

Evaluation of new **MiniCollect[®]** FX Sodium Fluoride/Potassium Oxalate Tubes

Background:

Greiner Bio-One has developed a newly designed MiniCollect[®] tube offering an integrated collection scoop. The advantage of the new tube is that capillaries and funnels are not needed to facilitate blood transfer from the puncture site into the MiniCollect[®] tube.

The MiniCollect[®] FX Sodium Fluoride/Potassium Oxalate capillary blood collection tube is also featured with a co-molded cap which can easily be removed during the collection and sampling process.

The interior of the tube is coated with spray-dried Sodium Fluoride and Potassium Oxalate. Potassium Oxalate acts as anticoagulant and Sodium Fluoride stabilizes the blood glucose and lactate levels.

MiniCollect[®] FX Sodium Fluoride/Potassium Oxalate tubes are intended for use for testing of glucose and lactate (lactic acid).

Study Objective:

A clinical evaluation was carried out to compare the performance of the new MiniCollect[®] FX Sodium Fluoride/Potassium Oxalate tube in comparison to old design of MiniCollect[®] Sodium Fluoride/Potassium Oxalate tube including 20 healthy subjects.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	MiniCollect [®] Glucose FX Sodium Fluoride/Potassium Oxalate 0.5 ml, spray dried (item No.:450482), old design
B	MiniCollect [®] Glucose FX Sodium Fluoride/Potassium Oxalate 0.5 ml, spray dried (item No.:450542), new design

The study has been approved by Ethics Commission. Informed consent has been given by all participants.

Directly after blood collection with venous blood, the tubes were carefully inverted according to the instructions for use for MiniCollect[®] blood collection tubes. Glucose was tested within 4 hours of collection using an AU680 instrument from Beckman Coulter. Analysis was performed with the instrument's accompanying reagents.

Determined parameters:

- Glucose
- Lactate

Conclusion:

Performance of the new MiniCollect® FX Sodium Fluoride/Potassium Oxalate tube with the co-molded cap and integrated scoop has been demonstrated in comparison to the old MiniCollect® FX Sodium Fluoride/Potassium Oxalate tube on the basis of the analytes tested.

Only results of 17 donors have been achieved because the venipuncture was not successful in case of 3 blood donors.

When comparing both tubes, the correlation was very high ($r = 0.99$) and no systematic deviation occurred. Statistically significant deviation was shown for Glucose without analytically significant difference.

Systematic deviations were not obtained for lactate either and the correlation found for both tubes was high ($r = 0.99$). Statistically significant deviation has been found, however those are not clinically relevant.

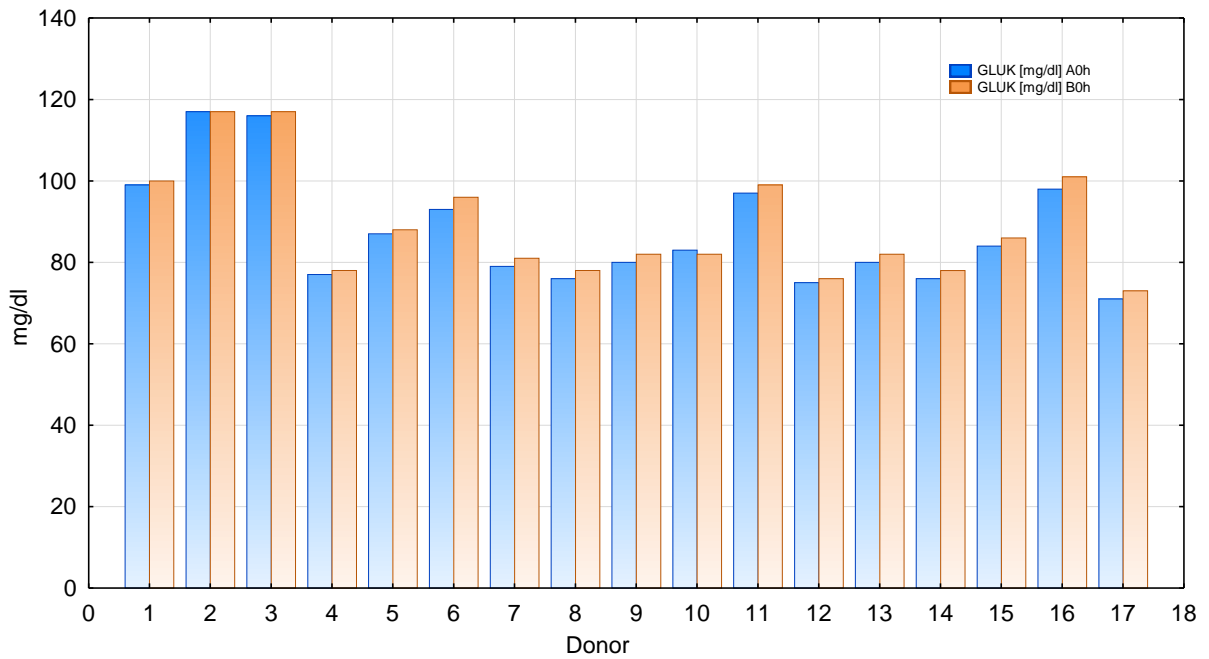
In summary, despite the deviations and results that have been found, the MiniCollect® FX Sodium Fluoride/Potassium Oxalate tube with the new design is substantially equivalent to the MiniCollect® FX Sodium Fluoride/Potassium Oxalate tube with the old design.

References:

- (1) Greiner Bio-One. MiniCollect® FX Sodium Fluoride/Potassium Oxalate Tubes. Instructions for Use. Kremsmünster, Austria. 2016.
- (2) Greiner Bio-One. MiniCollect® Product Manual. Kremsmünster, Austria. 2016.
- (3) Guideline published by the Chamber Association for Medical Practitioners of the State of Germany concerning the quality assurance of quantitative analyses of Medical Laboratories, Germany (2001). Rev.2003
- (4) ISO 6710:1995(E), *Single-use containers for venous blood specimen collection*. International Standard. 1995
- (5) EP07-A2: *Interference Testing in Clinical Chemistry*; Approved Guideline – Second Edition, CLSI 2011.
- (6) EP09-A2-IR: *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline — Second Edition (Interim Revision). CLSI 2011.
- (7) H01-A6: *Tubes and Additives for Venous and Capillary Blood Specimen Collection*; Approved Standard – Sixth Edition CLSI 2011
- (8) H04-A6: *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens* – Approved Standard – Sixth Edition CLSO 2011
- (9) RILIBÄK: Guideline of the German Medical Association for Quality Assurance.

Glucose (Gluc)

Normal range: 74 - 106 mg/dl



Lactate (LAC)

Normal range: 10 - 22 mg/dl

