

## Product Data

### Product Name: IMPROVACUTER<sup>®</sup> Gel & Clot Activator 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 |
|----------------|----------------------|-----------|--------|--------------|----------------|---------------|-------------|-------|-----------------|
| 623060242      | Gel & clot Activator | 13×100mm  | 6ml    | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 623050242      | Gel & clot Activator | 13×100mm  | 5ml    | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 623040242      | Gel & clot Activator | 13×100mm  | 4ml    | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 623030242      | Gel & clot Activator | 13×100mm  | 3ml    | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 622030242      | Gel & clot Activator | 13×75mm   | 3ml    | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 622350242      | Gel & clot Activator | 13×75mm   | 3.5ml  | Safety Cap   | /              | PET           | transparent | Gold  | 100/1000        |
| 624070242      | Gel & clot Activator | 16×100mm  | 7ml    | Safety Cap   | /              | PET           | transparent | Gold  | 50/1000         |
| 624080242      | Gel & clot Activator | 16×100mm  | 8ml    | Safety Cap   | /              | PET           | transparent | Gold  | 50/1000         |
| 624850242      | Gel & clot Activator | 16×100mm  | 8.5ml  | Safety Cap   | /              | PET           | transparent | Gold  | 50/1000         |
| 623060202      | Gel & clot Activator | 13×100mm  | 6ml    | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 623050202      | Gel & clot Activator | 13×100mm  | 5ml    | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 623040202      | Gel & clot Activator | 13×100mm  | 4ml    | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 623030202      | Gel & clot Activator | 13×100mm  | 3ml    | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 622030202      | Gel & clot Activator | 13×75mm   | 3ml    | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 622350202      | Gel & clot Activator | 13×75mm   | 3.5ml  | Safety Cap   | /              | PET           | paper       | Gold  | 100/1000        |
| 624070202      | Gel & clot Activator | 16×100mm  | 7ml    | Safety Cap   | /              | PET           | paper       | Gold  | 50/1000         |
| 624080202      | Gel & clot Activator | 16×100mm  | 8ml    | Safety Cap   | /              | PET           | paper       | Gold  | 50/1000         |
| 624850202      | Gel & clot Activator | 16×100mm  | 8.5ml  | Safety Cap   | /              | PET           | paper       | Gold  | 50/1000         |

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

### Subject and application

The clot activator sprayed on the inner wall of tube can accelerate clotting. Particles in the white or brownish film on the interior surface activate clotting when tubes are mixed 5-8 times by inversion. The tube contains a gel barrier polymer at the tube bottom. The density of this material causes it to move up ward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from the clot. Serum may be aspirated directly from the collection tube, eliminating the need to transfer to another container.

See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency Sections.

### Product photo



## Composition and raw material:

### Tubing:

- Tubing material: polyethylene terephthalate (PET)
- Diameter and height: 13mmx75mm, 13x100mm, 16x100mm

### Safety cap:

- Raw material: Safety cap against aerosol, in polyethylene
- Color: Golden

### Rubber stopper:

- Raw material: Butyl rubber

Additive: Gel and clot activator

## Raw material certifications

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

## Shelf life

18 (eighteen) months for PET 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

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

## Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The recommended minimum clotting time for IMPROVACUTER® Gel & Clot Activator Tube is 30 minutes. Tubes with clot activator or/and gel should be inverted 5-8 times.

**Minimum Clotting Time Recommendations(Room Temperatures)**

| Product                   | Time(min) |
|---------------------------|-----------|
| Gel & Clot Activator Tube | 30        |

## 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 ) |
| Gel & Clot Activator Tubes                  | 1800-2200 | 10           |

## Information on the label and symbols

### Symbol and Mark Key

|  |   |   |
|--|---|---|
|  Single Use   |  In Vitro Diagnostic Medical Device      |  Date of Manufacture          |
|  Expiry Date  |  Temperature Limitation                  | <b>REF</b> Catalog Number   |
|  Batch Code   |  Lower Limit of Temperature              |  Consult Instructions for Use |
|  Sterile      |  Upper Limit of Temperature              |  Biological Risk              |
|  This End Up  |  Method of Sterilization (Irradiation)   |  Fragile, Handle with Care    |
|  Manufacturer |  Authorized Representative               |  Keep Away from Sunlight      |
|  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)



**Product Technical Data**  
**Gel & Clot Activator Tube**

|             |     |
|-------------|-----|
| Document No |     |
| Page        | 4/4 |
| Version     | A/2 |

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-A6 Procedures 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