From Automating Muscle to Augmenting the Brain

How Artificial Intelligence Will Change the Clinical Laboratory

An exciting new survey from Siemens Healthineers of 200 hospital or laboratory senior executives and lab directors explored the not-so-distant future of the impact of artificial intelligence (AI) on the in vitro diagnostic (IVD) laboratory. Sixty-nine percent expect widespread adoption of AI in the IVD lab within the next four years, and 92 percent expect AI to have a significant impact on healthcare eventually. This is good news for patients and providers, as AI is expected to reduce cost, improve the patient experience, and increase efficiency industrywide. To better understand these AI trends and expectations, let's understand what AI truly is and how the industry got here.

AI has the ability to transform care delivery: From improved diagnostic accuracy to better patient care, it will propel the industry forward. But AI is a daunting topic—the vast changes, unknown risks, and uncharted territory can overwhelm experts and novices alike. Still, this type of change isn't unprecedented in the industry; the introduction of X-ray technology in the late 19th century evoked many of the same fears yet ultimately transformed the healthcare industry.

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Siemens Healthineers: 2018 Future of Artificial Intelligence in the Diagnostic Lab Survey

Global health system leaders and in vitro diagnostic laboratory senior management shared their insights on the role of AI in the IVD lab in the coming years.

ReRez Research of Dallas, Texas, conducted the survey in May 2018. The respondents included the following:

20%
Germany

25%
U.S.

15%
U.K.

15%
Italy

25%
China
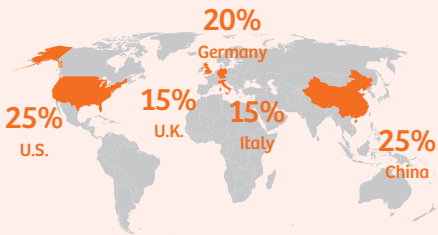
200 Responses

Lab Type

62% Hospitals

23% Reference Labs

14% Health Systems or IDNs

Role

80% Lab Directors

20% Executive Leadership

All roles have decision-making responsibility.

X-rays Herald New Era of Medical Technology

In 1895, German physicist Wilhelm Roentgen discovered X-rays and used the new technology to scan his wife's hand. Seeing the photo of her skeletal fingers, she remarked, "I have seen my own death." X-rays became an instant medical phenomenon, allowing doctors to see what they'd never seen before. For the first time in history, doctors could evaluate internal signs, leading to a major leap forward in diagnostic capability.

But this initial fascination began to give way to two fundamental fears: invasion of privacy and unintended consequences. But, the clear value that X-ray imaging provided to healthcare pushed the industry to address privacy and safety challenges, and X-rays continue to play a vital role in medical imaging today.

Healthcare is on the precipice of another major leap forward: artificial, or augmented, intelligence. Many of the same trepidations persist, from concerns for patient confidentiality and privacy to fear of unintended consequences that come with machines that will become more intelligent than humans. Yet, as with X-rays, AI will transform healthcare in fundamental ways. In this white paper, we will discuss what AI is and why it is relevant for IVD laboratories, examine the road to AI, consider how regulation will impact its adoption, and provide tangible actions that organizations can take today to prepare for this emerging technology.

What Is AI?

For the purposes of this white paper, focusing on healthcare and specifically the IVD lab, we define artificial intelligence as follows:

AI refers to sophisticated software systems that enable computers to augment, or even emulate, human intelligence and decision making.

Beneath the heading of AI is "machine learning," which uses algorithms to parse and learn from data and then applies this learning to provide insight and make informed recommendations. The system learns by mimicking the perception and decision making of experts. By analyzing large amounts of training data that has been curated with known outcomes (such as oncological imaging where the diagnosis is known), the system recognizes patterns and applies what it has learned to new scans, automatically perceiving and analyzing signs to make determinations. If the algorithm makes an error in detection or diagnosis, it can be corrected by the expert. Subsequent versions of the algorithm can then learn from these mistakes.

The key distinction between AI and other software or computer-based technologies is that AI has the capacity to learn and improve from data and experience. Other technologies can handle complex tasks but cannot perform actions or form conclusions to augment clinicians' and patients' care decisions that are not specifically programmed.

In healthcare, the massive datasets used in training, validation, and subsequent continuous learning may originate from clinical records, population electronic health records, medical research, laboratory information systems (LIS) data, and diagnostics such as scans, imaging, and video.

Diagnostic Decision Support System

Computer-aided detection and diagnosis uses algorithms to analyze the data available in a patient electronic health record (EHR), lab test results, diagnostic imaging, etc., to suggest possible diagnoses to the clinician, which improves accuracy by almost 9 percent.[1] This technology is known as a diagnostic decision support system (DDSS). One example is automated cardiac risk assessment, which uses global cardiac risk scores in combination with lab data and EHRs to computerize risk stratification. As both the quality and quantity of available data increase through careful curation, the reliability of automated diagnostic and therapeutic recommendations will continually improve.

A DDSS lowers costs and improves patient outcomes in three primary ways:

- Recommends the ideal mix of tests to determine a diagnosis.

- Automates mundane aspects of the clinician's job, allowing him or her to prioritize more-critical tasks.

- Delivers faster and more accurate diagnoses and treatments with improved algorithms.

The purpose of the DDSS is not to replace diagnosticians, but rather to augment their decision making. As Warry van Gelder of Netherlands-based Result Laboratorium said, *"There's a lot to expect in the coming 2–3 years. AI will be used for laborious and dull types of work that can be easily automated without interfering with the real expertise of the doctors. There will still be a lot of work done by doctors, but it will be a different type of work. It will focus on their real expertise, which can't be easily translated to AI programs."*

Predictive Maintenance

Beyond clinical decision making within the lab, AI can also support operations. By monitoring diagnostic equipment across labs, AI can use machine learning to recognize patterns that predict issues before they result in system failures or unplanned downtime, increasing workforce productivity and optimizing clinical operations.

The ability of AI-based systems to anticipate problems with equipment enables timely, scheduled, predictive maintenance that can help reduce costs and improve patient outcomes by identifying and solving problems proactively. Predictive maintenance systems also inspire confidence in test results, because clinicians know that lab conditions and instrument functionality are optimally maintained.

Most Believe in AI's Impact, But Are Unsure Where to Begin

In the 2018 Artificial Intelligence in the Diagnostic Lab survey:

• 69 percent believe that AI will be implemented in the clinical lab within the next four years.
• 54 percent do not know where to begin.

In fact, the path to AI has already begun:

• 49 percent of all labs are already engaged with AI.
• 34 percent planning to engage with AI in the future.

> *"I definitely think AI will make an impact, but I think it's early. We're utilizing algorithms to identify patients who have care gaps in their treatment plans. It's not quite AI—it is more an early precursor. In the future, we're going to see a lot more sophistication with AI in identifying what patients need."*
>
> **Eric Carbonneau**
> **Director Core Laboratory Operations**
> **TriCore Reference Laboratories**
> **United States**

But, as Carbonneau states, we are still in the early days:

• Only 20 percent are at the implementation stage.
• Only 29 percent are discussing or trialing AI.

Clinical Laboratories Unsure How to Start with AI

92%

Most believe AI will have an important impact

19%

Few know where to begin with AI
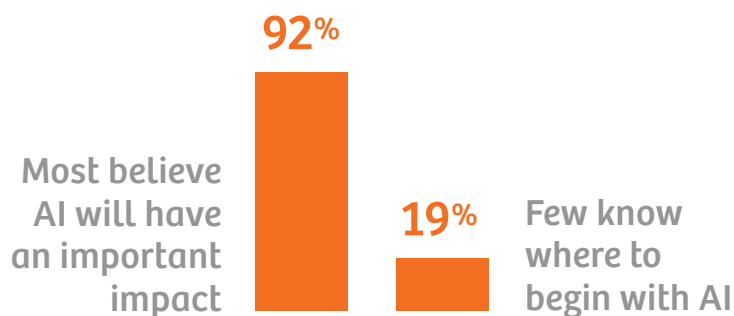
In the same survey, 69 percent of respondents believe that AI will be implemented in the clinical lab within the next four years. In fact, the path to AI has already begun. Forty-nine percent of all labs are already engaged with AI, with 34 percent planning to engage with AI in the future. But, as Carbonneau states, we are still in the early days, with only 20 percent at the implementation stage and 29 percent discussing or trialing AI.

Automating Laboratory Diagnostics: the Road to AI

Stage 1: Automation replaces manual labor

Investment in innovative laboratory technology such as automation has reduced manual labor and increased efficiency throughout the diagnostic testing process. Most, if not all, hospital and reference laboratories have already implemented some form of automation.

Lab Engagement in AI

34%

Planning to engage

20%

Implementing or implemented

29%

Discussing or trialing

19%

Not engaged
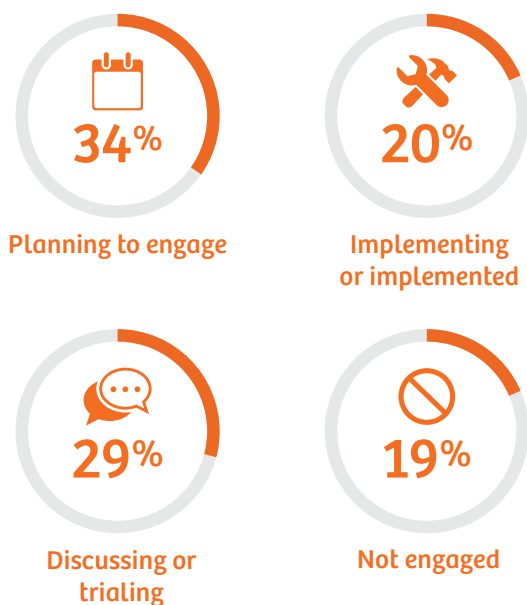
Stage 2: Digitalization automates information flow

Rules-based programming has replaced many human tasks and judgment decisions in the clinical laboratory, accelerating workflow and reducing errors. Digitalization has replaced handwritten results manually compiled and forwarded to physicians. Technology has evolved to include automated test ordering, autoverification, workflow management, intelligent tube routing, and clinical decision support.

Autoverification enables consistent and accurate confirmation of test results without human intervention. It increases efficiency and reduces human error by having software perform a time-consuming, repetitive task, significantly increasing workforce productivity.

Additionally, predictive maintenance technology reduces critical downtime for key analyzers by constantly monitoring systems and proactively determining the optimal time for repair before an unexpected problem can disrupt operations.

Machine Learning and Pattern Recognition in Molecular Diagnostics

Syndromic molecular testing looks at the broad range of pathogens associated with a particular syndrome or condition, rather than testing for each potential pathogen one at a time. Using multiplex molecular panels, it conducts a large array of tests simultaneously on a single patient sample using real-time analysis at the molecular level (RNA and DNA). Compared to other lab tests, these innovative technologies produce a great deal of data from both the individual patient sample and other sources. As this data expands in quantity and complexity, it becomes more difficult for clinicians to review and interpret the results to make diagnoses.

AI-driven decision support software can assist clinicians by recognizing patterns within a patient's symptoms, history, and risk profiles to not only identify the cause of the disease, but, in some cases, the best therapeutic path forward.

Currently, machine learning trains the analytical software with thousands of previous patient samples to accurately analyze the raw data from each new patient sample.

As AI technology is further implemented, incorporating more data from the laboratory, hospital network, and even global population, systems can evaluate additional risk factors and uncover patterns that doctors haven't yet identified or are currently too large to interpret. This will improve and personalize the immediate patient diagnosis and also help physicians understand other factors contributing to diseases.
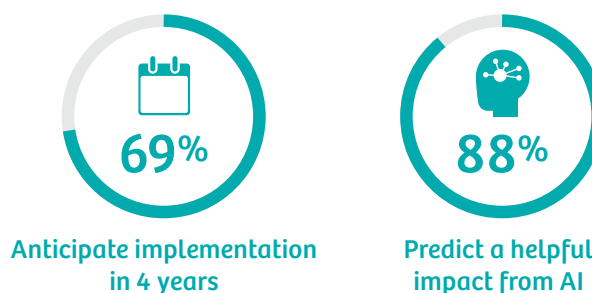
MIT/Harvard Experiment
Identifying Cancer: Artificial Intelligence vs. Pathologists[2]

99.5%

96%

92%

100%

95%

90%

AI alone | **Pathologists alone** | **Pathologists supported by AI**
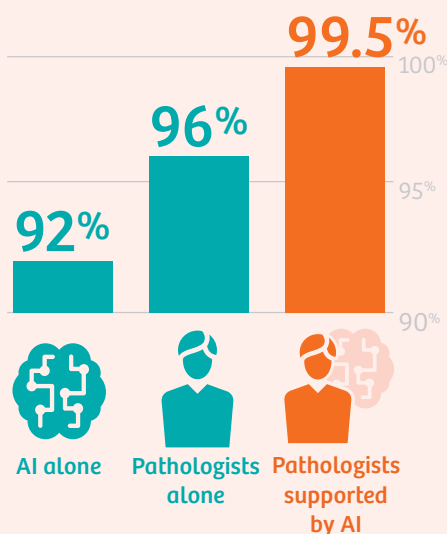
Stage 3: Lab leaders see AI in the near future
Healthcare—and the diagnostic lab in particular—is rapidly approaching AI. Sixty-nine percent of executives and lab directors anticipate implementation in the lab within four years, and 88 percent predict AI will be important for the diagnostic lab. Survey respondents envision better patient-care pathways, improved detection and diagnosis of rare conditions, and better prevention of chronic diseases.

Where Lab Leaders See AI in the Future

69%

Anticipate implementation in 4 years

88%

Predict a helpful impact from AI

Early AI processes will reduce or eliminate manual effort and speed decision-making work but are not expected to fully replace the physician and lab technologist. Instead, AI will support laboratory clinicians by streamlining the mundane aspects of their day, enabling them to focus on the complex cases.

To illustrate the potential, consider the results of a joint MIT/Harvard experiment from 2016.[2] The team evaluated the performance of three groups in correctly identifying cancerous lymph nodes:

• Pathologists alone

• AI alone

• Pathologists supported by AI

Individual pathologists outperformed AI, correctly identifying 96 percent versus 92 percent of diseased nodes. However, when the pathologists were supported by AI through computer-aided detection/diagnosis, they were able to accurately diagnose 99.5 percent of the cases. The team determined that most of the errors made by the pathologists were due to time constraints, and when AI quickly eliminated simple cases, the humans could take their time on complex scans and ensure accuracy.
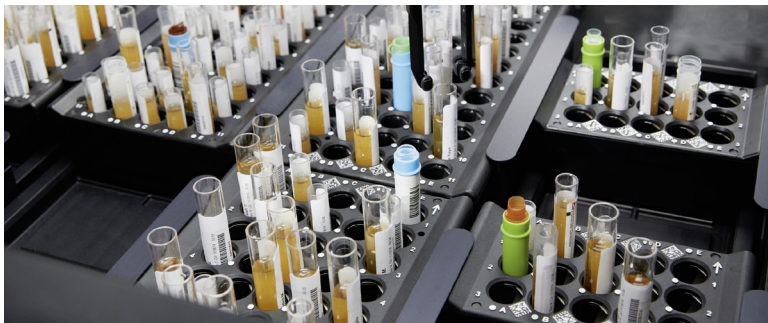
Stage 4: AI becomes mainstream

Eventually, as it continues to learn and improve, AI will handle more non-patient interactions. AI is expected to transform the full patient-care continuum, from checking a patient's EHR to ordering tests and even integrating diagnostic information, symptoms, risk profiles, and demographics to recommend diagnoses and treatment options.

In fact, 90 percent of survey respondents believe that AI will have a valuable impact on the diagnostic process within the next decade. Further, respondents believe that AI will lead to a reduction in errors (88 percent), improved TAT (86 percent), better patient outcomes (81 percent), and fewer unwarranted variations (78 percent).

AI Optimizing Workflow

While the value of AI in diagnostic decision support is clear, AI can also streamline workflow.

For example, in the diagnostic lab, an AI-driven vision system can:

- Characterize sample container types as they are loaded onto an instrument.
- Distinguish different tubes, pediatric microcollection devices, and tube-top sample cups.
- Automatically determine how to route and handle each sample.

In the CT lab, 3-D cameras can recognize anatomical landmarks including the patient's shape, positioning, and height and align the table to:

- Precisely position the patient.
- Reduce errors in the image.
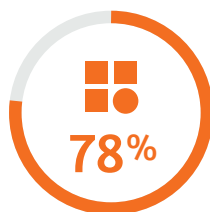- Avoid nonreimbursed rescans.

Objectives of AI in the Lab
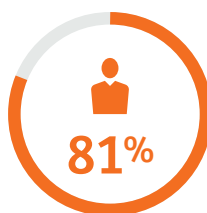
90% Improve diagnostic accuracy

78% Reduce unwanted variations

88% Reduce errors
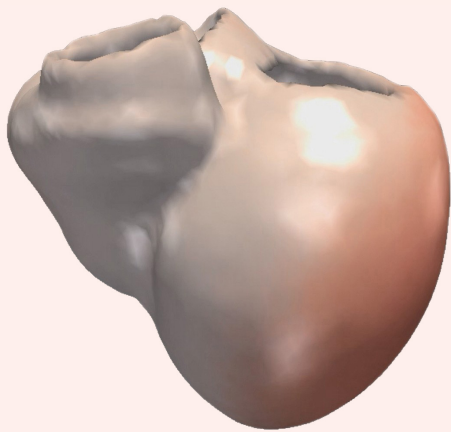
86% Improve turn-around time

81% Achieve better patient outcomes

Integrating Laboratory Data and Imaging for a Holistic View

AI can create a real-time virtual model—a "digital twin"—of the heart, by combining multiple diagnostic modalities, including:

• Ultrasound
• MRI
• X-ray
• Cardiac assays, including
  high-sensitivity troponin

Cost, lack of training, and regulation are barriers to mainstream adoption of AI. Implementation will require both patients and the medical community to develop confidence in AI's findings as well as effective oversight and approvals from regulatory agencies. Let's examine the current state of regulation and project how it may change in the next few years.

> *"In cases of discrepancy between test and diagnosis results, AI may automatically find these exceptions and remove errors and redundant information by analyzing large amounts of data."*
>
> **Dr. Ling Qiu**
> **Vice Director, Department of Lab Medicine**
> **Peking Union Medical College Hospital (PUMCH)**
> **China**

The Evolution of Regulation

Healthcare leaders have expressed concern about the impact of regulation on AI's adoption: 81 percent believe that regulation will be a significant hurdle. Much of this concern stems from the current state of regulation, which is evaluating AI in the same way as traditional technologies.

The existing regulatory-approval framework was developed for "static" software and requires that each new release be submitted for review. But AI systems are inherently dynamic and continuously evolving, with their ability to autonomously analyze and learn from information and use this data to make correlations, predictions, and decisions. Further, data privacy laws such as the Health Insurance Portability and Accountability Act (HIPAA) in the U.S. and the General Data Protection Regulation (GDPR) in Europe affect how systems access and share data, which impacts AI's ability to learn.

Recognizing the potential for AI advancement, global regulators are exploring how to balance patient safety and confidentiality with the need for innovation. For example, the U.K.'s Committee on Artificial Intelligence has tasked the National Health Service (NHS) to outline data sharing plans by the end of 2018.[3]

In the U.S., the Food and Drug Administration (FDA) has for the past 20 years approved computer-assisted detection and diagnostic devices possessing progressively increasing degrees of autonomy. Recently, the FDA approved AI-driven healthcare tools to interpret computed tomography angiography (CTA) images for indications of a stroke,

ophthalmic scans for diabetic retinopathy, and X-rays for hard-to-identify wrist fractures. The FDA has also introduced the Digital Health Innovation Action Plan to foster innovation while continuing to protect public safety.

Given the current regulations, it is important to focus on incremental improvements. As Dr. Ankur Kapoor, director of Vision Technologies and Solutions at Siemens Healthineers, states, *"In these early days, AI is better with things like automation, where you don't need to be perfect, just better."* As regulations evolve and pioneering programs become accepted across the industry, organizations that have introduced early-stage AI will be better prepared to holistically adopt the technology.

> *"Who is to blame when AI makes a mistake? We can't start early enough in discussing these issues."*
>
> **Warry van Gelder**
> **Medical Director**
> **Result Laboratorium**
> **Netherlands**

Ultimately, regulation will catch up with the new technology—it always does. X-rays were overregulated in 1913,[4] but scientists and regulators worked together to introduce progressive radiation-dose reduction and ease restrictions, creating standards that are still in use today. As with X-rays, the promise of AI's impact on the field of healthcare will drive cooperation between regulators and AI developers to implement the technology safely without restricting innovation.

In addition to regulation, reimbursement is critical to the adoption of AI. The reduced costs, increased efficiency, and improved outcomes enabled by AI can be realized only if providers implement innovative products and services. Both public and private payers need to incentivize adoption of AI through changes in reimbursement policies.

How to Prepare for AI

To effectively prepare for AI, changes must occur at both the industry and organization level. AI needs large sets of data from which to learn and adapt, and no individual organization will be able to supply a sufficient volume of information. As one example of the scale that is necessary, in the U.S., the National Institutes of Health (NIH) All of Us Research Program aims to gather data on a diverse million-person cohort to customize care and improve diagnostic accuracy by expanding precision medicine.

The healthcare industry must come together as a whole to move toward accessible, interoperable, standardized, and curated data sources from which AI can thrive. Best practices should be observed to avoid potential bias within the data that can skew diagnostic conclusions. It is also vital to ensure that data is anonymized, securing the privacy of protected health information without losing the usefulness and integrity of the data.

In parallel, individual organizations should prepare for their internal implementation of AI and educate key decision makers on its value. Cybersecurity should not only be a top priority to protect patient data, operations, and IT systems, but also an integral part of system design.

Industry changes
The entire healthcare industry will benefit from changing the way data is formatted and collected. Sixty-six percent of executives and directors believe that lack of standardization will pose significant challenges in implementing AI. Currently, data is siloed within individual departments, hospitals, or healthcare systems, often in proprietary or irregular formats. This restricts AI's training, validation, adoption, and continuous learning process.

By standardizing the data structure and access that link healthcare systems and population data both nationally and globally, the industry will enable individual systems and networks to access and implement transformative AI applications. By participating in steering and standards-setting groups, such as AdvaMedDx, the Precision Medicine World Conference (PMWC), the Medical Imaging & Technology Alliance (MITA), and the Global Medical Technology Alliance (GMTA), healthcare leaders can help guide the discussion and use this interaction to define their own internal strategies and tactics.

Organizational changes
To best prepare for emerging AI, healthcare organizations should educate key decision makers as well as modernize their current technology. To avoid a technical skill gap when implementing AI, organizations should establish a plan to train existing staff and enact a hiring strategy to bring on new people with the right skills. By the time the technology becomes more widespread, organizations will be primed for a smooth integration and upgrade process. To further mitigate the challenges inherent with migrating to any new technology, organizations should plan a roadmap to modernize their current technical capabilities (automation, digitalization, etc.) to set the stage for AI implementation.

> *"AI will increase the prestige of laboratory diagnostics because we will be providing more accurate data. If big data is used together with laboratory data, it will gain more importance."*
>
> **Mustafa Serteser**
> **Professor**
> **Acibadem University**
> **Turkey**

Picturing an Exciting Future
AI will reduce costs while improving diagnostic accuracy and the patient experience. Further, it will enable a connected clinical laboratory from beginning to end. Dr. Ankur Kapoor of Siemens Healthineers envisions this AI-driven future: *"AI streamlines workflow, improves throughput, and improves efficiency for doctors and technicians so they can focus their expertise where it matters."* Just as automated systems and intelligent software have replaced mundane human effort, AI will soon exceed human intelligence, offering insight that can transform care delivery.

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