Evaluation of new MiniCollect® 9NC Coagulation Tubes

**Background:**
Venous blood with sodium citrate is the most commonly obtained examination sample for coagulation determinations. The additive functions as an anticoagulant by chelating calcium. Greiner Bio-One has developed a newly designed MiniCollect® 9NC Coagulation tube offering an integrated collection scoop. The MiniCollect® 9NC Coagulation blood collection tube is also featured with a colour coded co-molded cap which can easily be removed during the collection and sampling process.

MiniCollect® Coagulation tubes are plastic, non-evacuated, sterile low sample volume tubes with a pre-defined nominal volume for achieving correct additive concentrations. The MiniCollect® 9NC Coagulation tube wall contains a 3.2% tri-sodium citrate dehydrate/citric acid monohydrate solution in accordance with the requirements of the international standards for evacuated blood collection systems - ISO 6710, CLSI H01-A6.

MiniCollect® 9NC Coagulation Tube is intended for collection of citrate anticoagulated whole blood samples for coagulation assays.

**Study Objective:**
A clinical evaluation was carried out to compare the performance of the MiniCollect® 9NC Coagulation tube with new design in comparison to the VACUETTE® 9NC Coagulation tube by enrolling 20 healthy donors.

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

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>VACUETTE® 9NC Coagulation (3.2%) 1 ml, (item No.: 454320)</td>
</tr>
<tr>
<td>B</td>
<td>MiniCollect® 9NC Coagulation (3.2%) 1 ml (item No.: 450413), new design</td>
</tr>
</tbody>
</table>

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

Directly after venous blood collection, the tubes were carefully inverted 5 times according to the instructions for use for MiniCollect® blood collection tubes. The tubes were centrifuged within 2h after blood collection in a temperature controlled centrifuge (15-24°C, swing-out bucket, Eppendorf 5415R) for 10 min at 3000g. Analysis was performed on an ACL Top 500 with the instrument’s accompanying reagents.

**Determined parameters:**
- Prothrombin time (PT)
- International normalized ratio (INR)
- Activated partial thromboplastin time (aPTT)
- Fibrinogen
- Factor Anti-Xa
Conclusion:
Performance of the new MiniCollect® 9NC Coagulation tube with integrated scoop and co-molded cap demonstrated equivalent performance to the VACUETTE® 9NC Coagulation tube for the coagulation parameters tested.

aPTT:
Statistically significant deviations (P<0.5) have been found between VACUETTE® 9NC Coagulation tube and MiniCollect® 9NC Coagulation tube with the new design. The deviations between both tubes were not clinically significant. Therefore equivalent performance can be confirmed for MiniCollect® 9NC Coagulation tube with new design and VACUETTE® 9NC Coagulation tube.

Anti-Xa:
Equivalent performance has been demonstrated between all samples. A slight deviation has been found in VACUETTE® tubes compared to MiniCollect® tubes without statistical significance and in a clinically acceptable range.

Fibrinogen:
Equivalent performance has been observed between all samples.

Prothrombin Time (PT, QUICK) and INR:
Statistically significant and systematic deviations have been observed between VACUETTE® 9NC Coagulation tubes and MiniCollect® 9NC Coagulation tubes regarding PT and INR. The difference has been assessed as being clinically not significant.

In summary, despite the deviations and results that have been found, the MiniCollect® 9NC Coagulation tube with new design is substantially equivalent to the VACUETTE® 9NC Coagulation tube.

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:
Prothrombin time (Quick) (Normal range: 80-130%)

Correlation: $r = 0.96668$
aPTT (Normal range: 25-37 sec.)

Correlation: $r = .95508$
**Fibrinogen** (Normal range: 1.89-5.94 g/l)

**Graph 1:**
- **X-axis:** Donor
- **Y-axis:** Fibrinogen in mg/dl
- **Legend:**
  - Blue: sample A Fib
  - Orange: sample B Fib
- **Correlation:** $r = 0.93896$

**Graph 2:**
- **X-axis:** sample A Fib
- **Y-axis:** sample B Fib
- **Correlation:** $r = 0.95$
- **95% Confidence Interval:**

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**Graphs:**
- The first graph shows the distribution of Fibrinogen levels across different donors for samples A and B.
- The second graph illustrates the correlation between sample A Fib and sample B Fib, with a high correlation coefficient.
Factor Anti-Xa (Normal range: 0.4 - 1 IU/ml (therapeutic) 0.2-0.4 IU/ml (prophylactical))
International normalized ratio (INR) Normal range: ~1 (0.8 - 1.2)