Performance Reproducibility of Positive Control Materials for Multiple Pathogens

Niall Haggerty[1], Sadhia Mohammed[1*], Shubana Kazi[1], Alastair Ricketts[1]

(1) Qnostics Ltd, Glasgow, UK, (*) presenting author.

Objectives

Molecular diagnostic assays play an important role in diagnosing disease, monitoring patient response to treatment, and provide an indication of disease progression. Laboratories adopt systems to monitor and manage assays to ensure reliable data, and to minimise potential random and systematic variation. External run controls are used to monitor the whole test process on a run to run basis, and are specifically recommended for use in ISO 15189. External controls which resemble a clinical sample in terms of format and composition can be used independently of a supplied kit control to verify consistency of performance between test kit batches, reagent lots, and potentially identify assay drift. The objective of this study was to assess the performance of characterised positive control materials for multiple targets extracted on two separate extraction platforms which could potentially be used as external run controls.

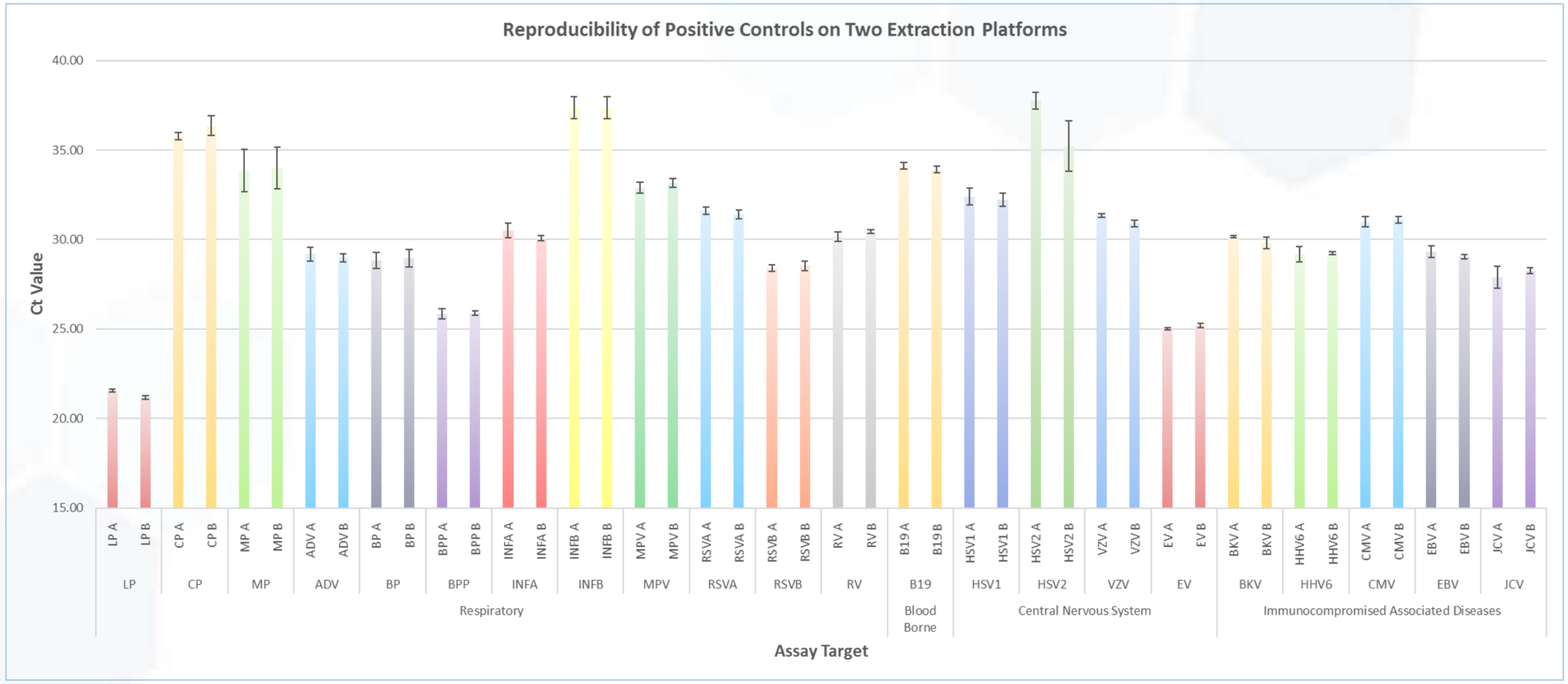
Methods

An extensive group of highly characterised positive control materials were tested, with four separate vials of positive control material tested per target. Each of the vials was thawed and split into aliquots. On the same day, one aliquot from each control vial was extracted on extraction platform A and another aliquot on extraction platform B. Sample eluates from both extraction platforms were amplified in duplicate on the same plate using target specific assays.

Results

Prior to further analysis outliers in each target data set were identified and removed through the application of Grubbs' test. Figure 1 shows a comparison of the mean C_t values for each assay target extracted on both extraction platform A and B. The standard deviation of the C_t values obtained for the controls for each target on each extraction platform were calculated and used to assign error bars in Figure 1. The results show that the performance of the positive control material for each target is robust and reproducible on both extraction platforms A and B. The results also show that there is no significant difference between the C_t values obtained for the positive control materials across both extraction platforms.

Figure 1 : Comparison of assay mean C_t values obtained for each target when extracted on two extraction platforms



Conclusions

The characterised control materials assessed in this study for multiple targets have been shown to be both robust and reproducible in performance across two different extraction platforms. Based on the data obtained in this study the materials assessed would therefore be suitable for use as external run controls within a laboratory quality managment system. As recommended by ISO 15189 such materials can be used to effectively monitor inter-assay run variation and identify potential assay drift.

Contact information: info@qnositcs.com

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