Building a Smarter Laboratory:

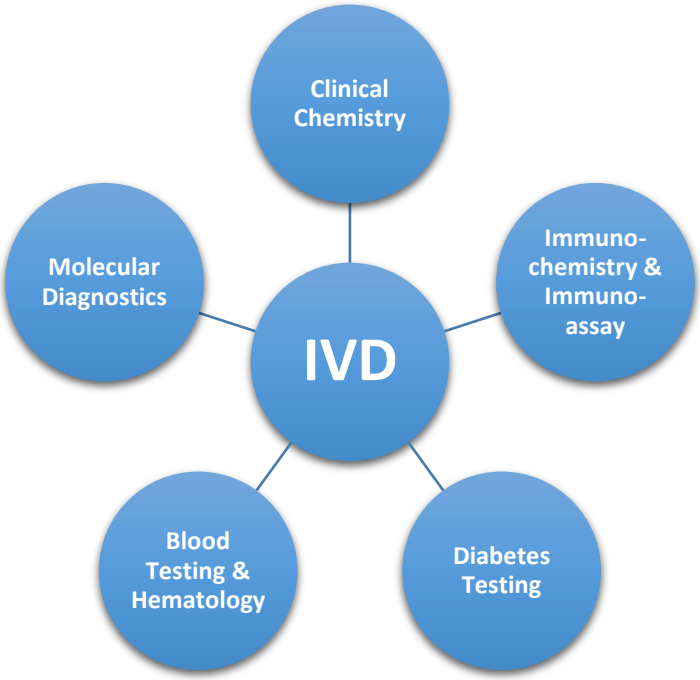
How RFID and Machine Vision are Improving In Vitro Diagnostic (IVD) Testing

UNDERSTANDING IVD TESTING

In Vitro Diagnostic (IVD) tests use human fluids to screen and assess diseases. This includes risk assessment and early detection, diagnosis, and prognosis. Clinicians can use IVD tests to aide in therapy selection and monitoring, or treatment assessment. IVD is a well-established medical tool with over 40,000 different products available.[i]

FUNCTION	PURPOSE
Screening	Risk Assessment
	Early Detection
Assessment	Diagnosis
	Staging and Prognosis
Management	Therapy Selection
	Monitoring/Treatment Assessment

IVD tests fall into several categories:



For example, immunochemistry tests measure specific antibodies to identify infectious diseases and the presence of foreign substances in human fluid or tissue.

Chemistry analyzers use reagents to produce a specific chemical reaction.

Hematology analyzers identify blood cells for diagnosis of a disease or condition.

And molecular diagnostic tests analyze human molecules at the DNA, RNA, or protein level for genetic code.

Great strides have been made in IVD testing, although organizations continue to invest in research and development to improve test capabilities and outcomes. Technological developments aim to provide clinicians and their patients with faster, more accurate and reliable results, the ability to conduct more customized tests simultaneously, and efficient recording of data.

CHALLENGES WITH IVD TESTING

Like any process, IVD tests have potential for errors. Therefore, developers are constantly searching for affordable ways to increase accuracy. Unlike other processes, the implications of errors in IVD tests are staggering. Misdiagnosis and mistreatment of conditions can be life-threatening. To ensure a standard of safety, American federal agencies involved in the regulation of IVDs include the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). Similarly, other nations have their own regulatory bodies for IVD testing standards.

"Errors at any stage of the collection, testing, and reporting process can potentially lead to a serious patient misdiagnosis. The human role in sample collection makes complete elimination of errors associated with laboratory testing unrealistic. Pre-analytical errors [from the point when fluid is obtained from the patient at the point of care, through transportation to the laboratory, through mechanical sorting] are largely attributable to human mistakes, and the majority of these errors are preventable. This is understandable, since the pre-analytical phase involves much more human handling, compared to the analytical and post-analytical phases."[ii]

According to "Quality Indicators to Detect Pre-Analytical Errors in Laboratory Testing" (The Clinical Biochemistry Reviews, 2012), pre-analytical errors account for up to 70% of all mistakes made in laboratory diagnostics, most of which occur during patient preparation, sample collection, transportation, and preparation for analysis and storage. This includes inappropriate tests that have been ordered, improper sample collection, transport delays, and illegible handwriting on requisition slips.

"Technologies such as barcodes, radio frequency identification, and wristbands can help overcome mistakes in patient identification. Automation through pre-analytical robotic workstations, specimen labelers, specimen management systems, and automated phlebotomy tray preparation can significantly reduce the rate of errors that are due to active human factors. Automated detection…is more reliable than visual observation."[iii]

RFID APPLICATIONS IN IVD

Radio frequency identification (RFID) technology is being used in virtually every industry. As RFID technology has become more widely available, compatible across systems, and competitively priced, medical device equipment manufacturers are increasingly using RFID as part of their IVD machines. RFID's small form factor and well-proven performance in demanding lab environments make it a particularly attractive addition. RFID tag labels have become affordable, self-adhesive, and deployable on curved

surfaces, such as test tubes. In addition, because RFID technology is scalable, it can be integrated easily into laboratory systems, providing an automated way to standardize on best practice across facilities. Because line of sight is not required with RFID, it can be embedded within a product or even molded into plastics.

RFID technology has proven to be an important technology in IVD testing because:

- RFID does not require line of sight
- RFID tags can store large amounts of data
- RFID tags have both read and write capabilities
- RFID tags can operate at ultra-low temperatures
- RFID tags can be read through (reasonable) amounts of frost and ice

IVD equipment, instruments, and reagents can be easily equipped with RFID tags, which have the ability to store important information such as product information (e.g., date of production, serial number, date of installation, number of uses remaining), auto-calibration criteria (e.g., media type, expiration date), and process control (e.g., number of tests completed, notification of test completion). This accurate, real-time electronic data is captured and automatically documented faster and more efficiently than can be accomplished by manual processes. It also eliminates inaccuracies caused by human error.

Below are just a few examples of how RFID is being used in IVD applications:

USE	DETAILS	BENEFIT
Secure Access	An RFID-enabled identification card is required to access equipment or perform specific tests	Provides security and traceability
Regular maintenance	RFID tags are used to monitor equipment and instrument usage in order to anticipate preventative maintenance	Equipment and instruments are constantly performing at an optimal level, ensuring accurate test results; Costly repairs or malfunction from neglect or overuse are eliminated
Sample Tracking	RFID enables specimen samples to be tracked in real-time from the time they are collected to when they reach their destination	Reduces errors and cost, ensures accuracy and provides traceability
Consumable Tracking	RFID tags are used to monitor the use of consumables, such as reagents or proprietary sample cartridges, and enable lab technicians to receive alerts for stock replacement, expiration dates, and recalls	Saves time by eliminating manual checks of liquid levels, reduces errors, and enables accurate inventory management

Consumable Authentication	Protects brand integrity and quality by ensuring the use of OEM-supplied reagents and media (i.e., anti-counterfeiting)	Ensures manufacturing and testing integrity and reliability of results
Ensure correct operational settings	Once the identification data on the tag has been read, the control unit automatically sets testing parameters such as pressure, flow rate, and operating time to match the requirements for the media that has been connected	Operational control settings reduce the risk of human error in setting operating variables to prevent harm to the instrument or invalidate tests

For more details regarding the use of RFID in Clinical Analyzers, see JADAK's whitepaper: "RFID in Clinical Analyzers" (LINK: https://www.jadaktech.com/rfid-in-clinical-analyzers/).

MACHINE VISION APPLICATIONS IN IVD

Machine vision, which is the use of image processing to inspect for visible characteristics, analyzes results and records findings, can be used at any phase of IVD testing, including pre-analytical, analytical, and post-analytical. Machine vision can be used to detect errors in handling, transportation, and preparation of samples. It is especially valuable in the pre-analytic phase of testing because it can be used to detect sample errors, automate processes, and remove human bias or errors caused by fatigue. Machine vision systems reduce manual labor and automate parts of the IVD testing process, improving the quality of testing by delivering improved accuracy, precision, and error detection. Additionally, automation has the benefit of improving speed and efficiency.

Optical detection technology is used by approximately 85% of the in-vitro diagnostic market, especially in clinical chemistry, immunoassays, hematology and point of care.[v] Machine vision can enhance optical detection technology by visually identifying defects, geometry, position, measurement, and distance.

On the analytical side, machine vision can often provide results faster, and more accurately, than other optoelectronic technologies, thus increasing the efficiency of the analyzer. From cell counting, identifying cancerous cells, to detecting growth, machine vision has the ability to delivery accurate and repeatable results.

It should be noted, however, that barcode reading is almost always needed within IVD devices. Conveniently, machine vision can be included within the same barcode device, eliminating other sensors and reducing the overall machine Bill of Materials cost.

Some examples of machine vision functions in IVD applications include:

RFID and Machine Vision in IVD

USE	DETAILS	BENEFIT
Barcode Reading	Machine vision can read barcodes on items to track test tubes or samples within the testing process or to validate the authenticity of products, such as reagents	Increases speed and throughput
Vial Presence/Absence Detection	Machine vision identifies presence of test tubes and vials in an assay or tray, alerting the machine to which locations require testing	Automation reduces the risk of human error while increasing speed
Alignment Detection	Machine vision can confirm vials or tubes are aligned properly for the next phase of testing	Reduces risk of tubes breaking due to misalignment
Sample Volume / Liquid Level Detection	Machine vision identifies amount of fluid within the tube and whether the amount is sufficient for designated tests; Machine vision is the most non-invasive and efficient means of measurement, compared to probes and sensors	Reduces human error of visual confirmation, as well as reducing likelihood of inaccurate results due to improper sample volume; Reduces likelihood of contamination
Cap Detection	Caps on vials and test tubes indicate which tests to run on specific samples. Machine vision can detect not only the presence of the cap, but also the cap type and color	Automated routing to appropriate tests based on cap information; Confirmation of cap presence before pipetting to avoid spillage
Sample Quality (Turbidity, Icteric, Lipidemic, and Hemolytic measures)	Turbidity, clots, and other particles can impact the reliability of tests; Machine vision can identify whether the specimen integrity is viable for accurate testing	Reduces human error and increases reliability of testing; Identifies poor quality samples before valuable machine time is wasted on invalid tests
Color Detection	Chemistry analyzers often rely on color detection for reaction; Machine vision can measure color within specific ranges	Better reliability and faster than human observance
Shape Identification	Cells are sometimes identified by shape to indicate presence/absence of a disease	More accurate results
Cell Counting	The number of cells present may indicate a particular condition	Precise information delivered

For more information on the use of machine vision in molecular diagnostics, read JADAK's whitepaper: "Machine Vision for Molecular Diagnostics" (LINK: https://www.jadaktech.com/rfid-in-clinical-analyzers/).

CONCLUSION

Since 1875, automated devices have been used for scientific investigation,[iv] and specifically in medical laboratories, where tests are carried out on clinical specimens. Due to the nature of clinical testing, there are many tedious and labor-intensive steps that can benefit from laboratory automation. Beyond saving time, money, and space, the use of technologies such as RFID and machine vision ultimately reduce human error and provide more accurate and personalized results, leading to better screening, assessment and management of disease.

A TRUSTED PARTNER

Medical device engineers looking to embed RFID or machine vision technologies into their equipment can benefit by partnering with companies that have deep detection and analysis engineering expertise. Many suppliers can offer RFID or machine vision products, but unlike most data collection manufacturers, JADAK is technology-agnostic and identifies the right technology or combination of technologies for specific applications. Furthermore, JADAK has a broad RFID and machine vision product portfolio, backed by engineers with the resources and technical expertise to help OEMs implement solutions to meet their specific needs and requirements.

JADAK's deep knowledge of RFID, machine vision and barcode in the medical industry, makes them uniquely positioned to solve many different types of challenges. By embedding the right technology into new and existing products, OEMs can gain the product differentiation and competitive advantage, while protecting revenue streams and brand integrity.

To learn more about JADAK's full line of detection and analysis products and services, contact them at 315-701-0678 or info@jadaktech.com

ABOUT JADAK:

JADAK, a business unit of Novanta, is a market leader in machine vision, RFID, barcode, printing, and color and light measurement products and services for original equipment manufacturers. The company designs and manufactures embedded detection and analysis solutions that help customers solve unique inspection, tracking, scanning and documenting challenges. The company is ISO 9001 and ISO 13485 registered.

Novanta is a trusted technology partner to OEMs in the medical and advanced industrial technology markets, with deep proprietary expertise in photonics, vision and precision motion technologies.

ThingMagic is JADAK's RFID line of products and services.

www.jadaktech.com

ENDNOTES:

[i] Wilke MH, Schenker M, Hoffmann G. Detection and documentation of DRG-relevant comorbidities using laboratory tests. Aust Health Rev. 2002;25:152–160

[ii] "No Preanalytical Errors in Laboratory Testing: A Beneficial Aspect for Patients," Indian Journal of Clinical Biochemistry, Accessed March 13, 2018

[iii] "Pre-analytical Errors: their Impact and how to Minimize them," Medical Laboratory Observer, May 18, 2014

[iv] Olsen, Kevin (2012-12-01). "The First 110 Years of Laboratory Automation Technologies, Applications, and the Creative Scientist". Journal of Laboratory Automation. 17 (6): 469–480. doi:10.1177/2211068212455631. ISSN 2211-0682. PMID 22893633

[v] http://www.omnica.com/optical-detection-technology/