Lunit SCOPE IO®

Harness TME insights with AI-powered immune phenotyping and feature analysis

Applications

Feature identification for biomarker formation based on H&E

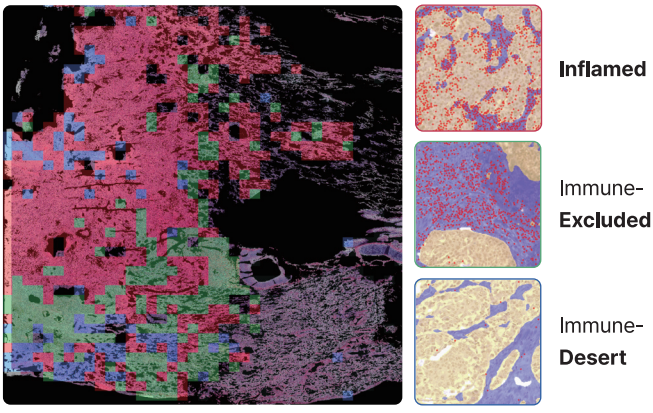
CDx Development with an AI-Powered H&E Based Digital Pathology Solution

Description

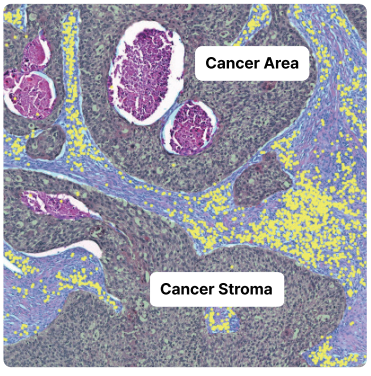
- Artificial Intelligence (AI)-based digital pathology image analysis software
- Precisely quantify immune phenotype based on a single H&E slide
- Apply across multiple cancer types
- Explore potential TME based biomarkers

Features

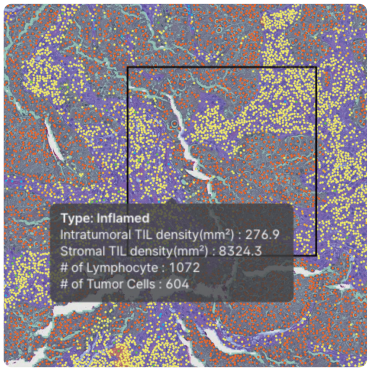
Immune Phenotyping



Cancer Area and Cancer Stroma Identification



Intratumoral TIL & Stromal TIL Density



TIL: tumor infiltrating lymphocytes
TME: tumor microenvironment

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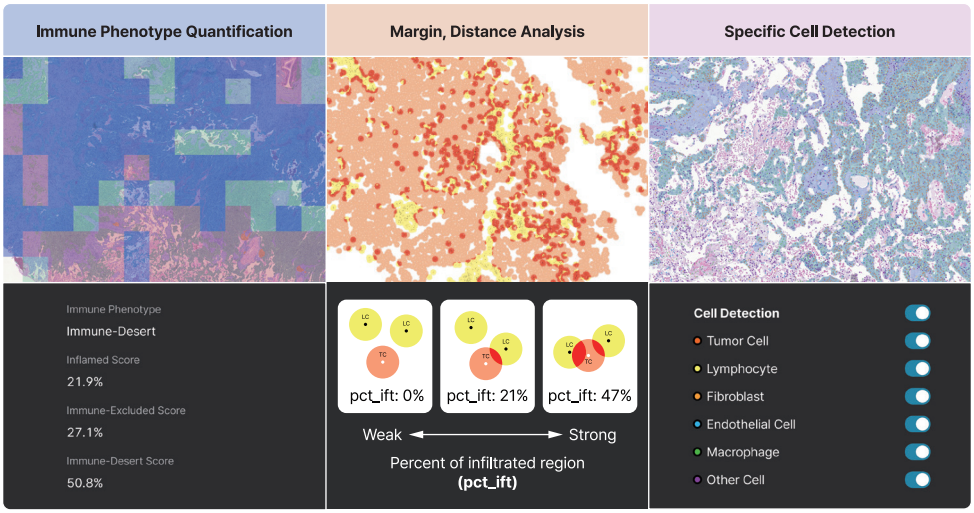
Pioneering AI-Driven Biomarker Development based on an H&E slide

Feature identification for biomarker formation based on H&E

AI-powered Advanced Feature Identification

- Tertiary Lymphoid Structures
- Necrosis
- Mitosis
- Selected histology predictor (e.g. squamous / non-squamous)
- Cell / nucleus size of each cell
- Cell size and variability
- TSR (Tumor-Stroma Ratio)
- Delineation of TSB (Tumor Stromal Border)
- Cell types identified include tumor cells, lymphocytes, macrophages, fibroblasts, and endothelial cells

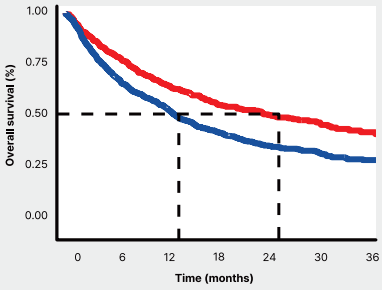


CDx development with an AI-powered H&E based digital pathology solution

Tumor-agnostic AI biomarker for patient selection of ICI clinical trials, validated in multiple peer-reviewed studies, in journals including JCO, JITC, and more

Multiple Lunit SCOPE IO biomarkers have shown promise for prediction of response to ICI trials

A. Quantification of immune phenotypes



Group	N	mOS (95% CI)	HR (95% CI), *P-value*
IIP	636	25.3 (19.5 - 32.8)	0.66 (0.57 - 0.75), <0.001
non-IIP	1170	13.6 (12.6 - 14.8)	

AI-defined IIP shows promise as a practical, tumoragnostic biomarker for predicting ICI therapy outcomes.

B. Density of endothelial cells[5]
Deep learning-powered H&E whole-slide image analysis of endothelial cells characterize tumor vascular environment and correlates treatment outcome to immunotherapy

C. Tertiary Lymphoid Structures[6]
AI-powered H&E whole-slide image analysis of tertiary lymphoid structure to predict response to immunotherapy in non-small cell lung cancer.

Versatility and end-to-end CDx capabilities

Pan-tumor application
- H&E trained, tuned, and validated across broad targets and tissue types

Scanner compatibility
- Compatible file types include Leica (.svs), Philips (.iSyntax, .tiff), 3D Histech (.mrxs), Hamamatsu (.ndpi) and other scanners at x40 magnification

Regulatory & QMS track record
- 3 Lunit SaMDs registered globally
- ISO 13485, US FDA 21 CFR Part 820, MDSAP

Scalable deployment
- Digital pathology platforms & CRO partners
- Global commercial footprint

Selected Publications List
1. J Clin Oncol 2022 Artificial Intelligence–Powered Spatial Analysis of Tumor-Infiltrating Lymphocytes as Complementary Biomarker for Immune Checkpoint Inhibition in Non–Small-Cell Lung Cancer
2. JITC 2024 Inflamed immune phenotype predicts favorable clinical outcomes of immune checkpoint inhibitor therapy across multiple cancer types
3. NPJ Breast Cancer 2023 Deep learning model improves tumor-infiltrating lymphocyte evaluation and therapeutic response prediction in breast cancer
4. J Clin Oncol 2023 A phase 3, randomized study of atezolizumab plus bevacizumab and chemotherapy in patients with EGFR or ALK mutated in non-small cell lung cancer (ATTLAS, KCSG_LU19-04)
5. ASCO 2025 Deep learning–powered H&E whole-slide image analysis of endothelial cells to characterize tumor vascular environment and correlate treatment outcome to immunotherapy
6. ASCO 2024 Artificial intelligence (AI) -powered H&E whole-slide image (WSI) analysis of tertiary lymphoid structure (TLS) to predict response to immunotherapy in non-small cell lung cancer (NSCLC)

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