Diagnosis of early stage pancreatic ductal adenocarcinoma using a serum biomarker signature


Introduction
Pancreatic ductal adenocarcinoma (PDAC) shows a very poor survival rate with less than 7% 5-year survival. By resecting more tumors when they are still confined to the pancreas, the overall 5-year PDAC patient survival rate would increase significantly. In an effort to achieve reliable early detection we have developed IMMray™ PanCan-d, a microarray-based blood test for diagnosis of PDAC patients.

Objective
The purpose of the IMMray™ PanCan-d microarray-based test is to detect both early and late stage PDAC from a blood sample.

The purpose of the IMMray™ PanCan-d microarray-based test is to detect serum biomarkers associated with PDAC.

Conclusions
- PDAC stage I and II patients were detected with 96% accuracy* and validated with a distinct patient cohort.
- PDAC stage I to IV patients were detected with 98% accuracy* and validated with a distinct patient cohort.
- Chronic pancreatitis was discriminated from PDAC with an accuracy* of 83%.
- IPMN samples of all grades were classified as positives.
- Six studies covering 2482 samples demonstrated robustness and high accuracy of the IMMray™ PanCan-d platform.
Results

Discovery: In a retrospective study on a South Scandinavian cohort, 1355 blood samples were analyzed.

The IMMray™ PanCan-d signature discriminated PDAC from healthy controls very accurately.

Validation: In a retrospective study on a North American cohort, 429 blood samples were analyzed.

The IMMray™ PanCan-d signature discriminated 90 patients in PDAC stage I and II from 888 healthy controls with an accuracy of 96%.

Methods

Antibody microarray slides are printed and incubated with biotinylated patient serum. Levels of bound antigens are detected by fluorescence scanning. State-of-the-art machine learning algorithms were employed in the development of the IMMray™ PanCan-d signature. Hundreds of analytes were thus reduced to generate a comprehensive signature capable of distinguishing PDAC from controls.

Studies performed on the IMMray™ PanCan-d platform

<table>
<thead>
<tr>
<th>STUDY</th>
<th>NO. OF SUBJECTS</th>
<th>AUC**</th>
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<tbody>
<tr>
<td>Ingvarsson et al 20081</td>
<td>44</td>
<td>1</td>
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<tr>
<td>Wingren et al 20122</td>
<td>103</td>
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<td>Gerdtsson et al 20153</td>
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<td>Gerdtsson et al 20164</td>
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<td>0.96</td>
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<td>South Scandinavian Study5</td>
<td>1355</td>
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<td>North American Validation Study5,6</td>
<td>429</td>
<td>0.96</td>
</tr>
<tr>
<td><strong>Total no. of subjects</strong></td>
<td><strong>2482</strong></td>
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</tr>
</tbody>
</table>

*Based on specificity and sensitivity values generated by the classification model. **Healthy controls vs PDAC patients.

References