE, 4658PE, 4698PE				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	483mm	254mm	295mm	3.0kg
Pallet (40 boxes)	1219mm	1016mm	1676mm	128kg
Product Codes: 4558PG, 4590PG, 4619PG, 4645PG, 4698PG, 4629PG, 4080PG				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	483mm	254mm	295mm	3.4kg
Pallet (40 boxes)	1219mm	1016mm	1676mm	145kg
Product Codes: 4042E, 4043E, 4042LH				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	419mm	191mm	267mm	1.4kg
Pallet (84 boxes)	1219mm	1016mm	1676mm	131kg
Product Codes: 4041E				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	432mm	283mm	356mm	2.4kg
Pallet (32 boxes)	1219mm	1016mm	1676mm	87kg
Product Codes: 4646E				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	432mm	283mm	356mm	3.5kg
Pallet (72 boxes)	1219mm	1016mm	1676mm	123kg
Product Codes: 4616E				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	381mm	216mm	305mm	3.0kg
Pallet (21 boxes)	1219mm	1016mm	1676mm	226kg
Product Codes: 4080PE, 4046E				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	381mm	216mm	305mm	3.1kg
Pallet (21 boxes)	1219mm	1016mm	1676mm	75kg
Product Codes: 4041LH				
Container Type	Length	Width	Height	Weight
SP Case (200 units)	406mm	216mm	394mm	2.36kg
Pallet (40 boxes)	1219mm	1016mm	1676mm	122kg

PRO-VENT® PLUS ARTERIAL BLOOD SAMPLING KIT

Product Code	Description
4558PE	3mL Luer Lock Syringe, 23g x 1" Needle
4616E	1mL Luer Slip Syringe
4618PE	1mL Luer Slip Syringe, 25g x 5/8" Needle
4619PE	1mL Luer Slip Syringe, 25g x 5/8" Needle, Needle-Pro®
4628PE	1mL Luer Slip Syringe, 23g x 1" Needle
4629PE	1mL Luer Slip Syringe, 23g x 1" Needle, Needle-Pro®
4645PE	3mL Luer Slip Syringe, 22g x 1" Needle, Needle-Pro®
4646E	3mL Luer Slip Syringe
4648PE	3mL Luer Slip Syringe, 22g x 1" Needle
4658PE	3mL Luer Slip Syringe, 23g x 1" Needle
4698PE	3mL Luer Slip Syringe, 23g x 1" Needle, Needle-Pro®

Product Code	Description
4590PG	3 mL Luer Lock Syringe 22g x 1" EDGE™ Needle
4558PG	3 mL Luer Lock Syringe 23g x 1" EDGE™ Needle
4619PG	1 mL Luer Slip Syringe 25g x 5/8" EDGE™ Needle
4629PG	1 mL Luer Slip Syringe 23g x 1" EDGE™ Needle
4645PG	3 mL Luer Slip Syringe 22g x 1" EDGE™ Needle
4698PG	3 mL Luer Slip Syringe 23g x 1" EDGE™ Needle

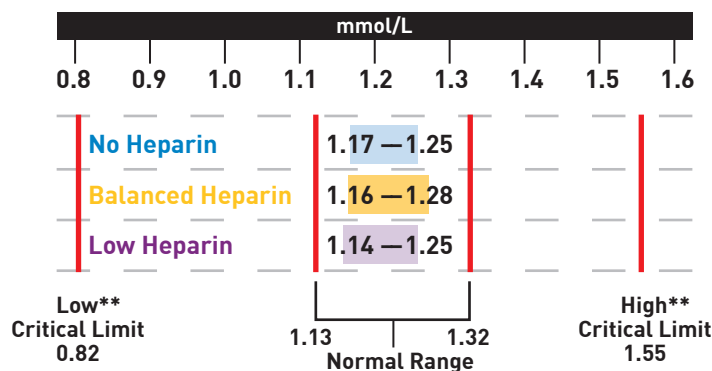
PORTEX® PULSATOR® DRY HEPARIN ARTERIAL BLOOD SAMPLING KIT

Product Code	Description
4046E	3mL Luer Lock Syringe
4080PE	3mL Luer Lock Syringe, 23g x 1" Needle
4080PG	3mL Luer Lock Syringe 23g x 1" EDGE™ needle

PORTEX® LINE DRAW PLUS DRY HEPARIN ARTERIAL BLOOD SAMPLING KIT

Product Code	Description
4041E	1mL Luer Slip Syringe
4042E	3mL Luer Lock Syringe
4043E	3mL Luer Slip Syringe
4042LH	3 mL Luer Lock Syringe (Low Heparin)
4041LH	1 mL Luer Slip Syringe (Low Heparin)

IONISED CALCIUM



* Data on file

** At Your Fingertips, *Advance for Administrators of the Laboratory*, 2004;13;12;81-88

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Smiths Medical is part of the global technology business Smiths Group plc. Please see the Instructions for Use/Operator's Manual for a complete listing of the indications, contraindications, warnings and precautions. Portex, Pulsator, Pro-Vent, Filter-Pr, Needle-Pro and the Smiths Medical and Portex design marks are trademarks of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries. All other names and marks mentioned are the trademarks or service marks of their respective owners. ©2015 Smiths Medical. All rights reserved. SS195283GL-082015