

CASE HISTORY

OTraces Utilizes the Technology of Sword Diagnostic to Enhance Cancer Detection

OTraces is turning to Sword Diagnostics for technology to enhance its BC Sera DX™ breast cancer screening test, which can detect breast cancer at earlier levels and with greater accuracy than current screening methods. In refining its first commercially available test, OTraces desired enhanced sensitivity for several key markers in its panel. By incorporating Sword's chemistry into its existing tests, OTraces obtained immediate improvements in sensitivity without having to invest in expensive detection instrumentation or test redesign. Clinical testing to date indicated a sensitivity and specificity in excess of 90-95%, a dramatic improvement over mammography.

"We have consistently achieved 3-4X improvement in sensitivity in several of our tests to date with Sword. I expect even better results once we optimize and adjust our assay for use with Sword's technology. Improving predictive power is heavily dependent on accurate measurements of probative low abundance proteins down below 1 pg/ml. Current ELISA methods are barely adequate. We expect further improvements with Swords detection methods."

*Keith Lingenfelter, CEO OTraces Inc.
Former VP Diagnostics, Igen (now Roche)*

Methods Show Better Breast Cancer Detection Than Mammography

While decreasing breast cancer mortality rates are largely credited to the use of mammography, they still miss up to 17% of tumors and return a false-positive result 1 out of 10 times. The false positive rate in the U.S. alone is estimated to add \$1.6 billion per year to the cost of mammography screening.

OTraces methods have shown a 97% sensitivity and 93% specificity on test populations. The OTraces test featuring Sword technology is expected to supplement and eventually replace older, less sensitive and less specific screening methods.

Results Promise Advancements in the Study and Detection of Other Diseases

Sword's product is easily integrated into ELISA assays without requiring expensive equipment, complex and time-consuming protocols or test redesign. This ease of integration makes it an ideal choice for use in the research and diagnostics markets. Providing enhanced sensitivity, accuracy and precision without compromise, Sword's reagents can improve detection of many markers for cancer and other disease states.

"The last time I saw such immediate impact and impressive results was when I was at IGEN International developing Electro-chemiluminescence (see Roche Elecsys Detection Systems) in the early 1990's."

*Keith Lingenfelter, CEO OTraces Inc.
Former VP Diagnostics, IGEN (now Roche)*



OTraces Inc.

Manufacturer of Advanced
Oncology Systems

SITUATION:

OTraces Inc. develops and provides advanced oncology systems to detect cancer earlier and more efficiently. With its LHS Chemistry System™ that elevates clinical blood testing to new levels of precision and sophistication, OTraces is in the process of launching its cancer detection technologies in the initial markets of Russia, Ukraine and Belarus.

CHALLENGE:

OTraces required enhanced biomarker detection in its blood-based breast cancer screening test.

SOLUTION:

Incorporating Sword's technology into the BC Sera DX™ test provided enhanced sensitivity and accuracy.

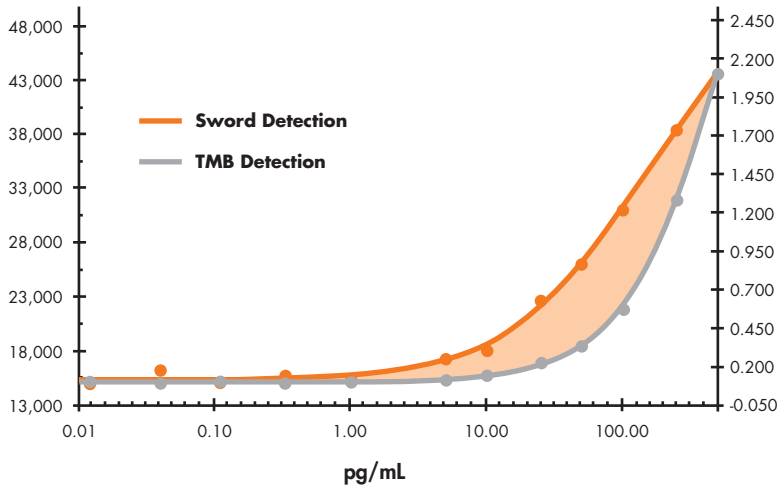
BENEFITS:

- Fewer false positives and false negatives in breast cancer screening
- Better diagnoses result in better treatment outcomes
- Potential for use in detection of other cancers

Sword Diagnostics is the developer of a new and novel immunoassay detection system that uses Raman spectroscopy and a proprietary chemistry that enhances currently available antibody-based tests to allow for earlier and more accurate diagnosis of diseases.

Data for Two Assays Generated by Otraces on Tecan M1000 Multimode Plate Reader

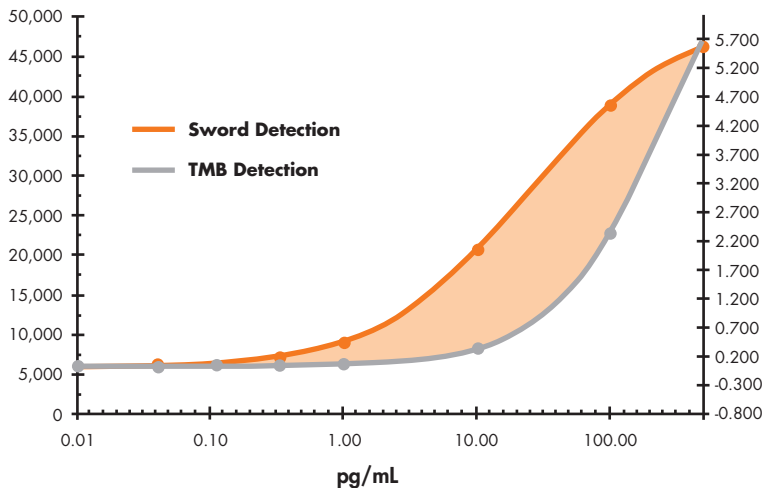
Assay #1



Tecan Infinite® M1000 Plate Reader

Sword improved the limit of detection (LOD) from 4.7 pg/ml to 0.9 pg/ml or 5X. Sword improved the precision by reducing the coefficients of variation (CV) from 6.1-13.2% to 0.8-3.9%. Improvements to curves can be seen above. Note that this data was generated with an assay optimized for TMB with no optimization for Sword. Further improvements are anticipated with optimization.

Assay #2



Sword improved the LOD from 0.36 pg/ml to 0.1 pg/ml or 3.6X. Sword improved the precision by reducing the CVs from 2.4-15.1% to 0.2-8.5%. Improvements to curves can be seen above. Note that this data was generated with an assay optimized for TMB with no optimization for Sword. Further improvements are anticipated with optimization.



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