Performance of Immunovia's Next-Generation Test in the CLARITI Clinical Validation Study

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Today's Presenters

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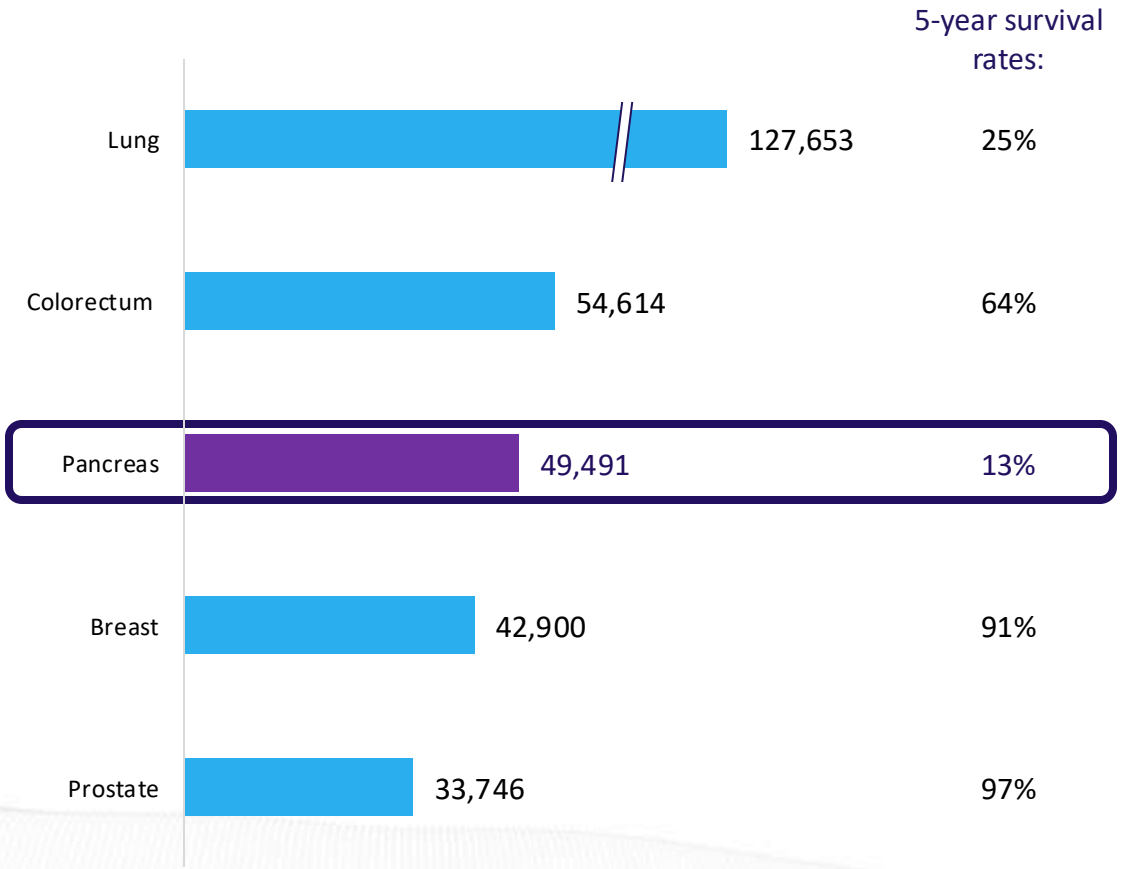
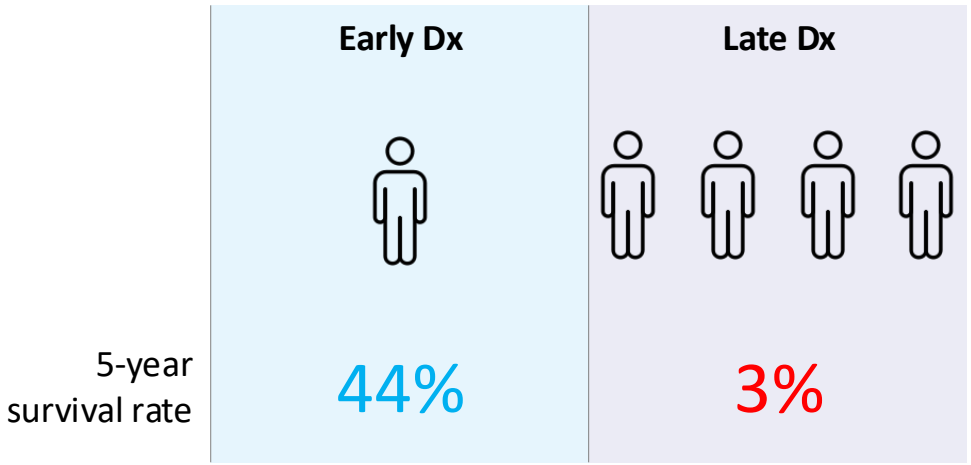
Significant unmet need for a simple and accurate blood test to detect pancreatic cancer early

Annual US cancer deaths[1,2]



Only 1 in 5 is diagnosed early when surgery is an option[2]



Sources: 1) GLOBOCAN 2022; 2) cancer.org

Accuracy in detecting pancreatic cancer requires both sensitivity and specificity

Sensitivity = The percentage of cancer cases that are successfully detected

Specificity = The percentage of controls correctly classified as non-cancerous

Imagine a study to test the clinical validity of a test. The study of 200 samples has 100 cancer cases and 100 non-cancerous controls

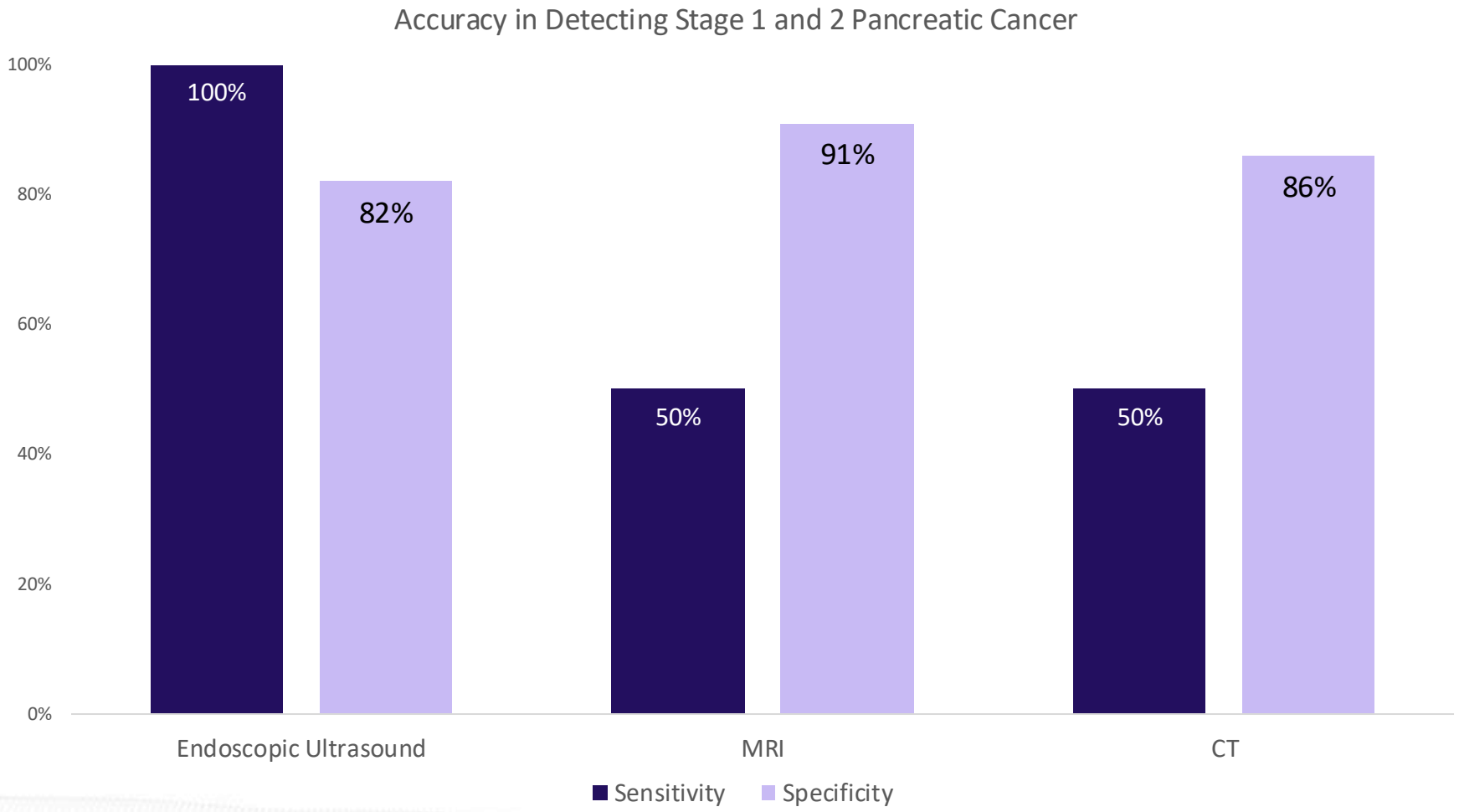
✓ A test with **60% sensitivity** would be positive for 60 of the 100 cancer cases.

X The other 40 cancer cases would not be detected

✓ A test with **80% specificity** would provide a negative result for 80 of the 100 controls.

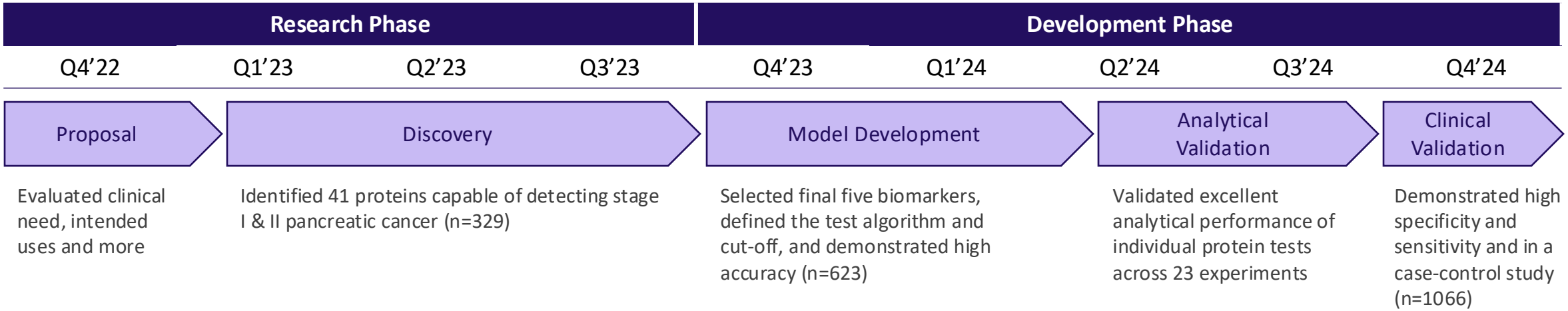
X The other 20 control cases would be incorrectly classified as positive for cancer, leading to unnecessary follow-up

The standard of care in pancreatic cancer surveillance is imaging—which has mixed performance in early detection



Sakamoto H, Kitano M, Suekoto Y et al. Ultrasound Med Biol. 2008;34(4):525–532.
Borbath I, Van Beers BE, Lonneux M et al. Pancreatol. 2005;5:553-561.

We have completed discovery, model development, analytical validation and clinical validation for our new test



Method performance was characterized by robust analytical validation

- We evaluated the performance of the ELISA assays used to measure each protein biomarker
- Goal: Show we can accurately, consistently and precisely measure each biomarker
- Validation performed following strict regulatory guidance
- Accuracy of quantitation matched model-development study
- Average precision of 7.5% was well within 15% success criteria
- Proteins are stable under analysis conditions in the lab
- Quality control samples were used during the clinical validation to ensure assay performance consistent with the validated performance

The CLARITI clinical validation study at a glance

- Designed to evaluate test accuracy: Identifying pancreatic cancer blood samples from non-cancerous control samples
- Primary goal: Test sensitivity greater than 65% and specificity greater than 90%
- Secondary goal: Test sensitivity and specificity superior to CA19-9, a commonly used biomarker for pancreatic cancer
- Largest clinical validation of a pancreatic cancer test ever conducted in a high-risk population
- High-risk controls represent the most important and more challenging comparison

The CLARITI study, the largest of its kind, included 1066 rare blood samples from top pancreatic cancer centers

immunovia

202 Stage 1 & 2 pancreatic cancer cases

864 High-risk controls

Institutions that supported the study with blood samples

PRECEDE
The Pancreatic Cancer Early Detection Consortium

UPMC
LIFE CHANGING MEDICINE

Icahn School of Medicine at Mount Sinai

OHSU

INOVA

Regional One Health

MOFFITT CANCER CENTER

UChicagoMedicine

COLUMBIA
COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

UNIVERSITÀ di VERONA

VCUHealth

Stanford MEDICINE

MAYO CLINIC

Providence

Oslo University Hospital

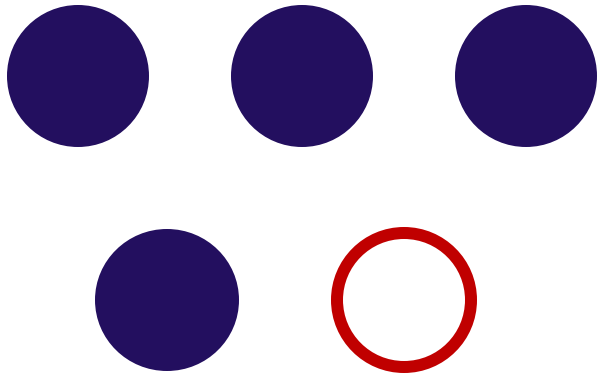
UC San Diego Health

McGill University Health Centre

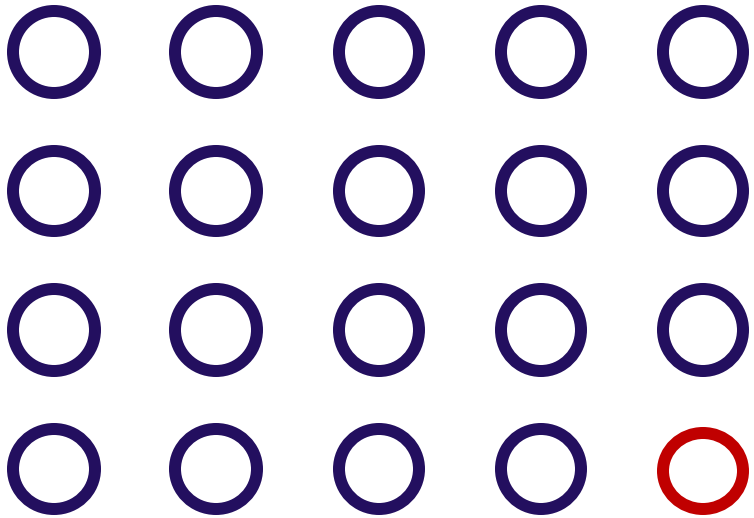
HONORHEALTH

The Immunovia test demonstrated 78% sensitivity and 94% specificity in the CLARITI study

With sensitivity of 78%, we would detect cancer in ~4 out of every 5 patients with stage 1 or 2 PDAC

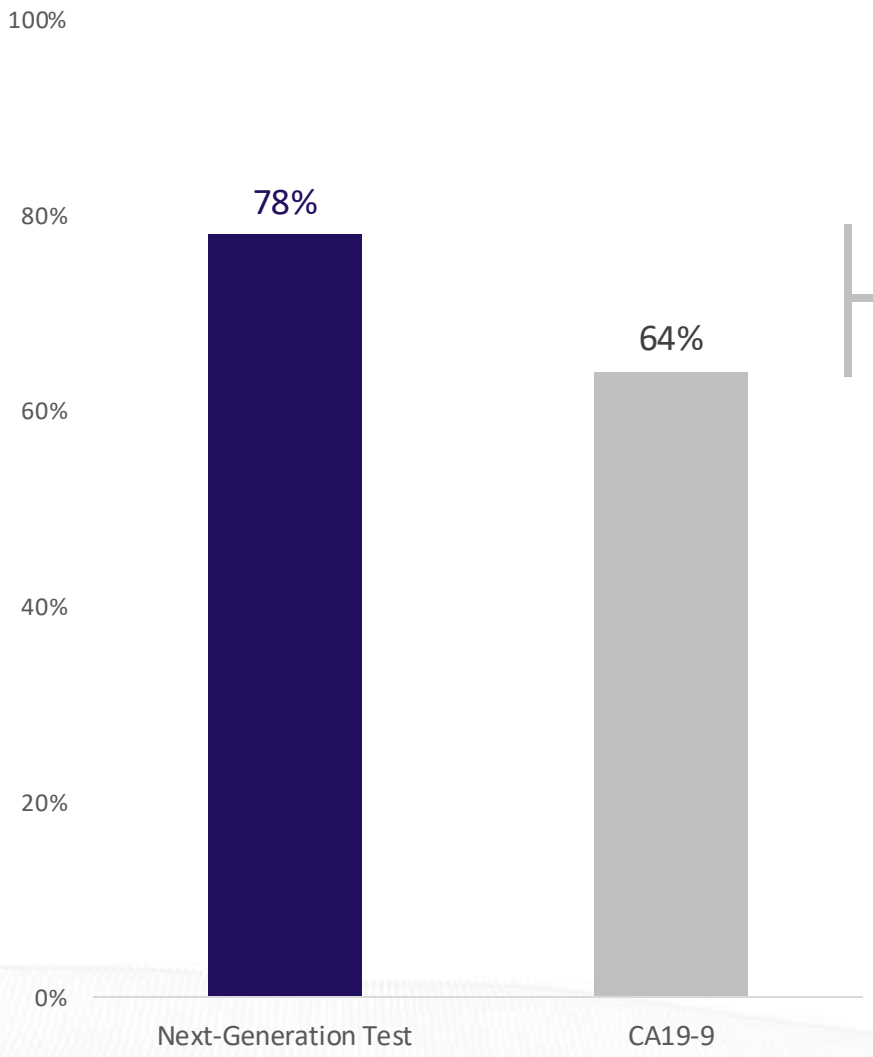


With specificity of 94%, we would have only one false positive for every 20 individuals tested who do not have PDAC



Data on file

The Immunovia test was significantly more sensitive than CA19-9 at the same specificity



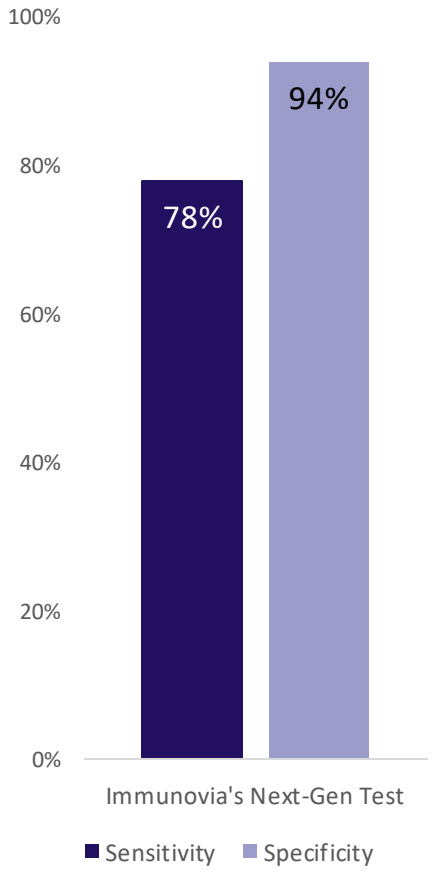
The Immunovia test was **14 percentage points** more sensitive than CA19-9 at the same specificity (p<0.001)

In the CLARITI study, the next-generation test identified 28 cancer cases that were missed by CA19-9

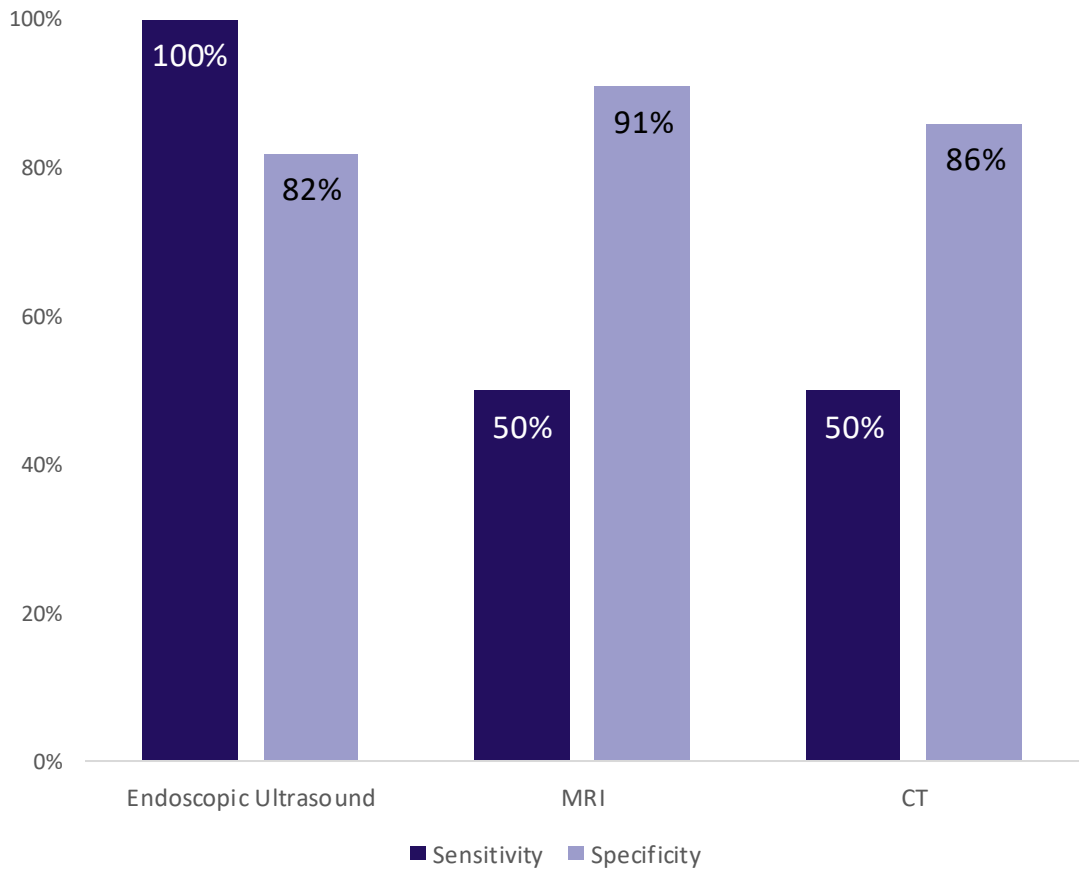
Data on file

Next-generation test performance compares very favorably to imaging and is much more convenient and less costly

Accuracy in Detecting Stage 1 and 2 PDAC in CLARITI (1)



Accuracy in Detecting Stage 1 and 2 Pancreatic Cancer in a Meta-analysis (2,3)

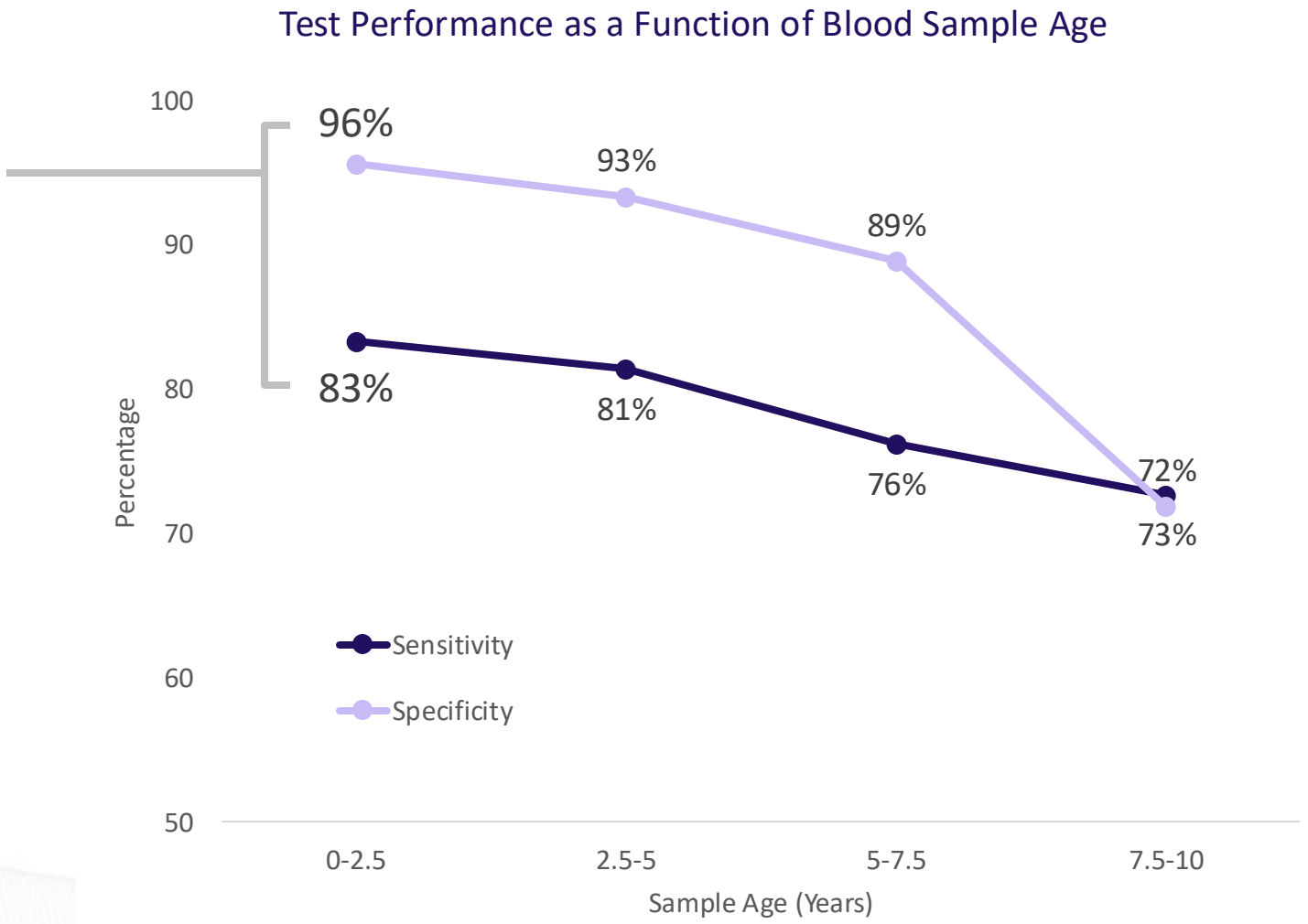


1. Data on file.
2. Sakamoto H, Kitano M, Suekoto Y et al. Ultrasound Med Biol. 2008;34(4):525–532.
3. Borbath I, Van Beers BE, Lonneux M et al. Pancreatol. 2005;5:553-561.

Note: Not a head-to-head comparison of the Immunovia test and imaging from the same study

The next-generation test performed even better in blood samples collected more recently

Clinical samples will be tested within days of collection, so real-world performance should be as good or better than results in the group of samples collected within the last 2.5 years



CLARITI clinical validation study conclusions

The primary endpoint of the study was met, with the Immunovia test showing high sensitivity (78%) and specificity (94%) in differentiating Stage I and II PDACs from true high-risk controls.

The test was significantly more sensitive than CA19-9 alone (+14% points), with equal specificity

Test performance was impacted by sample age with a sharp decrease in sensitivity and specificity for samples > 5 years old

Patient samples < 2.5 of age showed the next-generation test had strong performance—83% sensitivity with 96% specificity—comparable to what was seen in MDS

Samples in clinical testing following product launch will be days old, enabling optimal test performance

Leading experts in pancreatic cancer have been enthusiastic about the next-generation test's performance in CLARITI

"Congratulations. These results are great."

"The specificity is impressive"

"[The test] still beat CA19-9 consistently across analyses and patient groups, even with sample age impacting the results."

"Great news. I appreciate…Immunovia's efforts in looking for better biomarkers in pancreas cancer!"

"Congratulations! Nice to see how well [the test] is performing"

Perspective from Aimee Lucas, MD

Chief of Gastroentrology & Hepatology, Mount Sinai

Professor of Medicine, Icahn School of Medicine

Member, Immunovia Scientific Advisory Board

Successful completion of the CLARITI study enables us to move forward with all parts of our strategic plan as planned

On track to launch the next-generation test in the US in the second half of 2025 as announced

Positive initial reaction from potential strategic partners;
ten meetings scheduled in December and January

Insights from CLARITI will guide clinical studies to secure reimbursement; we will execute the clinical study plan announced previously

Successful validation study reaffirms our Q3 guidance of 12 months of runway with current cash + TO2 and TO3 warrant proceeds

Questions & Answers