

Use of Micro-Electro-Mechanical Systems (MEMS) Technology to Evaluate Specimen Temperature Profiles During Various Biobanking Processes

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INTRODUCTION

Pre-analytical variables account for a significant portion of laboratory errors and can affect the reliability of clinical and epidemiological results and future utility of specimens in precision medicine applications. It is important to control or standardize sample management processes to promote the reliability with downstream analyses relying on specimen integrity.

No technologies for sample identification combine sample level temperature-sensing with identification and tracking. Bluechiip's MEMS wireless technology was evaluated in our current and contrived sample management practices at ultralow conditions (i.e., -45°C to -85°C). We present an evaluation of a robust process for sample management whereby chain of custody and sample temperature are documented using Bluechiip's MEMS wireless technology.

Materials

- Bluechiip Matchbox Readers and/or Handheld Readers (HHR)
- Bluechiip-enabled vials
- Bluechiip Extended Lead Read Head
- Techni-ICE™ (i.e., ice blanket) Bluechiip Stream software
- Bluechiip Box Tag Read Head
- Cryoboxes affixed with Bluechiip CryoBox tags
- Vial solution (1mL %FBS+HBSS)

METHODS

Evaluation of the Receipt and Accessioning Processes

Bluechiip vials simulate the lifecycle of an ultralow clinical samples within the biobank (i.e., receipt, QC of vials, scan into LIMS, allocation to a cryobox, and storage/ retrieval). Technicians processed Bluechiip-enabled vial or box tags in contact with a Custom Read Head. The Bluechiip Matchbox Reader (Matchbox) and HHR each used a Custom Read Head extending to the vial, which were scanned for identification and temperature recording on an intermittent basis (Image 1). Bluechiip's Stream software logged all user, sample ID, and temperature data for analysis.

Evaluation of Storage and Retrieval Processes

Cryoboxes were registered to the Bluechiip Stream software and equilibrated on dry ice with the HHR with Box Tag Read Head. Cryoboxes contained 9 Bluechiip vials surrounded by 72 cryovials each filled with solution (simulating thermal load) (Image 2). The HHR with Box Tag Read Head tracked specimen temperature from accessioning, to hold in transport cart, to storage in the ultralow overnight with retrieval via cart (Image 3). Readings also simulated hold times typical for storage and retrieval.

Evaluation of Practices During Specimen Handling

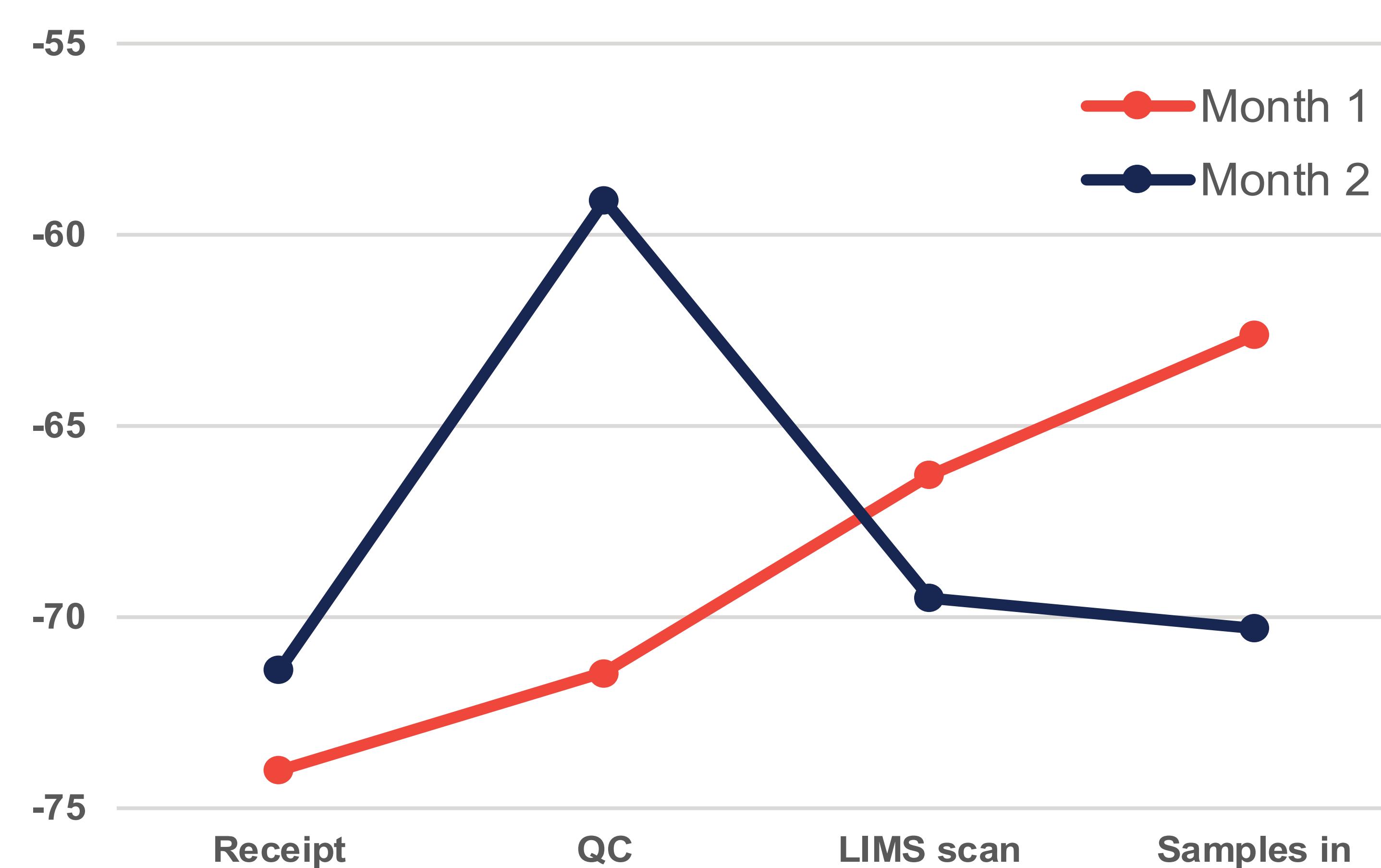
Bluechiip-registered cryoboxes and vials were equilibrated on dry ice. The HHR with Box Tag Read Head tracked temperature under various simulated specimen handling conditions—simulating scan time, cryoboxes and vials with/without supporting dry ice, vials without protective thermal mass of neighboring vials (Images 4, 5, 6), removing vials from dry ice via hand or forceps.

RESULTS

Evaluation of the Receipt and Accessioning Process

Three to four technicians accessioned individual Bluechiip-enabled vials as per SOP. Median temperature values are represented from eight separate days of observations spanning a two month period—Month #1 Bluechiip vials were piled during QC step, vs. Month #2 vials spread out flat on dry ice (Figure 1).

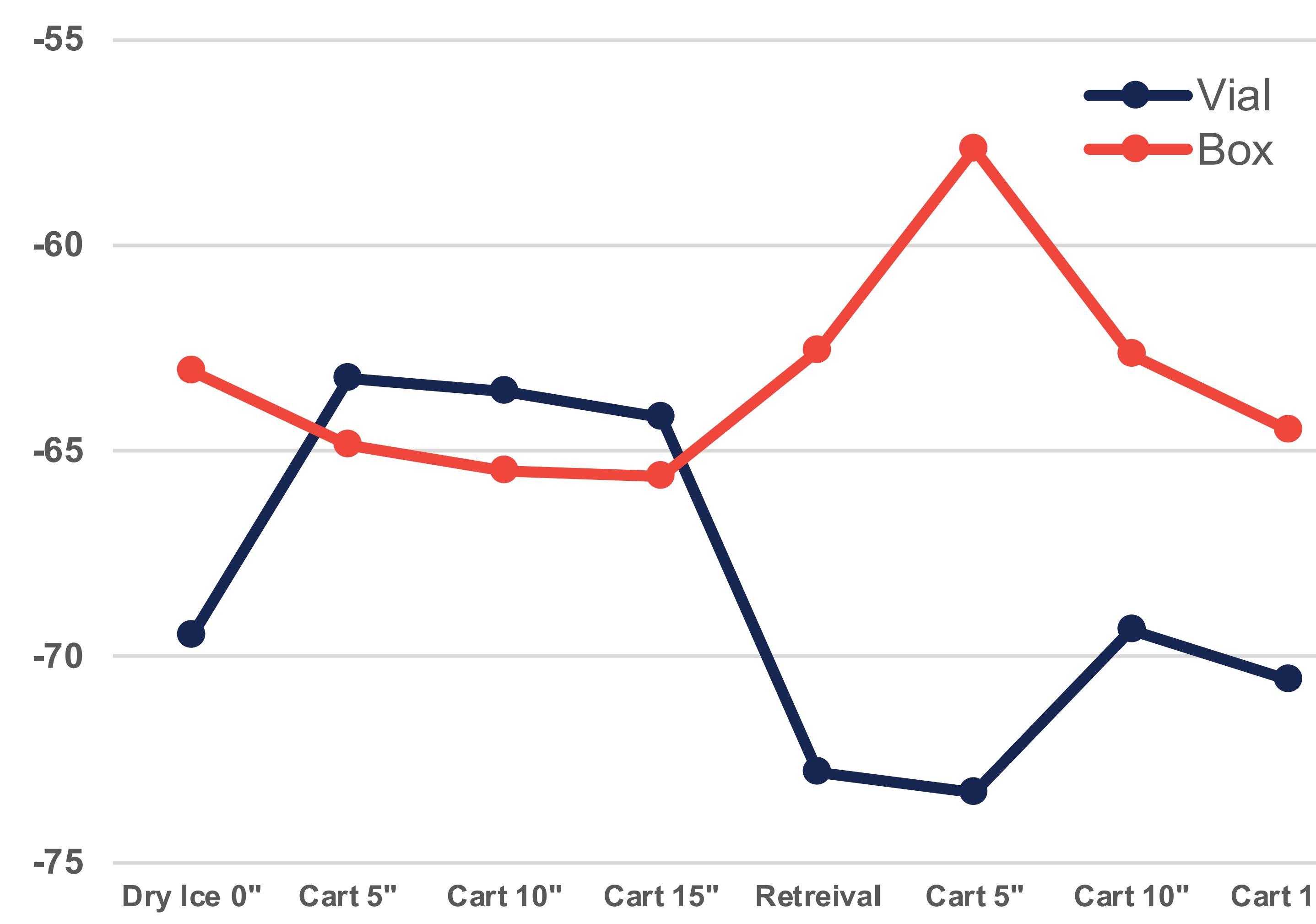
Figure 1: Temperatures (°C) during accessioning



Evaluation of Storage and Retrieval Processes

Recorded means of replicate readings for 3 cryoboxes and 3 vials (Figure 2).

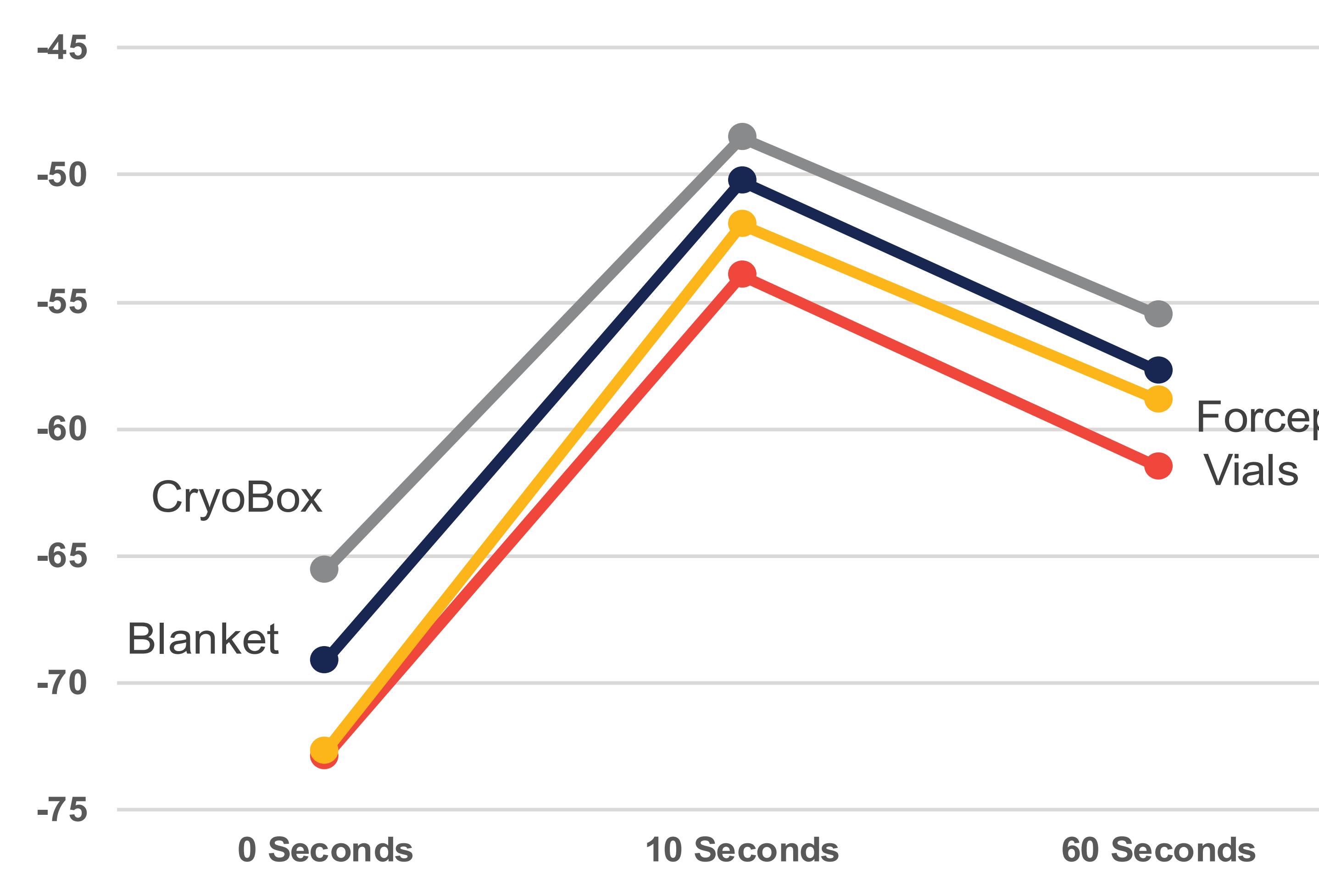
Figure 2: Temperatures (°C) during storage and retrieval



Evaluation of Practices for Specimen Handling

Vials directly on ice do not exceed -50°C (Figure 3).

Figure 3: Temperatures (°C) during handling conditions



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CONCLUSION

Using Bluechiip's MEMS wireless technology, we demonstrated that samples are maintained within ultralow conditions from receipt, storage and retrieval, which support our current procedures for sample management. We have also identified best practices:

- equilibrate boxes to temperature before adding vials
- ensure sufficient dry ice in thermal pan
- maintain samples on dry ice through process including transport to/from storage
- minimize direct handling of specimens
- provide vials with optimal contact to dry ice

Biobanks specializing in clinical study support will find Bluechiip MEMS wireless technology useful as it can generate an empirical understanding of specimen disposition throughout its life cycle. This critical information can be especially important when troubleshooting equivocal results because of analyte stability in biofluids or artifacts in anatomical pathology of frozen tissues.

Continued use with Bluechiip tags in a range of consumables and with various readers enhances specimen chain of custody and temperature monitoring along with user identification at independent workstations. The ultimate goal is to customize reader technology and end-user hardware amenable for best practices and continuous improvement with sample management processes and seamless integration with Laboratory Information Management System (LIMS).