Evaluating the Suitability of Instruments to be used for Quantitative Haemoglobin (Hb) testing of SANBS Donors

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SANBTC –Sun City
28-31 August 2017
Background

• Current donor screening Method in SANBS
• Copper Sulphate (SG: 1,0530g/cm³ ± 0, 0005)
• Failed Copper Sulphate Test – Determine Hb using Hemocue Instruments
• Initiated a tender to implement quantitative Hb screening methods for all donor collection sites (mobile and fixed)
• Instruments received for evaluation included:
  1. Hemospect (Non-invasive, finger scanning)
  2. Hemochromax
  3. Hemocue Hb 201
  4. Hemocue Hb 301
• The Advia 2120 is the current SANAS ISO17025 accredited instrument used in SANBS for Hb testing and used as the gold standard for this evaluation
Instruments Evaluated

- Hb 301
- Hb 201
- Hemochromax
- Hemospect
Acceptance Criteria

- Results obtained using manufacturer’s control must be within acceptable ranges (Refer to package inserts).
- Precision / Reproducibility must be <2SD, <0.15 as per current QC Criteria
- Comparison of Hb for instrument to the Advia must have correlation >0.80
Method

• Tested daily control samples on all instruments according to manufacturer’s instrument manual.
• Tested control material in duplicate, for 5 consecutive days in the morning and in the afternoon, recorded results.
  – No control material available for Hemospect
• Tested minimum of 30 donor Hb samples using instruments and Siemens Advia 2120 in QC
• Reviewed and analysed results
Method Cont.

• Comparison was done twice:
  – Using venous on POC instruments and Advia (32 volunteers)
  – Using capillary samples on POC and venous sample on Advia (38 volunteers)
  – In both instances the Hemospect finger scanning was compared to the venous samples on Advia
Method Cont.

• Precision was measured by determining the SD of 20 replicates of manufacturer’s controls run over 5 days.

• Sensitivity and specificity was measured by dichotomizing results to <12.5 (sensitivity) or >12.5 (specificity)
## Results

<table>
<thead>
<tr>
<th>Summary</th>
<th>Expected result</th>
<th>Hemospect (Non-invasive)</th>
<th>HemoChromax</th>
<th>HemoCue 201</th>
<th>HemoCue 301</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accuracy</td>
<td>Complies (Yes/No)</td>
<td>N/A</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Precision</td>
<td>&lt;2SD, &lt;0.15</td>
<td>N/A</td>
<td>0.04 / 0.06</td>
<td>0.09 / 0.06</td>
<td>0.09 / 0.13</td>
</tr>
<tr>
<td>Correlation (venous/capillary)</td>
<td>&gt;0.80</td>
<td>0.46</td>
<td>0.93</td>
<td>0.87</td>
<td>0.85</td>
</tr>
<tr>
<td>Correlation (venous)</td>
<td>&gt;0.80</td>
<td>0.46</td>
<td>0.97</td>
<td>0.99</td>
<td>0.99</td>
</tr>
<tr>
<td>Specificity (venous/capillary)</td>
<td>&gt;95.0</td>
<td>80.6</td>
<td>97.2</td>
<td>97.2</td>
<td>97.2</td>
</tr>
<tr>
<td>Specificity (venous)</td>
<td>&gt;95.0</td>
<td>85.19</td>
<td>88.89</td>
<td>92.59</td>
<td>100.00</td>
</tr>
<tr>
<td>Sensitivity (venous/capillary)</td>
<td>&gt;95.0</td>
<td>0</td>
<td>50.0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Sensitivity (venous)</td>
<td>&gt;95.0</td>
<td>20.00</td>
<td>100.00</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>
Correlation

Hb of 38 subjects using 5 platforms (capillary & venous)

Hb of 32 subjects using 5 platforms (Venous sample)
Correlation to Gold Standard

Venous (Advia) / Capillary (POC)

Venous (Advia & POC)
Correlation to Gold Standard

Venous (Advia) / Capillary (POC)

- Venous (Advia & POC)
Discussion

• Manufacturer control results met the specifications indicated in the respective package inserts, specifically for accuracy and reproducibility.
• No accuracy & precision results for Hemospect
• Correlation obtained using venous (Advia) and capillary (POC)samples are lower than using venous sample only
• Correlation for Hemospect and Advia was poor for both groups.
Sensitivity and Specificity

• Sensitivity was measured as a proportion of subjects with Advia Hb<12.5 of which the test being assessed gives the right answer. Advia <12.5 = True Positive. Only 2 donors had Hb of <12.5 when using venous/capillary samples and 5 donors when using venous samples only, hence not sufficient data to analyse.

• Specificity was measured as the proportion of subjects that have an Hb of >12.5 by Advia of which the test being evaluated gives the correct answer. Advia > 12.5 = True Negative. Low Specificity, 80.6 (V/C) on the Hemospect would result in large number of donors being deferred.
Conclusion

- Hemochromax and both Hemocue instruments are suitable for the determination of Hb levels of SANBS donors.
- The correlation obtained between the non-invasive Hemospect instrument and the Advia instrument is 0.46 making it unsuitable for use in SANBS.
- It should be noted that there is a difference in correlation using venous and capillary samples when measuring Hb.
- Bigger study will have to be conducted to conclude on sensitivity and specificity.
- The use of both venous and capillary samples for this study makes the SANBS study particularly robust.
Acknowledgement

• SANBS QC
• SANBS Donor Collections
• Volunteers
Thank you