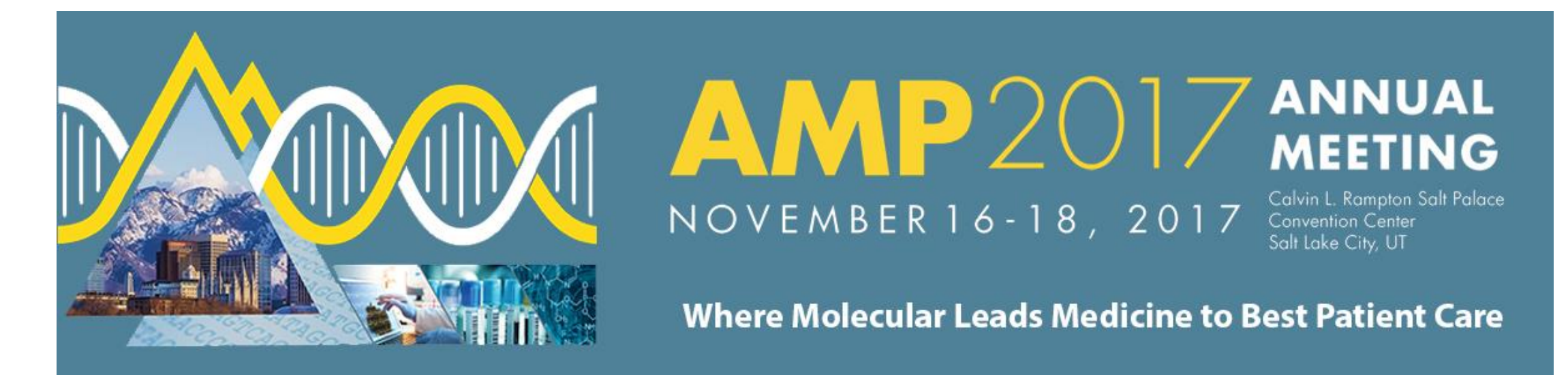


Evaluation of the Focus Diagnostics Simplexa HSV 1 & 2 Direct for Detection and Differentiation of Herpes Simplex Virus 1 and 2 in Neonatal Swab Specimens



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Introduction

Herpes simplex virus (HSV) testing is routinely performed for newborns at risk of exposure to the virus during labor and vaginal delivery. Though polymerase chain reaction (PCR) has been accepted as the method of choice for HSV detection in cerebrospinal fluid in adults and children,¹ viral culture is still the recommended method for HSV detection in neonatal eye, mouth, and nasopharyngeal swabs.²

Since HSV can take from 2-5 days to grow in culture, PCR may serve as a more efficient alternative for virus detection in the neonatal period. Therefore, the purpose of our study was to determine the concurrence rate of HSV detection using viral culture versus Simplexa HSV 1 & 2 Direct, and to determine the limit of detection (LoD) of the PCR-based method in detecting four different strains of HSV in neonatal swab specimen matrix.

Results

Collection Site	Qualitative Results isolates/total (culture)	Qualitative Results detected/total (PCR)
Eye	0/8	0/8
Throat	0/6	0/6
Skin	0/6	0/6
Rectum	0/5	0/5
Nose	0/1	0/1
Genitalia	0/1	0/1
Unknown	0/1	0/1

References

- Sauerbrei A, Wutzler P. Laboratory diagnosis of central nervous system infections caused by herpesviruses. *J Clin Virol.* 2002;25(1):S45-S51.
- Kimberlin DW, Baley J. Guidance on management of asymptomatic neonates born to women with active genital herpes lesions. *Pediatrics.* 2013 Feb;131(2):383-6.
- Simplexa™ HSV1&2 Direct. MOL2150. Rev E. August 28, 2015. <https://www.focusdx.com/pdfs/pi/OUS/MOL2150.pdf>

Methods

- 28 neonatal swab specimens tested for HSV 1 and 2 by culture for clinical diagnostic purposes from January 1, 2016 - May 31, 2016 were included in the study.
- All specimens were kept frozen in viral transport media at -70 C.
- The specimens were run on Simplexa HSV 1 & 2 Direct following the manufacturer's instructions.³
- The results obtained by PCR and viral culture were compared to determine the concurrence between the two methods.
- Specimens negative for HSV by PCR and culture were used as matrix for serial dilutions of titered viral stocks.
- The highest dilution at which 12 out of 12 replicates were detectable and the initial 50% tissue culture infectivity dose (TCID₅₀) were used to determine the LoD for each strain.
- The minimum number of infectious HSV virions that the Rapid format ELVIS HSV ID Test System can detect after 16-hours of incubation compared to MRC-5 and CV-1 cell cultures after 7 days incubation is one (1) when determined by TCID₅₀.



Virus Strain	LoD Concentration (TCID ₅₀ /mL)	Qualitative Results (detected/total)	Mean Ct ± SD
HSV-1 McIntyre	0.034	12/12	36.4 ± 0.67
HSV-1 HF	0.5	12/12	35.9 ± 0.52
HSV-2 G	0.018	12/12	36.0 ± 0.62
HSV-2 MS	0.05	12/12	35.2 ± 0.42

Conclusions

- The Simplexa HSV 1 & 2 Direct assay demonstrated **high specificity, sensitivity, and reproducibility** in detection of the four HSV strains.
- The results may be reported within a few hours of collection and therefore facilitate prompt decision making regarding patient treatment and discharge from the hospital
- The assay offers a promising alternative to viral culture in evaluation of neonatal swab specimens for suspected HSV infection.