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IMMray® PanCan-d Blinded Validation Study

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Objectives

The IMMray® PanCan-d **Blinded Validation Study** aimed to validate the clinical performance of the IMMray® PanCan-d test in differentiating pancreatic ductal adenocarcinoma (PDAC) stages I-IV vs. familial/hereditary high-risk individuals (PanFAM clinicaltrials.gov) and healthy controls. The study was performed by Immunovia, Inc. in Marlborough, MA and sample identity was blinded to Laboratory Technologists and the Laboratory Director throughout the study.

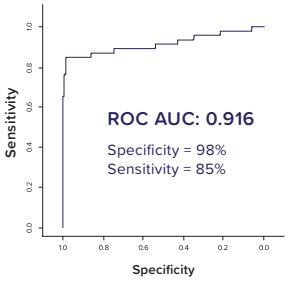
Patients and Methods

In total, 591 patient serum samples were analyzed with IMMray® PanCan-d biomarker signature and CA 19-9 assay. Patient samples from 167 PDAC (stage I-IV), 203 high-risk individuals from the familial/hereditary risk group, and 221 healthy controls were tested. All these samples were freshly collected through our study collaborators at eleven reference sites in USA and Europe. Test results were automatically generated, using validated custom software with locked model algorithms and predefined Decision Value cut offs for sample classification. Data was then uploaded automatically to Orchard Harvest Laboratory Information System before sample identity was un-blinded to enable calculation of the clinical test performance in terms of specificity, sensitivity and ROC AUC values.

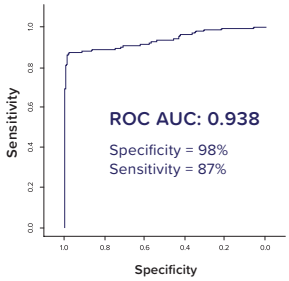
PDAC				Controls		
Stage I	Stage II	Stage III	Stage IV	Stage pending	Healthy controls	Familial/heriditary risk group
24	32	38	57	16	221	203

Results

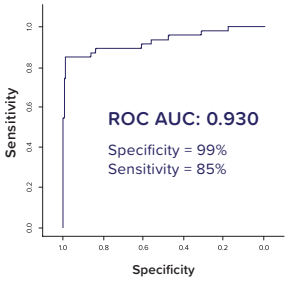
A. PDAC Stage I&II vs Familial/Hereditary controls high-risk individuals



B. PDAC Stage I-IV vs. Familial/Hereditary controls high-risk individuals



C. PDAC Stage I&II vs. Healthy controls



D. PDAC Stage I-IV vs. Healthy controls

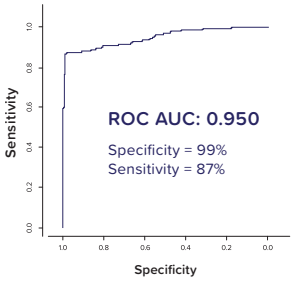


Fig 1. *In total, 519 individuals were analyzed. Combining **IMMray® PanCan-d 8-plex** signature with CA 19-9, the results from the test demonstrated:*

A) Specificity of 98%, sensitivity of 85% and ROC AUC value of 0.92 differentiating PDAC (stage I&II) from familial/hereditary high-risk individuals

B) Specificity of 98%, sensitivity of 87% and ROC AUC value of 0.94 differentiating PDAC (stage I-IV) from familial/hereditary high-risk individuals

C) Specificity of 99%, sensitivity of 85% and ROC AUC value of 0.93 differentiating PDAC (stage I&II) from healthy controls

D) Specificity of 99%, sensitivity of 87% and ROC AUC value of 0.95 differentiating PDAC (stage I-IV) from healthy controls

Conclusions

In the IMMray® PanCan-d **Blinded Validation Study** we demonstrated the clinical performance of the IMMray® PanCan-d test by differentiating between PDAC stage I & II and familial/hereditary risk group patients achieving a specificity of 98% and sensitivity of 85%. Sample identity was blinded to Laboratory Technologists and the Laboratory Director throughout the study.

PDAC VS Familial/Hereditary Controls	Stage I & II PDAC	All stages PDAC
Sensitivity	84.8%	86.8%
Specificity	98.4%	98.4%
NPV (3% Prevalence)	99.5%	99.6%
PPV (3% Prevalence)	62.1%	62.7%
NPV (1% Prevalence)	99.8%	99.9%
PPV (1% Prevalence)	34.9%	35.4%

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References

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