

LungLifeAI™

Half Year Results – June 2023

August | 2023 ●●●



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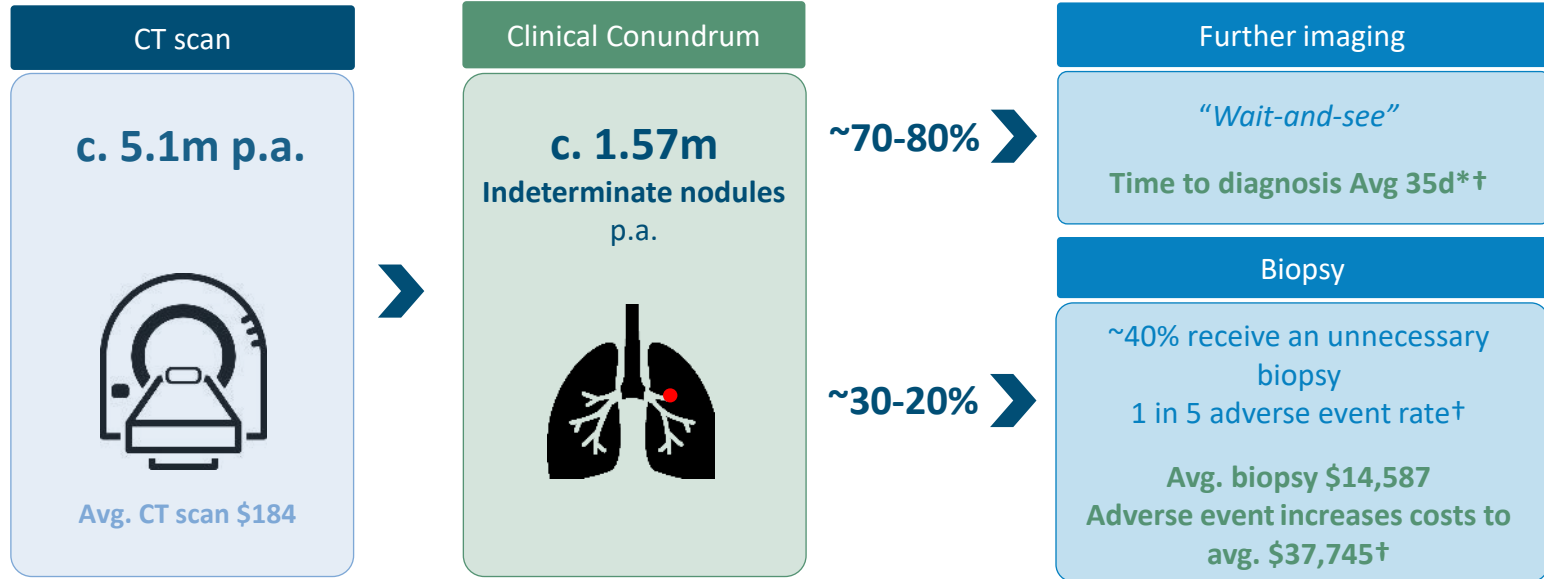
LungLifeAI[™] is a diagnostics company focused on the early detection of lung cancer from **a simple blood draw** enhanced by Artificial Intelligence.



Our purpose is simple.
To be a driving force in the early detection of lung cancer.



Primary Clinical Pathway



†Lokhandwala *et al* (2016), Handy *et al* (2020) ‡Jemal and Fedewa 2017 # Gould *et al* (2015)

*Average time to diagnosis incorporates both “wait-and-see” and biopsy pathways



Last update (Feb 2023)

Actions Since

Ongoing

Validation Study

- 13 hospitals activated (+3 additional VAs)

- 17 total sites activated
- Enrolment complete
- Initiated final data collection/verification and site close-out processes

- Continue to estimate study readout by September

Regulatory

- Initiated FDA de novo application

- Continue FDA de novo application
- Successful biannual CAP audit complete

- Continue preparing FDA application and submission documents

Reimbursement

- Final pricing determination – Crosswalk
- National Medicare price of \$2,030 assigned to LungLB®

- Finalized Early Access Program design and policy
- Enrolled in key state Medicaid programs
- Onboarded Market Access professional

- Continue Market Access activities

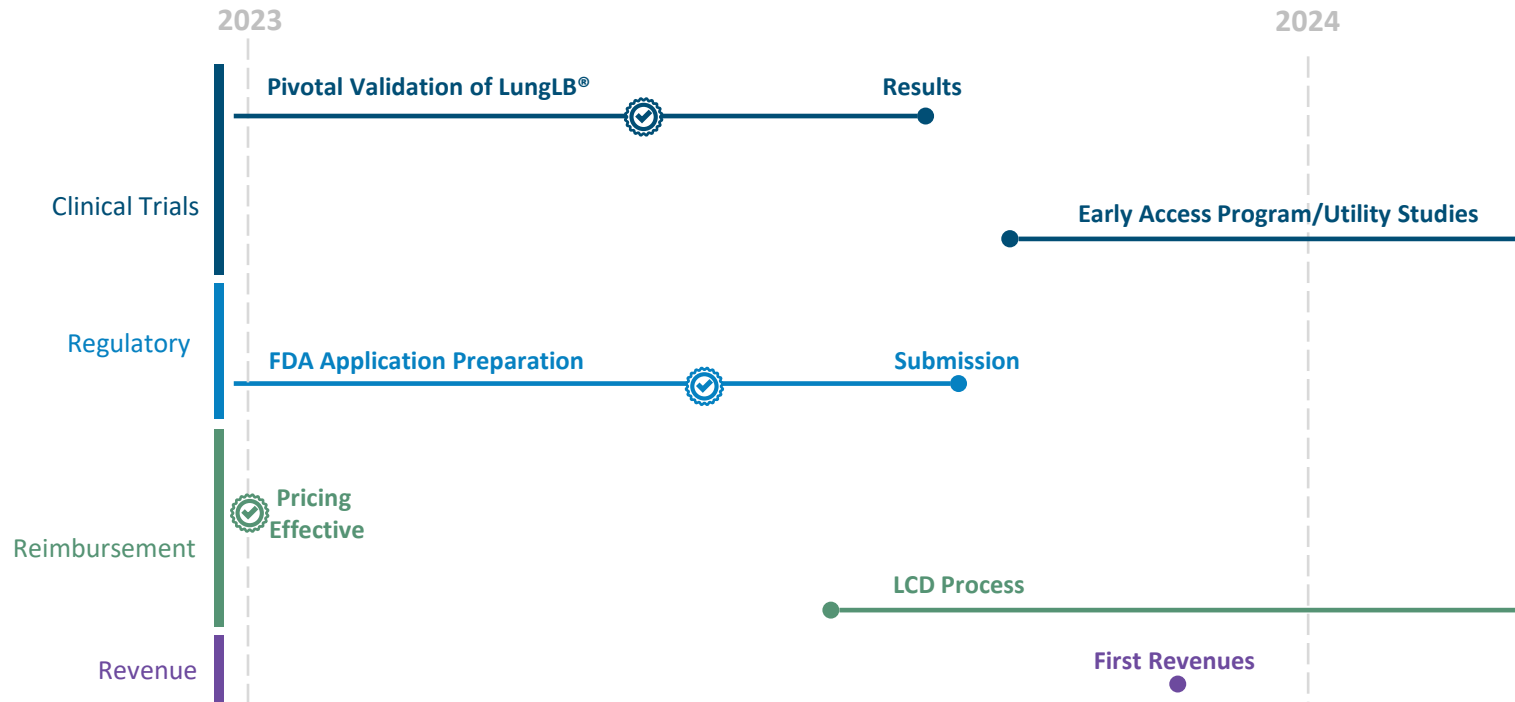
Additional Highlights

- Pilot and health econ studies submitted for publication
- EDRN partnership

- Health economics manuscript published
- Pilot study manuscript published
- Commenced enrollment for EDRN
- Industry guest speaker at Global Lung Cancer Summit



Notional timeline





Financial Highlights



- Cash at 30 June 2023 - \$5.36m. At 31 December 2022 - \$8.01m.
- Cash used by operating activities - \$2.70m. Six months to 30 June 2022 - \$3.26m
- Continued cash runway to mid 2024.
- Capacity with current equipment – c. 5,000 tests per year, equates to revenue of c. \$10.0m



Cash Flow Statement

	\$'000
Cash used by operating activities	(2,700)
Cash used by investing activities	(5)
Cash used by financing activities	(44)
Cash and deposits at 30 June 2023	5,361

Income Statement

	\$'000
Revenue	23
Administrative expenses	(2,687)
Depreciation and share based charge	(245)
Finance income	127
Finance charge	(22)
Tax	(3)
Loss for year	(2,807)



Balance Sheet

	\$'000
Receivables, incl long term	497
Cash and deposits	5,361
Tangible assets	445
Intangible assets	5,818
Trade and other payables	(970)
Leases and other liabilities	(698)
Share capital	(3)
Reserves	(92,960)
Accumulated losses	82,510

Intangible asset is the license with Mount Sinai



Urgent Unmet Need for Early Detection



High Prevalence



Someone in US diagnosed every 2.5 mins



Almost 25% of all cancer deaths in US, 130,180 deaths in 2022¹

Poor Early Detection



Surgery can cure – but only 20% of US cases diagnosed early



>1.5m lung nodules identified p.a. in US

Lack of Screening



c. 14.2m Americans eligible for free screening (2020: 6.8m)

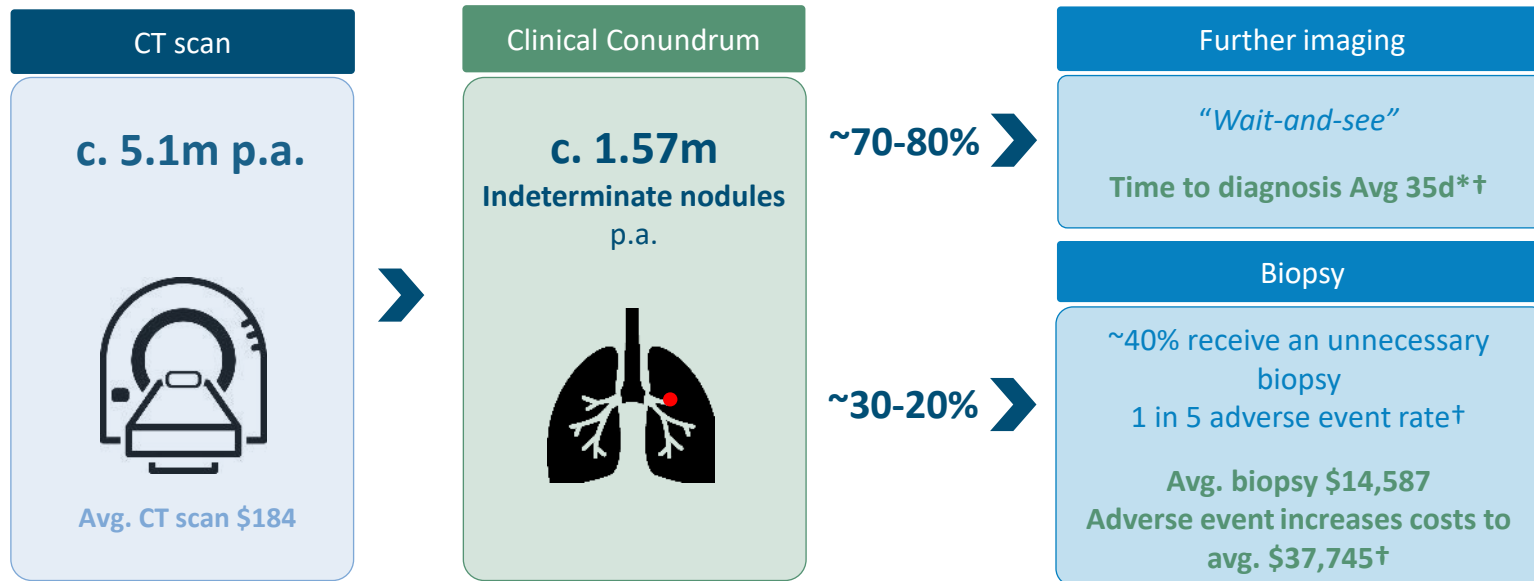


Only 5.8% of those eligible are screened

Nodules found incidentally by CT scan still account for majority of early diagnosis



Primary Clinical Pathway



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*Average time to diagnosis incorporates both “wait-and-see” and biopsy pathways



Why We Believe our LungLB[®] test is an
Answer

- » Test is a simple blood draw; CTCs and FISH are two familiar technologies
- » Strong performance across all lung cancer stages/subtypes
- » Peer-review manuscript published June 2023 – BMC Pulmonary Medicine
- » Plasma is currently preserved for complimentary analysis



PERFORMANCE

- 77% Sensitivity
- 72% Specificity
- 89% Positive Predictive Value

LAI-001: Evaluation of LungLB[®] in subjects with indeterminate lung nodules

- Pivotal validation study
- Enrolment complete (May 2023)
- 425 study participants
- 17 sites across the US



NATIONAL CANCER INSTITUTE

Early Detection Research Network

BU-UCLA Biomarker Characterization Center

- First independent validation of LungLB[®]
- Validate additional novel cell-based biomarkers
- 600 samples over the 5-year grant period

“Real-world” patients enrolled in our study:

- Majority of nodules are small, which represent earliest cancers and most challenging to detect
- >65% of participants of Medicare age: also important for reimbursement
- Study diversity gives confidence in test performance across multiple patient demographics



14mm

Small average
nodule size



67 yrs

Average Participant
Age



52%

Female
Participation



25%

Underrepresented
Group Participation



8 of 17

study sites are
Veteran's Hospitals



24%

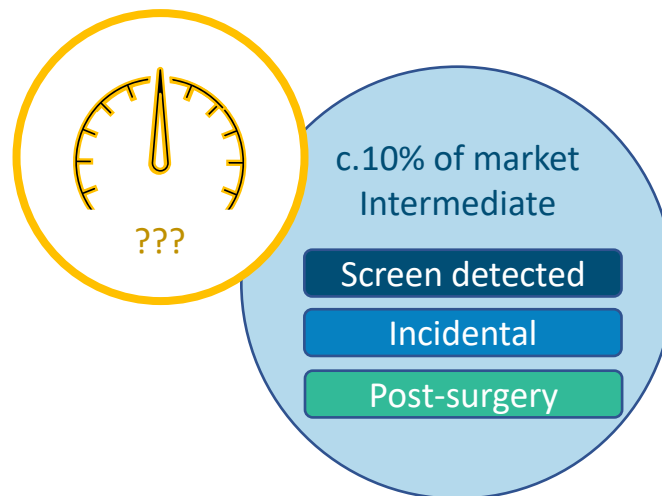
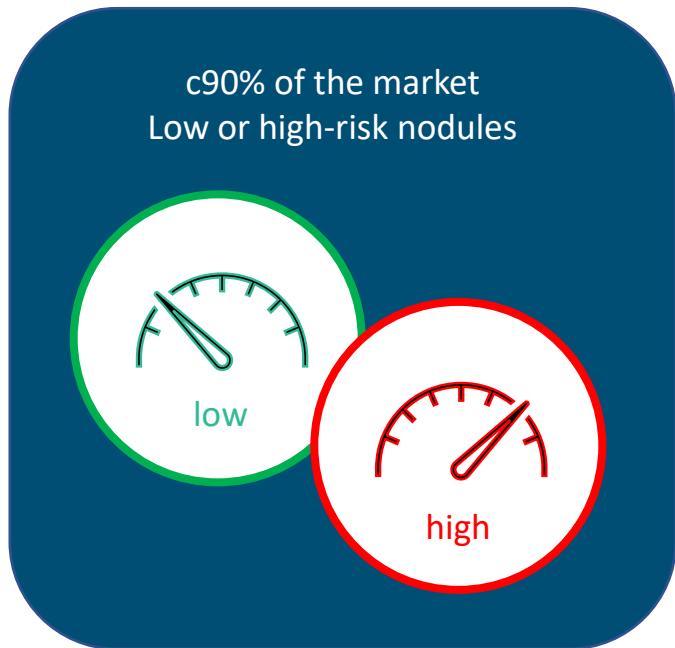
Never
smokers



Market Opportunity



Total lung cancer early detection market opportunity in US is significant



Source: American College of Radiology LungRADS



Commercialisation



▼ We have regulatory support to begin commercialisation



✓ 2019 - LungLB® qualified as a Laboratory Developed Test, LDT



✓ 2021



✓ 2022

▼ FDA is voluntary but is expected to support uptake



🎯 **Submission targeted 2023** – provides confidence to all stakeholders, rigorous study design requirements and adjunct claim is a good entry point

▼ Reimbursement is the next most important step



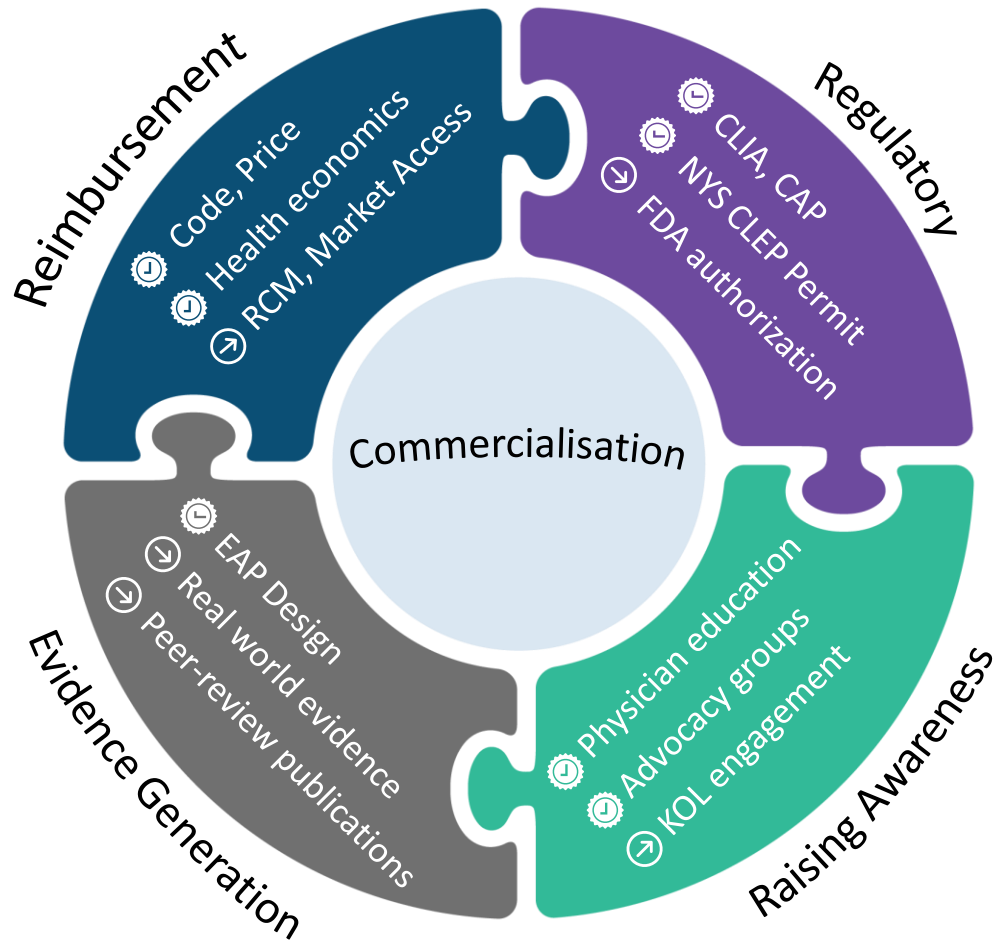
✓ Jan 2022 – PLA code granted



✓ Nov 2022 – LungLB® assigned national Medicare price at \$2,030 per test



🎯 **Coverage** – Assessment under MoIDX – supported by validation and clinical utility studies





In Summary



Pivotal Study
Enrollment and
Results



FDA de Novo
submission



Expanded
Reimbursement
(Medicaid/
Private Payor)



Initiate Clinical
Utility Studies



Nominal First
Revenues

LungLifeAI™ aims to be a driving force in the early detection of lung cancer.

Our Vision is to invert the 20:80 ratio such that at least 80% of lung cancers are diagnosed early.





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Our purpose is simple.
To be a driving force in the early detection of lung cancer.



Appendices



Executive Team

Paul Pagano, PhD

CEO & CSO



Amgen
CytomX



David Anderson

CFO



Audit Partner BDO, Crowe
FD Strategic Minerals Plc (AIM)
FD Hakkasan and C|T Group



Non-Executive Directors



Roy Davis

Independent Non-Executive Chairman



Gyrus Group, Optos, Medica, Edinburgh Molecular Imaging,
Foster & Freeman, RAIR Health



Andrew Boteler

Independent Non-Executive Director



Riverford Organic Farmers Ltd, Octopus VCT plc,
Gooch & Housego



James McCullough

Independent Non-Executive Director



Current CEO of Renalytix AI,
Verici Dx, Exosome Dx



Sara Barrington

Non-Executive Director



Current CEO of Verici Dx,
LungLife AI, Exosome Dx, Kantaro



Steven M. Dubinett, MD

Dean of Medicine,
Former Chief of Pulmonary Medicine
University of California, Los Angeles

Michael J. Donovan, PhD MD

University of Miami
Mount Sinai Health Systems

Claudia Henschke, PhD MD

Radiology
Mount Sinai Health Systems

David Yankelevitz, MD

Interventional Radiology
Mount Sinai Health Systems

Joshua D. Kuban, MD

Interventional Radiology
MD Anderson Cancer Center

Ruth Katz, MD

Professor of Pathology/Cytopathology
MD Anderson Cancer Center

Max P. Rosen, MD MPH

Chair of Radiology
UMass Memorial Medical System

Drew Moghanaki, MD MPH

Chief of Thoracic Oncology
University of California, Los Angeles



Simplicity



- Simple blood draw
- Familiar technologies: CTC and FISH
- Report: Positive/Negative

Care Pathway



- Blood tests are already required prior to biopsy
- Aid in the decision-making process: biopsy vs wait-and-see

LungLB[®] is an easy test to order and simple to understand

Advocates



“We appreciate that LungLife’s test was developed without requirement for smoking history”

Pulmonologists



“I’m starting a nodule clinic at our hospital and we’re looking for a technology like LungLB to help triage patients”

Researchers

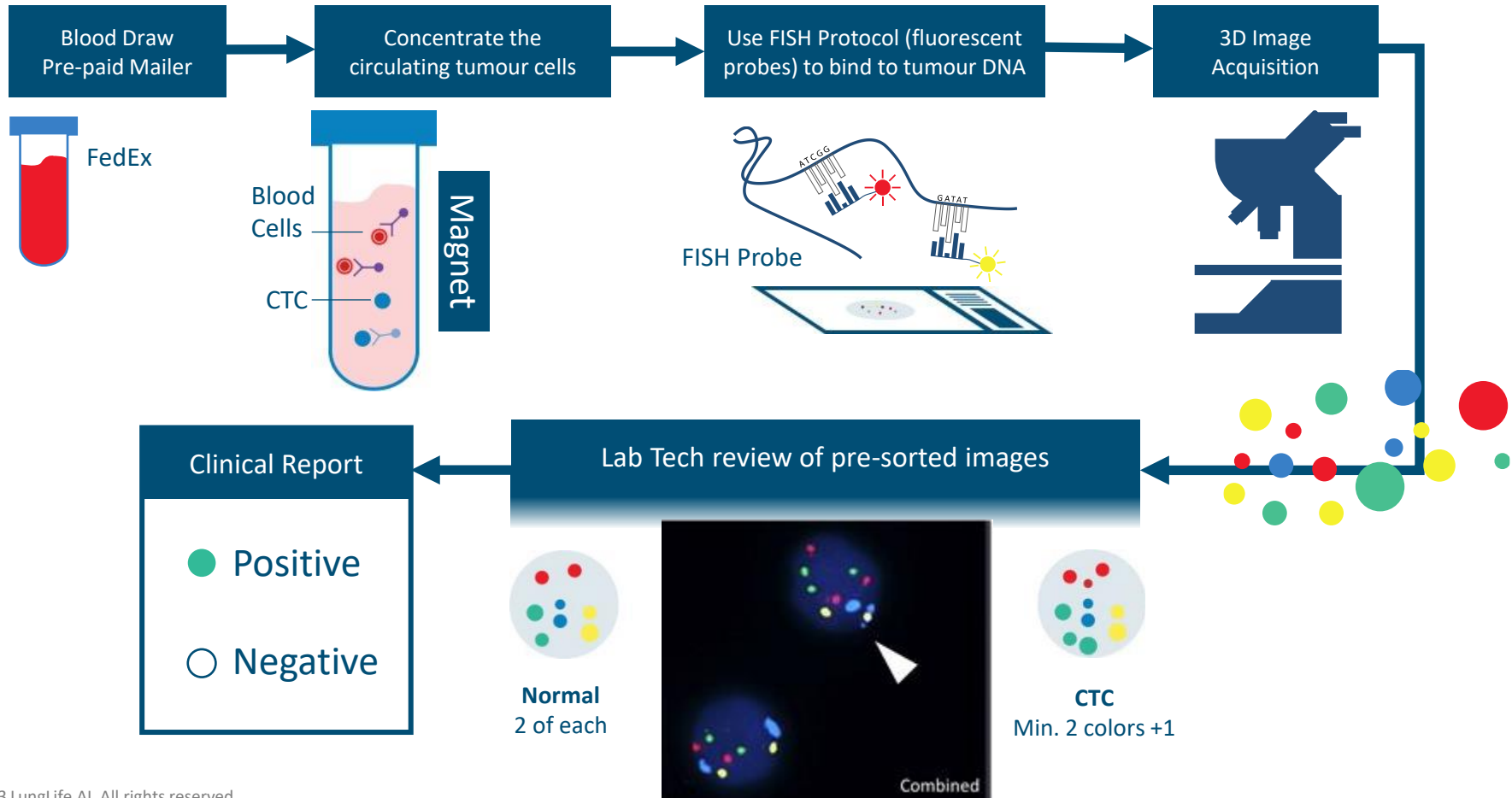


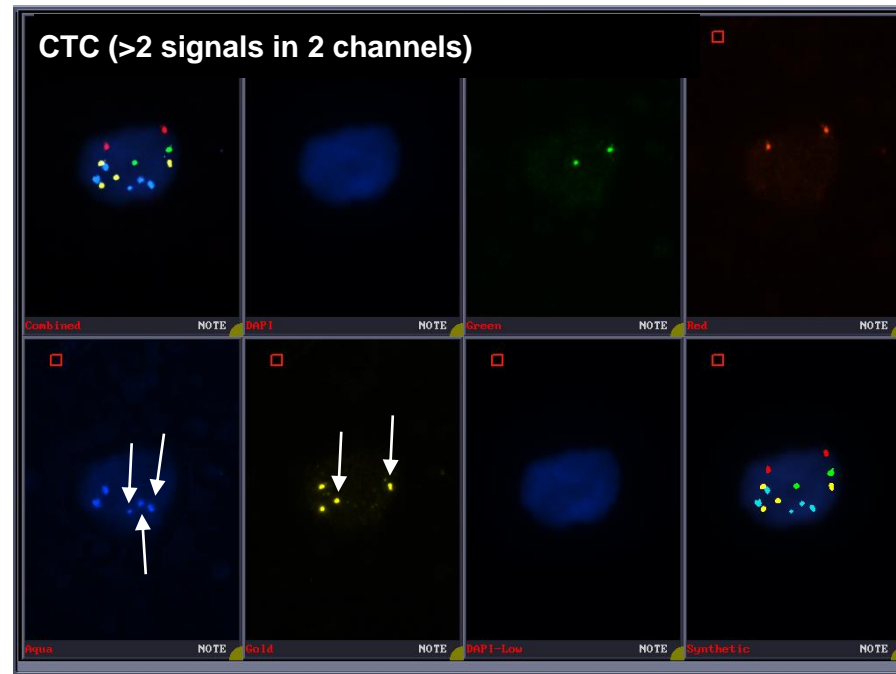
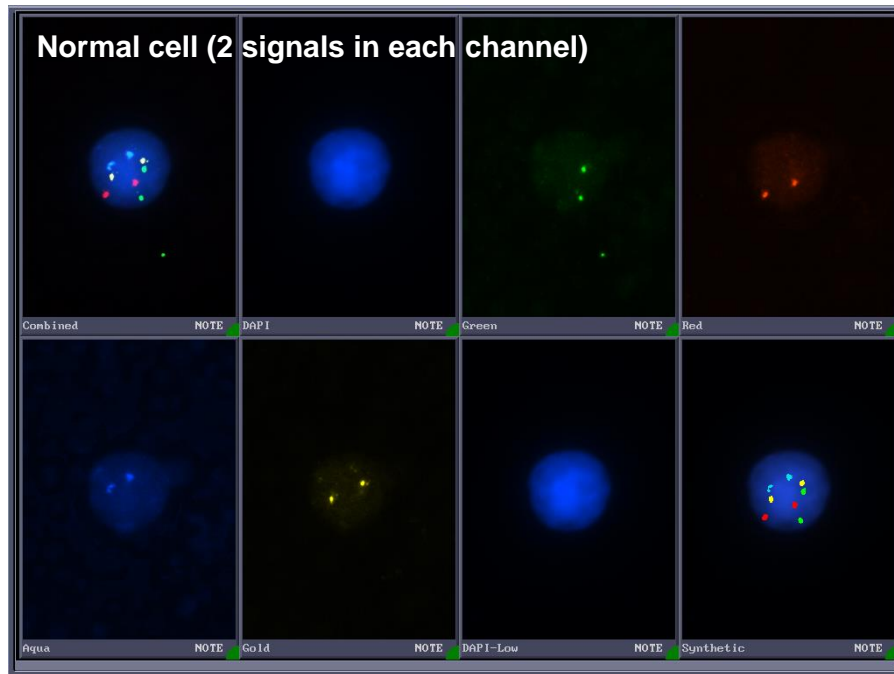
“EDRN members would be interested in LungLB’s potential to facilitate early detection of multiple cancer types”

Pulmonologists



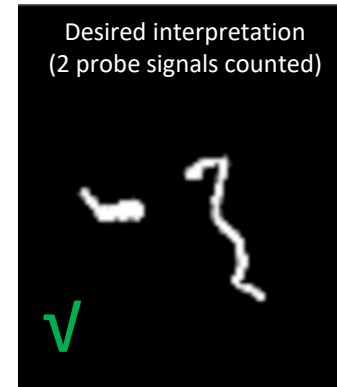
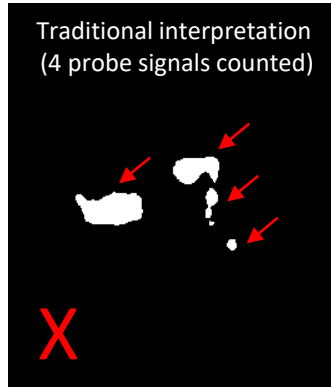
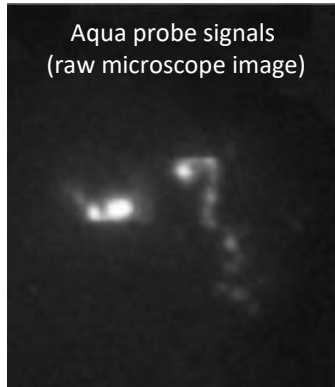
“Sometimes I need to convince other docs to take action on a suspected cancer: I think LungLB may be able to help with this”







Not all FISH images are easily interpreted



Our AI algorithm co-developed with Persistent Systems provides:

- Enhanced sensitivity: A 4-point improvement in the cancer detection rate
- Enhanced specificity: >60% reduction in miscategorised CTC vs standard FISH microscope software
- Improved objectivity and reproducibility: Algorithm defines “true” probe signal parameters