Commercial Test Model Study – A multicenter survey

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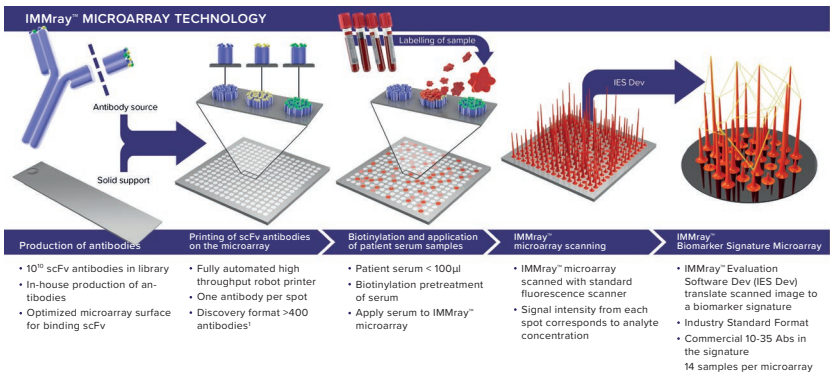
Objectives

IMMray™ PanCan-d **Commercial Test Model Study** aimed to select and lock the IMMray™ PanCan-d commercial biomarker signature and evaluate its performance in differentiating pancreatic ductal adenocarcinoma - PDAC (stage I-IV), vs. controls, simulating a commercial test situation. In the current study, serum samples obtained from patients with non-specific but concerning symptoms, including diabetics, as well as healthy individuals collected from several sites both in EU & USA were analyzed.

Patients and Methods

In total, 1113 patient serum samples were analyzed with a focused IMMray™ set up and CA 19-9 assay. Patient samples from 315 PDAC (stage I-IV), 488 non-PDAC symptomatic individuals (including 79 diabetes and 56 chronic pancreatitis) and 310 healthy controls were tested. All these samples were freshly collected through our Key Opinion Leaders at eight reference sites in USA and Europe. Data analysis was performed, using Immunovia's software algorithms and the data were divided into training and test sets. The test performance was evaluated and displayed as ROC AUC values and sensitivity/specificity.



PDAC					Controls	
Stage I	Stage II	Stage III	Stage IV	Stage non-confirmed	Healthy controls	Symptomatic controls (including diabetes)
No. 34	55	64	118	44	310	488

Results

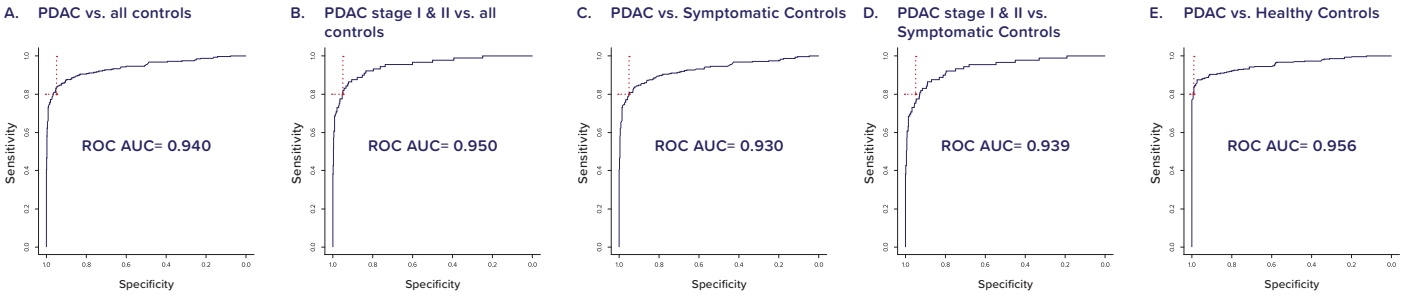


Figure 1. *In total, 1113 individuals were analyzed. Combining IMMray™ **PanCan-d 8-plex** signature with CA 19-9, the results from the test set showed*
A) ROC AUC value of 0.940 differentiating PDAC (stage I-IV) from all controls (symptomatic + healthy + diabetes),
B) ROC AUC value of 0.950 differentiating PDAC Stages I & II from all controls (symptomatic + healthy + diabetes),
C) ROC AUC value of 0.930 differentiating PDAC (stage I-IV) from symptomatic control individuals,
D) ROC AUC value of 0.939 differentiating PDAC Stages I & II from symptomatic control individuals,
E) ROC AUC value of 0.956 differentiating PDAC (stage I-IV) from healthy controls.
The red point on the plots A-D (E) represents the specificity and the sensitivity at the cut-off of 0.95% (0.99%) and 80%, respectively.

Conclusions

In the **Commercial Test Model Study (CTMS)**, we showed for the first time that the IMMray™ PanCan-d 8-plex signature, together with CA 19-9, has the capacity to differentiate between PDAC stage I & II and all controls, including diabetes, symptomatic, healthy individuals, with a clinically relevant accuracy of 0.950. In the CTMS, we also locked and tested the model algorithms, which were subsequently incorporated in the final IMMray™ PanCan-d test set up.

Important notes:

- The 8-plex biomarker signature facilitated quality control and improved assay reproducibility.
- Patent was filed July 2020 for the locked commercial IMMray™ PanCan-d 8-plex biomarker signature.

References

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