



Biosensor Technology Multi-parameter Measurement





Accuracy Evaluation of β -Ketone Monitoring System

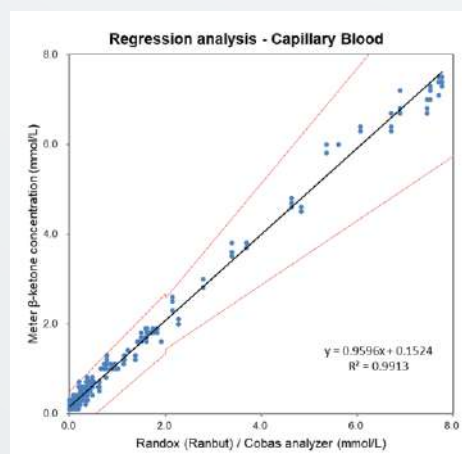
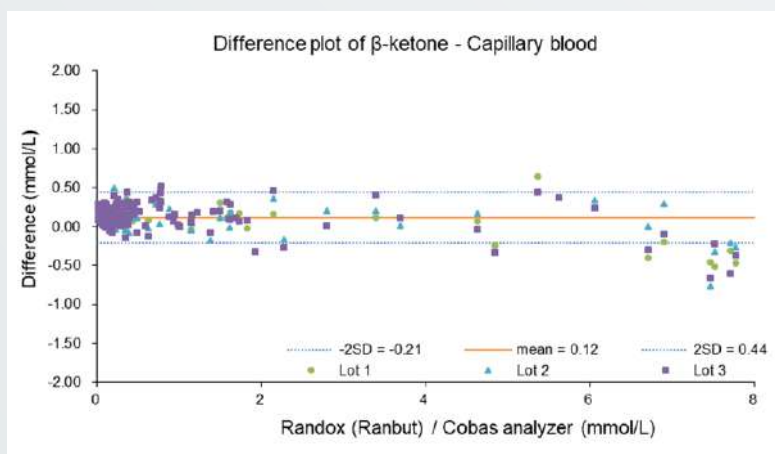


- The report was conducted by using three different lots of β -ketone test strips with capillary and venous whole blood sample.
- This clinical accuracy study was carried out from a total of 160 subjects, aged between 20 and 87.
- The reference method is the Randox D-3 Hydroxybutyrate (Ranbut) assay on the Cobas c311 analyzer.
- Good correlation was found between β -ketone test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9913$; slope = 0.9596 and intercept = 0.1524, $n=480$).
- The study showed accurate performance with 99.5% of the capillary blood ketone values fell within ± 0.5 mmol/L of the reference ketone concentrations ≤ 2 mmol/L. And 97.9% of the capillary blood ketone values fell within $\pm 20\%$ of the reference ketone concentrations > 2 mmol/L.
- Out of total 480 tests, 99.4% results fell in the range of ± 0.5 mmol/L & $\pm 20\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is ≤ 2 mmol/L, 99.5% of the test results fell within ± 0.5 mmol/L.
- When the reference concentration is > 2 mmol/L, 97.9% of the test results fell within $\pm 20\%$.

β-ketone meter with test strips	Overall		Test results of the β-ketone device fulfilling specified error limit at β-ketone concentrations ≤2 mmol/L			Test results of the β-ketone device fulfilling specified error limit at β-ketone concentrations >2 mmol/L				
	Within ±									
	n	±0.5mmol/L or 20%	n	±0.3mmol/L	±0.5mmol/L	n	5%	10%	15%	20%
Capillary blood (Subjects, N=160)	480	477 (99.4%)	432	393 (91.0%)	430 (99.5%)	48	23 (47.9%)	41 (85.4%)	46 (95.8%)	47 (97.9%)
Venous blood (Subjects, N=160)	480	480 (100%)	387	353 (91.2%)	387 (100%)	93	56 (60.2%)	85 (91.4%)	92 (98.9%)	93 (100%)

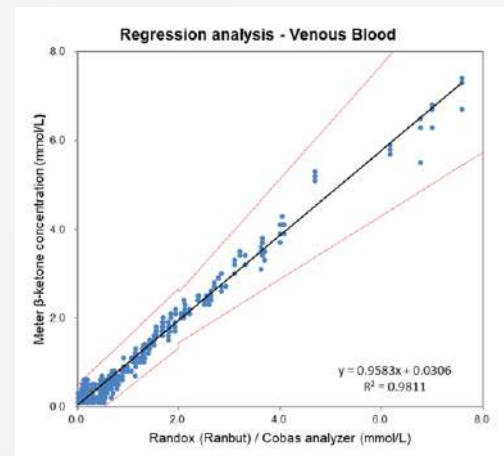
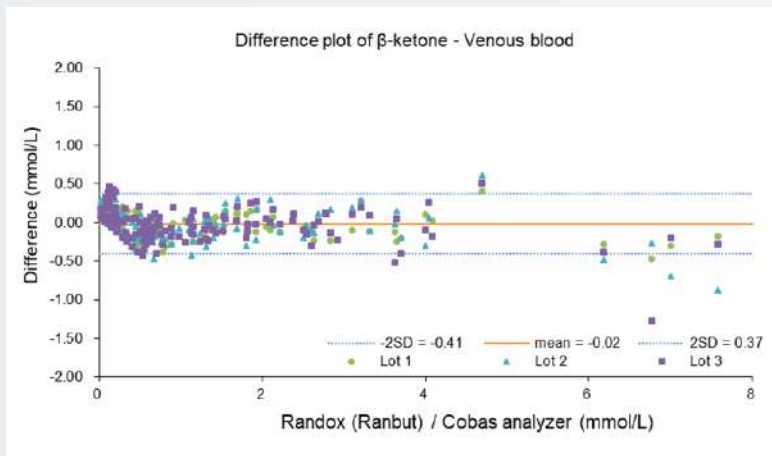


- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.21 to 0.44 mmol/L. The mean difference plot showed a small negative bias of 0.12 mmol/L.

Venous Blood Test Result

- When the reference concentration is ≤ 2 mmol/L, 100% of the sample results fell within ± 0.5 mmol/L.
- When the reference concentration is > 2 mmol/L, 100% of the sample results fell within $\pm 20\%$.

β-ketone meter with test strips	Overall		Test results of the β-ketone device fulfilling specified error limit at β-ketone concentrations ≤2 mmol/L			Test results of the β-ketone device fulfilling specified error limit at β-ketone concentrations >2 mmol/L				
	Within ±									
	n	±0.5mmol/L or 20%	n	±0.3mmol/L	±0.5mmol/L	n	5%	10%	15%	20%
Capillary blood (Subjects, N=160)	480	477 (99.4%)	432	393 (91.0%)	430 (99.5%)	48	23 (47.9%)	41 (85.4%)	46 (95.8%)	47 (97.9%)
Venous blood (Subjects, N=160)	480	480 (100%)	387	353 (91.2%)	387 (100%)	93	56 (60.2%)	85 (91.4%)	92 (98.9%)	93 (100%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.41 to 0.37 mmol/L. The mean difference plot showed a small negative bias of -0.02 mmol/L.



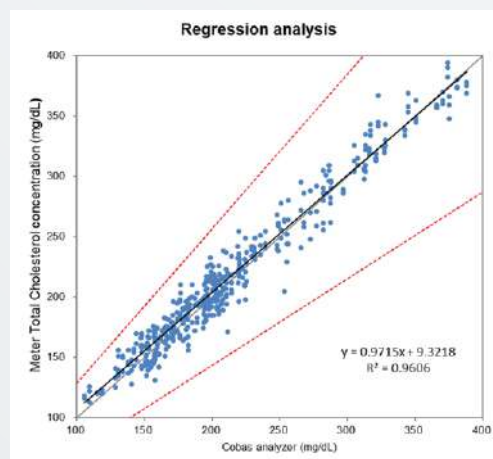
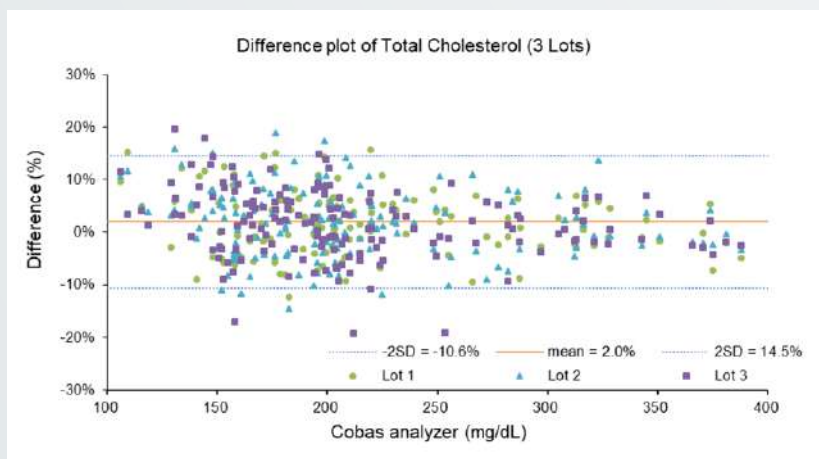
Accuracy Evaluation of Total Cholesterol Monitoring System

- The report was conducted by using three different lots of total cholesterol test strips on capillary whole blood sample.
- This clinical accuracy study was carried out from a total of 160 subjects, aged between 20 and 87.
- The comparative reference was cholesterol reagent method on the Cobas analyzer.
- Good correlation was found between total cholesterol test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9606$; slope = 0.9715 and intercept = 9.3218, $n=480$).
- The study showed accurate performance with 97.5% of the capillary blood sample measured total cholesterol values fell within $\pm 15\%$ of the reference total cholesterol measurement at concentrations > 100 mg/dL.
- Out of total 480 tests, 97.5% results fell in the range of $\pm 15\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is > 100 mg/dL, 97.5% of the capillary blood sample results fell within $\pm 15\%$.

Total cholesterol meter with test strips	Subjects (N=)	Test results of total cholesterol device fulfilling specified error limits at total cholesterol concentrations > 100 mg/dL (> 2.58 mmol/L)				
		Test results (n=)	Within $\pm$			
			5%	10%	15%	20%
Capillary blood	160	480	266 (55.4%)	420 (87.5%)	468 (97.5%)	480 (100%)

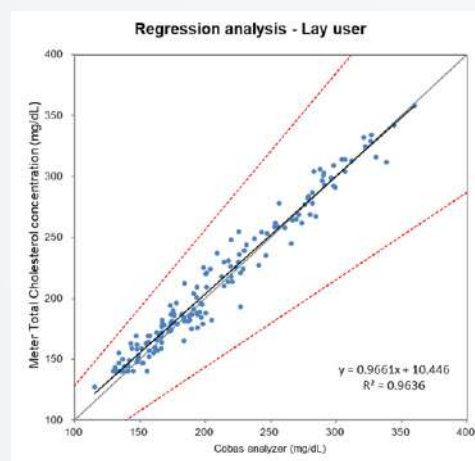
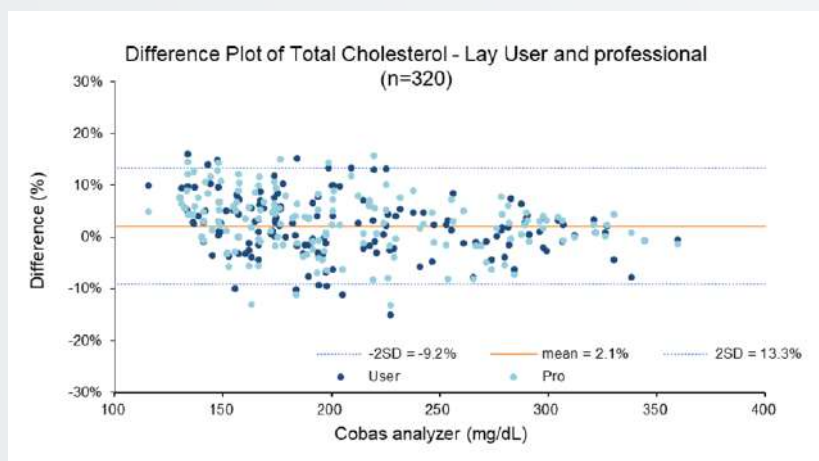


- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -10.6% to 14.5%. The mean difference plot showed a small bias of 2.0%.

End User Test Result

- When the reference concentration is > 100 mg/dL, 98.8% of the capillary blood sample results fell within $\pm 15\%$.

Total cholesterol meter with test strips	Subjects (N=)	Test results of total cholesterol device fulfilling specified error limits at total cholesterol concentrations >100 mg/dL (>2.58 mmol/L)				
		Test results (n=)	Within $\pm$			
			5%	10%	15%	20%
User performance	160	160	100 (62.5%)	145 (90.6%)	158 (98.8%)	160 (100%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -9.2% to 13.3%. The mean difference plot showed a small bias of 2.1%.



Accuracy Evaluation of Uric Acid Monitoring System

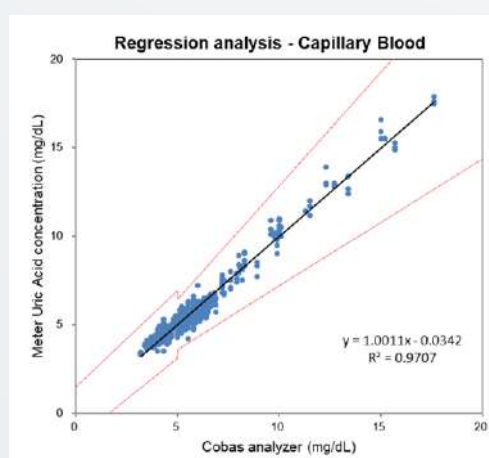
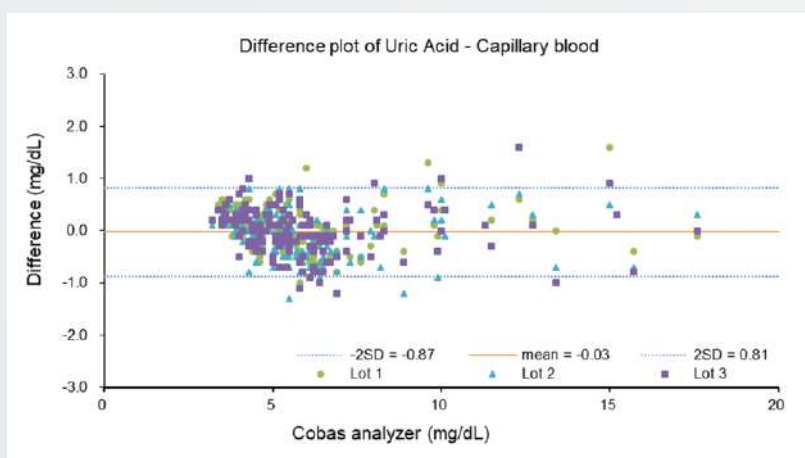


- The report was conducted by using three different lots of uric acid test strips on capillary whole blood sample.
- This clinical accuracy study was carried out from a total of 160 subjects, aged between 20 and 87.
- The comparative reference was uric acid reagent method on the Cobas analyzer.
- Good correlation was found between uric acid test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9707$; slope = 1.0011 and intercept = 0.0342, $n = 480$).
- The study showed accurate performance with 97.4% of the capillary blood sample measured uric acid values fell within $\pm 15\%$ of the reference uric acid measurement at concentrations $> 5\text{mg/dL}$.
- Out of total 480 tests, 97.4% results fell in the range of $\pm 15\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is $> 5\text{ mg/dL}$, 97.4% of the capillary blood sample results fell within $\pm 15\%$.

Uric acid meter with test strips	Overall		Test results of the uric acid device fulfilling specified error limit at uric acid concentrations ≤5 mg/dL			Test results of the uric acid device fulfilling specified error limit at uric acid concentrations >5 mg/dL				
	Within ±									
	n	±1.5 mg/dL or 20%	n	±0.8 mg/dL	±1.5mg/dL	n	5%	10%	15%	20%
Capillary blood (Subjects, N=160)	480	479 (99.8%)	171	169 (98.8%)	171 (100%)	309	173 (56.0%)	266 (86.1%)	301 (97.4%)	308 (99.7%)

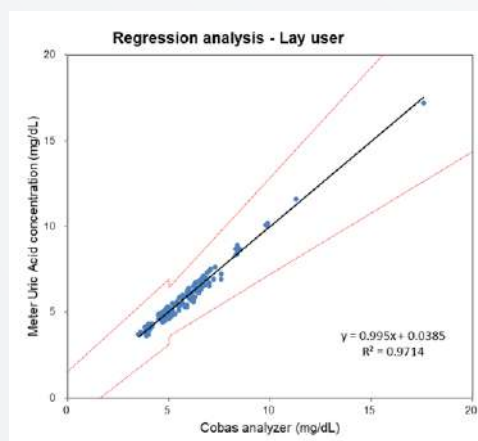
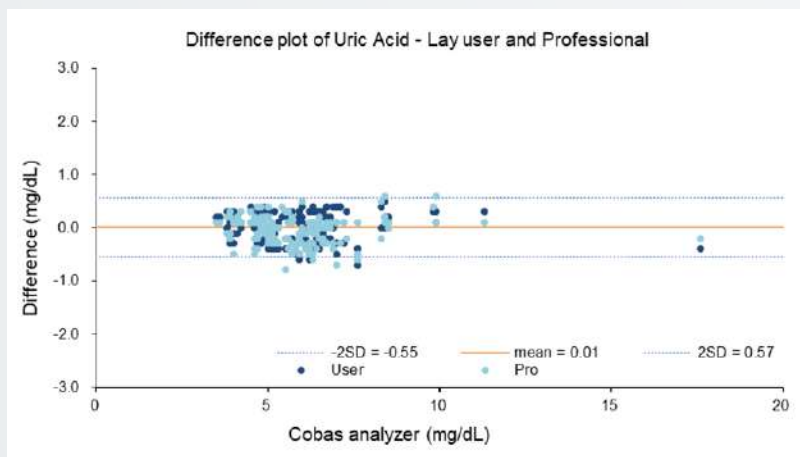


- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.87 mg/dL to 0.81 mg/dL .
The mean difference plot showed a small bias of -0.03 mg/dL .

End User Test Result

- When the reference concentration is > 5 mg/dL, 100% of the capillary blood sample results fell within $\pm 15\%$.

Uric acid meter with test strips	Overall		Test results of the uric acid device fulfilling specified error limit at uric acid concentrations ≤5 mg/dL			Test results of the uric acid device fulfilling specified error limit at uric acid concentrations >5 mg/dL				
	Within ±									
	n	±1.5 mg/dL or 20%	n	±0.8 mg/dL	±1.5mg/dL	n	5%	10%	15%	20%
User performance (Subjects, N=160)	160	160 (100%)	52	52 (100%)	52 (100%)	108	71 (65.7%)	107 (99.1%)	108 (100%)	108 (100%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.55 mg/dL to 0.57 mg/dL. The mean difference plot showed a small bias of 0.01 mg/dL.



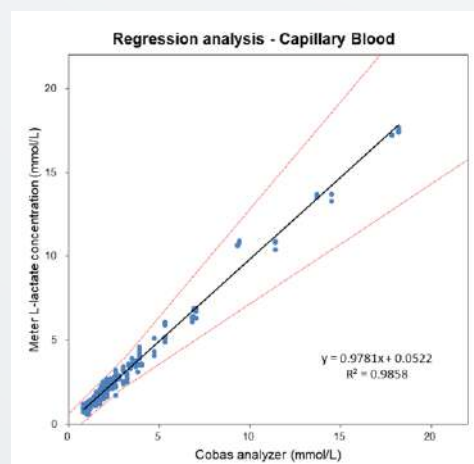
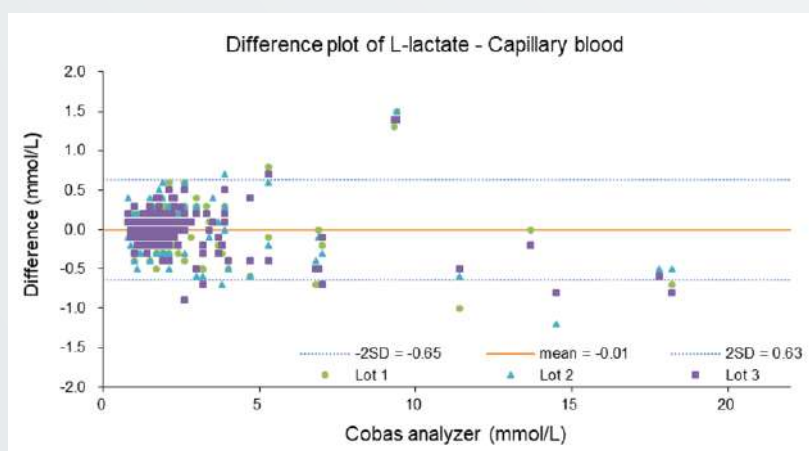
Accuracy Evaluation of Lactate Monitoring System

- The report was conducted by using three different lots of lactate test strips on capillary and venous whole blood sample.
- This clinical accuracy study was carried out from a total of 160 subjects, aged between 20 and 87.
- The comparative reference was lactate reagent method on the Cobas analyzer.
- Good correlation was found between lactate test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9858$; slope = 0.9781 and intercept = 0.0522, $n=480$).
- The study showed accurate performance with 85.7% of the capillary blood sample measured lactate values fell within $\pm 15\%$ of the reference lactate measurement at concentrations $> 3\text{ mmol/L}$.
- Out of total 480 tests, 85.7% results fell in the range of $\pm 15\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is $> 3\text{ mmol/L}$, 85.7% of the capillary blood sample results fell within $\pm 15\%$.

L-lactate meter with test strips	Overall		Test results of the L-lactate device fulfilling specified error limit at L-lactate concentrations ≤3 mmol/L			Test results of the L-lactate device fulfilling specified error limit at L-lactate concentrations >3 mmol/L				
	Within ±									
	n	±0.6 mmol/L or 20%	n	±0.3 mmol/L	±0.6 mmol/L	n	5%	10%	15%	20%
Capillary blood (Subjects, N=160)	480	477 (99.4%)	396	356 (89.9%)	394 (99.5%)	84	27 (32.1%)	60 (71.4%)	72 (85.7%)	83 (98.8%)

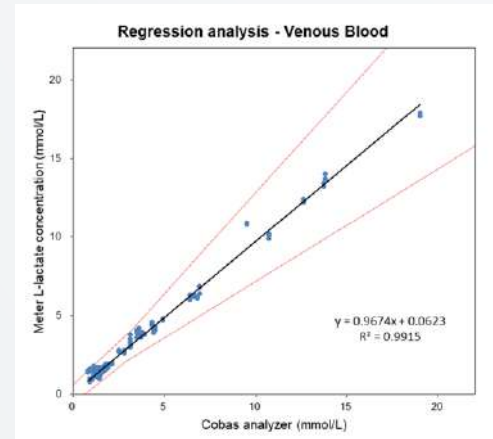
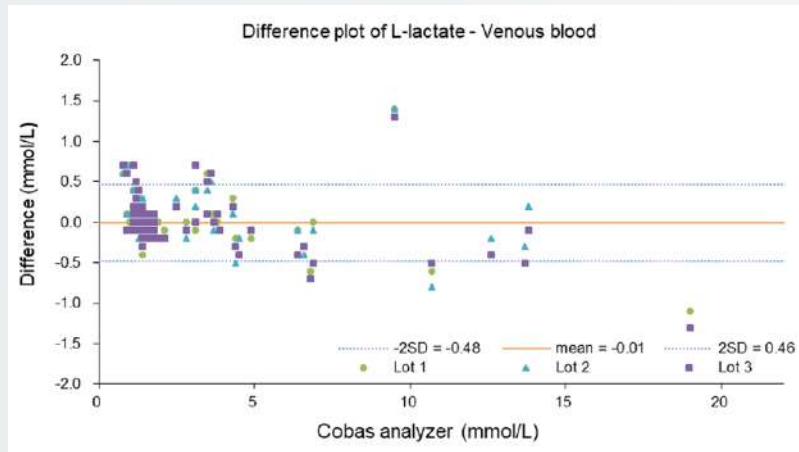


- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.65 mmol/L to 0.63 mmol/L . The mean difference plot showed a small negative bias of -0.01 mmol/L .

Venous Blood Test Result

- When the reference concentration is > 3 mmol/L, 93.9% of the capillary blood sample results fell within $\pm 15\%$.

L-lactate meter with test strips	Overall		Test results of the L-lactate device fulfilling specified error limit at L-lactate concentrations ≤3 mmol/L			Test results of the L-lactate device fulfilling specified error limit at L-lactate concentrations >3 mmol/L				
	Within ±									
	n	±0.6 mmol/L or 20%	n	±0.3 mmol/L	±0.6 mmol/L	n	5%	10%	15%	20%
Venous blood (Subjects, N=160)	480	475 (99.0%)	414	400 (96.6%)	410 (99.0%)	66	37 (56.1%)	51 (77.3%)	62 (93.9%)	65 (98.5%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.48 mmol/L to 0.46 mmol/L. The mean difference plot showed a small bias of 0.01 mmol/L.



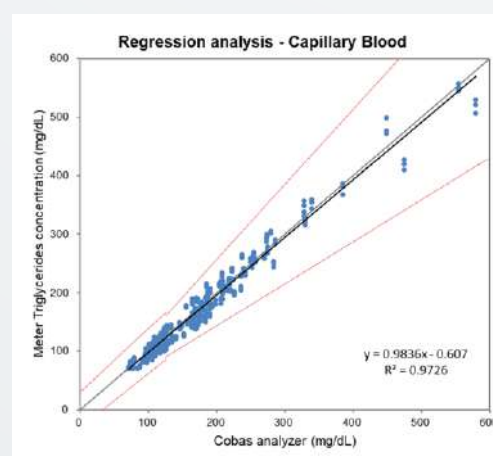
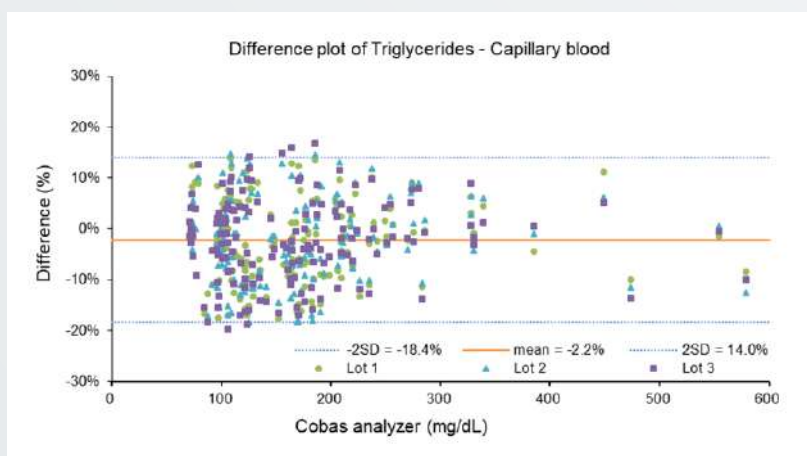
Accuracy Evaluation of Triglycerides Monitoring System

- The report was conducted by using three different lots of triglycerides test strips on capillary whole blood sample.
- This clinical accuracy study was carried out from a total of 160 subjects, aged between 20 and 87.
- The comparative reference was triglycerides reagent method on the Cobas analyzer.
- Good correlation was found between triglycerides test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9726$; slope = 0.9836 and intercept = -0.607 mg/dL, $n = 960$).
- The study showed accurate performance with 94.6% of the capillary blood sample measured triglycerides values fell within $\pm 15\%$ of the reference triglycerides measurement at concentrations > 125 mg/dL.
- Out of total 480 tests, 94.6% results fell in the range of $\pm 15\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is > 125 mg/dL, 94.6% of the capillary blood sample results fell within $\pm 15\%$.

Triglycerides meter with test strips	Overall		Test results of the triglycerides device fulfilling specified error limit at triglycerides concentrations ≤125 mg/dL				Test results of the triglycerides device fulfilling specified error limit at triglycerides concentrations >125 mg/dL				
	Within ±										
	n	±20 mg/dL or 20%	n	±10 mg/dL	±15 mg/dL	±20 mg/dL	n	5%	10%	15%	20%
Capillary blood (Subjects, N=160)	480	476 (99.2%)	204	150 (73.5%)	185 (90.7%)	200 (98.0%)	276	114 (41.3%)	206 (74.6%)	261 (94.6%)	276 (100%)

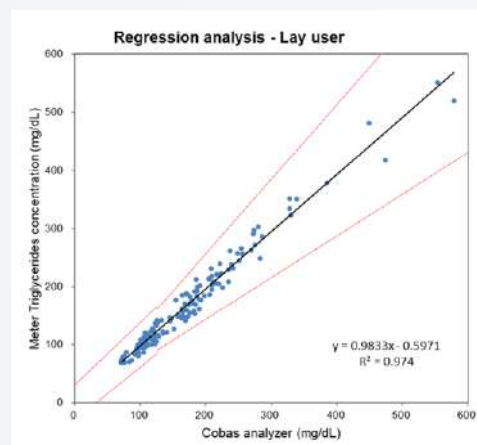
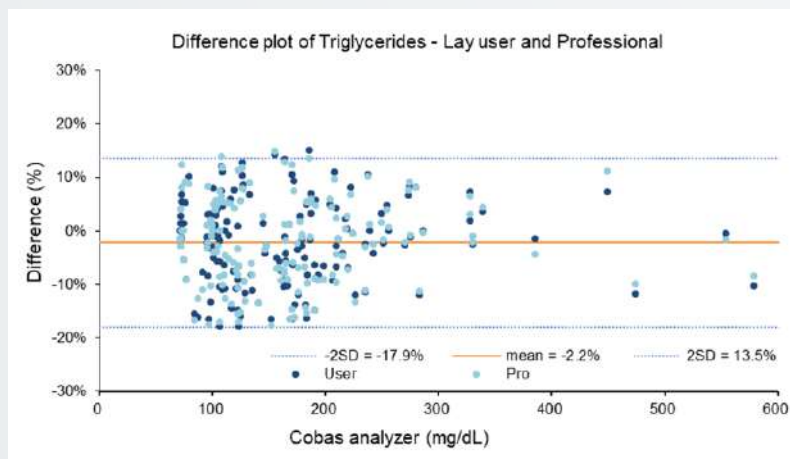


- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -18.4% to 14.0%. The mean difference plot showed a small bias of -2.2%.

End User Test Result

- When the reference concentration is > 125 mg/dL, 94.6% of the capillary blood sample results fell within $\pm 15\%$

Triglycerides meter with test strips	Overall			Test results of the triglycerides device fulfilling specified error limit at triglycerides concentrations ≤125 mg/dL			Test results of the triglycerides device fulfilling specified error limit at triglycerides concentrations >125 mg/dL				
	Within ±										
	n	±20 mg/dL or 20%	n	±10 mg/dL	±15 mg/dL	±20 mg/dL	n	5%	10%	15%	20%
User performance (Subjects, N=160)	160	159 (99.4%)	68	50 (73.5%)	62 (91.2%)	67 (98.5%)	92	40 (43.5%)	66 (71.7%)	87 (94.6%)	92 (100%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -17.9% to 13.5%. The mean difference plot showed a small bias of -2.2%.



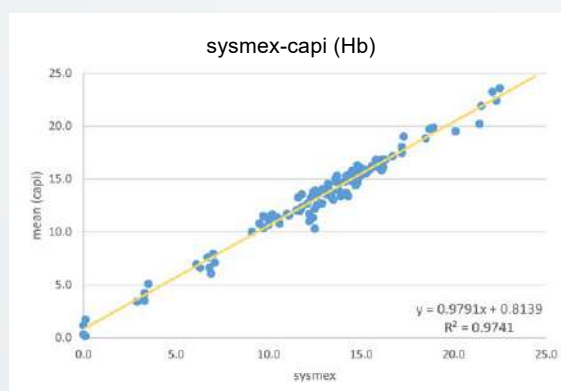
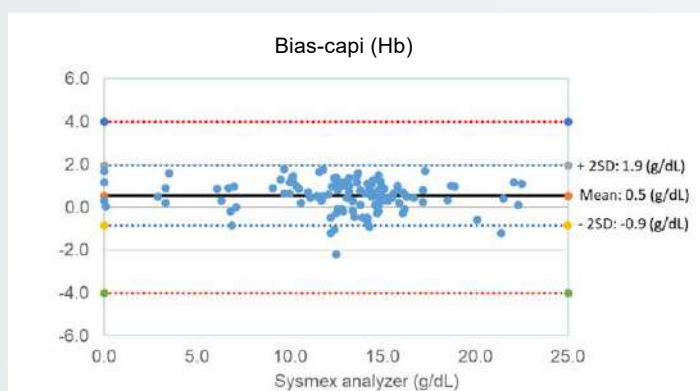
Accuracy Evaluation of Hemoglobin Monitoring System

- The report was conducted by using three different lots of hemoglobin test strips on capillary whole blood sample.
- This clinical accuracy study was carried out from a total of 122 subjects.
- The comparative reference was hemoglobin reagent method on the Sysmex Haematology Automated analyzer.
- Good correlation was found between triglycerides test strips on capillary sample and comparative method results by regression analysis ($R^2 = 0.9741$; slope = 0.9791 and intercept = 0.8139 g/dL, $n = 122$).
- The study showed accurate performance with 98.1% of the capillary blood sample measured hemoglobin values fell within $\pm 15\%$ of the reference hemoglobin measurement at concentrations ≥ 10 g/dL.
- Out of total 122 tests, 98.1% results fell in the range of $\pm 15\%$ from the reference value.

Capillary Blood Test Result

- When the reference concentration is > 10 g/dL, 98.1% of the capillary blood sample results fell within $\pm 15\%$.

Hb meter	Overall		Test results of the Hb concentration <10			Test results of the Hb concentration ≥10				
	Within ±									
	n	±1.5 g/dL or 20%	n	±0.8 g/dL	±1.5 g/dL	n	5%	10%	15%	20%
Capillary blood sampling	122	120 (98.3%)	15	7 (46.6%)	13 (86.6%)	107	62 (57.9%)	92 (85.9%)	105 (98.1%)	107 (100%)



- Analysis of difference plot showed the 95% limits of agreement between two methods ranged from -0.9g/dL to 1.9g/dL. The mean difference plot showed a small bias of 0.5g/dL.

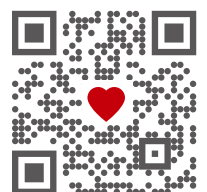


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