TaiDoc

Biosensor Technology
Glucose Measurement

XPER Technology | EF Technology | 2+2 Technology

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Glucose Strip Technology

The blood glucose monitoring system uses advanced technology and exceeds the system accuracy requirements of ISO 15197: 2013 & EN ISO 15197: 2015

Technology	I Biochemistry	II Biochemistry	III 2+2 Bio Tech.	IV EF Tech.	V XPER Tech.
Enzyme	**GOD**	**GDH-FAD**	**GDH-FAD**	**GDH-FAD**	**GDH-FAD**
Sample Size (μL)	**0.5**	**0.5**	**1.0**	**0.5**	**0.5**
Reaction Time (Seconds)	**5**	**5**	**5**	**6**	**5**
Measurement Range (mg/dL)	**20-600**	**20-600**	**10-700**	**20-650**	**10-800**
Hematocrit Range (%)	**30-55**	**35-60**	**0-70**	**20-65**	**0-70**
QC Identification	**No**	**No**	**Yes**	**No**	**Yes**
Oxygen Interference	**Yes**	**No**	**No**	**No**	**No**

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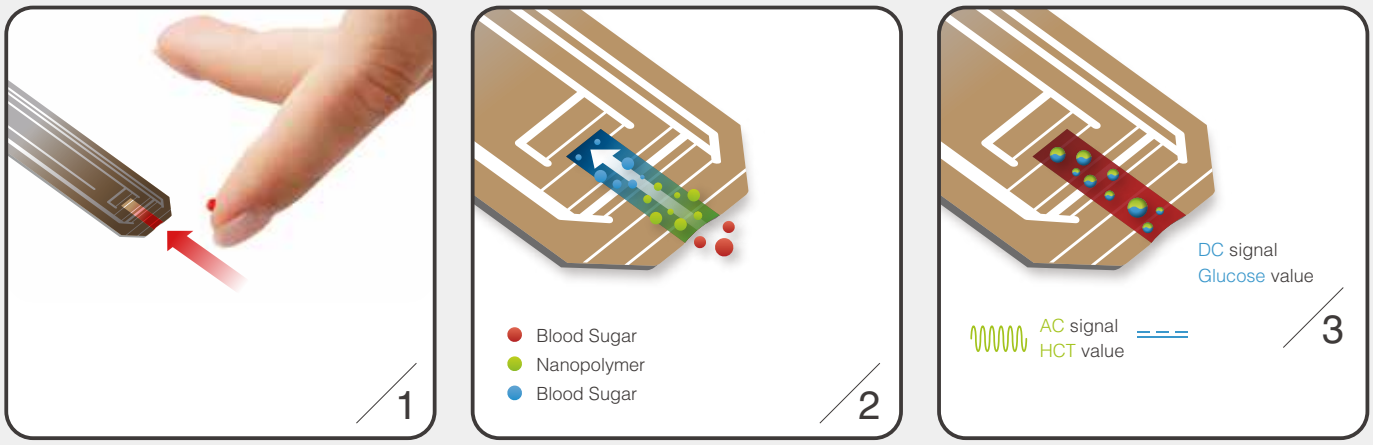
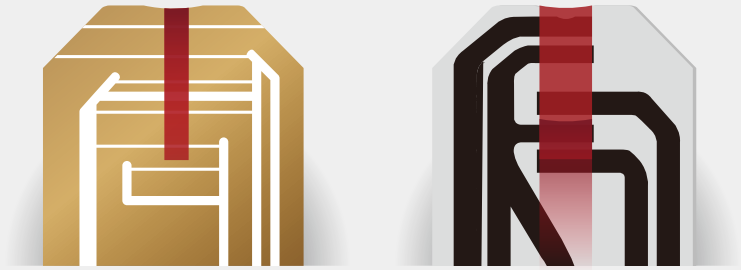
XPER Technology

Accuracy Evaluation of TaiDoc XPER Technology

- The report was conducted by AMCR Institute and tested three different lots of test strips in duplicates.
- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated XPER technology (TD-4289) met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- The study showed the accurate performance of XPER technology monitoring system (TD-4289) could be used on healthcare professionals and self-testing.
- Out of total 600 tests, average 97% (>95%) results fell in the range of ± 10 mg/dL & ±10% from the reference value.





Laser Cutting　　Printing

Venous Test Result

- When the sample < 100 mg/dL, 100% of the sample results fell within ±15 mg/dL; average 98.9% of the results fell within ±10 mg/dL.

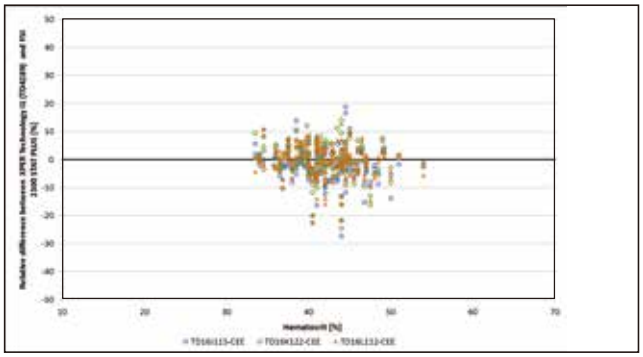
Reagent system lot	Within ± 5 mg/dl (Within ± 0.28 mmol/l)	Within ± 10 mg/dl (Within ± 0.56 mmol/l)	Within ± 15 mg/dl (Within ± 0.83 mmol/l)
TD16J115-CEE	44 / 58 (75.9 %)	56 / 58 (96.6%)	58 / 58 (100%)
TD16K122-CEE	45 / 58 (77.6%)	58 / 58 (100%)	58 / 58 (100%)
TD16L112-CEE	40 / 58 (69.0%)	58 / 58 (100%)	58 / 58 (100%)

- When the sample ≥ 100 mg/dL, average 96.2% of the sample result fell within ±10%.

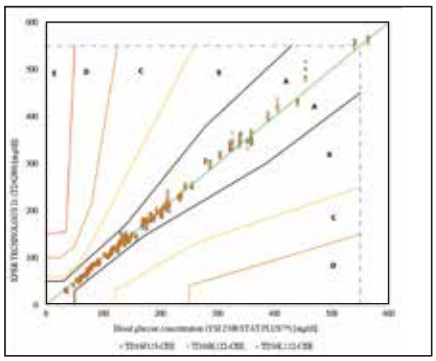
Reagent system lot	Within ± 5%	Within ± 10%	Within ± 15%
TD16J115-CEE	100 / 142 (70.4 %)	133 / 142 (93.7 %)	140 / 142 (98.6 %)
TD16K122-CEE	102 / 142 (71.8%)	138 / 142 (97.2 %)	142 / 142 (100 %)
TD16L112-CEE	100 / 142 (70.4%)	139 / 142 (97.9 %)	142 / 142 (100 %)

- In the venous blood test result, the acceptable bias within ± 10 mg/dL & ±10% (within ± 0.56 mmol/L & ±10%) reached average 97% of all results within bias limited from reference value (YSI) between 33.5 to 563.5 mg/dL (1.86 - 31.31mmol/L).

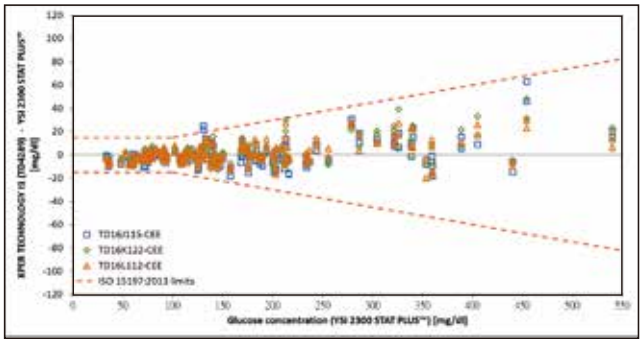
Reagent system lot	Within ± 5 mg/dl (Within ± 0.28 mmol/l)	Within ± 10 mg/dl (Within ± 0.56 mmol/l)	Within ± 15 mg/dl (Within ± 0.83 mmol/l)
TD16J115-CEE	144 / 200 (72.0 %)	189 / 200 (94.5 %)	198 / 200 (99.0 %)
TD16K122-CEE	147 / 200 (73.5%)	196 / 200 (98.0 %)	200 / 200 (100 %)
TD16L112-CEE	140 / 200 (70.0%)	197 / 200 (98.5 %)	200 / 200 (100 %)



- Haematocrit dependency for XPER (TD-4289) with three reagent system lots.
- No HCT interference, 100% of result fell within 0-70%.



- CEG for XPER (TD-4289) which provided accurate results compared to the lab reference method (YSI); 100% of individual glucose measured values fell within zone A.



- Absolute differences shows XPER (TD-4289) obtained accurate results compared to lab reference (YSI 2300)
- All results met current accuracy standard of ISO 15197: 2013 and EN ISO 15197: 2015

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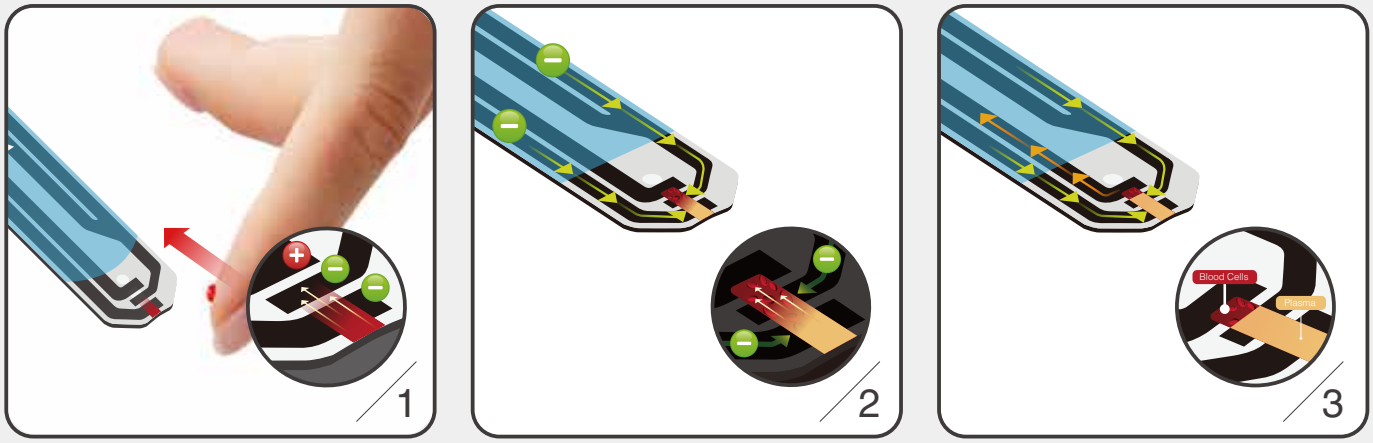
EF Tech.

Accuracy Evaluation of TaiDoc EF Technology

- The report was conducted by AMCRI Institute and tested three different lots of test strips in duplicates.
- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated EF technology (TD-4183) met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- The study showed the accurate performance of EF technology BGM (TD-4183) could be used on healthcare professionals and self-testing.
- Out of 600 venous tests, 100% of results fell in the range of ± 15 mg/dL & 15% from the reference value.



Venous Test Result

- When the sample < 100 mg/dL, 100% of the sample results fell within ±15 mg/dL.

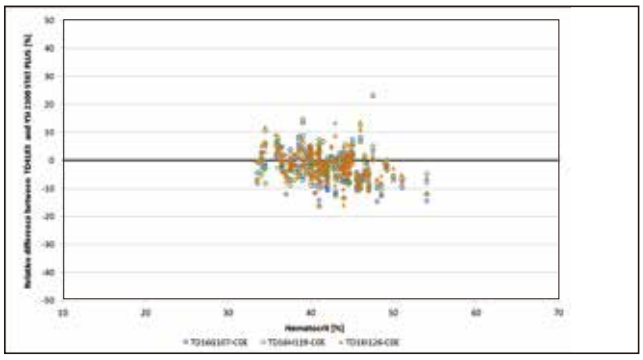
Reagent system lot	Within ± 5 mg/dl (Within ± 0.28 mmol/l)	Within ± 10 mg/dl (Within ± 0.56 mmol/l)	Within ± 15 mg/dl (Within ± 0.83 mmol/l)
TD16G107-C0E	38 / 58 (65.5%)	56 / 58 (96.6%)	58 / 58 (100%)
TD16H119-C0E	39 / 58 (67.2%)	57 / 58 (98.3%)	58 / 58 (100%)
TD16I126-C0E	44 / 58 (75.9%)	56 / 58 (96.6%)	58 / 58 (100%)

- When the sample ≥ 100 mg/dL, 100% of the sample result fell within ±15%.

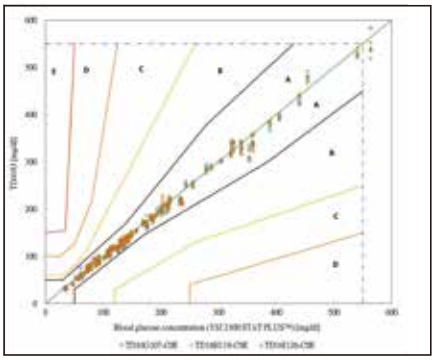
Reagent system lot	Within ± 5%	Within ± 10%	Within ± 15%
TD16G107-C0E	99 / 142 (69.7%)	134 / 142 (94.4%)	134 / 142 (94.4%)
TD16H119-C0E	104 / 142 (73.2%)	137 / 142 (96.5%)	137 / 142 (96.5%)
TD16I126-C0E	109 / 142 (75.4%)	138 / 142 (97.2%)	138 / 142 (97.2%)

- In the venous blood test result, the acceptable bias within ± 15 mg/dL & ± 15% (within ± 0.83 mmol/L & ± 15%) reached 100 % of all results within bias limited from reference value (YSI) between 33.5 - 563.5 mg/dL (1.86 to 31.31 mmol/L).

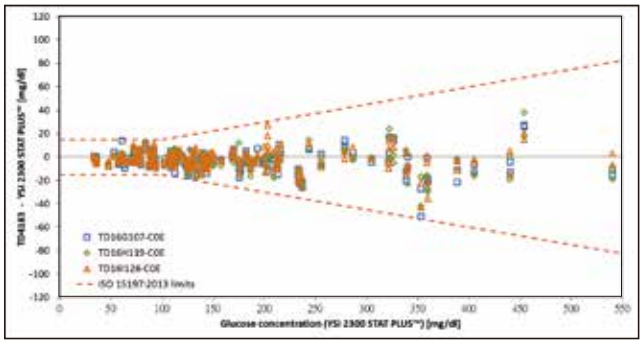
Reagent system lot	Within ± 5 mg/dL & ± 5% (Within ± 0.28 mmol/L & ± 5%)	Within ± 10 mg/dL & ± 10% (Within ± 0.56 mmol/L & ± 10%)	Within ± 15 mg/dL & ± 15% (Within ± 0.83 mmol/L & ± 15%)
TD16G107-C0E	137 / 200 (68.5 %)	190 / 200 (95.0 %)	200 / 200 (100 %)
TD16H119-C0E	143 / 200 (71.5 %)	194 / 200 (97.0 %)	200 / 200 (100 %)
TD16I126-C0E	151/ 200 (75.5 %)	194 / 200 (97.0 %)	200 / 200 (100 %)



- Haematocrit dependency for EF technology (TD-4183) with three reagent system lots.



- CEG for EF technology (TD-4183) which provided accurate results compared to the lab reference method (YSI); 100% of individual glucose measured values fell within zone A.



- Absolute differences shows EF (TD-4183) obtained accurate results compared to lab reference (YSI 2300).
- All results met current accuracy standard of ISO 15197: 2013 and EN ISO 15197: 2015

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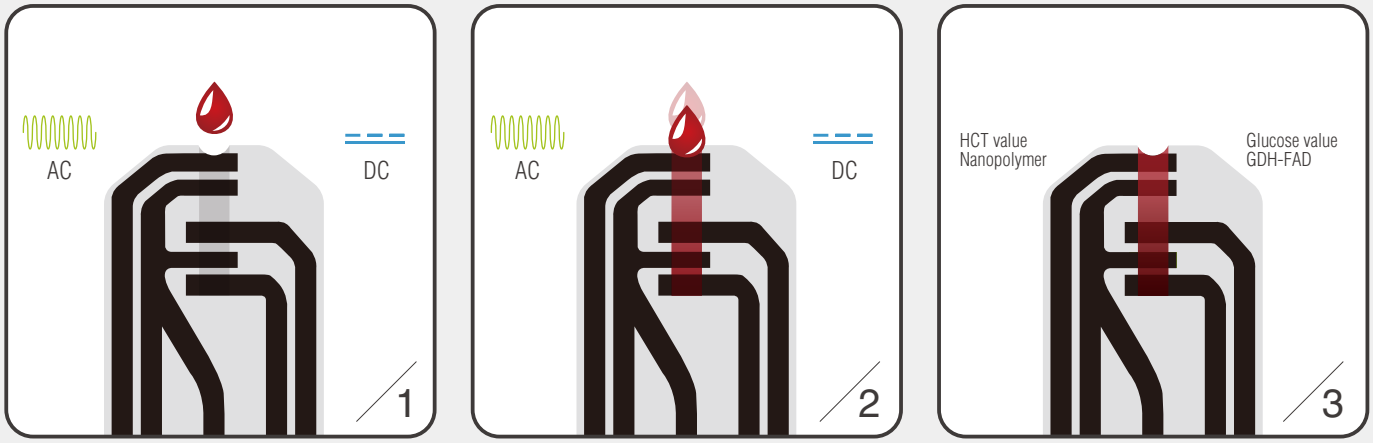
2+2 Bio Signal

Accuracy Evaluation of TaiDoc 2+2 Technology

- The report was conducted by AMCRI Institute and tested three different lots of test strips in duplicates.
- The clinical accuracy study followed the guideline of ISO 15197: 2013 and EN ISO 15197: 2015.
- Clinical data demonstrated 2+2 technology (TD-4206) met the current accuracy standards of ISO 15197: 2013 and EN ISO 15197: 2015.
- The study showed the accurate performance of 2+2 technology monitoring system (TD-4206) could be used on healthcare professionals and self-testing.
- Out of total 600 tests, average 96.1% (>95%) results fell in the range of ± 10 mg/dL & ± 10% from the reference value.



Venous Test Result

- When the sample < 100 mg/dL, 100% of the sample results fell within ±15 mg/dL; average 98.9% of the results fell within ±10 mg/dL.

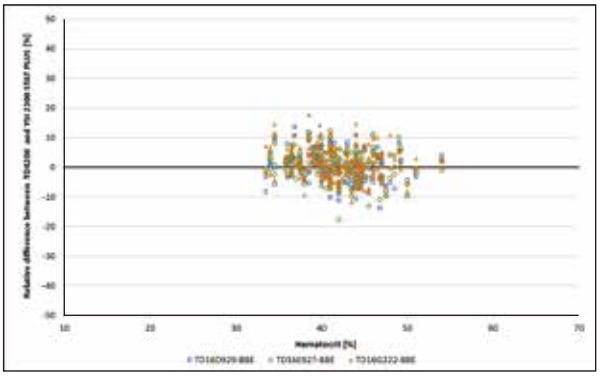
Reagent system lot	Within ± 5 mg/dl (Within ± 0.28 mmol/l)	Within ± 10 mg/dl (Within ± 0.56 mmol/l)	Within ± 15 mg/dl (Within ± 0.83 mmol/l)
TD16D929-BBE	52 / 58 (89.7%)	58 / 58 (100%)	58 / 58 (100%)
TD16E927-BBE	46 / 58 (79.3%)	57 / 58 (98.3%)	58 / 58 (100%)
TD16G222-BBE	44 / 58 (75.9%)	57 / 58 (98.3%)	58 / 58 (100%)

- When the sample ≥ 100 mg/dL, average 95.1% of the sample result fell within ±10%.

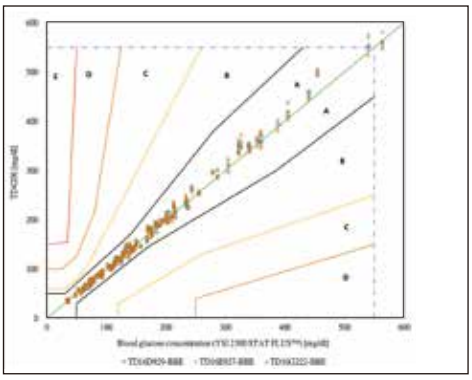
Reagent system lot	Within ± 5%	Within ± 10%	Within ± 15%
TD16D929-BBE	92 / 142 (64.8%)	138 / 142 (97.2%)	142 / 142 (100%)
TD16E927-BBE	94 / 142 (66.2%)	133 / 142 (93.7%)	142 / 142 (100%)
TD16G222-BBE	99 / 142 (69.7%)	134 / 142 (94.4%)	142 / 142 (100%)

- In the venous blood test result, the acceptable bias within ± 10 mg/dL & ± 10% (within ± 0.56 mmol/L & ± 10%) reached average 96.1% of all results within bias limited from reference value (YSI) between 33.5 to 563.5 mg/dL (1.86 - 31.31mmol/L).

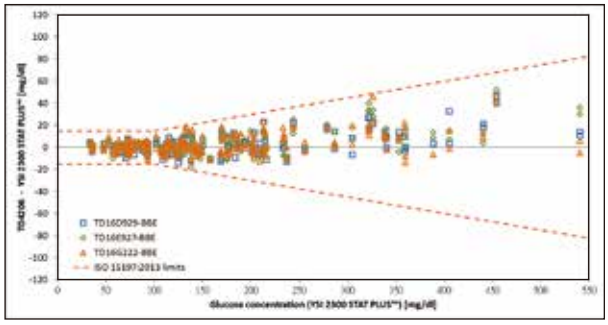
Reagent system lot	Within ± 5 mg/dl (Within ± 0.28 mmol/l)	Within ± 10 mg/dL & ± 10% (Within ± 0.56 mmol/L & ± 10%)	Within ± 15 mg/dL & ± 15% (Within ± 0.83 mmol/L & ± 15%)
TD16D929-BBE	144 / 200 (72.0%)	196 / 200 (98.0%)	200 / 200 (100%)
TD16E927-BBE	140 / 200 (70.0%)	190 / 200 (95.0%)	200 / 200 (100%)
TD16G222-BBE	143 / 200 (71.5%)	191 / 200 (95.5%)	200 / 200 (100%)



- Haematocrit dependency for 2+2 technology (TD-4206) with three reagent system lots.
- No HCT interference, 100% of results fell within 10-70%.



- CEG for 2+2 technology (TD-4206) which provided accurate results compared to the lab reference method (YSI); 100% of individual glucose measured values fell within zone A.



- Absolute differences shows 2+2 (TD-4206) obtained accurate results compared to lab reference (YSI 2300).
- All results met current accuracy standard of ISO 15197: 2013 and EN ISO 15197: 2015.

TaiDoc

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