

Stability of Lyophilised General Serum Chemistry QAP Material

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Introduction

The stability of QAP material is a common query received from our participants, particularly when samples may have been exposed to extreme temperatures and delays in transport prior to receipt. This study in collaboration with Clinipath Pathology, Kalgoorlie was designed to test the stability of the RCPAQAP material during transport in hot conditions.

Methods

Two boxes containing 2 identical sets of RCPAQAP General Serum Chemistry material (GSC, Cycle 107) were sent via commercial courier from Sydney, NSW to Kalgoorlie, Western Australia; one box at ambient temperature and the other with ice bricks. Both boxes were fitted with an inner polystyrene “esky”. Data loggers were included with the samples and the temperature data subsequently downloaded. The samples (covering 8 levels) were then re-constituted and analysed on a Roche Cobas Integra 400 in the same run.

Results

The data logger download showed temperature extremes ranging from 4 to 46 °C and -6 to 36 °C for the ambient and ice brick shipments respectively (Figures 1A and 1B). Spiking of temperatures to the upper extremes as the goods moved between courier trucks was also observed. Transport took 3 days.

Figure 1A: Data logger results for material shipped in ambient conditions.

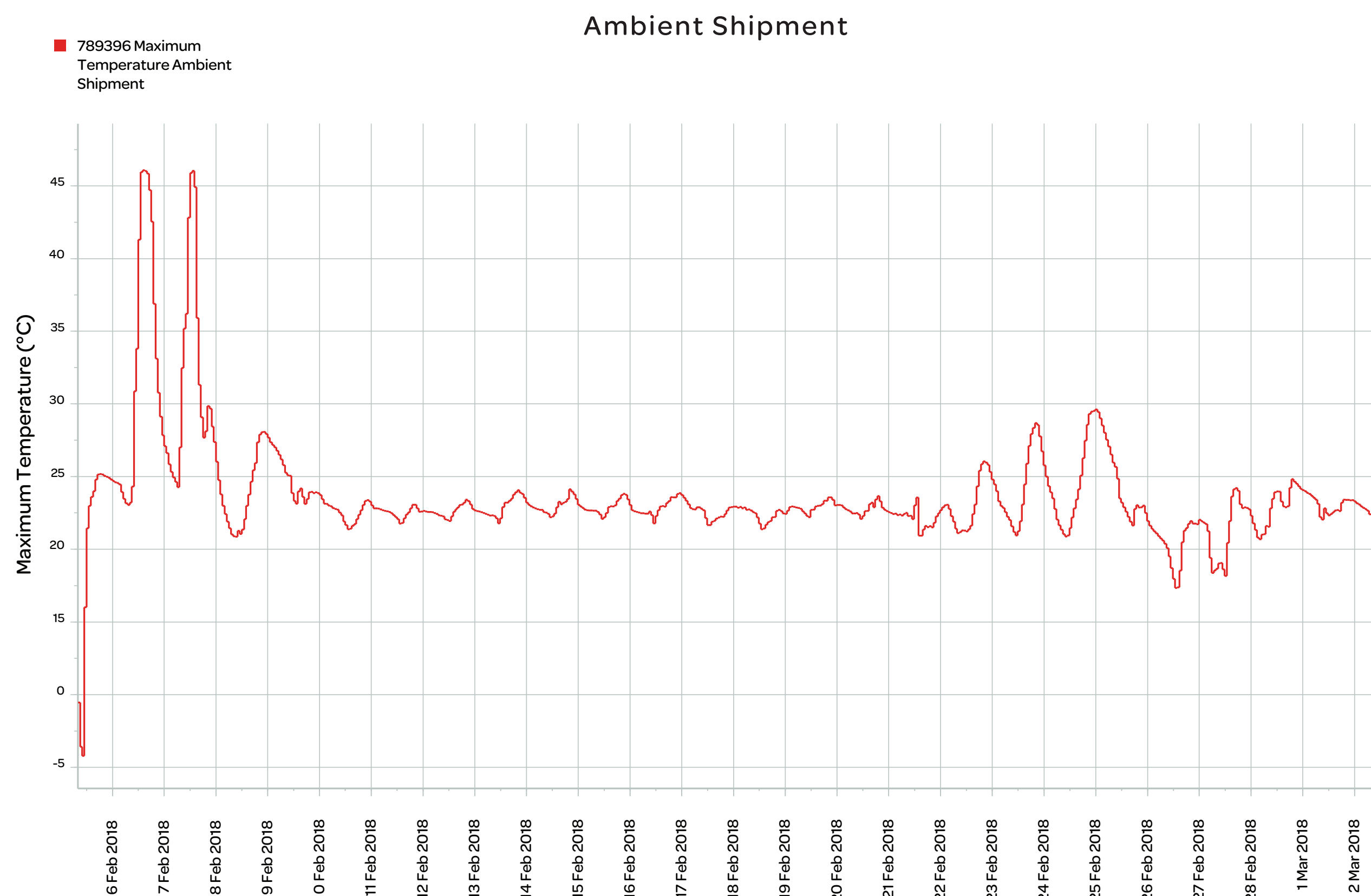
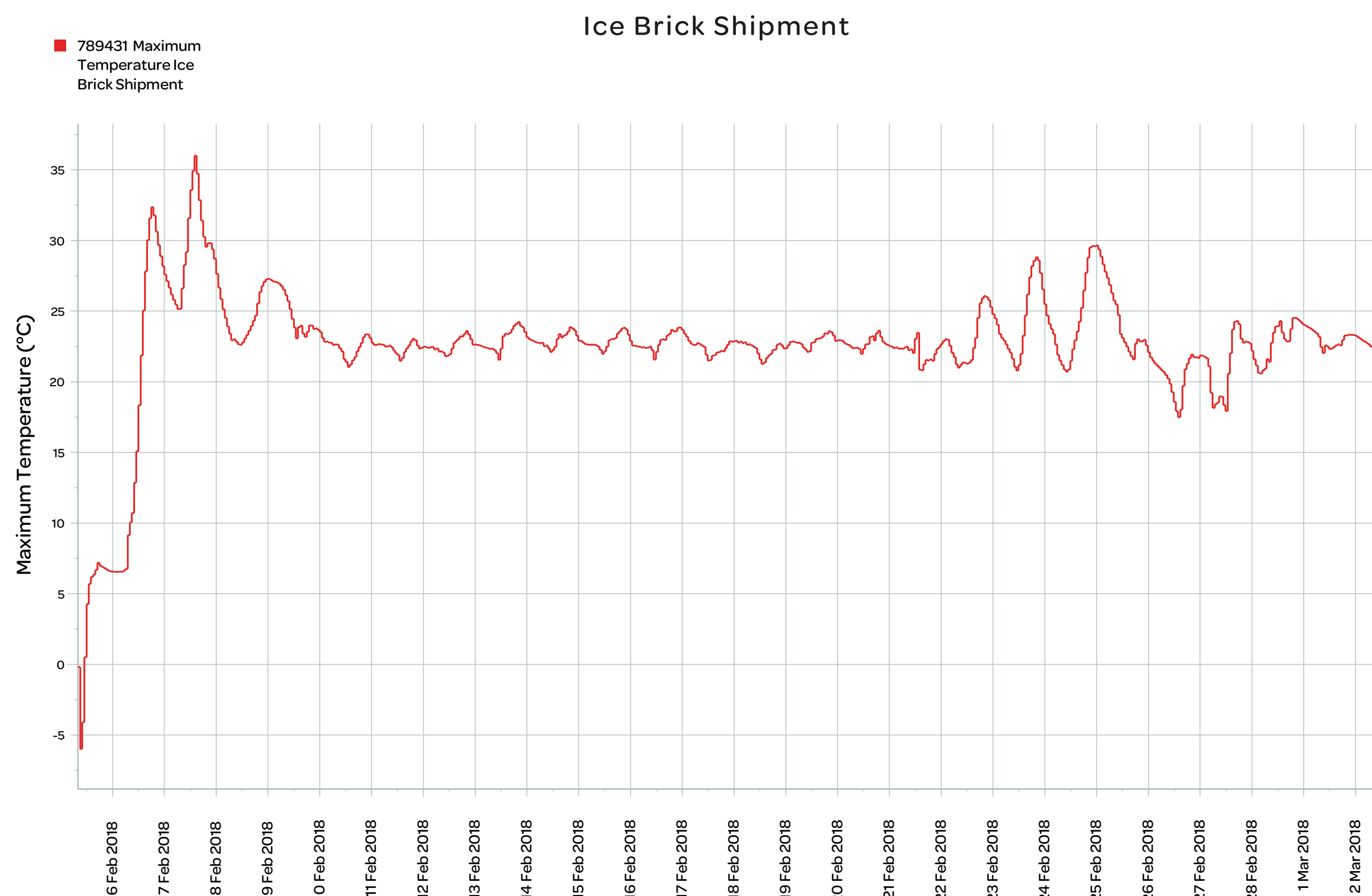


Figure 1B: Data logger results for material shipped with ice bricks.



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Map: Distance covered for the shipment of the two boxes.

For the 26 General Serum Chemistry analytes investigated (*apart from Magnesium), the % difference in results (ambient vs. ice bricks) across 8 linearly related levels (low to high) ranged from -4.6 (Urea 2.1 vs 2.2 mmol/L; Figure 2) to 5.6 (ALP 348 vs 368 U/L; Figure 3) which were all within their respective Analytical Performance Specifications (APS). Even the largest % differences, seen for some enzymes (up to 2% for CK, ALT, AST, GGT, Amylase; 3% for LD, Lipase and 5.6% for ALP) (Figure 2) were still within the expected precision of the assay.

*There was a separate (documented) inter-vial variability problem with the higher levels of Magnesium in the 2018 material where recoveries were noted to be inconsistent across all laboratories. This was thought to be a manufacturing issue.

Figure 2: Percentage difference for hot and cold results for chemistry analytes. Magnesium had an outlier, due to the inter-vial variability in the 2018 lyophilised material.

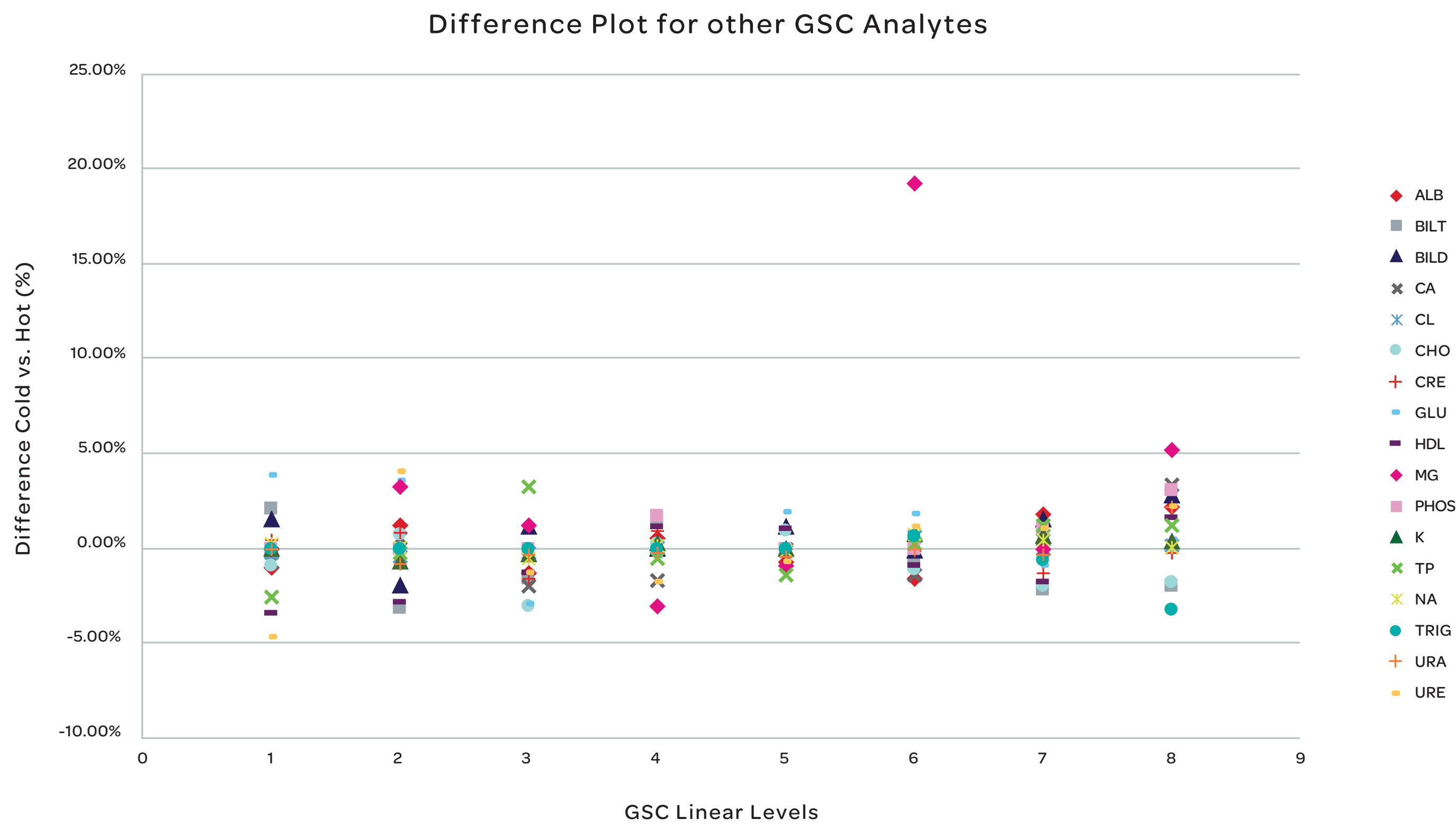
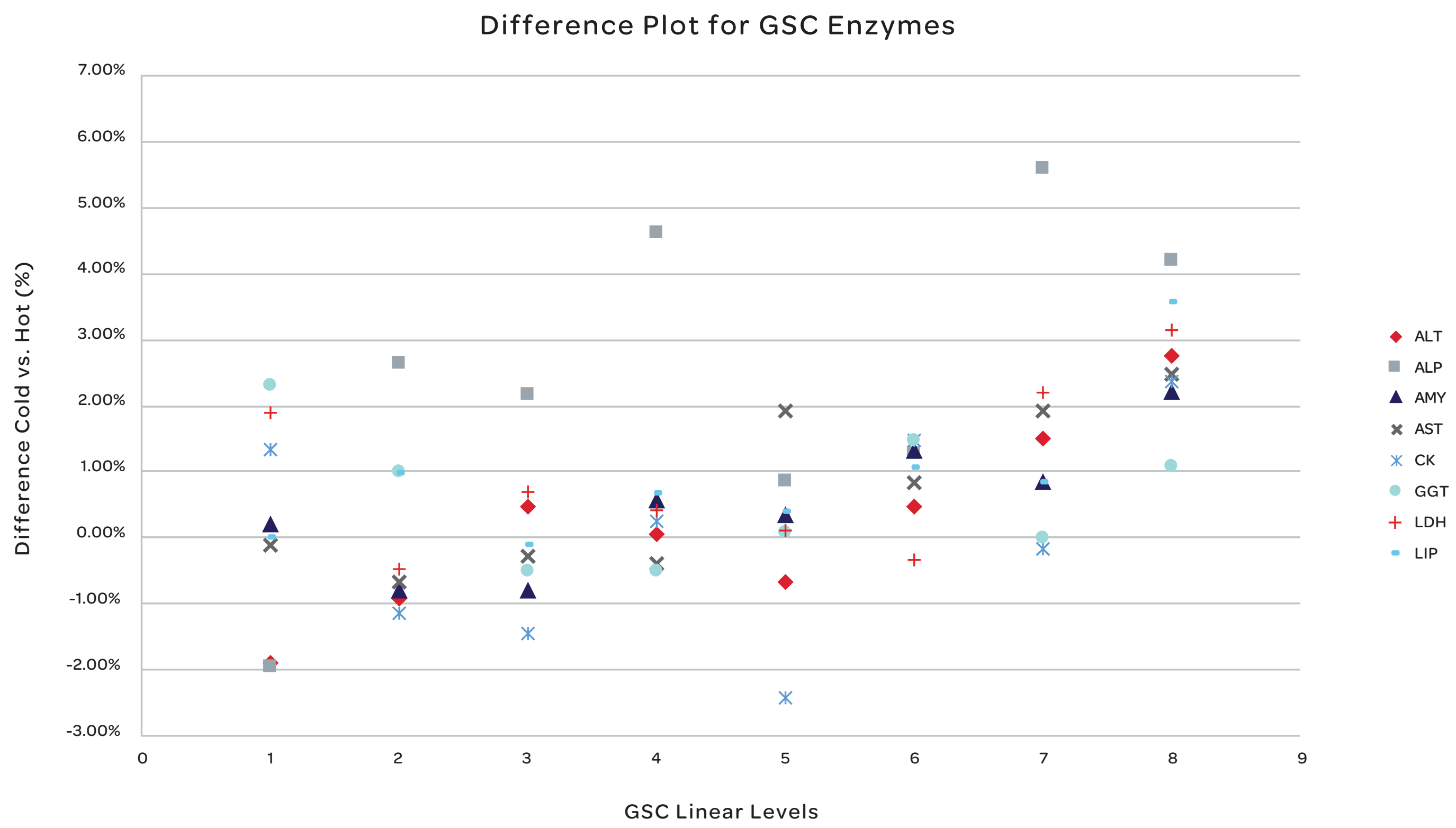


Figure 3: Percentage difference for hot and cold results for enzymes.



Conclusion

While acknowledging that this investigation has a limited sample size, it does support other evidence (historical data) that the stability of lyophilised RCPAQAP material for common chemical pathology analytes is not compromised during transport in hot climates.

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