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APPLICATION

NOTE

Use and Application of
VACUETTE® FC Mix Tubes

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GLUCOSE STABILIZATION RIGHT FROM THE BEGINNING

Diabetes is amongst the top ten leading causes of death in the United States, affecting approx. 10 % of the population. There are 26.8 million Americans diagnosed with diabetes and the American Diabetes Association estimates that there are another 7.3 million people who currently remain undiagnosed.¹

On the other side of the globe, in China, the numbers look similar. With a prevalence of around 114 million people, diabetes also affects 11.5 % of the total population.²

The International Diabetes Federation (IDF) estimates that the global number of 463 million adults will rise to 700 million within the next 20 years. There are another 374 million people at risk of developing type 2 diabetes and governments as well as social organizations are encouraged to prioritize diabetes care and control. The IDF further recommends initiatives that not only increase awareness, but also guarantee appropriate care and resources to tackle all impacts of the disease. Besides extensive approaches to develop lifestyle programmes to promote healthy choices and reduce risk factors, research and data acquisition is of high importance.³ There is a need to extend screening and diabetes monitoring.

Different tests are used to help diagnose diabetes such A1C (HbA1c), Fasting Plasma Glucose or Oral Glucose Tolerance Test and other analytes that play a role in metabolism. High glucose levels could also just be indicated at random glucose tests and need to be observed⁵.

CHALLENGES IN GLUCOSE DETERMINATION

Time from collection until separation of plasma and cells, temperature as well as cell count strongly affect glucose levels possibly leading to false low results. It can subsequently lead to clinical misdiagnosis and incorrect patient therapy followed by increased health costs. Therefore, most laboratories use tubes containing an inhibitor to prevent an in-vitro drop due to glycolysis. The most common stabilizer is sodium fluoride which is used in blood collection tubes to preserve glucose. Unfortunately, fluoride alone is not able to stabilize the in-vivo glucose level immediately. It inhibits the enzyme enolase in the glycolytic pathway (see Fig.1) to prevent the degradation of glucose without any effect within the first few hours.⁶

Studies show that the loss of glucose can be as much as up to 12mg/dl (of the initial 100mg/dl) glucose within the first 2 hours at room temperature⁷. In samples of patients with leukemia, glucose can drop by as much as 10-20%, depending on cell count⁸. Since the publication of guidelines and recommendations⁹ for the analysis of glucose for diabetes management, several studies and reports^[10; 11] have been published on the effect of citrated fluoride samples for the determination of in-vivo glucose concentration.

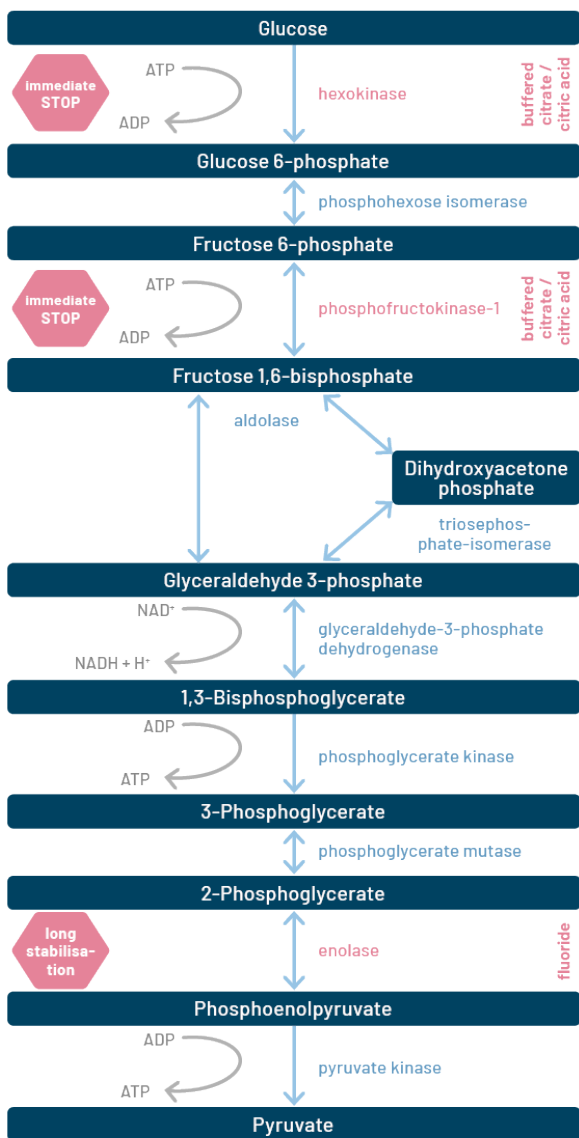


Figure 1: Effect of additives on glycolysis¹⁶

PERFORMANCE OF SODIUM FLUORIDE AND CITRATE (FC)

VACUETTE® FC Mix Tubes are citrated and therefore can help to prevent the initial loss of glucose within the first few hours from collection, until fluoride shows its effect. Buffered Na₂EDTA, citric acid, sodium citrate and sodium fluoride are used to decrease the pH and block the pH dependent enzymes, which would be active in the initial stage of the glycolysis cascade¹². The immediate stabilization leads to in-vivo glucose values without the unpredictable loss.

Performance evaluations¹⁴ were carried out to analyze the glucose stability in VACUETTE® FC Mix Blood Collection Tubes (see Table 1).

When whole blood is stored at room temperature, the glucose concentration is stable for up to 24 hours.

Centrifuged plasma samples are stable for up to 48 hours at room temperature or at 4-8°C. These samples were centrifuged within 20 minutes after collection.

48 hours stability is also possible, when whole blood is kept cool directly after collection and remains at 4-8°C.

	Whole Blood	Plasma	
	<i>Immediate refrigeration increases the stability to up to 48 hrs</i>	<i>Immediate centrifugation (within 20 minutes) increases the stability to up to 48 hrs</i>	
24 hours stability	20-25 °C (room temperature)	4-8 °C (refrigerated)	20-25 °C (room temperature)
48 hours stability	4-8 °C (refrigerated)	4-8 °C (refrigerated)	20-25 °C (room temperature)

Table 1: Glucose stability in VACUETTE® FC Mix Tubes under various storage conditions

PRODUCT APPLICATION

MIXING OF TUBES

The FC Mix additive is a powder which ensures that there is no dilution effect due to any liquid, but it does require thorough mixing. Ten full inversions are needed to mix the additive with the patient's blood sample right after collection. This is an important step that supports full functionality of all ingredients.¹⁵



Figure 2: Turning the tubes upside down and back is one full inversion.

ORDER OF DRAW

Because the additive is a mixture of different chemicals, the tubes should be collected late in the order of draw similar to regular fluoride tubes too.¹⁵

- / (Blood Culture)
- / Sodium Citrate
- / Serum
- / Heparin
- / EDTA
- / Sodium Fluoride

CENTRIFUGATION

To obtain plasma, the tubes should be centrifuged at 1800g for 10 minutes¹⁵.

HANDLING SUMMARY^[14; 15]

- / To ensure optimal glucose stabilization, the tubes must be inverted 10x directly after blood collection.
- / Early centrifugation of blood cells help stabilize in-vivo glucose.
- / Collect late in the order of draw.
- / Should the tubes be expected to be stored longer than 24 hours at room temperature, samples should be centrifuged immediately after blood collection to be stored for up to 48 hours at room temperature.
- / To obtain plasma, the tubes should be centrifuged at 1800g for 10 minutes.
- / Centrifuged aliquots (i.e. plasma) from VACUETTE® FC Mix Tubes can be stored for up to 48 hours at room temperature. Tubes should be centrifuged as soon as possible.
- / Refrigerating of the samples (4–8 °C, 39– 46 °F) is also suitable for 48 hours for glucose stabilization in plasma or whole blood.

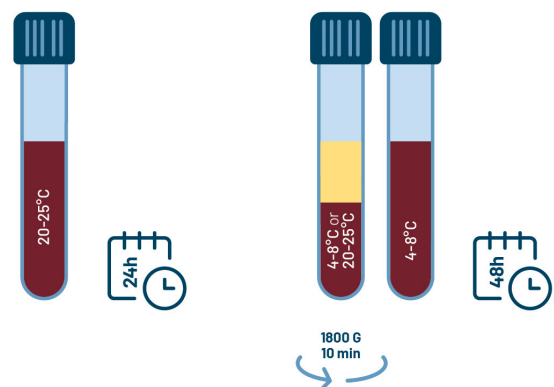


Figure 3: Stability of sample material at different storage conditions.

FAQS

How often does the tube have to be inverted?

10 full inversions are recommended.

Can I use a partially filled tube?

It is not recommended to use an incorrectly filled tube. For accurate results, correct ratio of additive to blood must be ensured.

What are the centrifugation settings?

1800g for 10 minutes

Can I also measure lactate in FC Mix tubes?

No, due to the pH change. The intended use is glucose determination.

Why do my samples become haemolytic?

There's a variety of reasons such as fluoride itself and the influence of time and collection method. To a certain degree this does not influence the results. Feel free to contact Technical Services for more information.

How long are the samples stable?

This depends on time and temperature. See IFU 980200 or Table 1 in this document.

How soon do I need to centrifuge the tubes to extend the stability to 48 hours?

In performance studies, tubes were centrifuged within 20 minutes after collection.

What is the benefit over standard fluoride tubes?

With VACUETTE® FC Mix tubes the variable loss within the first 2 hours of collection can be avoided. The glucose value is stabilized at time of collection.

SPECIFICATIONS

VACUETTE® FC Mix Tubes

Legal manufacturer	Greiner Bio-One GmbH Bad Haller Str. 32 A-4550 Kremsmünster
Sterility	Sterile interior: SAL 10 ⁻⁶ (SAL = Sterility Assurance Level)
Material	PET tube, PE cap, PP ring, synthetic rubber stopper
Latex and Phthalates	none used
Additive	Buffered Na ₂ EDTA, citric acid, sodium citrate and sodium fluoride
Product Storage Before Use	Store tubes at 4-25°C (40-77°F). General 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.)
Packaging	24 racks of 50 pcs., 1200 pcs. in total



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