O165
Oral Session
Viral diagnostics in the immunocompromised

DETECTION OF HERPES SIMPLEX VIRUS 1 AND 2, AND VARICELLA ZOSTER VIRUS USING THE QUIDEL MOLECULAR HSV 1+2/VZV ASSAY ON THREE REAL TIME PCR PLATFORMS

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Objectives: Cell culture and clinical diagnosis of cutaneous and mucocutaneous lesions for HSV and VZV lack sensitivity and specificity. We evaluate a multiplexed real time PCR (RT-PCR) assay for the detection and differentiation of HSV-1, HSV-2, and VZV using three RT-PCR platforms.

Methods: A total of 443 fresh cutaneous (n=138) or mucocutaneous (n=305) swab specimens were collected from patients with herpetic lesions. Swabs were eluted into 3.0 ml viral transport medium prior to testing. Each specimen was tested using the Quidel Lyra Molecular HSV/VZV Assay (Lyra), run in parallel on the Cepheid SmartCycler II (SC), ABI 7500 FastDx (FDx), and ABI QuantStudio (QS). A 100 µL portion of specimen eluate was added to 25 µL of process buffer and heated at 60°C for 5 min. A 5 µL portion of the heat treated sample was combined with 15 µL of Lyra QMol HSV 1+2/VZV master mix and was analyzed by RT-PCR. Traditional and ELVIS cell culture was used as gold standard comparator.

Results: Sensitivity and specificity of Lyra for each target on the 3 RT-PCR platforms are presented in Table 1. There were three 'false negative' Lyra results for HSV-1 across the 3 RT-PCR platforms. One was negative by Lyra on all 3 RT-PCR platforms but was positive by ELVIS and alternative RT-PCR test; one was negative by Lyra on the QS only and was positive by ELVIS, and alternative RT-PCR test; and one was negative on the FDx only but positive by ELVIS and alternative RT-PCR test. There were three 'false negative' Lyra results for HSV-2. One was negative by Lyra on SC only and positive by ELVIS and alternative RT-PCR test; and two were negative by Lyra on FDx only but positive by ELVIS and alternative RT-PCR test. The single 'false negative' Lyra result for VZV was negative by Lyra on the FDx only but positive by cell culture and alternative RT-PCR test. These data support the true sensitivity of the Lyra HSV 1+2/VZV Assay on each RT-PCR platform as presented in Table 1.

	SmartCycler II	ABI 7500 FastDx	ABI QuantStudio
HSV-1			
Sensitivity	98.2% (56/57)	96.5% (55/57)	96.5% (55/57)
Specificity	98.4% (372/378)	97.9% (372/380)	96.9% (369/381)
HSV-2			
Sensitivity	98.4% (62/63)	95.2% (60/63)	100% (63/63)
Specificity	95.4% (355/372)	95.7% (358/374)	94.1% (353/375)
VZV			
Sensitivity	100% (22/22)	95.5% (21/22)	100% (22/22)
Specificity	97.2% (278/286)	97.2% (280/288)	97.6% (282/289)

Conclusions: The Lyra HSV1+2/VZV Assay demonstrated comparable sensitivity and specificity for the detection of HSV-1, HSV-2, and VZV on 3 different RT-PCR platforms. This allows flexibility for laboratories using single test and 96-well platforms for RT-PCR testing of specimens for HSV and VZV. Because nucleic acid extraction is not required prior to RT-PCR analysis, results are available in as little as 90 min.