Evaluation of new MiniCollect® Lithium Heparin (Separator) 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® Lithium Heparin Separator capillary blood collection tube is also featured with a co-molded cap which can easily be removed during the collection and sampling process.

Clotting is inhibited by the presence of a spray dried Lithium Heparin coating the interior of the tube. Heparinised plasma is the virtually cell-free supernatant following the centrifugation of whole blood. Heparin works by accelerating the inhibition of factor Xa by antithrombin III.

MiniCollect® Lithium Heparin (Separator) Tubes are used to collect, transport, separate and process capillary blood for testing plasma in the clinical laboratory.

Study Objective:
A clinical evaluation was carried out to compare the performance of the new MiniCollect® LH Lithium Heparin Separator tube in comparison to old design of MiniCollect® LH Lithium Heparin Separator tube including 50 healthy and 81 pathological subjects.

Study design:
The following tube types were used in this study:

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>A</td>
<td>MiniCollect® Lithium Heparin Separator 0.8ml (Item No.: 450479), old design</td>
</tr>
<tr>
<td>B</td>
<td>MiniCollect® Lithium Heparin Separator 0.8 ml (Item No.: 450535), new design</td>
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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 8 times according to the instructions for use for MiniCollect® blood collection tubes. After blood collection, the tubes were centrifuged within 120 min in a temperature controlled centrifuge (15-25°C) for 10 min at 3000g. (centrifuge: Eppendorf 5810R, swing bucket) The listed analytes were tested using an AU680 and DxI800 from Beckman Coulter. Analysis was performed with the instruments’ accompanying reagents.

Determined parameters:
- Albumin
- Alkaline phosphatase (ALP)
- Lactate Dehydrogenase (LDH)
- Alanine Transaminase (ALT)
- Aspartate Transaminase (AST)
- Gamma-glutamyl Transpeptidase (GGT)
- Uric Acid
- Total Bilirubin
- Cholesterol
- Triglyceride
- Sodium
- Potassium
- Chloride
- Calcium
- Phosphate
Conclusion:
Performance of the new MiniCollect® LH Lithium Heparin Separator tube has been demonstrated in comparison to the old MiniCollect® LH Lithium Heparin Separator tube on the basis of the analytes tested.

Healthy subjects: On the basis of the parameter tested, the performance of both tubes was comparable, although slight deviations have been found for GGT, glucose, LDH, fT3, TSH, potassium and LDH with a slight tendency to a systematical deviation between both tubes for glucose and uric acid as well as for potassium (within analytical tolerance range) and LDH, however without clinical significance.

Pathological subjects: Statistically significant deviations have been found for the following parameters: albumin, calcium, cholesterol, phosphate, potassium, magnesium, total protein, uric acid, TSH, CK, and total bilirubin. All statistically significant deviations have been found to be in a clinically acceptable range and the deviations were not analytically significant. The correlation of these parameters between both samples was very high ($r > 0.97$) with LDH, GGT and total bilirubin being analytically significant. The deviation found for LDH and GGT extend to both directions and indicate a random error. The deviation of total bilirubin was systematically but in a clinically acceptable range. Deviations have been found for LDH but did not lead to any systematic differences. The mean values and standard deviations did not reveal differences at all.

Total Bilirubin indicates very slight systematic deviations, but in a clinically acceptable range. Subject 43 has shown high deviations for the parameters ALP, ALT, AST, GGT, LDH, Triglyceride, and Urea which most likely have been caused by preanalytical errors.

In summary, despite the deviations and results that have been found, the MiniCollect® LH Lithium Heparin Separator tube with the new design is substantially equivalent to the MiniCollect® LH Lithium Heparin Separator tube with the old design.

References:
(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


(9) RILIBÄK: Guideline of the German Medical Association for Quality Assurance.

**Results in detail:**

Albumin (Alb) Normal range: 35 - 52 g/l

Healthy subjects

![Graph showing healthy subjects Albumin levels](image)

Pathological subjects

![Graph showing pathological subjects Albumin levels](image)

Correlation: r = 0.99179

![Graph showing correlation](image)

Correlation: r = 0.99415

![Graph showing correlation](image)
Lactate Dehydrogenase (LDH) Normal range: (f) < 247 U/l   (m) < 248 U/l

Healthy subjects

Pathological subjects

Alanine transaminase (ALT) Normal range: (m) < 50 U/l (f) < 35 U/l

Healthy subjects

Pathological subjects
Aspartate transaminase (AST) Normal range: (m) < 50 U/l (f) < 35 U/l

Healthy subjects

Pathological subjects

Gamma-glutamyl Transpeptidase (GGT) Normal range: (f) < 55 U/l (m) < 38 U/l

Healthy subjects

Pathological subjects
Alkaline Phosphatase (ALP) Normal range: 60 - 200 U/I

Healthy subjects

Pathological subjects

Correlation: $r = 0.99864$

Glucose (Gluc) Normal range: 74 - 106 mg/dl

Healthy subjects

Pathological subjects

Correlation: $r = 0.99246$
Uric Acid (UA) Normal range: (f) 3.5 - 7.2 mg/dl  (m) 2.6 - 6.0 mg/dl

Healthy subjects

Pathological subjects

Total Bilirubin (TBili) Normal range: 0.3 - 1.2 mg/dl

Healthy subjects

Pathological subjects
Cholesterol (Chol) Normal range: < 200 mg/dl

Healthy subjects

Pathological subjects

Correlation: r = 0.99884

Correlation: r = 0.99614

Triglyceride (TG) Normal range: normal ≤ 150 < borderline high < 200 high < 500 very high

Healthy subjects

Pathological subjects

Correlation: r = 0.99981

Correlation: r = 0.99221
Sodium (Na) Normal range: 136 - 146 mmol/l

Healthy subjects

Pathological subjects

Potassium (K) Normal range: Plasma 3.4 - 4.5 mmol/l

Healthy subjects

Pathological subjects
Chloride (Cl) Normal range: 101 - 109 mmol/l

Healthy subjects

Pathological subjects

Correlation: \( r = 0.94407 \)

Correlation: \( r = 0.97304 \)

Calcium (Ca) Normal range: 2.20 - 2.65 mmol/l

Healthy subjects

Pathological subjects

Correlation: \( r = 0.99072 \)

Correlation: \( r = 0.97553 \)
Phosphate (Phos) Normal range: 0.81 - 1.45 mmol/l

Healthy subjects

Pathological subjects

Magnesium (Mg) Normal range: (f) 0.73 - 1.06 mmol/l   (m) 0.77 - 1.03 mmol/l

Healthy subjects

Pathological subjects
Iron Normal range: (f) 12.5 - 32.2 µmol/l  (m) 10.7 - 32.2 µmol/l

Urea Normal range: 17 - 43 mg/dl
Creatine Kinase (CK) Normal range: (f) ≤ 171 U/l     (m) ≤ 145 U/l

Healthy subjects

Pathological subjects

Total Protein (TP) Normal range: 66 - 83 g/l
Free Triiodothyronine (fT₃) Normal range: 2.5 - 3.9 pg/ml

Healthy subjects

Pathological subjects

Free Thyroxine (fT₄) Normal range: 0.61 - 1.12 ng/dl

Healthy subjects

Pathological subjects
Thyroid-stimulating Hormone (TSH) Normal range: 0.1 - 3.5 μIU/ml

Healthy subjects

Pathological subjects

Cortisol Normal range: morning 6.7 - 22.6 μg/dl afternoon > 10 μg/dl

Healthy subjects

Pathological subjects