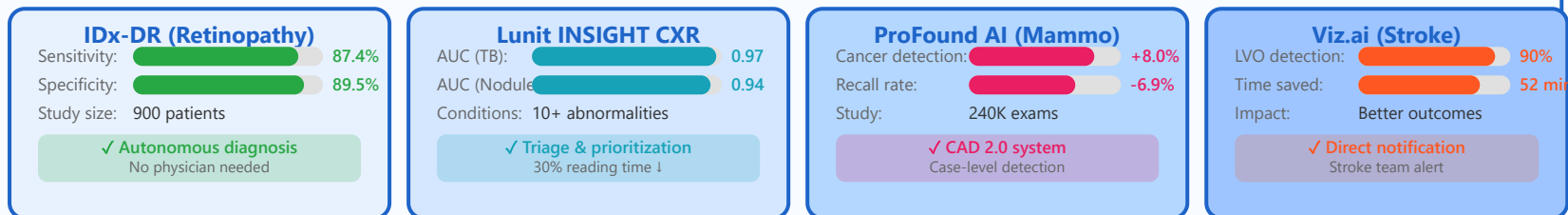
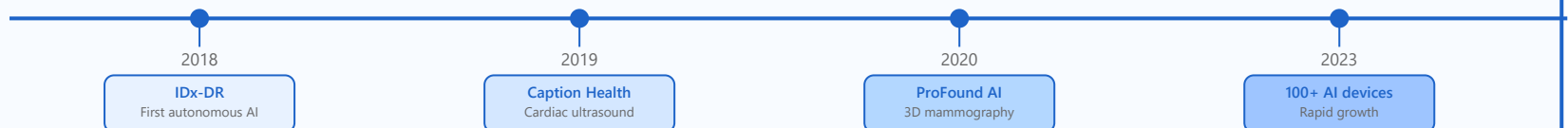


Clinical Case Studies: AI in Medical Imaging

FDA-Approved AI Systems: Real-World Performance



FDA Approval Timeline



Diabetic Retinopathy

FDA-approved IDx-DR system. Autonomous diagnosis without physician review

Chest X-ray Screening

Qure.ai qXR, Lunit INSIGHT CXR. Detection of 20+ thoracic abnormalities

Mammography CAD

iCAD ProFound AI, Transpara. 5-8% increase in cancer detection rate

Stroke Detection

Viz.ai, RapidAI. Automated LVO detection and care team notification

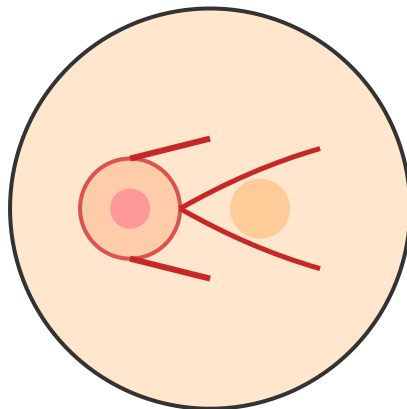
Pathology Applications

Digital pathology with AI. Cancer detection in biopsies, PD-L1 scoring

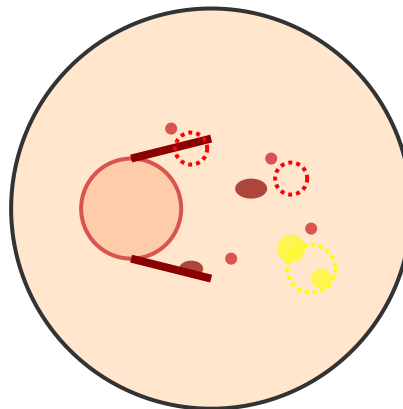
Detailed Case Studies and Clinical Applications

1 Diabetic Retinopathy Detection: IDx-DR System

Normal Retina



Diabetic Retinopathy



AI Detection Process

1. Image Acquisition

- Non-mydriatic fundus camera

2. Quality Check

- Automated image quality assessment

3. AI Analysis

- Deep learning detection algorithm

4. Autonomous Decision

- Immediate result
- No physician review required

Clinical Significance

Technical Specifications

- First FDA-approved autonomous AI diagnostic system (April 2018)
- Detects more-than-mild diabetic retinopathy
- Primary care settings without ophthalmologist
- Addresses healthcare access disparities
- Point-of-care screening capability

- Convolutional neural network architecture
- Trained on 1.3 million retinal images
- 87.4% sensitivity, 89.5% specificity
- Result in under 1 minute
- Works with standard fundus cameras

Clinical Impact: In a multi-center study of 900 patients, IDx-DR demonstrated the ability to provide immediate screening results in primary care settings, reducing the need for specialist referrals by 60% while maintaining high diagnostic accuracy. The system detected referable diabetic retinopathy with performance exceeding the FDA's prespecified targets.

Patients Screened (2018-2023):

75,000+

Average Diagnosis Time:

60 seconds

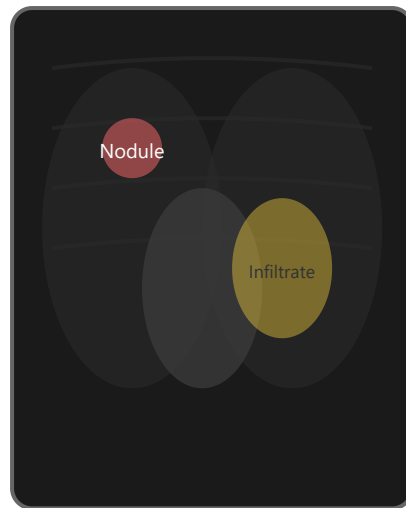
Positive Predictive Value:

91.6%

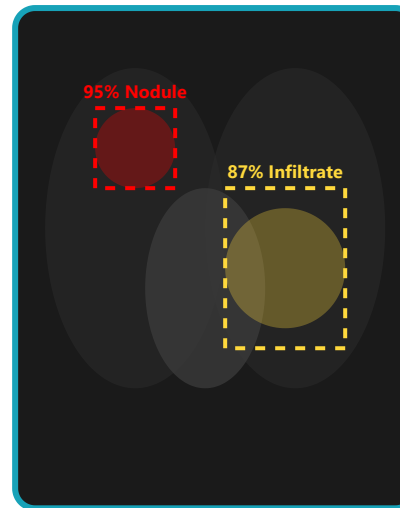
2

Chest X-ray Screening: Lunit INSIGHT CXR & Qure.ai

Chest X-ray Analysis



AI Detection Overlay



Detectable Conditions

Pulmonary Conditions:

- Tuberculosis (AUC: 0.97)
- Pneumonia / Infiltrates
- Pulmonary nodules (AUC: 0.94)
- Pneumothorax
- Pleural effusion

Cardiac Conditions:

- Cardiomegaly
- Pulmonary edema

Other Findings:

- Fibrosis / Atelectasis
- Calcification
- Fractures

Clinical Applications

- Emergency department triage and prioritization
- Tuberculosis screening in high-burden regions
- COVID-19 pneumonia detection during pandemic
- Reducing radiologist workload (30% time reduction)
- Quality assurance and double-reading

System Capabilities

- Multi-class abnormality detection (10+ conditions)
- Lesion localization with bounding boxes
- Heatmap visualization for interpretation
- Critical finding alerts and worklist prioritization
- Integration with PACS systems

Real-World Impact: Lunit INSIGHT CXR has been deployed in over 3,000 medical institutions across 50+ countries. In tuberculosis screening programs, the AI achieved sensitivity comparable to expert radiologists while processing images 100x faster, enabling mass screening campaigns in resource-limited settings. Studies show a 30% reduction in reading time and improved detection of subtle findings.

TB Detection Sensitivity:

97.0% (AUC)

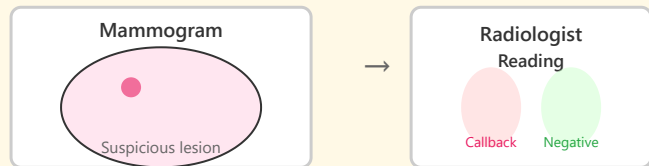
Processing Time per Image:

2-3 seconds

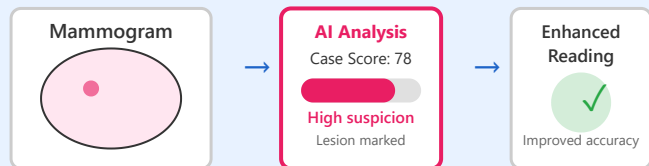
3 Mammography CAD: ProFound AI & Transpara

Mammography Screening Workflow

Traditional Screening



AI-Assisted Screening (ProFound AI)



Clinical Performance Improvements

Cancer Detection Rate

Traditional: 4.2%

With AI: 4.5%

+8.0%

False Positive Rate / Recall

Traditional: 10.4%

With AI: 9.7%

-6.9%

Reading Efficiency

63 sec/case

Study: 240,000 screening exams analyzed
Real-world performance in clinical practice

Faster

Key Features

- 3D tomosynthesis and 2D mammography analysis
- Case-level suspicion scoring (0-100 scale)
- Lesion localization with confidence levels
- Comparison with prior examinations
- Integration with radiologist workflow

Clinical Benefits

- 8% increase in cancer detection (absolute)
- 7% reduction in false-positive recalls
- Earlier detection of interval cancers
- Reduced reader variability
- Support for less experienced readers

ProFound AI Study Results: In a retrospective study of 240,000 mammography exams, ProFound AI demonstrated significant improvements in both cancer detection and recall rates. The AI system detected 8% more cancers compared to traditional screening while simultaneously reducing unnecessary callbacks by 7%. This dual benefit addresses two major challenges in breast cancer screening: improving sensitivity while maintaining or improving specificity.

Additional Cancers Detected:

+8.0% improvement

Reduction in False Positives:

-6.9% fewer callbacks

AUC Performance:

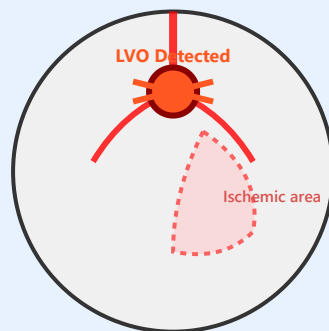
0.89 - 0.92

4

Stroke Detection: Viz.ai & RapidAI

Large Vessel Occlusion (LVO) Detection & Response

CT Angiography Analysis



AI Confidence: 94%

Automated Notification & Care Coordination

T = 0 min



CT Scan
Completed

AI Analysis

T = 5 min



Alert Sent
Stroke team
Interventionalist
ED physician

T = 30 min



Team Ready
Cath lab prepared
Team assembled
Patient en route

T = 60 min



Treatment
Thrombectomy
started

Traditional vs AI-Assisted Workflow

Traditional time to treatment: **142 minutes**

AI-assisted time to treatment: **90 minutes**

52 minutes saved - "Time is brain"

System Workflow

Clinical Outcomes

- Automated CT/CTA analysis upon completion
- Real-time LVO detection (90% sensitivity)
- Immediate mobile app notification to stroke team
- Case details and images shared instantly
- Direct communication platform for coordination

- 52-minute reduction in time-to-treatment
- Increased thrombectomy rates (appropriate cases)
- Improved functional outcomes (mRS scores)
- Better coordination between hospitals
- Reduced door-to-groin puncture time

Time-Critical Impact: Viz.ai's stroke detection platform has been used in over 1,500 hospitals, analyzing more than 3 million CT scans. Studies show that AI-assisted workflow reduces time from imaging to treatment by an average of 52 minutes. In stroke care, this translates to saving approximately 2 million neurons per minute, significantly improving patient outcomes. The system has helped coordinate transfers for appropriate thrombectomy candidates and reduced unnecessary transfers.

LVO Detection Sensitivity:

90%

Average Time Saved:

52 minutes

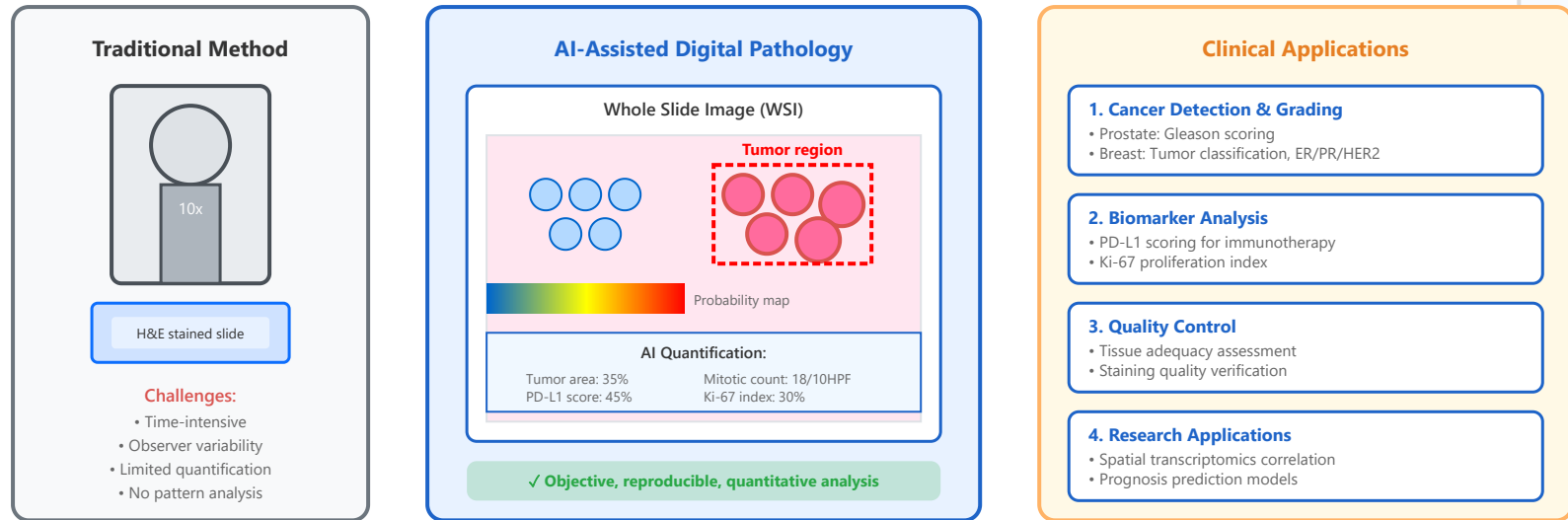
Hospitals Using Platform:

1,500+

5

Digital Pathology with AI

AI-Assisted Pathology Workflow



Technology Platforms

- Paige AI (FDA-approved cancer detection)
- PathAI (biopsy analysis & biomarkers)
- Proscia (workflow optimization)
- Ibex Medical Analytics (Galen platform)
- Deep learning on whole slide images (WSI)

Key Advantages

- Objective, quantitative measurements
- High reproducibility (inter-observer agreement)
- Detection of subtle morphological patterns
- Automated biomarker quantification
- Integration with molecular pathology data

Paige Prostate System: The first FDA-approved AI system for digital pathology (2021) assists pathologists in detecting prostate cancer on biopsy specimens. In validation studies, the AI achieved 98.3% sensitivity with 2.8 false positives per case, performing comparably to experienced pathologists. The system reduces review time while maintaining diagnostic accuracy, particularly helpful for detecting small tumor foci that might be missed in routine screening.

Cancer Detection Sensitivity:

98.3%

PD-L1 Scoring Agreement:

$\kappa = 0.89$ (high concordance)

Review Time Reduction:

25-40%