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B-275 Retrospective Study for Mpox Detection: Validation of a Real Time PCR Kit for its Fast Diagnosis

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BACKGROUND: In an increasingly globalised and interconnected world, a small outbreak of an infectious disease (such as monkeypox in 2022) can turn into a global health emergency. In this context, global health systems must develop effective strategies to interrupt transmission as early as possible by identifying cases and sources of infection. Since clinical diagnostic products must be externally validated to comply with current regulations, the aim of this collaborative and retrospective study was to evaluate the clinical sensitivity and specificity of the VIASURE *Monkey pox* Real time PCR detection kit (CerTest Biotec) for the detection of monkeypox by Real time PCR.

METHODS: This is a retrospective and collaborative study conducted at the Microbiology Department of the Miguel Servet University Hospital at the request of the company CerTest Biotec SL with the approval of the Aragon research ethics committee (PI22/412; 5 Oct 2022). A total of 192 suspected MPX samples were collected in 2022–2023. RealStar Orthopoxvirus PCR kit 1.0, Altona Diagnostics and Sanger sequencing were used as reference techniques. Clinical sensitivity and specificity (95% CI) were calculated with MetaDisc 1.4 software, while overall concordance and quantitative correlation between both real-time PCR kits was checked with the statistical package SPSS v24 (IBM Corporation).

RESULTS: All the results obtained by the kit under study coincided with the reference kit ones (being 69 of them positives for monkeypox). Therefore, clinical sensitivity and specificity values are 100%. Furthermore, the overall agreement was almost perfect (100, 98–100) as was the Spearman correlation test ($r_s = 0.78$; $P < 0.001$). All positive samples were sequenced and confirmed the presence of the virus.

CONCLUSION: This retrospective study demonstrates the good clinical parameters and strong overall agreement of the VIASURE® Monkey pox virus Real Time PCR detection kit (CerTest Biotec) compared to both the RealStar Orthopoxvirus PCR 1.0 kit and Sanger sequencing results. In addition, the stabilised, ready-to-use format allows storage at room temperature, and facilitates transport, as it does not need to be refrigerated. This makes it environmentally friendly and reduces additional costs.