

CASE STUDY

Beyond Cool: RFID disentangles cryopreservation storage and management



UK, Hertfordshire, London

Cryogatt and HID Global improve processes for the most critical assets

Challenges

The cryogenic storage industry faces many challenging hurdles while maintaining the correct freezer temperatures (ranging from -80 °C [-112°F] for tissue samples to Dewar’s at -196°C [-321°F]) for stem cell vials, other live research material and fertility specimens. Operators have to comply with government mandates forcing storage facilities to maintain accurate data of samples precise location, detailed description, and handling procedures.

Historically, samples were identified by handwritten or printed labels and more recently, bar coding. When material samples are stored at extremely low temperatures, vials are subject to intense frosting, making traditional identification difficult to read and document. It is vitally important to protect each sample from being damaged by a rise in temperature during the inventory process. Additionally, labels can become dislodged or illegible. This process is damaging. Additionally, identifying and finding a particular vial or straw is timely and grave mistakes can occur.

As storage facilities increase, there are calls for tighter regulation and control. Auditing each sample is cumbersome and a lengthy process requiring two highly qualified staff members working under strict health and safety timelines. Sample racks hold approximately 100 vials or straws with each freezer or dewar containing many hundreds of these racks. Every single straw or vial must be manually identified by reading each individual label. This process is not always accurate, and statistically incurring a 9% error rate. These errors can result in legal damages and are frequently quoted in the press.

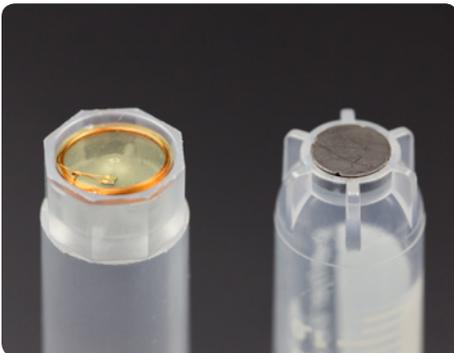
Radio Frequency Identification (RFID) is now commonly used at ambient temperatures and above in many industrial and consumer applications. The focus of many new developments today is to survive high temperatures > 200°C (392°F) for industrial paint-shop processes and other applications. On the other end, there are medical applications with the need of conserving live samples at freezing temperatures matching the boiling point for liquid nitrogen of -196°C (-321°F). Live biological samples need to be kept below -135°C (-211°F) to avoid degradation. Uncontrolled temperature increase during inventory or retrieval of vials and straws is the biggest threat destroying viable samples. Until now, RFID solutions did not address these types of harsh environments, as these low temperatures are typically outside the specification of such products.

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Dr. Ross Hawkins,
Principal Scientist, Division
of Advanced Therapies,
NIBSC

The Solution consist of:

- Vials, trays, sleeves and straws embedded with tiny Glass and Piccolino tags utilizing HID Global HF Vigo™ Direct Bonding technology
- Associated hardware, including patented Cryogatt readers that work at -196°C
- Cryogatt Software to accurately record, identify, locate and deliver auditable reporting of stored frozen assets



Solution

Using a highly durable RFID tag designed for harsh environments with acceptable frequencies, Cryogatt Systems Ltd. worked with HID Global to develop an RFID tagging system to quickly and accurately identify and deliver a detailed audit of stem cell vials, fertility straw samples and other material cryogenically stored in laboratories, bio-banks and fertility clinics.

This is achieved using HID Global's RFID HF tags and specially designed Cryogatt readers. Tags are attached to samples cryogenically stored and to trays already positioned in deeply frozen storage. Each tag remains passive (inactive) in storage. When in proximity of an RFID reader, the tags are wirelessly identified and encoded. As the vial sample is tagged, each sample is logged and its position recorded. The solution is simple, easily integrates with a facility's existing IT system, and delivers accurate and timely records of all stored samples.

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Results

Through extensive research, testing and deployments, HID Global and Cryogatt have partnered to produce viable tags used in extremely low temperatures for vial storage at fertility clinics or other storage facilities. The ruggedness of HID Global RFID tags, with patented Direct Bonding Technology, survives the harshness of cryogenic storage at -196° C (-321° F). This is with over two million hours mean time between failures (MTBF), resulting in not a single failure being recorded by the National Institute of Biological Standards and Control (NIBSC) in the past two years. Other suppliers' RFID tags and chips were tested with mixed or negative results. For example, the unqualified tags only read in room temperature, lacked the required memory or performed inconsistently.

Tiny Glass and Piccolino tags utilizing the HID Global HF Vigo™ Direct Bonding technology are embedded into cryogenic storage vessels. This patented technology allows creating extremely compact and robust transponders with high memory and security features.

"In close cooperation with their end-customers, Cryogatt and HID Global engineers successfully designed the proper tags and readers for this innovative application. It was an exciting challenge to work at the lower end of the temperature scale, where often materials and electronics behave differently than at room temperature," said Richard Aufreiter, Director Product Management, Identification Technologies at HID Global.

Optimizing cryogenic work processes

NIBSC is a global leader in the characterization, standardization and control of biological medicines. NIBSC plays a major role in assuring the quality of biological medicine worldwide through the provision of materials, testing products and research. Expert scientists also provide advice on a routine basis and in response to world - wide emergencies. NIBSC is the world's major producer and distributor of WHO international standards and reference materials (supplying over 95% of biological international standards).

The organization has approximately 200,000 vials of biological materials frozen in liquid nitrogen vapor (between -140°C and -190°C), using an antiquated process to track and manage longer term storage needs. Stock-taking exercises indicated a historic annual error rate of up to 1%. The older vials date back 50 years, resulting in a higher location error rate. Without periodic difficult inventory location exercises,



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accurately locating the older vials might be difficult. Liquid nitrogen storage space is at a premium. Efficiency of storage is paramount to maximize space as much as possible, but to avoid the dangers of mixing the locations of different cell banks, many storage spaces go unfilled. Whilst the vigilance of staff over recent years has maintained a high level of storage location accuracy, more robust solutions were needed to guarantee accuracy and maximize efficiency of storage.

NIBSC implemented the new Cryogatt RFID solution and several hundred vials are now tagged with the new rugged RFID tags from HID Global across three liquid nitrogen freezers. Deploying advanced RFID technology, NIBSC is now able to accurately track, streamline inventory and simplify the management process of long term vials. The solution delivers accurate data of available storage space down to the precise vessel, optimizing limited storage space. Getting in and out of storage freezers as quickly as possible is critical. Exposure of vials above the transition temperature of -135°C , increases the risk of damaging the cells. On average, it is now two to five times faster to search and retrieve samples, thus reducing the risk of damage. Additionally, access to detailed and accurate information will significantly enhance quality system audit demands.

“The Division of Cell Biology at NIBSC has adopted the Cryogatt system of software and RFID readers to track cryo-tubes used in the production of cell banks. Having gained 24 months experience of reliable reading at -190°C , the system is now being brought into routine use,” said Dr. Ross Hawkins, Principal Scientist, Division of Advanced Therapies, NIBSC.

As vials of cells at NIBSC are stored over a period of decades, it is essential that any changes to their storage process will continue to work in the long term. Hence a three year trial of the Cryogatt technology has been initiated and has currently completed year two. The solution is experiencing zero failure in RFID tags so far and is on track for a full deployment across NIBSC’s routine cell banking operation.

Bristol Royal Infirmary (BRI) is a teaching hospital in the UK with a research department storing short (24 hours) and long-term (five years) vials of biological samples. Currently, the management and coordination of research samples is complicated and is not ideal using spreadsheets. BRI is looking to streamline the management process and expedite locating the samples needed. Also, complying with the Medicines and Healthcare Products Regulatory Agency (MHRA) standards is crucial.

Implementing the advanced RFID solution by HID Global and Cryogatt has helped laboratory staff easily locate the sample vials and read the information quickly and accurately. Samples are stored in -80°C freezing temperatures across five freezers. Quite often, the exact location of a particular probe is not known and the retrieval is a time-consuming and a costly manual process. With the Cryogatt system, pick lists are simple to create, enabling an accurate pull of samples needed.

“Traceability is accurate to satisfy regulatory standards and saves hours of searching,” said Kirsty Stevenson, Manager Cold Storage, Pathology Department, Bristol Royal Infirmary. Also, the lab is able to optimize the storage space: In the past, up to 100 trays contained usable storage going unnoticed, because it was not clear where or how much space was left available for new probes.

The research department is now running more efficiently using the solution; the plan is to primarily utilize the Cryogatt system for long-term (five year) studies in order to gain the most benefit.



Advancing the future with innovative identification

Worldwide regulations are tightening the audit belts on how laboratories manage biological sample storage. Clinics are becoming apprehensive about the risk of human error, and the legal ramifications of not properly identifying samples. Applying RFID technology and automation solutions is recognizable across cryogenic storage and management. Benefits include:

- Improves accuracy – delivers a secure source to quickly locate and identify vial samples
- Optimizes storage space – increases visibility of usable storage, and optimize dewar utilization
- Precise audit trail – complies with regulatory standards, pass scheduled and drive by audits
- Keeps samples safe – reduces risk of damaging viable cells or other bio samples by accidentally raising the temperature above -135°C (-211°F) during slow inventory or retrieval processes. (Live samples must be kept below this temperature at all times to remain properly conserved).
- Saves time and costs – reading storage trays in bulk at liquid nitrogen vapor-phase temperatures and knowing the exact location of each probe in seconds saves time and costs, compared to recording frosted probes individually via a barcode or human eye.

Deploying a solution capable of surviving a harsh and highly regulated cryogenic storage environment is critical to the success of laboratories, hospitals, fertility clinics and healthcare agencies world-wide. "It ensures fast and efficient traceability and provides comfort that the data is accurate for that next compliance audit," said Geoff Morris, Engineering Director, Cryogatt Systems LTD.