Developing *H*ealth Technology

a GORDON-KEEBLE GP division

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Evgueni Ovenessov
President of
TECHNOMEDICA
ul. Kasatkina, 7
Moscow 129301
RUSSIA.

June 22, 1998

Dear Mr. Ovanessov,

Please find attached our report of a trial carried out for us at Edinburgh Paediatric Hospital comparing the hospital laboratory Sysmex Hb meter and your MiniHem 523 portable Hb meter.

This test was a simple comparison between the two instruments in order to check the accuracy and reproducibility of the MiniHem against an acceptably accurate Hb meter.

Ideally the MiniHem would have been tested against an absolute standard, but for our purposes a confirmation that the instrument is comparable to a UK hospital standard is satisfactory.

I am pleased to confirm that the report indicates that this is the case and we are keen to introduce this instrument into our product range.

Best regards,

James P. Manfield.
(Manager).

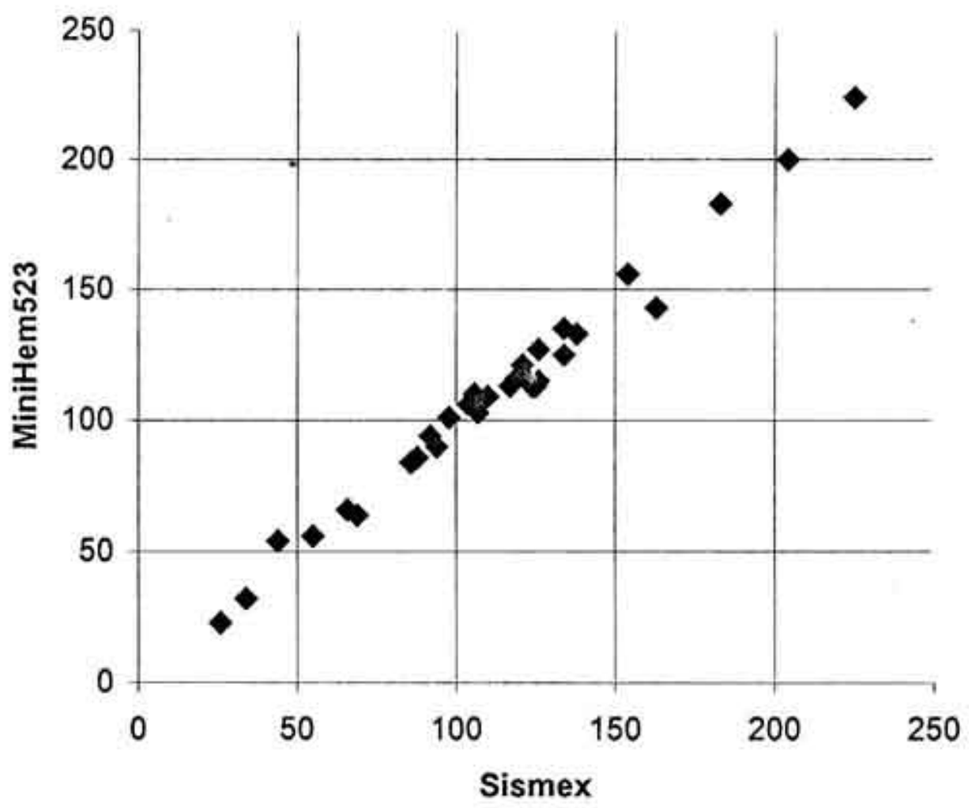
Comparison of SE9000 HgB Estimations and MiniHem 523 Estimations

The following trial was performed at Edinburgh Paediatric Hospital, UK in October 1997.
The MiniHem 523 Portable Haemoglobinometer manufactured by Technomedica, Russia was tested alongside the hospital laboratory Sysmex SE9000 instrument.
Testing was performed on behalf of Developing Health Technology, UK. by Dr. T. Healy.
This report is written by Developing Health Technology.

Temperature: 22°C
Reagents: 0.04% Ammonia
Whole Blood between 4 and 24 hours old, random selection, anticoagulated using EDTA stored at room temperature before analysis.
Analysed samples = 31

Sysmex	MiniHem
26	23
34	32
44	54
55	56
66	66
69	64
86	84
88	86
92	94
94	90
98	101
104	106
106	110
107	103
110	109
117	113
119	116
121	121
123	115
124	113
125	113
126	115
126	127
134	135
134	125
138	133
154	156
163	143
183	183
204	200
225	224

Correl.	Slope
0.99211	1.02213



The instrument offers good reproducibility and it was found to correlate exceptionally well at low levels @ 30-70 (Anaemia levels) and the variance at 'normal' levels is not clinically significant. There appeared to be a larger variance in values from neonates due to transient HbF but this was not studied in depth as the main use for Developing Health Technology would not be on neonates. For the higher levels found in polycythaemia it may be that a double dilution of the sample may suffice to bring values into a level where the correlation is acceptable.

Conclusion

As most of our customers are in developing countries, our conclusion is based on what is suitable for their needs. In our market there has been a need for such a device as this, which offers accuracy at a reasonable cost. We are favourably impressed with the ruggedness and ease of use of the instrument. The lack of expensive or difficult to obtain consumables is also a big plus point along with the various options for power supply (may be run on standard or re-chargeable batteries or from the mains). The MiniHem offers a vastly superior accuracy over the low cost - but unsatisfactory - visual comparison instruments that are available, but is still at an affordable price. Our one criticism is that the appearance could be made more aesthetically pleasing; but as for its practicality and accuracy, for the price we could not fault it.