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A-298 Performance Analysis of Three Mpox Real Time PCR Kits With Lesion Swab Clinical Samples

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BACKGROUND: The appearance of skin lesions can be a symptom of infection or reactivation of the HSV-1, HSV-2, VZV or *T. pallidum* or even monkeypox virus infection. Due to the contact-bound ease of spread of these pathogens, an accurate and fast diagnosis, such as PCR-based testing, is key to a good epidemiological management. The aim of this study was to determine the clinical performance of three qPCR assays.

METHODS: A total of 334 cutaneous swabs collected from patients attended at the Hospital Universitario Miguel Servet were analysed using the three assays under study: VIASURE *Herpes virus 1, Herpes virus 2 & Varicella Zoster* Virus Real Time PCR Detection Kit, VIASURE *Treponema pallidum* Real Time PCR Detection Kit and VIASURE *Mpox* Real Time PCR Detection Kit. Samples were collected between December 2021 and November 2022. These samples were requested through the Biobanco del Sistema de Salud de Aragón (BSSA) and have the approval of the Aragón Ethics Committee (PI22/409). DNA/RNA extraction was performed using the automated extraction method magLEAD® 12gC instrument with the MagDEA Dx SV kit and amplification was performed using the thermocycler CFX96™ Real-Time PCR Detection System (BioRad). The obtained results were compared with the reference assays RealStar® Orthopoxvirus PCR Kit 1.0 (Altona) and Allplex™ Genital ulcer assay (Seegene®).

RESULTS: After data analysis a very good overall agreement was obtained for all the studied targets.

CONCLUSION: The assays under study demonstrated to be a good tool for differential analysis in skin lesions compatible with HSV-1, HSV-2, VZV, *T. pallidum* or mpox virus infection. In addition, the shared thermal protocol of the assays allowed for the simultaneous detection in the sample, creating a personalized panel option for the user, as opposed to the reference assays employed, which required two separate analyses, taking longer to reach the full assessment of the sample.

Table 1. Summary of obtained results.

	Overall agreement	TP	TN	FP	FN	Sensitivity	Specificity	PPV	NPV
Herpes Simplex virus type 1	1 (0.98–1)	49	285	0	0	1 (0.92–1)	1 (0.98–1)	1 (0.92–1)	1 (0.98–1)
Herpes Simplex virus type 2	1 (0.98–1)	50	284	0	0	1 (0.92–1)	1 (0.98–1)	1 (0.92–1)	1 (0.98–1)
Varicella Zoster Virus	1 (0.98–1)	30	304	0	0	1 (0.88–1)	1 (0.98–1)	1 (0.88–1)	1 (0.98–1)
Treponema pallidum	1 (0.98–1)	35	299	0	0	1 (0.90–1)	1 (0.98–1)	1 (0.90–1)	1 (0.98–1)
Mpox virus	1 (0.98–1)	38	295	0	0	1 (0.90–1)	1 (0.98–1)	1 (0.90–1)	1 (0.98–1)