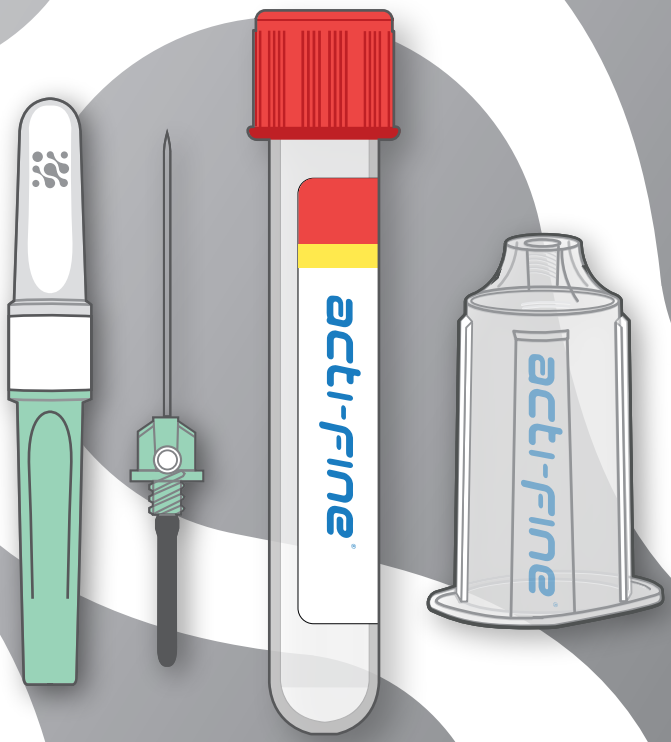
GRANAT BIO TECH



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Our Objective

Alexander Shishov
General Director
Granat Bio Tech LLC

We offer end–to–end manufacturing – from casting to packaging. This means that quality control is guaranteed by the **Granat Bio Tech** team at all stages of product manufacturing.

We are always there to listen to our clients and are ready to work on new products in collaboration with laboratories.

Our primary objective is that our products remove any concerns from laboratories about testing at the pre–analytical stage.

Granat Bio Tech Philosophy

Combining the world's best practices and customer experience of using vacuum systems to create a superior product.

Control all stages of manufacturing: from prototyping to analysis of user feedback. Select the best suppliers of raw materials for manufacturing.

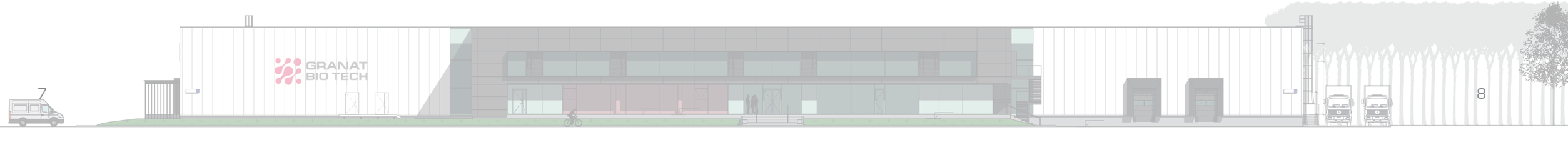
Develop innovations in manufacturing and assembly processes to make it possible for clients to order customized products.

Based on the principles of continuous guaranteed high quality, the founders of **Granat Bio Tech** made the decision to build the first end-to-end facility for the manufacturing of vacuum tubes in Russia.

In 2021 **Granat Bio Tech** manufacturing plant received international certificates from TÜV AUSTRIA for the conformity of our quality management system to ISO 9001–2015 and ISO 13485–2017 for the design, development, manufacturing and distribution of medical devices for in-vitro diagnostics.

The **Granat Bio Tech** manufacturing plant is equipped with unique modern machinery to supply products that comply with global standards and are highly competitive with European analogues. End-to-end manufacturing – from casting to packaging – allows us to guarantee quality at all manufacturing stages.

Manufacturing lines accurately create a vacuum in the tubes and introduce additives. This is how an optimal additive to blood ratio is ensured when blood is collected, this is especially important for the study of haemostasis.



Benefits of Cooperation with Granat Bio Tech

200 000 000
tubes per year

80 000 000
double-ended needles per year

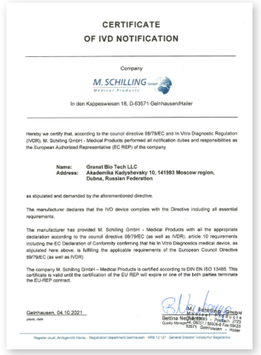
40 000 000
holders per year

6 000 м²
Production space

rapid supply of high-quality products
with a balance shelf life of more than 80% of total shelf life (at the time of supply)

customization
of the product to take into account our clients' individual needs

expert support
at all stages of using our products



CERTIFICATE
OF IVD NOTIFICATION

Company
M. SCHILLING GmbH – Medical Products

In den Kappewiesen 18, D-63571 Gelnhausen/Hailer

Hereby we certify that, according to the council directive 98/79/EC and In Vitro Diagnostic Regulation (IVDR), M. Schilling GmbH – Medical Products performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of the company

Name: Granat Bio Tech LLC
Address: Akademika Kadyshevskiy 10, 141980 Moscow region, Dubna, Russian Federation

as stipulated and demanded by the aforementioned directive.

The manufacturer declares that the IVD device complies with the Directive including all essential requirements.

The manufacturer has provided M. Schilling GmbH – Medical Products with all the appropriate declaration according to the council directive 98/79/EC (as well as IVDR). article 10 requirements including the EC Declaration of Conformity confirming that his In Vitro Diagnostics medical device, as stipulated here above, is fulfilling the applicable requirements of the European Council Directive 98/79/EC (as well as IVDR).

The company M. Schilling GmbH – Medical Products is certified according to DIN EN ISO 13485. This certificate is valid as long as the certification of the EU REP will expire or one of the both parties terminate the EU-REP contract.

Gelnhausen, 04.10.2021

CERTIFICATE

TÜV AUSTRIA

Management system as per
EN ISO 9001:2015 | GOST R ISO 9001-2015

In accordance with TÜV AUSTRIA Standards & Compliance procedures, it is hereby certified that

GRANAT BIO TECH LLC
Akademika Kadyshevskogo str., 10,
141980, Dubna, Moscow region,
Russian Federation

applies a management system in line with the above standard for the following scope

Development, design, production and sale of single-use plastic medical devices for taking / collecting, transporting and storing biological material for in vitro and in vivo diagnostics.

Certificate Registration No. 007-2021-0007
Valid until: 2024-05-30
Initial certification: 2021-05-31

Certification authority
TÜV AUSTRIA Standards & Compliance

Moscow, 2021-05-31

ZERTIFIKAT | CERTIFICATE | CERTIFICADO | CERTIFICAT | CERTIFICATO

CERTIFICATE

TÜV AUSTRIA

Management system as per
EN ISO 13485:2016 | GOST ISO 13485-2017

In accordance with TÜV AUSTRIA Standards & Compliance procedures, it is hereby certified that

GRANAT BIO TECH LLC
Akademika Kadyshevskogo str., 10,
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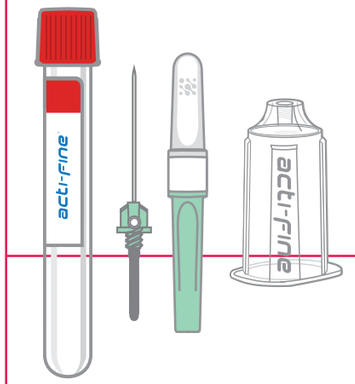
ISO 9001:2015

ISO 13485:2016

Acti–Fine® Vacuum Venous Blood Collection System makes the pre–analytical stage much safer and easier. It is comfortable for both the patient and the staff who are collecting samples. In addition, the highest possible quality of obtained sample is ensured.

Acti–Fine® Vacuum Blood Collection Systems consist of a Vacuum tube, a holder and a double–ended needle. The connections between all of the components is very strong and completely airtight.

Granat Bio Tech has developed system components that perfectly fit each other and have passed all the necessary inspections and validations.



Advantages of the Acti–Fine® Vacuum System

Safety of healthcare workers

Lower infectious risks for healthcare workers during transportation and centrifugation of the tube due to the safety screw thread. Such a screw thread completely excludes the possibility of loss of airtightness, helps avoid emergency situations, and prevents any aerosol effect when the tube is opened in the laboratory.

Pre–analytical stage errors are excluded

Acti–Fine® systems help avoid pre–analytical errors associated with additive dosing. A filling mark on the Vacuum tube allows users to clearly see the exact additive to blood ratio. The label for patient details is in English as this helps avoid sample identification errors and reduces unnecessary costs for retesting.

Preservation of samples

Preservation of samples during transportation and long–term storage (deep freezing is possible) is ensured due to tight caps with a screw thread and the unbreakable material of the tubes – polyethylene terephthalate, which has a proven minimal activity when in contact with blood.

Wide range

A wide choice of tubes with different additives for various tests. Additives are pre–introduced into the tube in a defined exact concentration to obtain the correct additive to blood ratio. It reduces, to a minimum, the number of operations to prepare blood specimens in the laboratory, and improves the overall performance of a laboratory.

Possibility of direct use as a primary tube in different automated analysers (savings in secondary plastic tubes).

There are tubes with pre–printed barcodes

Pre–barcoded tubes for blood collection ensure additional protection against the use of tubes with the improper additive or expired tubes.

Such tubes have pre–printed barcodes containing information on the type of additive and the shelf life of the tube.

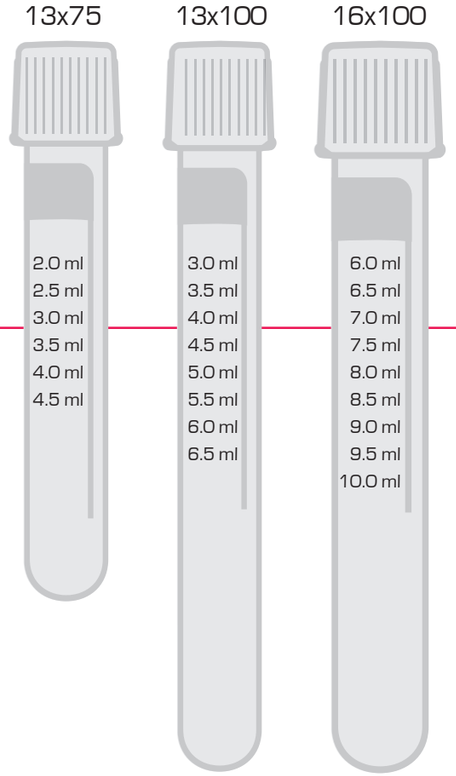
Thin–walled double–ended needle with flashback chamber

Modern technologies allow the inner diameter of the needle to be increased by making their walls thinner, without any loss of bending strength and sharpness. It is preferable to use thin–walled needles to lower the risk of mechanical haemolysis.

Convenience of using the Acti–Fine® system for blood collection

Acti–Fine® holders have a centrally located screw thread for double–ended needles, this ensures a reliable connection with puncturing devices and vacuum tubes during blood collection from the patient. To make the insertion of the vacuum tube into the holder easier, the holder's base has an outer ring (finger grips). The ribbed surface of the holder has longitudinal reinforcing ribs to ensure that the orientation of the needle is bevel up and make the blood collection procedure is very easy to perform.

Tube Size



Acti–Fine® tubes are available in three main sizes.

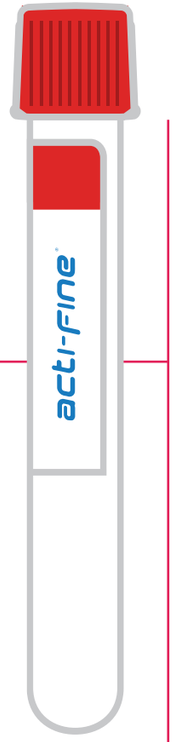
Tubes of each size include a variety of volumes for the convenient and effective use of the vacuum system within the scope of laboratory procedures.

Range of Acti–Fine® Vacuum Tubes

Type of test Additive	
Secondary tubes, tubes for aliquoting	No additives
Testing of haemostasis system	Tri–sodium citrate (1:9) or CTAD
Clinical chemistry, serology, EIA, bacteriology, for blood typing	Silica (silicon dioxide)
	Thrombin (express activator)
	Silica with separation gel (silicon dioxide)
	Thrombin with separation gel (express acti–vator)
Plasma testing in biochemistry and immunology (vitamins, hormones, immune status)	Heparin sodium, lithium or ammonium salt
	Heparin lithium salt with separation gel
Haematology, immunochemistry, molecular diagnostics	EDTA
Molecular identification of viruses, parasite microorganisms and bacteria	EDTA with separation gel
Determination of unstable analytes – enzymes, hormones	EDTA and aprotinin
Determination of blood sugar level	Sodium fluoride, potassium oxalate
	Sodium fluoride and K3EDTA
	Sodium fluoride and sodium heparin
Collection, transportation and storage of urine	No additives
	With preservative
	With boric acid

*White markings for tubes with no additives and pink for tubes with aprotinin are chosen in accordance with GOST R 53079.4. Yellow is used for tubes with a clot activator/thrombin and gel and is chosen on the basis of the sorter operating principle and to exclude errors at the pre–analytical stage.

Acti–Fine® Vacuum Venous Blood Collection Tubes with Clot Activator



Acti–Fine® Vacuum blood collection tubes contain microparticles of silicon dioxide (Silica SiO2) which is applied to the internal walls of the tube and activate blood clotting.

Acti–Fine® tubes are used in immunochemical and biochemical tests and drug monitoring.

Centrifugation conditions
1300 g,
10 min, 25 C°

Sign on label
Z with clot activator

Cap colour
red

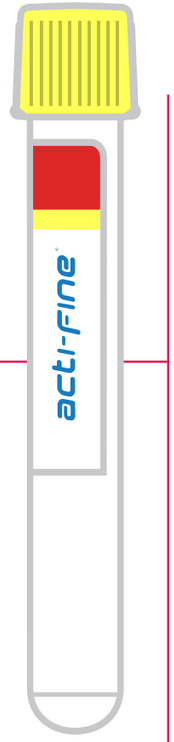
Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10012000	13*75	2,0	50
2	10012500		2,5	50
3	10013000		3,0	50
4	10013500		3,5	50
5	10014000		4,0	50
6	10014500		4,5	50
7	11013000	13*100	3,0	50
8	11013500		3,5	50
9	11014000		4,0	50
10	11014500		4,5	50
11	11015000		5,0	50
12	11015500		5,5	50
13	11016000		6,0	50
14	11016500		6,5	50
15	12016000	 16*100	6,0	50
16	12016500		6,5	50
17	12017000		7,0	50
18	12017500		7,5	50
19	12018000		8,0	50
20	12018500		8,5	50
21	12019000		9,0	50
22	12019500		9,5	50
23	12010000		10,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with Clot Activator, Gel



Acti–Fine® Vacuum blood collection tubes contain microparticles of silicon dioxide (Silica SiO2) which is applied to the internal walls of the tube and activate blood clotting.

The separator, in the form of gel at the bottom of the tube, is used to separate the obtained serum from the clot.

Tubes with separation gel are used to ensure a stable barrier between the clot and the serum during sample transportation and storage.

Acti–Fine® tubes are used in immunochemical and biochemical tests and drug monitoring.

Clotting time: 30 min.

Centrifugation conditions
2500–3000 g, 10 min, 25 C°

Sign on label
Z with clot activator, gel

Cap colour
yellow

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10022000	13*75	2,0	50
2	10022500		2,5	50
3	10023000		3,0	50
4	10023500		3,5	50
5	10024000		4,0	50
6	11023000	13*100	3,0	50
7	11023500		3,5	50
8	11024000		4,0	50
9	11024500		4,5	50
10	11025000		5,0	50
11	11025500		5,5	50
12	11026000		6,0	50
13	12026000	 16*100	6,0	50
14	12026500		6,5	50
15	12027000		7,0	50
16	12027500		7,5	50
17	12028000		8,0	50
18	12028500		8,5	50
19	12029000		9,0	50
20	12029500		9,5	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with 3.8% Sodium Citrate

Acti–Fine® Vacuum blood collection tubes for testing the haemostasis system contain a buffered tri–sodium citrate solution with 3.8% citrate content (0.129 mol/L). Additive to blood ratio: 9:1.

Acti–Fine® tubes with 3.8% sodium citrate are used in the testing of the haemostasis system.

The triangular filling mark helps to clearly determine an accurate additive to blood ratio, allows users to fill the tube properly and minimize the risk of diagnostic error.

Centrifugation conditions
PPP–1500–2000 g, 10 min, 25 C°

Sign on label
9NC sodium citrate 3.8%

Cap colour
light–blue

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Blood volume, mL	Blood volume with additive, mL	Pieces per pack
1	10131800	 13*75	1,80	2,0	50
2	10132000		2,00	2,2	50
3	10132300		2,30	2,5	50
4	10132500		2,50	2,7	50
5	10132700		2,70	3,0	50
6	10133000		3,00	3,3	50
7	10133200		3,20	3,5	50
8	10133500		3,50	3,8	50
9	10133600		3,60	4,0	50
10	10134100		4,05	4,5	50
11	11134500	 13*100	4,50	5,0	50
12	11135000		5,00	5,5	50
13	11135400		5,40	6,0	50
14	11135800		5,80	6,4	50
15	12136000	 16*100	6,00	6,6	50
16	12136300		6,30	7,0	50
17	12136800		6,80	7,5	50
18	12137200		7,20	8,0	50
19	12137700		7,70	8,5	50
20	12138100		8,10	9,0	50
21	12138500		8,50	9,4	50
22	12139000		9,00	10,0	50

Acti–Fine®Vacuum Venous Blood Collection Tubes with 3.2% Sodium Citrate

Acti–Fine® Vacuum Tubes for the testing of the haemostasis system contain a buffered tri–sodium citrate solution with 3.2% citrate content (0.109 mol/L). Additive to blood ratio: 9:1.

Tubes with 3.2% sodium citrate are used in the testing of the haemostasis system.

The triangular filling mark helps to clearly determine an accurate additive to blood ratio, allows users to fill the tube properly and minimize the risk of diagnostic error.

Centrifugation conditions
PPP–1500–2000 g, 10 min, 25 C°

Sign on label
9NC sodium citrate 3.2%

Cap colour
light–blue

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

GRANAT BIO TECH

	Catalogue number	Tube size, mm	Blood volume, mL	Blood volume with additive, mL	Pieces per pack
1	10121800	 13*75	1,80	2,0	50
2	10122000		2,00	2,2	50
3	10122300		2,30	2,5	50
4	10122500		2,50	2,7	50
5	10122700		2,70	3,0	50
6	10123000		3,00	3,3	50
7	10123200		3,20	3,5	50
8	10123500		3,50	3,8	50
9	10123600		3,60	4,0	50
10	10124100		4,05	4,5	50
11	11124500	 13*100	4,50	5,0	50
12	11125000		5,00	5,5	50
13	11125400		5,40	6,0	50
14	11125800		5,80	6,4	50
15	12126000	 16*100	6,00	6,6	50
16	12126300		6,30	7,0	50
17	12126800		6,80	7,5	50
18	12127200		7,20	8,0	50
19	12127700		7,70	8,5	50
20	12128100		8,10	9,0	50
21	12128500		8,50	9,4	50
22	12129000		9,00	10,0	50

Acti–Fine®Vacuum Venous Blood Collection Tubes with K2EDTA

Acti–Fine® Vacuum blood collection tubes for testing the haemostasis system contain K2EDTA (1.8 mg/mL of blood).

EDTA blocks the clotting cascade by the way of binding calcium ions to ensure the stability of red cells, white cells and platelets in the blood sample for up to 24 hours.

It is recommended to make a blood smear within 4 hours of the sample being collected.

Centrifugation conditions
2000 g, 10 min, 25 C°

Sign on label
K2E with K2EDTA

Cap colour
lavender

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10072000	13*75	2,0	50
2	10072500		2,5	50
3	10073000		3,0	50
4	10073500		3,5	50
5	10074000		4,0	50
6	10074500		4,5	50
7	11074000	13*100	4,0	50
8	11074500		4,5	50
9	11075000		5,0	50
10	11075500		5,5	50
11	11076000		6,0	50
12	11076500		6,5	50
13	12076500	16*100	6,5	50
14	12077000		7,0	50
15	12077500		7,5	50
16	12078000		8,0	50
17	12078500		8,5	50
18	12079000		9,0	50
19	12079500		9,5	50
20	12070000		10,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with K2EDTA, Gel

Acti–Fine® Vacuum Tubes for collecting EDTA–plasma contain K2EDTA (1.8 mg/mL of blood) and separation gel.

EDTA blocks the clotting cascade by way of binding calcium ions.

Tubes with separation gel are used to ensure a stable barrier between formed elements and blood plasma.

Acti–Fine® tubes with EDTA and separation gel are used in molecular genetic and immunologic tests. EDTA plasma is used as a test material.

Centrifugation conditions
2500 – 3000 g, 10 min, 25 C°

Sign on label
K2E with K2EDTA, gel

Cap colour
lavender, yellow line on the label

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10082000	 13*75	2,0	50
2	10082500		2,5	50
3	10083000		3,0	50
4	10083500		3,5	50
5	10084000		4,0	50
6	11084000	 13*100	4,0	50
7	11084500		4,5	50
8	11085000		5,0	50
9	11085500		5,5	50
10	11086000		6,0	50
11	12086000	 16*100	6,0	50
12	12086500		6,5	50
13	12087000		7,0	50
14	12087500		7,5	50
15	12088000		8,0	50
16	12088500		8,5	50
17	12089000		9,0	50
18	12089500		9,5	50

Acti–Fine®Vacuum Venous Blood Collection Tubes with K3EDTA

Acti–Fine® Vacuum blood collection tubes for testing the haemostasis system contain K3EDTA (1.8 mg/mL of blood).

EDTA blocks the clotting cascade by way of binding calcium ions to ensure the stability of red cells, white cells and platelets in the blood sample for up to 24 hours.

It is recommended to make a blood smear within 4 hours of the sample being collected.

Centrifugation conditions
2000 g,
10 min, 25 C°

Sign on label
K3E with K3EDTA

Cap colour
lavender

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10092000	 13*75	2,0	50
2	10092500		2,5	50
3	10093000		3,0	50
4	10093500		3,5	50
5	10094000		4,0	50
6	10094500		4,5	50
7	11094000	 13*100	4,0	50
8	11094500		4,5	50
9	11095000		5,0	50
10	11095500		5,5	50
11	11096000		6,0	50
12	11096500		6,5	50
13	12096000	 16*100	6,0	50
14	12096500		6,5	50
15	12097000		7,0	50
16	12097500		7,5	50
17	12098000		8,0	50
18	12098500		8,5	50
19	12099000		9,0	50
20	12099500		9,5	50
21	12090000		10,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with EDTA and Transparent Labels

Acti–Fine® Vacuum blood collection tubes for testing the haemostasis system contain EDTA salts to block the clotting cascade by way of binding calcium ions to ensure the stability of red cells, white cells and platelets in the blood sample for up to 24 hours.

It is recommended to make a blood smear within 4 hours of the sample being collected.

Transparent labels ensure:

- total visual control of sample state
- optimal solution for ESR analysers making optical measurements in automated mode
- easier automated control while sorting and dosing samples in analysers

Centrifugation conditions
2000 g,
10 min, 25 C°

Sign on label
K2E with K2EDTA /
K3E with K3EDTA

Cap colour
lavender

Tube size
13x75 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

Acti–Fine® Vacuum Venous Blood Collection Tubes with K2EDTA

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10072005	 13*75	2,0	50
2	10072505		2,5	50
3	10073005		3,0	50
4	10073505		3,5	50
5	10074005		4,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with K3EDTA

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10092005	 13*75	2,0	50
2	10092505		2,5	50
3	10093005		3,0	50
4	10093505		3,5	50
5	10094005		4,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with Lithium Heparin

Acti–Fine® Vacuum blood collection tubes for plasma contain heparin salts which are applied to the internal walls of the tube (heparin content: 12–30 IU/mL of blood).

As an anticoagulant, heparin activates antithrombins and blocks the clotting cascade in the blood sample.

Acti–Fine® tubes for collecting plasma are used in a wide range of biochemical, immunochemical, serologic, and immunohematology tests.

Centrifugation conditions
2000 g,
10 min, 25 C°

Sign on label
LH with lithium heparin

Cap colour
green

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10032000	 13*75	2,0	50
2	10032500		2,5	50
3	10033000		3,0	50
4	10033500		3,5	50
5	10034000		4,0	50
6	10034500		4,5	50
7	11034000	 13*100	4,0	50
8	11034500		4,5	50
9	11035000		5,0	50
10	11035500		5,5	50
11	11036000		6,0	50
12	11036500		6,5	50
13	12036000	 16*100	6,0	50
14	12036500		6,5	50
15	12037000		7,0	50
16	12037500		7,5	50
17	12038000		8,0	50
18	12038500		8,5	50
19	12039000		9,0	50
20	12039500		9,5	50
21	12030000		10,0	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with Lithium Heparin , Gel

Acti–Fine® Vacuum blood collection tubes for plasma contain heparin salts which are applied to the internal walls of the tube (heparin content: 12–30 IU/mL of blood).

As an anticoagulant, heparin activates antithrombins and blocks the clotting cascade in the blood sample.

Tubes with a separation gel are used to ensure a stable barrier between the formed elements and blood plasma after centrifugation.

Acti–Fine® tubes for collecting plasma are used in biochemical tests and express testing so that there is no need to wait up to 30 minutes for clotting.

Centrifugation conditions

2500–3000 g, 10 min, 25 C°

Sign on label

LH with lithium heparin and gel

Cap colour

green, yellow line on the label

Tube size

13x75 mm
13x100 mm
16x100 mm

Packaging

50 pcs per pack

Manufacturer

Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10042000	13*75	2,0	50
2	10042500		2,5	50
3	10043000		3,0	50
4	10043500		3,5	50
5	10044000		4,0	50
6	11044000	13*100	4,0	50
7	11044500		4,5	50
8	11045000		5,0	50
9	11045500		5,5	50
10	11046000		6,0	50
11	12046000	16*100	6,0	50
12	12046500		6,5	50
13	12047000		7,0	50
14	12047500		7,5	50
15	12048000		8,0	50
16	12048500		8,5	50
17	12049000		9,0	50
18	12049500		9,5	50

Acti–Fine® Vacuum Venous Blood Collection Tubes with Sodium Heparin

Acti–Fine® Vacuum blood collection tubes for plasma contain heparin salts which are applied to the internal walls of the tube (heparin content: 12–30 IU/mL of blood).

As an anticoagulant, heparin activates antithrombins and blocks the clotting cascade in the blood sample.

Acti–Fine® tubes for collecting plasma are used in a wide range of biochemical, immunochemical, serologic, and immunohematology tests.

Centrifugation conditions

2000 g,
10 min, 25 C°

Sign on label

NH with sodium heparin

Cap colour

green

Tube size

13x75 mm
13x100 mm
16x100 mm

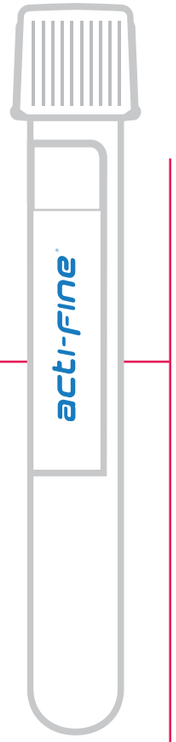
Packaging

50 pcs per pack

Manufacturer

Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10052000	13*75	2,0	50
2	10052500		2,5	50
3	10053000		3,0	50
4	10053500		3,5	50
5	10054000		4,0	50
6	10054500		4,5	50
7	11054000	13*100	4,0	50
8	11054500		4,5	50
9	11055000		5,0	50
10	11055500		5,5	50
11	11056000		6,0	50
12	11056500		6,5	50
13	12056000	 16*100	6,0	50
14	12056500		6,5	50
15	12057000		7,0	50
16	12057500		7,5	50
17	12058000		8,0	50
18	12058500		8,5	50
19	12059000		9,0	50
20	12059500		9,5	50
21	12050000		10,0	50



Acti–Fine® Vacuum blood collection tubes with no additives do not contain any agents or separation elements. They are used for waste or aliquoting.

Centrifugation conditions
2000 g,
10 min, 25 C°

Sign on label
no additives

Cap colour
white

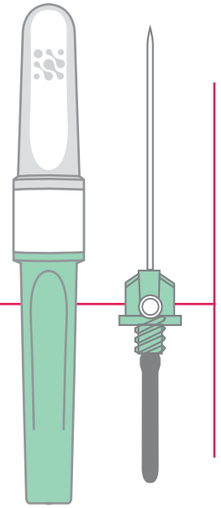
Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10192000	13*75	2,0	50
2	10192500		2,5	50
3	10193000		3,0	50
4	10193500		3,5	50
5	10194000		4,0	50
6	10194500		4,5	50
7	11194000	13*100	4,0	50
8	11194500		4,5	50
9	11195000		5,0	50
10	11195500		5,5	50
11	11196000		6,0	50
12	11196500		6,5	50
13	12196000	16*100	6,0	50
14	12196500		6,5	50
15	12197000		7,0	50
16	12197500		7,5	50
17	12198000		8,0	50
18	12198500		8,5	50
19	12199000		9,0	50
20	12199500		9,5	50
21	12190000		10,0	50

Supported by the Industrial Development Fund



Acti–Fine® Double–Ended Needles with a Flashback Chamber are designed to collect venous blood using holders and vacuum tubes. The flashback chamber in double–ended needles creates a controlled blood flow when the needle has punctured the vein.

Needle structure – a one–piece device, which excludes the risk of unintended disassembly of the needle and therefore prevents the possibility of staff infection while collecting blood. A silicone coating on the outer and inner surface of the needle ensures a smooth and painless procedure when drawing blood from patients.

	Catalogue number	Size	Pieces per pack
1	20212500	**21G x 1"** 0.8X25 mm	100
2	20213800	**21G x 1½"** 0.8X38 mm	100
3	20222500	**22G x 1"** 0.7X25 mm	100
4	20223800	**22G x 1½"** 0.7X38 mm	100

Colour coding according to GOST ISO 6009

Green – needle **21G (0,80 mm)**

Black – needle **22G (0,70 mm)**

STERILE R
Sterilised by radiation

For single use only

Storage temperature
+2°C ... +35°C

Packaging
100 pcs per pack

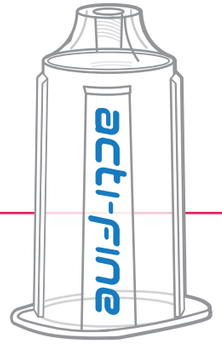
Shelf life
60 months

Manufacturer
Granat Bio Tech LLC
Russia

Double–ended needles shall be disposed of in accordance with the rules and standards set out in SanPiN 2.1.7.2790 Sanitary and Epidemiological Requirements for Handling Medical Waste

Supported
by the Industrial
Development Fund

idf



Holders are made of high–quality colourless transparent plastic.

They are used with vacuum tubes and puncturing devices (double–ended needles, winged needles and Luer–adapters) for blood collection.

- Centrally located screw thread ensures a strong reliable connection with puncturing devices
- Fix the puncturing device and ensure convenient direction and connection of Vacuum tube with a diameter of 13 or 16 mm and a height of 75 or 100 mm
- Higher level of safety for staff because contact to biomaterials is completely excluded;
- Maximum comfort for the patient during blood collection to the vacuum tube;
- No impact on biomaterial;
- Easy for healthcare workers to use the devices.

GRANAT BIO TECH

	Catalogue number	Pieces per pack
1	30001010	10
2	30002050	50
3	30003100	100

For single use only

Non–sterile

Storage temperature
+4°C ... +40°C

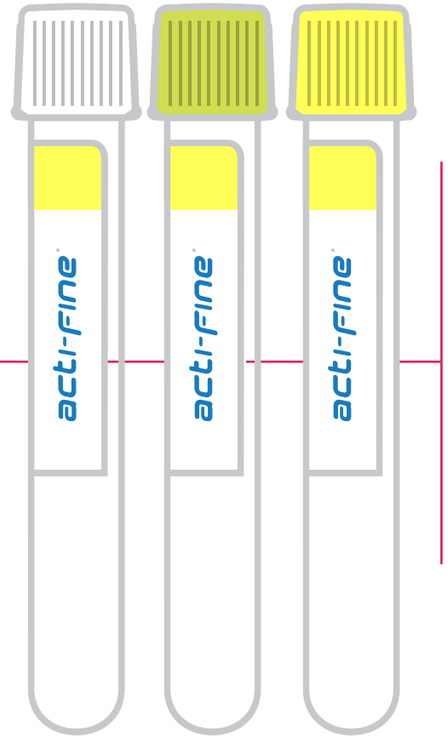
Packaging
10/50/100 pcs per polyethylene

Shelf life
36 months

Manufacturer
Granat Bio Tech LLC
Russia

Holders shall be disposed of in accordance with the rules and standards set out in SanPiN 2.1.7.2790 Sanitary and Epidemiological Requirements for Handling Medical Waste.

Acti–Fine® Vacuum Tubes for Urine Collection



FASIE

Acti–Fine® Vacuum Tubes for urine testing ensure airtight transportation and prevent biomaterial spill when the tube is opened. Collection of urine samples using a closed system excludes the necessity of sample transfer and provides a high–quality pure sample to the laboratory.

Acti–Fine® Vacuum Tubes for urine testing are compatible with the all of the most frequently used automated urine analysers.

Preservatives in the vacuum tubes for urine collection ensure the stability of the sample without cooling and sample intactness.

Type of test	Cap colour	Additive	Inverting rate	Centrifugation conditions	Maximum time before test
Clinical urine test, biochemical urine test	white	with no additives	–	400 g, 5 min, in a cooling centrifuge, 15–25°C	4 h – without cooling; 12 h – if stored at +4°C (for biochemical tests)
	yellow	with preservative	8		72 h – without cooling
Microbiological urine test	pistachio	with boric acid			24 h – without cooling

Shelf life of Vacuum tubes
18 months
upon sterilization

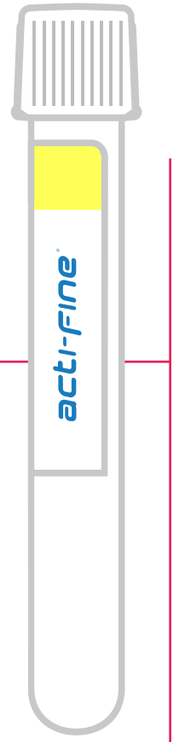
Storage temperature
+4°C ... +25°C

Avoid direct sunlight

Relative humidity maximum
80% at +25°C

Transportation temperature from +2 at +35C°, maximum relative humidity 80% at +25C°

Do not store or transport tubes at temperatures below 0°C!



FASIE

Acti–Fine® Vacuum Tubes for urine, with no additives, are used for collecting and/or transporting urine samples.

Tubes with no additives are used in routine tests (biochemical and clinical urine tests), urine may be stored for up to 12 hours, provided that samples are cooled down to +4°C immediately upon collection and delivered to the laboratory in a timely manner (on the same day).

Vacuum Tubes with no additives may be used in microbiological urine tests.

Centrifugation conditions
400 g, 5 min,
в центрифуге с
охлаждением, 15 – 25 °C

Sign on label
Z with
no additives

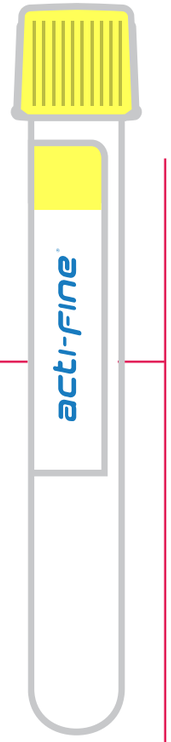
Cap colour
white

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10304000	13x75	4,0	50
2	11305000	13x100	5,0	50
3	11306000		6,0	50
4	12307000	16x100	7,0	50
5	12308000		8,0	50
6	12309000		9,0	50
7	12309500		9,5	50



FASIE

Acti–Fine® Vacuum Tubes for urine, with a preservative, are used for collecting and/or transporting urine samples in cases of long–distance delivery.

Tubes, with a preservative, are used in routine tests (biochemical and clinical urine tests), urine may be stored at room temperature for up to 72 hours

Centrifugation conditions
400 g, 5 min, in a cooling centrifuge, 15–25°C

Sign on label
with preservative

Cap colour
yellow

Tube size
13x75 mm
13x100 mm
16x100 mm

Packaging
50 pcs per pack

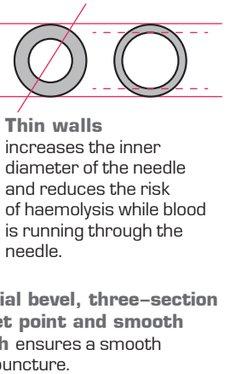
Manufacturer
Granat Bio Tech LLC
Russia

	Catalogue number	Tube size, mm	Tube volume, mL	Pieces per pack
1	10324000	13x75	4,0	50
2	11325000	13x100	5,0	50
3	11326000		6,0	50
4	12327000	16x100	7,0	50
5	12328000		8,0	50
6	12329000		9,0	50
7	12329500		9,5	50

One–piece needle
excludes the risk of unintended disassembly of the needle and removes the possibility of staff infection while collecting blood.

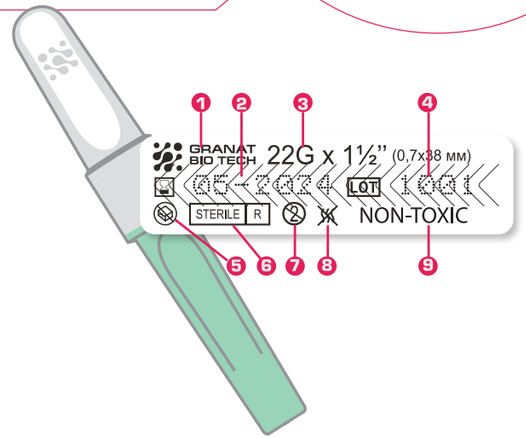
Flashback chamber
in double–ended needles allows a controlled blood flow when the needle has punctured the vein and makes the task easier for healthcare workers.

Silicone coating of the outer and inner surface of the needle ensures that the procedure for drawing patient blood is smooth and painless.

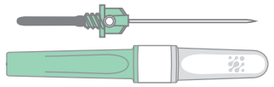
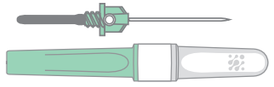
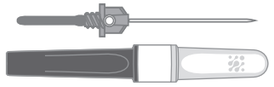
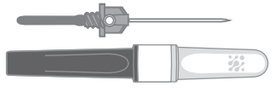


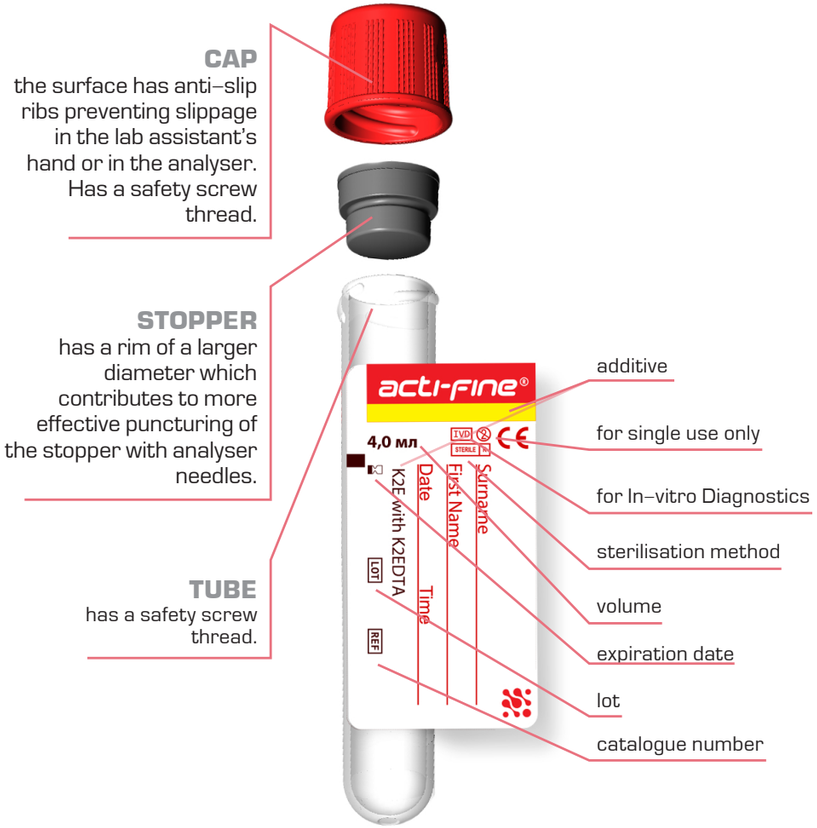
Thin walls
increases the inner diameter of the needle and reduces the risk of haemolysis while blood is running through the needle.

Special bevel, three–section lancet point and smooth polish ensures a smooth venepuncture.



1. manufacturer's logo
2. expiration date [month–year]
3. needle dimensions (diameter x length)
4. batch number
5. Do not use if package is damaged
6. Non–pyrogenic
7. For single use only
8. Sterile
9. NON–TOXIC

	Cap colour	GAUGE scale coding	Length (mm)	Diameter (mm)	Use
	Green	21G	38	0,8	Blood collection from patients over the age of 3 with normal or deeper lying veins
	Green	21G	25	0,8	Blood collection from patients over the age of 3 with normal or superficial veins
	Black	22G	38	0,7	Blood collection from patients under the age of 3 and patients with complicated, normal or deeper lying veins
	Black	22G	25	0,7	Blood collection from patients under the age of 3 and patients with complicated, superficial veins



Additive	Sign on label
with no additives	Z
with clot activator	Z
with clot activator, gel	Z
with thrombin	Z
with thrombin, gel	Z
with 3.2% sodium citrate	9NC
with 3.8% sodium citrate	9NC
with CTAD stabilizer (sodium citrate, theophylline, adenosine and dipyridamole)	CTAD
with lithium heparin	LH
with lithium heparin, gel	LH

Additive	Sign on label
with sodium heparin	NH
with ammonium heparin	AH
with K2EDTA	K2E
with K2EDTA, gel	K2E
with K2EDTA, aprotinin	K2E
with K3EDTA	K3E
with K3EDTA, aprotinin	K3E
with sodium fluoride, potassium oxalate	FXм
with sodium fluoride, K3EDTA	FE
with sodium fluoride, sodium heparin	FH
with K2EDTA, gel	K2E

Shelf life of Vacuum tubes

6 months
after sterilization, if trisodium citrate and CTAD are used as additives

18 months
after sterilization when other additives or no additives are used

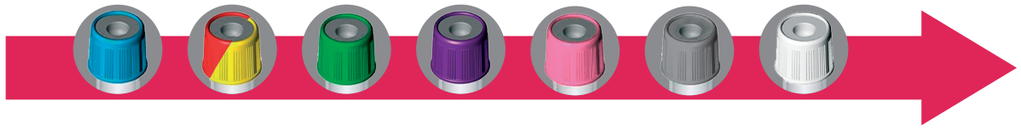
Transportation temperature from +2 to +35C°, maximum relative humidity 80% at +25C°

Storage temperature +4°C ... +25°C

Avoid direct sunlight

Maximum relative humidity 80% at +25°C

Order of tube filling



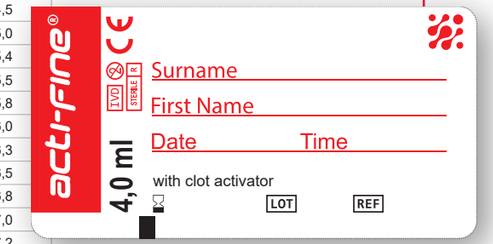
This order of blood collection complies with Practical Recommendations for Venous Blood Sample Collection for Laboratory Tests RFLM 02.04. 2021

Colour coding of the vacuum tubes (colour of safety cap and label for additive identification) complies with GOST ISO 6710, except for the tubes with no additives.

When using additives other than those specified in the table, the vacuum tubes must be identified by way of added description.

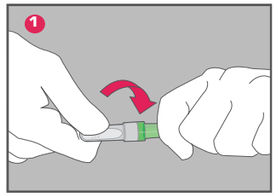
Type of test	Cap colour	Additive	Inverting rate	Minimal clotting time	Centrifugation conditions	Maximum time before test analysis
Secondary tubes, tubes for aliquoting	White	With no additives	–	60 min	2000g, 10 min, 25C°	3 hours
Testing of haemostasis system	Light-blue	Tri-sodium citrate (1:9) or CTAD	3-4	Tubes with anticoagulant	PRP-150 g, 5 min; PPP-1500-2000 g, 10 min; For analysis of plasma co-agulation factors or for deep freezing of plasma – 2000-2500 g, 20 min, 25°C	3 hours
Clinical chemistry, serology, EIA, bacteriology, for blood typing	Red	Silica (serum with silicon dioxide)	5-6	30 min	2000 g, 10 min, 25°C	3 hours
		Thrombin (express activator)		10 min		
	or yellow	Silica with separation gel (serum with silicon dioxide)		30 min	2500-3000 g, 10 min, 25°C	48 hours after centrifugation
		Thrombin with separation gel (express activator)		5 min		
Biochemistry, immunology, serology, immunohematology	Green	Heparin sodium, lithium or ammonium salt	8-10	Tubes with anticoagulant	2000 g, 10 min, 25°C	3 hours
		Heparin lithium salt with separation gel				48 hours after centrifugation
Haematology, immunochemistry, molecular diagnostics	Lavender	EDTA	8-10	Tubes with anticoagulant	2000 g, 10 min, 25°C	24 hours
		EDTA with separation gel			2500-3000 g, 10-15 min, 25°C	6 hours
Determination of unstable analytes-enzymes, hormones	Pink	EDTA and aprotinin	8-10	Tubes with anticoagulant	1800-2200 g, 10-15 min, 25°C	24 hours
Determination of blood sugar, lactate and glycosylat-ed haemoglobin	Grey	sodium fluoride, potassium oxalate	8-10	Tubes with anticoagulant	1800-2200 g, 10 min, 25°C	24 hours
		sodium fluoride and K3EDTA				
		sodium fluoride and sodium heparin				

A	B	C	D	E	F	G		H	
Type or kind of item, starting with 10		Additive		Vacuum volume		Variant		Label	
Number (AB)	Designation	Number (CD)	Designation	Number (EF)	Designation (mL)	Number (G)	Designation (mL)	Number (H)	Designation
10	tube 13×75	01	with clot activator	9	0,9	0	50	0	ordinary
		02	with clot activator and gel	10	1,0			1	pre-barcoded
		03	with lithium heparin	14	1,4			2	peel-off barcode
		04	with lithium heparin and gel	15	1,5	1	100	3	digital code
		05	with sodium heparin	18	1,8			4	peel-off digital code
		06	with ammonium heparin	20	2,0			A	customised (the number complies with the customer internal code)
11	tube 13×100	07	with K2EDTA	23	2,3			B	
		08	with K2EDTA and gel	25	2,5			...	
		09	with K3EDTA	27	2,7			Y	
		10	with thrombin	30	3,0			Z	
		11	with K3EDTA and aprotinin	32	3,2				
		12	with 3.2% sodium citrate	35	3,5				
12	tube 16×100	13	with 3.8% sodium citrate	36	3,6				
		14	with CTAD	40	4,0				
		15	with K2EDTA and aprotinin	41	4,05				
		16	with thrombin and gel	45	4,5				
		17	with sodium fluoride and potassium oxalate	50	5,0				
		18	with sodium fluoride and K3EDTA	54	5,4				
		19	with no additives	55	5,5				
		20	with sodium fluoride and sodium heparin	58	5,8				
		30	with no additives	60	6,0				
		31	with boric acid	63	6,3				
		32	with preservative	65	6,5				
				68	6,8				
				70	7,0				
				72	7,2				
				75	7,5				
				77	7,7				
				80	8,0				
				81	8,1				
				85	8,5				
				90	9,0				
				95	9,5				

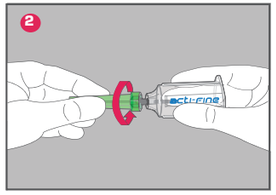


Unique identification number designating the quantity of certain items with similar components.

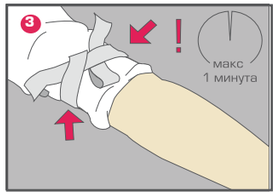
Single-use **Acti-Fine®** holder



Remove the safety cap from the valve part of the double-ended needle. If the label perforation is torn or damaged, throw the needle away.

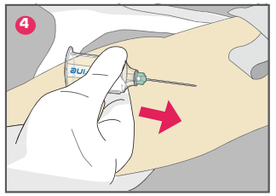


Screw the double-ended needle perpendicularly into the holder. Make sure the needle is fixed tightly.

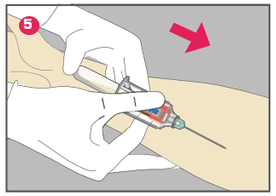


Apply a tourniquet 7–10 cm above the venipuncture site. Find a vein. Disinfect the venipuncture site twice in the direction from the centre to the periphery.

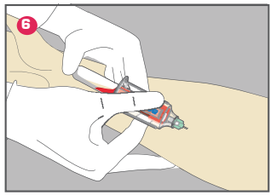
Sterile **Acti-Fine®** double-ended needle



Remove the other part of the cap from the double-ended needle. Perform venipuncture.

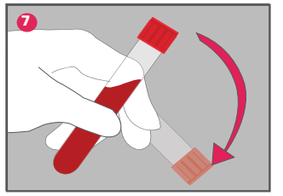


Insert the first tube into the holder so that the needle pierces the rubber part of the cap. Loosen or remove the tourniquet as soon as blood starts filling the first tube.

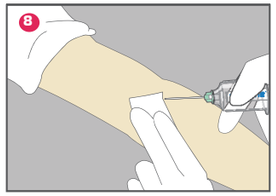


Blood will start filling the tube under negative pressure. As soon as blood stops flowing into the tube, remove it from the holder. If you need to fill several tubes, observe the recommended order of blood collection.

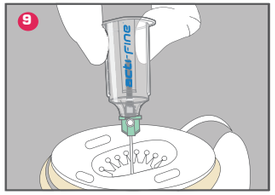
Sterile **Acti-Fine®** Vacuum Blood Collection Tube



Immediately after removing the tube from the holder, invert it 180° to mix the blood with the agent.
The inverting rate must comply with the instruction on the tubes.



As soon as blood fills the last tube, remove the double-ended needle from the vein carefully, at the same time pressing a dry sterile piece of cotton wool to the venipuncture site until it stops bleeding. After clotting, apply a bandage or antiseptic band-aid to the venipuncture site.



Put the used needles and holders into the special bins.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
от 23 марта 2021 года № РЗН 2019/8079

На медицинское изделие
Пробирки вакуумные "Acti-Fine®" для забора венозной крови с добавками и без по ТУ 32.50.50-001-00057974-2017

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская обл., г. Дубна, ул. Академика Кадышевского, д. 10

Производитель
Общество с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская обл., г. Дубна, ул. Академика Кадышевского, д. 10

Место производства медицинского изделия
ООО "Гранат Био Тех", Россия, 141980, Московская обл., г. Дубна, ул. Академика Кадышевского, д. 10

Номер регистрационного досье **№ РД-38971/105447 от 25.01.2021**

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.13.190**

Настоящее регистрационное удостоверение имеет приложение на 4 листах

приказом Росздравнадзора от 23 марта 2021 года № 2392
допущено к обращению на территории Российской Федерации
Заместитель руководителя Федеральной службы по надзору в сфере здравоохранения **Л.Ю. Павлюков**

0055873

Vacuum Tubes

Product Registration Certificate No. RZN 2019/8079
issued on 23 March 2021.
Acti-Fine® Vacuum Tubes meet the requirements of GOST R 50444, GOST ISO 6710.
TU 32.50.50-001-00057974-2017

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
от 15 июня 2020 года № РЗН 2020/10795

На медицинское изделие
Иглы двусторонние "Acti-Fine®" для взятия венозной крови с камерой вакуализации по ТУ 32.50.13-001-00057974-2019

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Производитель
Общество с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Место производства медицинского изделия
ООО "Гранат Био Тех", Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Номер регистрационного досье **№ РД-30434/80953 от 12.12.2019**

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.13.110**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 15 июня 2020 года № 4965
допущено к обращению на территории Российской Федерации
Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0046999

Double-ended needles

Product Registration Certificate No. RZN 2020/10795
issued on 15 June 2020.
Double-Ended Needles meet the requirements of GOST R 50444, GOST ISO 7864, GOST 19126, GOST ISO 11607-1

The Registration Certificate may be amended from.
To download the currently valid document, please use the link on the label.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
от 11 ноября 2020 года № РЗН 2020/12532

На медицинское изделие
Держатели одноразовые "Acti-Fine®" для вакуумных систем взятия венозной крови по ТУ 32.50.50-002-00057974-2020

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Производитель
Общество с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Место производства медицинского изделия
ООО "Гранат Био Тех", Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Номер регистрационного досье **№ РД-36385/60153 от 24.09.2020**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.50.190**

приказом Росздравнадзора от 11 ноября 2020 года № 10455
допущено к обращению на территории Российской Федерации
Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0052768

Holders

Product Registration Certificate No. RZN 2020/12532 issued on 11 November 2020.
Acti-Fine® Holders meet the requirements of GOST R 50444

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ
от 09 августа 2021 года № РЗН 2021/15036

На медицинское изделие
Пробирки вакуумные «Acti-Fine®» для сбора проб мочи по ТУ 32.50.50-003-00057974-2020

Настоящее регистрационное удостоверение выдано
Обществу с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Производитель
Общество с ограниченной ответственностью "Гранат Био Тех" (ООО "Гранат Био Тех"), Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Место производства медицинского изделия
ООО "Гранат Био Тех", Россия, 141980, Московская область, г. Дубна, ул. Академика Кадышевского, д. 10

Номер регистрационного досье **№ РД-41047/27168 от 26.04.2021**

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции по видам экономической деятельности **32.50.50.190**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 09 августа 2021 года № 7567
допущено к обращению на территории Российской Федерации
Руководитель Федеральной службы по надзору в сфере здравоохранения **А.В. Самойлова**

0068704

Urine collection tubes

Product Registration Certificate No. RZN 2021/15036
issued on 09 August 2021.
Acti-Fine® Vacuum Tubes meet the requirements of GOST R EN 14254

The Registration Certificate may be amended from.
To download the currently valid document, please use the link on the label.

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For product information or support on how to use our products, please contact Granat Bio Tech LLC

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