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Performance reproducibility of positive control materials for multiple pathogens

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Background: 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. This study assesses the performance of characterised positive control materials for multiple targets extracted on two separate extraction platforms.

Material/methods: An extensive group of positive control materials were tested, with four separate vials of positive control material tested per target. Each control vial was thawed and split into 220µl extracts. On the same day, one aliquot from each control material vial was extracted on extraction platform A and another aliquot on extraction platform B. Sample eluates from both extraction systems were amplified on the same plate using target specific in-house assays.

Results: Outliers in each target data set were identified through the application of Grubb's **a**nalysis and removed from further analysis. Figure 1 shows a comparison of the mean Ct values for each assay target extracted on two extraction platforms. The standard deviation of the Ct values obtained for the four positive controls for each specific assay target on each extraction platform were calculated and used to assign error bars in Figure 1. The results show that the positive control material for each target is robust and reproducible on both extraction platforms. The results show that there is no significant difference between the Ct values obtained for the positive control materials across both extraction platforms.

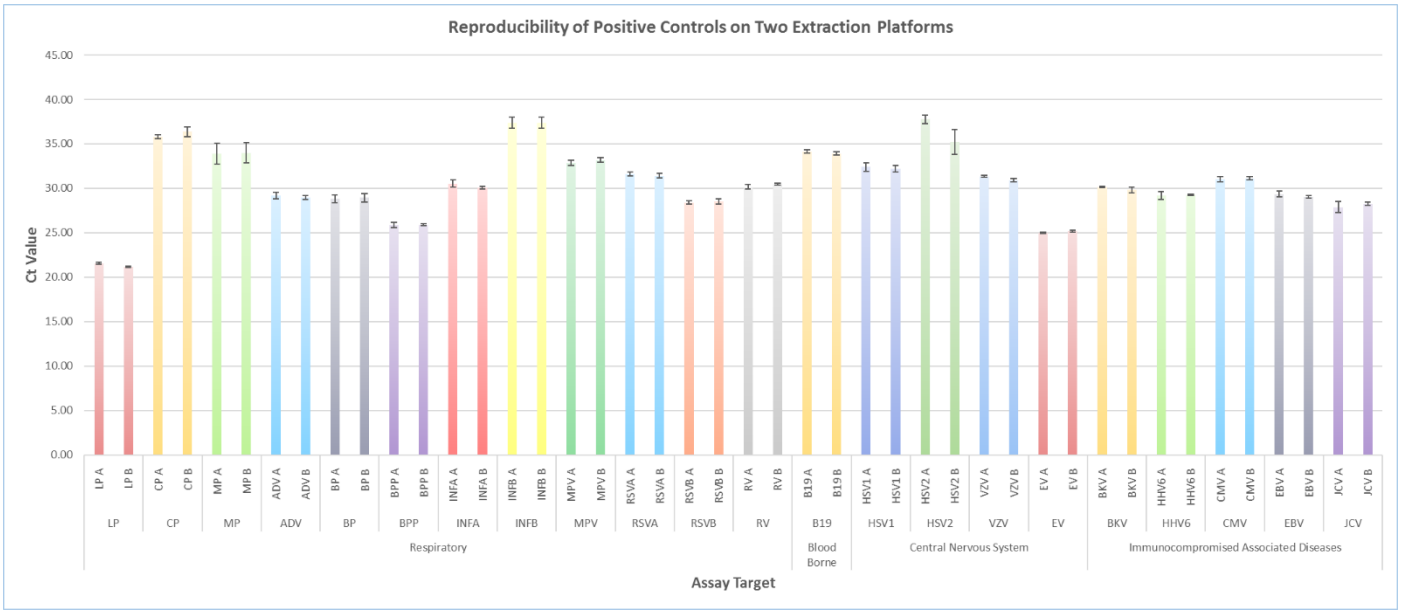

Figure 1: Comparison of assay mean Ct values obtained for each target when extracted on two extraction platforms.

Conclusions: The positive control materials assessed in this study for multiple targets have been shown to be both robust and reproducible in performance. These control materials have been shown to be suitable for use as external run controls based on the data from this study and as recommended by ISO 15189 can be used to effectively monitor inter-assay run variation and identify potential assay drift.