IMPROVACUTER® Evacuated Blood Collection System

IMPROVACUTER® Gel & Clot Activator Tube

For In Vitro Diagnostic Use

Intended Use

IMPROVACUTER® Gel & Clot Activator Tube is a single use tube used to collect, transport, separate, and process venous blood specimens to obtain serum for clinical chemistry and immunology assays. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

Product Description

IMPROVACUTER® Gel & Clot Activator Tube is evacuated tubes with color-coded (see table below) Conventional Closure or Safety Cap. The clot activator sprayed on the inner wall of tube can accelerate clotting. The tube contains a gel barrier polymer at the tube bottom. The density of this material causes it to move upward 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.

The tube is in accordance to the requirements and recommendations of CLSI GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition", and the international standards ISO 6710 "Single use containers for venous blood specimen collection".

See each shelf package or case label for approximate draw volume. Tube stoppers are lubricated with silicone to facilitate stopper insertion.

The tube interior is sterile and the product is for single use only. See Limitations of System, Cautions and Warnings, Specimen Collection and Handling, Analytic Equivalency.

Tube Closure Color Code

Product	Conventional Closure Color	Safety Cap Color
IMPROVACUTER® Gel & Clot Activator Tube	Gold	Rubber stopper: Gray Cap: Gold

Limitations of System

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with smaller draw volume may fill more slowly than tubes of the same size with greater draw volume.

For the tubes which should be centrifuged to obtain serum for testing, whether separator gel is present or not, standard processing conditions do not necessarily completely sediment all cells. Accordingly, cell -based metabolism, as well as natural degradation may affect serum analytical concentration or activities. It is recommended that testing for TBIL be performed as soon after collection and separation as possible. Due to natural degradation, delay in separation of the serum from the cellular mass or in testing after separation will result in erroneous results for those analytes.

Therapeutic drug monitoring (TDM), blood banking and infectious disease performance were not validated in IMPROVACUTER® Gel & Clot Activator Tubes. It's recommended that laboratory evaluation shall be conducted before clinical tests.

The flow properties of the barrier material are temperature-related. Tubes should not be re-centrifuged once barrier has formed.

Cautions and Warnings

Cautions

1. Do not use blood collection tubes if foreign matter is present.
2. Prevention of Backflow
   Since IMPROVACUTER® Gel & Clot Activator Tubes contain chemical additives, it is important to avoid possible backflow from the tube during blood collection, to minimize the risk of adverse patient reactions. To guard against backflow, observe the following precautions:
   a) Place patient's arm in a downward position.
   b) Hold tube with the stopper uppermost.
   c) Release tourniquet as soon as blood appears in tube.
3. Do not shake. Vigorous mixing may cause foaming or hemolysis.
4. If tubes are not mixed 5 to 8 times immediately after collection, incomplete separation of serum may occur. This may also result in delayed clotting and fibrin formation.
5. Separation of serum from cells by centrifugation should take place within 2 hours of collection to prevent erroneous test results.
6. Remove stoppers with a twist and pull motion. Removal by rolling with the thumb is not recommended.
7. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
8. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
9. Always use appropriate centrifuge carriers or inserts. Use of tubes with cracks or excessive centrifugation g-force 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.

Warnings

1. Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage,and potential exposure to bloodborne pathogens.
2. Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adaptors and blood collection sets) according to the policies and procedures of your facility. Obtain Appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector, if the blood collection device provides one. IMPROVE does not recommend reshielding used needles. However, the policies and procedures of your facility may differ and must always be followed.
3. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
4. Transferring a sample collected using a syringe and needle to a tube is not recommended. Additional manipulation of sharps, such as hollow bore needles, increases the potential for Needle stick injury.
5. Transferring samples from syringe to an evacuated tube using a non-sharps device should be performed with caution for the following reasons:
   - Depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure.
   - Using a syringe for blood transfer may also cause over or under filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results.
   - Evacuated tubes are designed to draw the volume indicated. Filling is complete when vacuum no longer continues to draw, though some tubes may partially fill due to plunger resistance when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
6. If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V. solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.
7. Discard blood collection tubes in biohazard containers approved for their disposal.

Storage

Storage tubes at 4-25℃（39-77°F）, unless there is other notice on the package or label. Do not use if color has changed. Do not use tubes after their expiration date.

NOTE: *Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e. vacuum loss, drying out of liquid additives, coloring, etc.)*

Specimen Collection and Handling

Open barrier bag using the tear notch on either right or left side of bag.

1. Prepare venipuncture site with an appropriate antiseptic. Use your institution's recommended procedure for standard venipuncture technique and sample collection.
2. Remove needle shield.
3. Perform venipuncture.
4. Place tube in holder and push tube forward until tube stopper has been penetrated. For optimum product performance: When blood begins to flow into tube, immediately adjust position of tube to side of holder (off center) to direct blood stream to the side wall of the tube.
5. Remove tourniquet as soon as blood appears in tube.
6. Wait until tube has filled to its stated volume and blood flow ceases.
7. Pull tube off needle inside holder.
8. Remove tube from holder.
9. Mix immediately and gently 5 to 8 times by inverting the tube. One inversion is turning the tube upside-down and returning it to its upright position.

10. Clotting Instruction

Allow blood to clot thoroughly before centrifugation. The recommended minimum clotting time for IMPROVACUTER® Gel & Clot Activator Tube is 30 minutes.

Notes: *Recommended time is based upon an intact clotting process. Patients with abnormal clotting due to disease, or those receiving anticoagulant therapy, as well as temperature of blood collection is low, require more time for complete clot formation. Anyway make sure the blood specimen clot completely before centrifugal. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to CLSI guidelines.*

11. Centrifugation

The following table gives recommended centrifuge RCF and time:

Centrifugation RCF and Time

Product Name	Recommended RCF（g）	Recommended Time（min） *
IMPROVACUTER® Gel & Clot Activator Tube (plastic)	1500-2200	10

** 10 minutes when using a swing bucket centrifuge and 15 minutes when using a fixed angle centrifuge.*

RCF is related to centrifuge speed setting (rpm) using the following equation:

$$rpm=\sqrt{\frac{RCF \times 10^5}{1.12 \times r}}$$

where "r", expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube

Caution: See centrifuge instruction manual for disinfection instructions.

12. Recommended Order of Draw: (according to CLSI GP41-A6 Standard)

1) Blood Culture tube
2) Coagulation tube
3) Serum tube with or without clot activator, with or without gel
4) Heparin tube with or without gel plasma separator
5) EDTA tube
6) Glycolytic Inhibitor tube

NOTE: *If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, if a coagulation specimen is drawn first, a discard tube (a non-additive or coagulation tube) is recommended to be drawn prior to this tube to ensure the proper anticoagulant-to-blood ratio. In addition, even though studies have shown that PT and APTT tests are not affected if drawn first in a tube series, it is advisable to draw a second tube for other coagulation assays, since it is not known whether or not these tests will be affected.*

NOTE: *Always follow your facility's protocol for Order of Draw.*

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IFU of Gel & Clot Activator Tube for USA

13. Barrier Information

The flow properties of the barrier material are temperature-related. Flow may be impeded if chilled before or during centrifugation. To optimize flow and prevent heating during centrifugation, set refrigerated centrifuges to 25℃ (77°F). Gel separation tubes should be centrifuged no later than 2 hours after collection.

Tubes should not be re-centrifuged once barrier has formed. Barriers are more stable when tubes are spun in centrifuges with horizontal (swinging bucket) heads than those with fixed angle heads.

Note: Some push-down filters may not be compatible with plastic tubes due to the tapered inner diameter of the tube.

Separated serum is ready for use. The tubes may be placed directly on the instrument carrier or serum may be pipetted into an analyzer cup. Some instruments can sample directly from a separator tube with the stopper in place. Follow the instrument manufacturer's instructions.

Analytic Equivalency

Evaluations of IMPROVACUTER® Gel & Clot Activator Tubes have been performed for representative analytes on typical instrument platforms. See Table 1.
Stability for 24 hours at room temperature and refrigerator temperature has been demonstrated for the listed analytes except room temperature for TBIL, TBIL at room temperature 20 hours were stable.

You may email: qd9@ improve-medical.com for IMPROVE MEDICAL Technical Services and information.

Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

References

ISO/ANSI/AAMI Standards

ISO 6710 Single-use containers for 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)

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 StandardSixth Edition

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

Table 1

IMPROVACUTER® Gel & Clot Activator Tube

Comparison Studies

Analyte	Instruments	No	Analyte	Instruments#
1 Total Protein	1, 2	22	Apolipoproteins A-I	1, 2
2 Albumin	1, 2	23	Apolipoproteins B	1, 2
3 Total Bilirubin	1, 2	24	CRP	1, 2
4 Direct Bilirubin	1, 2	25	Rheumatoid Factor	1, 2
5 AST	1, 2	26	C3	1, 2
6 ALT	1, 2	27	C4	1, 2
7 ALP	1, 2	28	IgG	1, 2
8 GGT	1, 2	29	IgA	1, 2
9 Cholesterol	1, 2	30	IgM	1, 2
10 Potassium	1, 2	31	CK-MB	1, 2
11 Glucose	1, 2	32	HCG	3, 5
12 Creatinine	1, 2	33	TSH	3, 8
13 Calcium	1, 2	34	Free T4	3, 8
14 Chloride	1, 2	35	Prolactin	3, 8
15 CK	1, 2	36	Ferritin	3, 6
16 Magnesium	1, 2	37	IgE	6, 7
17 Phosphorous	1, 2	38	Troponin	4, 5
18 Triglyceride	1, 2	39	CMV-IgM	9, 10
19 Blood Urea Nitrogen	1, 2	40	CMV-IgG	9, 10
20 Sodium	1, 2	41	VZV-IgG	9, 10
21 Uric acid	1, 2			

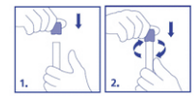
Instruments #

1: Roche Modular PPI
2: Beckman DXC 800
3: Abbott i2000
4: Abbott Axsym
5: BECKMANN access Ⅱ
6: Roche E170
7: UNICAP Immuno CAP
8: Bayer Centaur
9: Anthos Microplate Reader
10: Bio-Tec Microplate Reader ELX800

Instructions for Removal of Safety Cap

1. Grasp the IMPROVACUTER® Tube with one hand, placing the thumb under the safety cap. (For added stability, place arm on solid surface).With the other hand, twist the safety cap while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPERIS LOOSENED.
2. Move thumb away before lifting safety cap. DO NOT use thumb to push safety cap off tube. To help prevent injury during safety cap removal, it is important that the thumb used to push upward on the safety cap be removed from contact with the tube as soon as the safety cap is loosened.
3. Lift safety cap off tube. In the unlikely event of the plastic shield separating from the rubber stopper, DO NOT REASSEMBLE CLOSURE. Carefully remove rubber stopper from tube.

Instructions for Reinsertion of Safety Cap



1. Replace safety cap over tube.
2. Twist and push down firmly until stopper is fully reseated.
   Complete reinsertion of the stopper is necessary for the safety cap to remain securely on the tube during handling.

Symbol and Mark Key

Sing Use	In Vitro Diagnostic Medical Device	Date of Manufacture
Expiry Date	Temperature Limitation	Catalog Number
Batch Code	Lower Limit of Temperature	Consult Instructions for Use
Sterile	Upper Limit if 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	

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