Samplix®

greiner BIO-ONE

CE

Evacuated Blood Collection System

EN

For In Vitro Diagnostic Use

Intended Use

Samplix® Evacuated Blood Collection Tubes are used for the collection of venous blood. Samplix® tubes are used to collect, transport, store and process blood for testing serum, plasma or whole blood in the clinical laboratory for professional use.

Product Description

Samplix® tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with colour-coded caps (see table below). The tubes, additive concentrations, and their permitted tolerances, are in accordance with the requirements and recommendations of the international standard ISO 6710 "Single-use containers for venous blood specimen collection" and the Clinical and Laboratory Standards Institute (CLSI). Additive choice depends on the analytical test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed. Tube interiors are sterile.

Samplix® Cap Colour Codes*

Description	Cap Colour
Serum Tubes	
CAT Serum Clot Activator	red
CAT Serum Sep Clot Activator (Gel Tubes)	dark yellow
Heparin Tubes	
LH Lithium Heparin	green
LH Lithium Heparin Sep (Gel Tubes)	light green
EDTA Tubes (haematology)	
K2E K2EDTA (also immuno haematology)	lavender
K3E K3EDTA (also immuno haematology)	lavender

***Example of standard colours. Colour may vary for specific order numbers and/or due to local requirements.**

Serum Tubes
All Serum tubes are coated with micronized silica particles which activate clotting when tubes are gently inverted.
Samplix® CAT Serum Sep tubes contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood clot and the serum. During centrifugation the barrier gel moves upward to the serum - clot interface, where it forms a stable barrier separating the serum from fibrin and cells. Serum may be aspirated directly from the collection tube, eliminating the need for transfer to another container.
Serum tubes are used for determinations in serum for routine clinical chemistry tests and hormones, serology, immunohaematology.

Heparin Tubes
The interior of the tube wall is coated with lithium heparin. The anticoagulant heparin activates antithrombin, thus blocking the coagulation cascade and producing a whole blood / plasma sample making it ideal for rapid analysis and analysis of blood from patients under anticoagulant therapy.
Samplix® LH Lithium Heparin Sep tubes contain a barrier gel that is present in the bottom of the tube. The specific gravity of this material lies between the blood cells and plasma. During centrifugation the gel barrier moves upward providing a stable barrier separating the plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container.
Heparin tubes are used for plasma determinations of routine clinical chemistry tests. Lithium determinations should not be performed in Lithium Heparin tubes.

EDTA Tubes
Samplix® K2EDTA tubes and K3EDTA tubes are used for testing whole blood in haematology. EDTA tubes may also be used for routine immunohaematology testing i.e. red cell grouping, Rh typing and antibody screens, viral marker testing in screening laboratories and molecular diagnostics. The interior of the tube wall is coated with either K2EDTA or K3EDTA. The EDTA binds calcium ions thus blocking the coagulation cascade.

Precautions/Cautions

1. Do not use tubes if foreign matter is present!
2. Handle all biological samples according to the policies and procedures of your facility.
3. Obtain appropriate medical attention in the case of any exposure to biological samples, since they may transmit HIV, viral hepatitis, or other bloodborne pathogens.
4. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
5. Transferring a sample from a syringe to a tube is not recommended. Additional manipulation of sharps increases the potential for needlestick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing 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 analysis results.
6. If blood is collected through an intravenous (IV) line, ensure that the line has been cleared of IV solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from IV fluid contamination.
7. The presence of ammonia is an intrinsic property of sterilized EDTA tubes. If used for determination of ammonia in human plasma, the establishment of a baseline is recommended. Alternatively, a lithium heparin plasma tube may be used if appropriate for the test method.
8. Do not use tubes after their expiration date.

Storage

Store tubes at 4–25°C (40–77°F).
***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, colouring, etc.)*

Limitation

1. Refer to the instrument assay's instructions for use for information on the correct sample material, correct storage and stability.
2. Heparin plasma should be separated from cells within 2 hours, either by centrifugation of gel tubes or by transferring plasma into a secondary container if no gel tubes are used. Primary Heparin Sep tubes are not recommended to be frozen.
3. Usual serum tubes are not suitable for the determination of trace elements.
4. Filled serum tubes can be frozen down to -20°C (-4°F). ***NOTE**: for detailed information see point Freezing/Thawing.*
5. During freezing process, the volume inside tubes should not be more than 2/3 of the nominal volume.
6. Not to be used at a high altitude from 1200 m (3937 ft) upwards.

Specimen Collection and Handling

READ THIS ENTIRE DOCUMENT BEFORE PERFORMING VENIPUNCTURE.
Equipment required for specimen collection.
Be sure that the following materials are readily accessible before performing venipuncture:
1. All necessary tubes, identified for size, draw and additive.
2. Disposable gloves and personal protective equipment.
3. Labels for positive patient identification of samples.
4. Blood collection needles and holders.
5. Alcohol swab for cleansing site.
6. Tourniquet.
7. Adhesive plaster or bandage.
8. Sharps disposal container for safe disposal of used material.

Recommended Order of Draw: (based on CLSI GP41ED7)
1 Blood culture
2 Sodium Citrate*
3 Serum / Serum Sep
4 Heparin / Heparin Sep
5 EDTA / EDTA Sep
6 Glycolytic inhibitor
7 Other additives

*When drawn first then only suitable for routine tests (i.e. PT and aPTT)
***NOTE**: If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, a discard tube is recommended to be drawn prior to ensure the proper blood-to-additive ratio.*
***NOTE**: Always follow your facility's protocol for order of draw*

Prevention of Backflow
Most evacuated blood collection tubes contain chemical additives. Therefore, it is important to avoid possible backflow from the tube, due to the possibility of adverse patient reactions. To prevent backflow from tube into the patient's arm, observe the following precautions:
1. Place patient's arm in a downward position.
2. Hold tube with the cap uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube contents do not touch cap or end of the needle during venipuncture.

Freezing/Thawing
Following the WHO recommendations (WHO/DIL/LAB/99.1 Rev.2), it is recommended to separate serum or plasma from blood cells for freezing process. Filled primary tubes withstand a freezing down to -20°C (-4°F). ***NOTE**: the total volume inside the tubes should not be more than 2/3 of the nominal volume. After complete filling of the tube during the blood collection, it may be necessary to remove serum or plasma from the centrifuged tube to obtain the correct fill volume for freezing.*
It is recommended to keep the centrifuged (according to the centrifugation recommendation) samples in the refrigerator for 2 hours prior to freezing. When the samples are cooled down, they can be transferred to the freezer at -20°C (-4°F). ***NOTE**: Freeze* Samplix® *tubes upright in an open metal rack.* Thawing is recommended at room temperature or in the refrigerator. After thawing, mix the sample thoroughly prior to analysis. ***NOTE**: it is only necessary to mix samples that contain a separator or have been aliquoted into a secondary tube.*
To achieve a clean heparin plasma, samples should be centrifuged and aliquoted before freezing.
For long-term storage it is recommended to use special cryo vials. Users should also establish their own freezing protocol.

Venipuncture Technique

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

1. Select tube or tubes appropriate for required specimen.
2. Remove the cover over the valve section of the needle.
3. Thread the needle into the holder. Be sure needle is firmly seated to ensure needle does not unthread during use. ***NOTE****: Do not bend the needle.*
4. Apply tourniquet as necessary (max. 1 minute).
5. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
6. Place patient's arm in a downward position.
7. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE CAP UPPER-MOST.
8. Push tube into the holder and onto the needle valve puncturing the rubber diaphragm. Centre tubes in holder when penetrating the cap to prevent sidewall penetration and subsequent premature vacuum loss. Always hold the tube in place with the thumb or finger to ensure complete vacuum draw. The fill mark allows for visual control of the correct filling of the tube. A tolerance of +/- 10% is allowed.
9. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE CAP OR END OF THE NEEDLE DURING PROCEDURE.
   NOTE*: Blood may occasionally leak from the needle sleeve. Practice universal standard precautions to minimize hazard exposure.*
   If no blood flows into tube or if blood flow ceases before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:
   a) Push tube forward until tube cap has been fully penetrated.
   b) Confirm correct position of needle in vein.
   c) If blood still does not flow, remove tube and place new tube onto the holder.
   d) If second tube does not draw, remove needle and discard. Repeat procedure from step 1.
10. When the first tube is full and blood flow ceases, gently remove it from holder.
11. Place succeeding tubes in holder, puncturing diaphragm to begin flow. Draw tubes without additives before tubes with additives. See recommended Order of Draw.
12. Gently invert the tubes immediately after blood collection to reach a proper mix of additive and blood. Turn the filled tube upside-down and return it to upright position. This is one complete inversion.
    NOTE*: Do not shake the tubes. Vigorous mixing may cause foaming or haemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and /or incorrect test results.*
13. As soon as blood stops flowing in the last tube, remove the tube and then the needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops. Once clotting has occurred, apply bandage if desired.
    NOTE*: After venipuncture, the top of the cap may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood. Any needle holder that becomes contaminated with blood is considered hazardous and should be disposed of immediately.*
14. Dispose of the used needle with holder using an appropriate disposal device. DO NOT RECAP. Recapping of needles increases the risk of needle stick injury and blood exposure.
    It is the laboratory's ultimate responsibility to verify that a change from one tube to another does not significantly affect analytical results obtained from patient samples.

NOTE*: Keep the tubes, especially serum, in an upright position.*

Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier; incomplete seating could result in the separation of the cap from the tube.
NOTE*: Samplix® Serum tubes should be centrifuged 30 minutes after blood collection to minimize post clotting (fibrin build up) in serum. This could lead to contamination of the analyser and to erroneous results.*
Blood from patients under anticoagulant therapy or patients with coagulation disorders might need longer than 30 minutes to clot. Serum tubes should be allowed to fully clot prior to centrifugation.

Tube Type	Inversions (mixing)	Recommended g-force relative centrifugal force (rcf)	Time (min)
Serum tubes / with Sep	5-10x	1800 - 2200 g	10-15
EDTA tubes			
Heparin Plasma tubes / with Sep			

Other centrifugation settings may also provide acceptable separation. ***NOTE****: Do not centrifuge higher than 3000 g*. Plasma tubes should ideally be centrifuged at 2200 g. It should be evaluated and validated by the laboratory (e.g. increased g-force and/or decreased time).
Tubes with a separator should be spun in a centrifuge with horizontal swing-out rotors to obtain a stable barrier.
NOTE: *If the gel movement is occasionally not adequate (especially due to a haematocrit >50%), it is recommended to use a higher g-force and longer centrifugation time.*
It is recommended that centrifugation temperature be maintained at 15-25°C (50°-77°F). Ideal separation of serum or plasma is achieved in this temperature range. Higher temperatures could have negative effects on the physical properties of the gel.
NOTE*: Tubes should be centrifuged no later than 2 hours after collection. Extended contact of blood cells with the serum or plasma, may lead to erroneous analysis results, hence centrifugation might be necessary sooner depending on the analyte. It is not recommended to re-centrifuge gel tubes once the barrier has been formed. The debris underneath the gel might contaminate the supernatant.*

Caps

The Samplix® Evacuated Blood Collection Tube cap can be removed with a simple pull action.

Disposal

1. The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
2. Disposable gloves prevent the risk of infection.
3. Contaminated or filled blood collection tubes must be disposed of in suitable biohazard disposal containers, which can then be autoclaved and incinerated afterwards.
4. Disposal should take place in an appropriate incineration facility or through autoclaving (steam sterilisation).

Label Information

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		*In vitro* diagnostic medical device
	Sterilized using irradiation		

References:
ISO / EN / ANSI/AAMI Standards
ISO 6710 “Single-use containers for venous blood specimen collection”
EN 14820 “Single-use containers for human venous blood specimen collection”
ISO 11137 ”Sterilisation of health care products – Requirements for validation and routine control – Radiation sterilisation”

Literature:
GP39-A6 "Tubes and Additives for Venous and Capillary Blood Specimen Collection", Approved Standard - 6th Edition
GP41-Ed7 "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture", Approved Standard - 7th Edition
GP44-A4 ”Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests”, Approved Guideline – 4th Edition
H20-A2 ”Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods”, Approved Standard - 2nd Edition.
H26-A2 ”Validation, Verification, and Quality Assurance of Automated Hematology Analyzers”, Approved Standard – 2nd Edition.
World Health Organisation (WHO) ”Use of anticoagulants in Diagnostic Laboratory Investigations” WHO/DIL/LAB/99.1 Rev.2

Greiner Bio-One GmbH
Bad Haller Str. 32,
4550 Kremsmünster, Austria

www.samplix-blc.com
office@at.gbo.com
Phone +43 7583 6791