Evaluation of Stability of Reference Materials for Infectious Disease Testing at Elevated Temperatures and Dry Stages

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INTRODUCTION

Biological reference materials for molecular diagnostics tests typically require cold chain logistics and storage for stability. However, refrigerated or frozen storage may not be available in resource limited settings. Even in industrial nations where cold storage is available, it adds to the cost and therefore limits accessibility of testing. To improve standardization and access to diagnostic testing, room temperature and elevated temperature storage of reference materials should be evaluated. SeraCare tested analytes such as viruses and bacteria at ambient temperature and elevated temperature in both liquid format and dry storage including lyophilization and ViveST™ Sample storage devices.

MATERIALS AND METHODS

Preparation of recombinant Ebola stability study material: SeraCare developed AccuPen™ Ebola GP/NG Reference Material. The reference material is formulated in defibrinated plasma with a v/v of 25µL and can be stored at 2-8 °C. These vials were lyophilized and stored at room temperature and 42 °C. ViveST™ samples were prepared by adding 250 µL of virus onto absorbent matrix and allowing to dry overnight. 1,2 These vials were stored at room temperature, 2-8 °C, and 42 °C. At each time point, the samples were tested in triplicates on an in-house developed TagMan® assay to assess the concentration in copies/mL.

Preparation of recombinant Creolin stability study material: heat inactivated Creolin bacteria in commutable matrix was prepared at 50°C to 55°C c/mL and aliquoted into microcentrifuge vials at 200 µL, fill volume. ViveST samples were prepared by adding 200 µL of virus onto absorbent matrix and allowing to dry overnight. Liquid vaccines were stored at 2-8 °C and room temperature, whereas ViveST™ vials were stored at room temperature and 42 °C. At each time point, the samples were tested in 2-3 replicates on Cepheid GenXpert™ instrument to assess the variation in Cycle Threshold (CT).

Preparation of Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG) stability study material:

Heat-inactivated Creolin Bacteria Stability Study Result: For Creolin OxA, comparison of test results in Figure 2 and Table 2 at different conditions showed that the bacteria was stable in liquid state and also on ViveST™ matrix at room temperature (< 2 Ct difference across 3 months of storage). A decline of 1.5 Ct was observed after 16 weeks stress at 42 °C, which is close to the results of 4 °C and 2-8 °C.

Heat-inactivated Creolin OXA Bacteria Stability Study Result: For Creolin OXA, comparison of test results in Figure 3 and Table 3 at different conditions showed that the bacteria was stable in liquid state and also on ViveST™ matrix at room temperature (< 2 Ct difference across 3 months of storage).

RESULTS AND DISCUSSION

Table 1: Comparison of Creolin final time point data at each condition for each storage system with zero time point data.

Table 2: Comparison of Creolin OXA final time point data at each condition for each storage system with zero time point data.

Table 3: Comparison of Creolin OXA final time point data at each condition for each storage system with zero time point data.

CONCLUSIONS

To standardize and improve the quality of diagnostic testing, room temperature or elevated temperature stable reference materials for infectious disease testing is required. In many African and Asian countries, temperatures of 40 °C or higher are not uncommon. The stability of the virus and bacteria at >42 °C in the lyophilized state or on the ViveST™ storage matrix indicates that these might be appropriate mechanisms for transport and storage.

To mimic different infectious disease material stability at elevated temperatures, both virus and bacteria were tested on ViveST dry storage system and in lyophilized form at 42 °C. Intracellular bacteria such as Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) were multiplied together to see the multiplexing effect on stability. The authors thank Alice Ku for her help in preparing the poster and ViveBio, LLC for their support during evaluation study.

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REFERENCES