RFID in In-Vitro Diagnostic Clinical Analyzers...

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Barcodes have been a long-standing auto identification and data capture technology in the clinical chemistry market, routinely used on test tubes, cartridges, vials, pipettes, and cuvettes. In typical diagnostic applications, tracking the patient specimen is critical. Barcode identification has been used to ensure that a unique identifier associates the specimen with each of the diagnostic processing steps, resulting in a secure sample chain of custody. The process typically includes automated steps and system redundancy to ensure patient safety and accurate diagnosis.

In today's rapidly changing medical testing environment, laboratory processes are becoming more efficient through the use of sophisticated diagnostic instruments, increased automation, and other commercially available technology. Over the past ten years, Radio Frequency Identification (RFID) technology has become widely available, and today it is routinely used in a variety of diagnostic applications. The use of RFID applications in laboratory automation is common, especially to validate and track consumables, such as reagents. Now the use of RFID is gaining popularity in In-Vitro Diagnostic (IVD) scenarios, with High Frequency (HF) RFID being used on test tubes and vials. HF Near Field Communication (NFC) capabilities are being used to quickly read diagnostic information stored in memory on wearable devices. And Ultra-High Frequency (UHF) RFID technology is being used in automation of large volumes of specimen containers read simultaneously.

Why is RFID gaining in popularity in IVD Applications?

The adoption of automation technologies by instrument manufacturers coincides with the commercialization of lower-cost RFID options ideally suited for automation systems that fit into modern diagnostic laboratories. 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 makes it an obvious technology choice. RFID tag labels are low cost, 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.

IVD medical devices and reagents are used to examine bodily fluids and tissue, including blood, serum, urine, and stool, to detect diseases, conditions and infections. The samples are collected from patients for analysis, with tests typically performed in laboratories. IVD machines often contain hundreds of vials of samples and tubes. Every sample must be correctly identified, then processed with the right reagent at the right time in the testing process. IVD instruments are fully automated machines with specimens transported automatically from stage to stage during the diagnostic process. RFID has numerous benefits in this automation process, including the support of inventory management, reduction of the cost of manual labor, and an increase in test accuracy.

What is the benefit of read/write capability in IVD?

RFID's ability to read hundreds of tags quickly and track for a one to one match makes it attractive for throughput and chain of custody. RFID is able to both read information at critical points in the diagnostic process and write information back to the tags on the specimen. The capacity to both read and write data repeatedly, at a far larger volume than can be embedded within barcode's single-use, read-only ability, is valuable in the IVD analysis process. The use of RFID in pathology labs can automate the capture of patient and specimen data with updates on the tube location and position in the workflow. The data collection can occur automatically, and the specimen's location can be transmitted back.

Use of RFID at status checkpoints in the laboratory automation process can ensure the veracity of the specimen, patient, time, and location data. RFID can list the container ID, the location at which the container RFID tag was read, and the time-stamp that was registered when the container was detected. The power of RFID to store valuable information in the integrated circuit chip on the consumable itself enables the collection of information that can be used for quality control. RFID transponders' read capability during specimen tracking enables recording of when and under what circumstances various operations occurred. For example, it can be used to record specific conditions,- such as weight, environmental parameters or cycle times. RFID can be used to identify when process variables are outside expected limits and alert operators when downtime may be imminent without corrective action.

How is data used in clinical diagnostic processes, including specimen quality?

RFID multiplies the number of possible ways data may be stored and utilized in a fully automated diagnostics process. The latest development in RFID technology is the incorporation of sensed data stored in memory. A large variety of diagnostic processes measure temperature control as one of the key determinants of specimen quality. RFID can provide assurance that an item includes 'cold chain custody' information. Low cost data logging can provide diagnostic

laboratory technicians with a means of recording data history on the RFID chip directly and automatically updating data at regular intervals. This capability is valuable in life science applications, where the quality of a specimen is determined, to a large degree, on the stable environmental conditions during storage and processing. To ensure a specimen has been maintained within prescribed temperature control limits is also possible through utilization of RFID by recording deviations and writing data to the chip when the specimen has been exposed to a temperature outside of the prescribed range.

What are the benefits of using RFID in clinical analyzer laboratories?

RFID provides numerous features that make it beneficial in clinical analyzer laboratories, including:

- Security, such as encryption and/or password protection
- Memory for tracking and storage of patient information in a single location
- Improved ability to trace and track the status of an object in the system, providing traceability records
- Support of greater automation of the work in process through intelligent sample routing
- Tracking and collection of data about sample drawing, revision level, lot number, calibration, configuration, and reagent information
- Elimination of problematic illegible Unique Device Identifier (UDI) tags
- Increased protection from damage and tamper resistance
- Automatic parameter settings
- Storage of reagent calibration information

The increasingly sophisticated fields of protein separation, drug discovery, Polymerase Chain Reaction (PCR) diagnostics, and environmental monitoring use advanced technologies, such as “lab on a chip” to allow for faster and more cost-effective biochemical sample reactions to be conducted than with traditional technologies. This is another application where the benefits of read and write capabilities of RFID can add value in the process.

Are there examples of laboratories that have used RFID technology?

Recently, the Mayo Clinic co-developed an RFID-based specimen tracking solution to help laboratories increase accuracy and reduce error rates in specimen labeling. RFID readers were placed at key locations along the specimen collection and delivery life cycle, reducing manual transcription processes at collection and accessioning areas. Not only did this improve accuracy, it also speeded the process, by decreasing the amount of time required to identify specimens or decipher handwritten information. RFID can increase productivity by eliminating manual transcription processes at collection and accessioning for each specimen. It can decrease time wasted looking for missing specimens, or trying to decipher handwritten specimen information. The automation of information also makes for easier certification and audit capability.

What are some other ways RFID is being used in the diagnostic processing of specimens?

RFID is becoming a valuable tool for reducing errors and increasing throughput for diagnostic processing of specimens that may be transported to multiple facilities. RFID can also be used for specimen tracking and document control in multiple facilities. While laboratory information management systems can easily accommodate the processes managed within the lab, specimen tracking becomes more complicated when processes are shared between multiple facilities.

In point-of-care diagnostics, for example, it is increasingly common to obtain specimens, such as blood and urine, outside of a laboratory, with specimens shipped to testing facilities where additional diagnostic procedures are performed. In these cases, it is beneficial to use RFID as a strategy for managing the incoming specimens at the accessioning phase. A shipping door, for example, may be outfitted with RFID readers capable of determining the contents of shipped specimens without opening the packaging, extending the automation benefits to a secondary facility. Most specimens are accompanied by documents and other items that may be tracked with RFID to ensure that each item will be tracked concurrently, reducing the reliance on manual processes.

So why use RFID in IVD Clinical Analyzers?

The increased use of RFID in IVD scenarios is attributable, in part, to lower-cost options becoming more widely available and performing well in demanding lab environments. RFID increases automation throughout the stages of the diagnostic process, supporting inventory management and increased accuracy.

For more information on RFID solutions in IVD applications, contact us at 315.701.0678 or via email at info@jadaktech.com.

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