COMPATIBILITY BETWEEN PRODUCTS FROM LEGAL MANUFACTURERS SOL-MILLENNIUM AND GREINER BIO-ONE

SCOPE
In order to show and prove the compatibility between products from legal manufacturers Sol-Millennium and Greiner Bio-One tests were planned and conducted. All relevant combinations between the products were considered and tested. The products were used according to the valid instructions for use. All deviations during testing had to be documented.
Following combinations of products were tested during GBO internal test protocol spp1005:

<table>
<thead>
<tr>
<th>Legal manufacturer Sol-Millennium</th>
<th>Legal manufacturer Greiner Bio-One</th>
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<tbody>
<tr>
<td>VACUETTE® SAFETY Winged Set + Luer Adapter</td>
<td>+ VACUETTE® Standard Tube Holder</td>
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<tr>
<td>VACUETTE® SAFETY Winged Blood Infusion Set</td>
<td>+ VACUETTE® Luer Adapter sterile</td>
</tr>
<tr>
<td>VACUETTE® SAFETY Winged Set + Holder</td>
<td>+ VACUETTE® Blood Collection Tube (all dimensions; 13x75, 16x100 &amp; ESR)</td>
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TEST SETTING
All combinations listed under 1. Scope were tested according to GBO internal testing procedure (vvo133) in a simulated use approach. The products were tested regarding following aspects:
- Proper fitting of all components (luer adapter in holder, tube in holder, mal in female luer)
- Leakage between male and female luer
- Leakage at luer connection or needle sleeve after 9 tubes are attached
- Loosening (disengagement) of any component during use
- Arbitrary visual deviations

For both combinations VACUETTE® SAFETY Winged Set with Luer Adapter + VACUETTE® Standard Tube Holder and VACUETTE® SAFETY Winged Blood Infusion Set + VACUETTE® Luer Adapter sterile both available item numbers (21 G & 23G) with 20 samples per item number were tested.

For the combination VACUETTE® SAFETY Winged Set + Holder + VACUETTE® TUBE (all dimensions; 13x75, 16x100 & ESR) one item number with 50 samples was tested (no second item number necessary since holder is identical for all item numbers/gauges).

Per combination each product was tested with 9 tubes (3x 13/75, 3x 16/100 and 3x ESR). After each tube the products were evaluated for previously defined aspects.

RESULT
The results show a full compatibility between products from legal manufacturers Sol-Millennium and Greiner Bio-One. The fitting of all components was given initially and after 9 tubes were attached. No leakage or loosening (disengagement) of any components during use was observed.
In total 130 VACUETTE® SAFETY Winged Sets were tested with a total of 1170 VACUETTE® TUBES.

CONCLUSION
Based on the results we Greiner Bio-One and Sol-Millennium hereby confirm the compatibility of product combinations (defined in chapter 1) of legal manufacturers Sol-Millennium and Greiner Bio-One.