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Evaluation of two commercial extraction platforms, EasyMAG(R) and eMAG(R), and impact upon amplification performance

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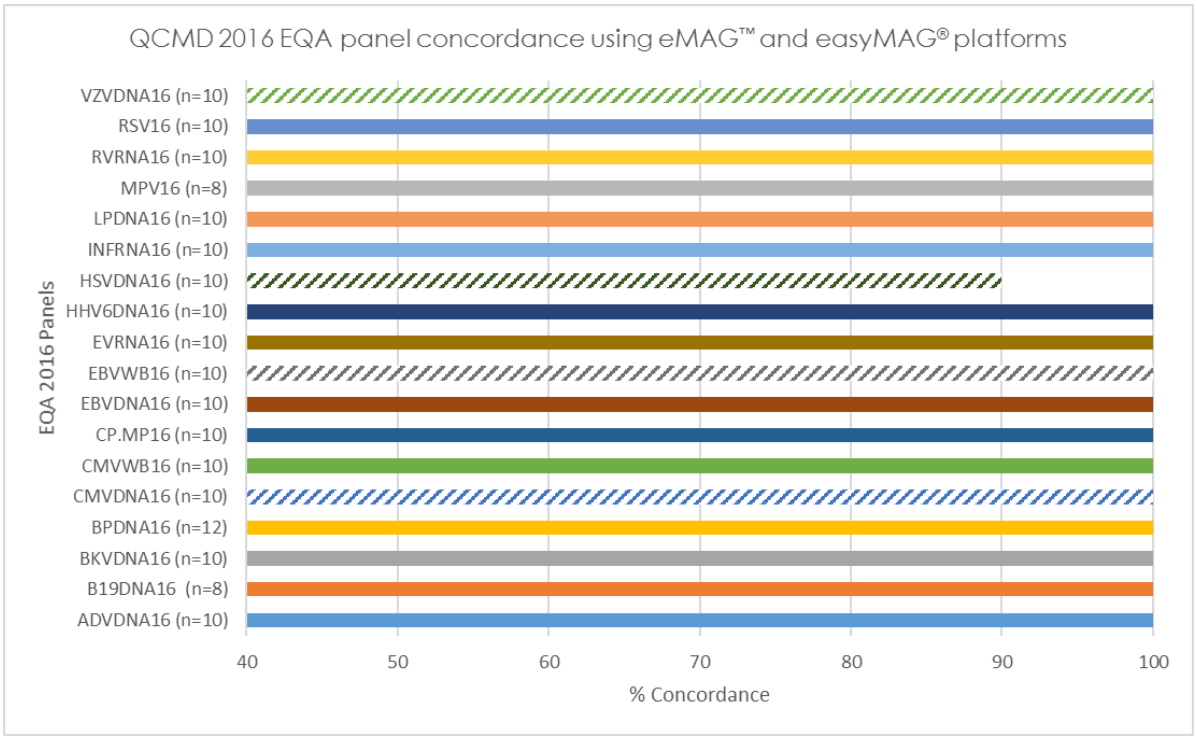
Background: The impact of extraction on the performance of downstream molecular assays is well documented. Therefore, robust and reproducible extraction performance is essential in modern clinical diagnostics for accurate qualitative detection and quantitative determination of pathogen load. The performance of the eMAG™ and easyMAG® extraction platforms were investigated using eighteen QCMD 2016 external quality assessment (EQA) panels. Samples were extracted from each platform in parallel, and were analysed to determine whether both platforms returned the same result (concordance at the extraction stage). The following panels were selected from EQA programmes: (i) Respiratory (LPDNA16, CP.MPDNA16, ADVDNA16, BPDNA16, INFRNA16, MPVRNA16, RSVRNA16 & RVRNA16); (ii) Blood Borne (B19DNA16); (iii) Central Nervous System (HSVDNA16, VZVDNA16 & EVRNA16); and (iv) Immunocompromised associated diseases (BKVDNA16, HHV6DNA16, CMVDNA16, CMVWB16, EBVDNA16 & EBVWB16). The panels covered a variety of different matrices. **Objective:** The aim of this study was to assess the performance of two commercially available extraction platforms to assess their ability to provide consistent and reliable results on EQA materials.

Material/methods: All EQA panels were extracted in line with the manufacturer's protocols, all amplification kits were run following manufacturer's protocols. Samples from each EQA panel were thawed / reconstituted and split into 220µl aliquots. On the same day one aliquot from each sample was processed on the eMAG™ (using automated extraction methods) and a second on the easyMAG®. The remaining aliquots were frozen for retest if required. Sample eluates from both systems were tested on the same amplification plate using bioMérieux R-gene® kits. Retests were run as duplicate extraction and amplification to verify performance.

Results: Figure 1 shows seventeen out of eighteen EQA panels tested observed 100% concordance between eMAG™ and easyMAG® platforms. The HSVDNA16 panel showed 90% concordance. The quantitative value for HSVDNA16 sample showed discordance between the eMAG™ and easyMAG®.

The sample was retested in duplicate and results remained discordant. The variation observed in target quantitation was not indicative of an issue with the extraction method as the internal control performed consistently through all tests, but indicates the sample may be potentially near or at the limit of quantitation of the PCR assay.



Conclusions: The results showed 100% concordance in performance between the two extraction platforms for 17 of the 18 EQA panels tested and 90% concordance for the remaining panel. There was no significant effect observed upon extraction using the eMAG™ and easyMAG®.