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Product Data

Product Name: IMPROVACUTER® No Additive Tube

Item Code and specification and package information:

| Catalog Number | Items | Tube Size | Volume | Closure Type | Additive State | Tube material | Label | Color | Pack/Carton Qty |
|-------------------|-------------|-----------|--------|--------------|-------------------|------------------|-------------|-------|--------------------|
| 603070242 | No additive | 13×100mm | 7ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 603060242 | No additive | 13×100mm | 6ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 603050242 | No additive | 13×100mm | 5ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 603040242 | No additive | 13×100mm | 4ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 603030242 | No additive | 13×100mm | 3ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 602040242 | No additive | 13×75mm | 4ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 602030242 | No additive | 13×75mm | 3ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 602020242 | No additive | 13×75mm | 2ml | Safety Cap | / | PET | transparent | Red | 100/1000 |
| 604080242 | No additive | 16×100mm | 8ml | Safety Cap | / | PET | transparent | Red | 50/1000 |
| 604090242 | No additive | 16×100mm | 9ml | Safety Cap | / | PET | transparent | Red | 50/1000 |
| 604950242 | No additive | 16×100mm | 9.5ml | Safety Cap | / | PET | transparent | Red | 50/1000 |
| 603070202 | No additive | 13×100mm | 7ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 603060202 | No additive | 13×100mm | 6ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 603050202 | No additive | 13×100mm | 5ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 603040202 | No additive | 13×100mm | 4ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 603030202 | No additive | 13×100mm | 3ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 602040202 | No additive | 13×75mm | 4ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 602030202 | No additive | 13×75mm | 3ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 602020202 | No additive | 13×75mm | 2ml | Safety Cap | / | PET | Paper | Red | 100/1000 |
| 604080202 | No additive | 16×100mm | 8ml | Safety Cap | / | PET | Paper | Red | 50/1000 |
| 604090202 | No additive | 16×100mm | 9ml | Safety Cap | / | PET | Paper | Red | 50/1000 |
| 604950202 | No additive | 16×100mm | 9.5ml | Safety Cap | / | PET | Paper | Red | 50/1000 |
| 603050202N | No additive | 13×100mm | 5ml | Safety Cap | / | PET | Paper | Blue | 100/1000 |

Note: the specification is not limited to the above table. Refer to product list for full specification.

Subject and application

IMPROVACUTER® No Additive Tubes are without additive in the inner wall of the tube. The No Additive Tube made of plastic is made of silicone inner wall membrane, forming a polar super hydrophilic tube wall, which can naturally induce platelet activation and promote blood coagulation. The No Additive Tube made of glass is processed with special technology to ensure the inner wall of the tube is clean. No Additive Tubes offer serum for determinations in chemistry, immunology and serology.

The medium recommended clotting time for serum tubes without Clot Activator is 60mins(glass) / 90mins(PET). See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

This product has to be used by professionally qualified personnel.



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Product photo



Composition and raw material:

Tubing:

-Tubing material: polyethylene terephthalate (PET), Medical used glass

-Diameter and height:13mmx75mm,13x100mm,16x100mm

Safety cap:

-Raw material: Safety cap against aerosol, in polyethylene

-Color: Red

Rubber stopper:

-Raw material: Butyl rubber

Additive: No

Raw material certifications

All raw materials used are non toxic, food and medical certified, as per European directives.

Shelf life

18 (eighteen) months for PET tubes from manufacturing date,

24 (twenty-four) months for Glass tubes from manufacturing date

Storage

Storage tubes at 4-25°C (39-77°F) , unless there is other notice on the package or label. All liquid preservatives and anticoagulants are clear and colorless. Do not use if they are discolored or contain precipitates. Clot activator may be white or brownish; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. EDTA or clot activator spray coated additives may have a brownish appearance; this does not affect the performance of the EDTA additive or clot activator. Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated. Sterilization

Shipping Information



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Normal shipping; Normal dry container

Sterilization

By irradiation as per European Union directives: UNI EN 552, UNI EN 556-1 ISO, 11137, UNI EN ISO 11737-2

Centrifugation

Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage.

The following table gives recommended centrifuge RCF and time using a horizontal head (swinging bucket) centrifuge:

| Centrifugation RCF and Time Recommendations | | | |
|---|-----------|------------|--|
| Product | RCF (g) | Time (min) | |
| No Additive Tubes | 1500-2200 | 10 | |

Information on the label and symbols

| Symbol and Mark | Key | |
|-----------------------|---|------------------------------|
| Single Use | In Vitro Diagnostic Medical Device | M Date of Manufacture |
| Expiry Date | | REF Catalog Number |
| Lot Batch Code | ↓ Lower Limit of Temperature | Consult Instructions for Use |
| STERILE Sterile | ↓ Upper Limit if Temperature | 🗞 Biological Risk |
| ∰ This End Up | STERILE R Method of Sterilization (Irradiation) | Fragile, Handle with Care |
| Manufacturer | EC REP Authorized Representative | |
| Recyclable Recyclable | ⚠ Caution, Consult Accompanying Documents | |

ISO/EN Standards

ISO 6710 "Single-use containers for venous blood specimen collection"

EN 14820 "Single-use containers for human venous blood specimen collection"

ISO 11137 "Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization"

Clinical and Laboratory Standards Institute (CLSI)



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GP39-A6 Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition

GP34-A Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline

GP41-A6Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition

GP44-A4 Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition.

H21-A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition