

Portex™ Dry Heparin Arterial Blood Sampling Kits

Device Classification

Class IIa

GMDN

Code Number: 31336

Term: Blood Sampling Kit, Arterial

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 Neutralised 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 neutralised for Ionic Calcium. The syringe is heparinised 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 analysed within 30 minutes. Follow NCCLS guidelines or health care facility protocol.

Device Components

Pro-Vent™ Syringe

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

Pulsator™ Syringe

Each Portex Pulsator dry heparin arterial blood sampling kit consists of a heparinised 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: Polypropylene
- › Heparin Type: Porcine intestinal mucosa based, neutralised for ionic Ca⁺⁺
- › Heparin Volume: Approximately 23 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-Pro™: Polypropylene
- › Needle-Pro EDGE™: Polypropylene, Stainless Steel, Acrylic Adhesive

Legal Manufacturer Site Name and Address

ICU Medical, Inc.

6000 Nathan Lane North

Minneapolis, MN 55442 USA

Country of Origin

USA

Sterilisation Method

Ethylene Oxide. The products are for single-use only and they cannot be re-sterilised.

Shelf-Life

A 3-year expiration date is assigned to the product as long as the packaging is undamaged and unopened.

Labelling 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) units. 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
Shipper Box (200 units)	483 mm	254 mm	295 mm	3,0 kg

Product Codes: 4558PG, 4590PG, 4619PG, 4645PG, 4698PG, 4629PG, 4080PG

Container Type	Length	Width	Height	Weight
Shelf box (50 units)	200 mm	213 mm	197 mm	
Shipper Box (200 units)	406 mm	216 mm	394 mm	3,4 kg

Product Codes: 4042E, 4043E, 4042LH

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	419 mm	175 mm	203 mm	1,4 kg

Product Codes: 4041E

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	432 mm	283 mm	356 mm	2,4 kg

Product Codes: 4646E

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	341 mm	224 mm	243 mm	3,5 kg

Product Codes: 4616E

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	341 mm	224 mm	243 mm	3,0 kg

Product Codes: 4080PE

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	635 mm	419 mm	203 mm	3,1 kg

Product Codes: 4046E

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	381 mm	216 mm	305 mm	3,1 kg

Product Codes: 4041LH

Container Type	Length	Width	Height	Weight
Shipper Box (200 units)	406 mm	216 mm	394 mm	2,4 kg

Pro-Vent Plus Arterial Blood Sampling Kit

Product Code	Description	Product Code	Description
4558PE	3mL Luer Lock Syringe, 23G x 25 mm (1") Needle	4590PG	3 mL Luer Lock Syringe 22G x 25 mm (1") Needle-Pro EDGE
4616E	1mL Luer Slip Syringe	4558PG	3 mL Luer Lock Syringe 23G x 25 mm (1") Needle-Pro EDGE
4618PE	1mL Luer Slip Syringe, 25G x 16 mm (5/8") Needle		
4619PE	1mL Luer Slip Syringe, 25G x 16 mm (5/8") Needle-Pro		
4628PE	1mL Luer Slip Syringe, 23G x 25 mm (1") Needle	4619PG	1 mL Luer Slip Syringe 25G x 16 mm (5/8") Needle-Pro EDGE
4629PE	1mL Luer Slip Syringe, 23G x 25 mm (1") Needle-Pro		
4645PE	3mL Luer Slip Syringe, 22G x 25 mm (1") Needle-Pro	4629PG	1 mL Luer Slip Syringe 23G x 25 mm (1") Needle-Pro EDGE
4646E	3mL Luer Slip Syringe	4645PG	3 mL Luer Slip Syringe 22G x 25 mm (1") Needle-Pro EDGE
4648PE	3mL Luer Slip Syringe, 22G x 25 mm (1") Needle		
4658PE	3mL Luer Slip Syringe, 23G x 25 mm (1") Needle		
4698PE	3mL Luer Slip Syringe, 23G x 25 mm (1") Needle-Pro	4698PG	3 mL Luer Slip Syringe 23G x 25 mm (1") Needle-Pro EDGE

Pulsator Dry Heparin Arterial Blood Sampling Kit

Product Code	Description
4046E	3mL Luer Lock Syringe
4080PE	3mL Luer Lock Syringe, 23G x 25 mm (1") Needle
4080PG	3mL Luer Lock Syringe, 23G x 25 mm (1") Needle-Pro EDGE

Portex Line Draw 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)

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