

# Diagnosis of Disseminated HSV Infection Using Plasma Samples on the ARIES Sample-to-Answer HSV 1&2 PCR Assay

Becky Fung, Sandy Paff, Danielle Ingebrigtsen, and Steve Miller  
Department of Laboratory Medicine, University of California San Francisco, San Francisco CA 94107

## Introduction

Two of the common human pathogens that cause infections in neonates, children and adults are HSV1 and HSV2. These viruses can establish latency after the primary infection, and can cause re-occurring lesions, and can lead to severe disease in immunocompromised patients. The ARIES system has the ability to execute all the necessary steps for the nucleic acid amplification and be completed in just 2 hours. This study examined the ability of ARIES HSV 1&2 assay to detect virus in plasma samples.

## Methods

Twenty positive plasma samples and 23 negative plasma samples were initially tested by Quantitative Real-time PCR by a reference lab and were later compared with ARIES HSV 1&2 assay. Limits of detection, precision, specificity and interference studies were performed in plasma matrix.

## Results

### Clinical Sample Comparison

Plasma	Reference Lab Assay (PCR)		
		Positive	Negative
Aries Result	Positive	18	0
	Negative	1	21

**Accuracy 97.5%,  
Sensitivity 95%  
Specificity 100%**

## Results

### Precision

Negative control(10 replicates)			
No HSV detected	Mean	Standard Deviation	%CV
Internal Control Ct	30.8	1.86	6.05
Internal Control Tm	76.2	0.12	0.15

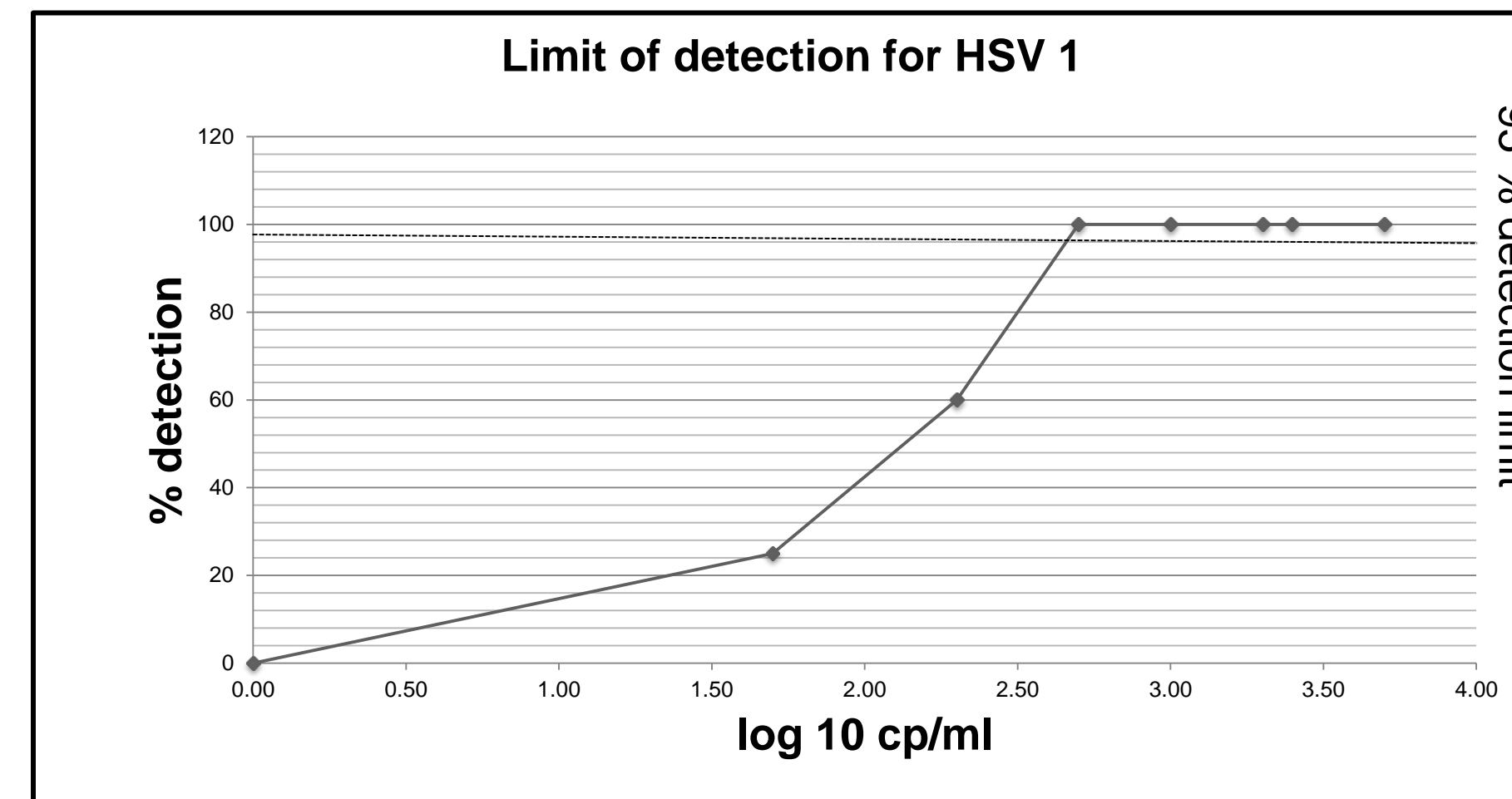
HSV 1&2 Positive Control (3 replicates)			
	Mean	Standard Deviation	%CV
HSV Ct	33.4	0.35	1.05
HSV1 Tm	85.3	0.15	0.18
HSV 2 Tm	87.6	0.06	0.07
Internal Control Tm	76.1	0.10	0.13

### Specificity

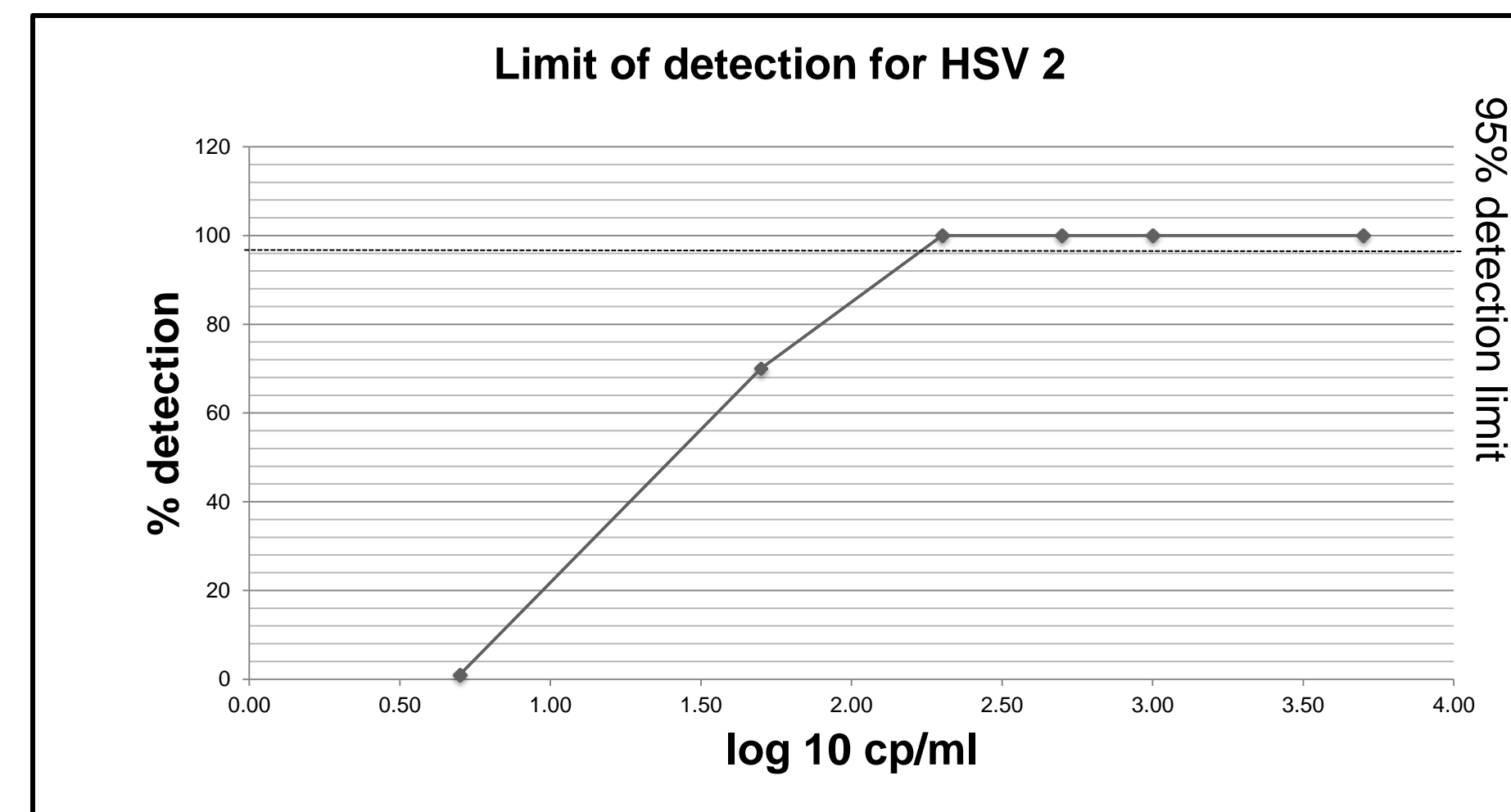
Virus	Amplification
HSV1	Detected
HVS 2	Detected
BKV	Not Detected
EBV	Not Detected
Enterovirus	Not Detected
Adenovirus	Not Detected
HHV6	Not Detected
Parvovirus	Not Detected
CMV	Not Detected

## Conclusions

- The ARIES HSV 1&2 assay can be adapted to plasma samples for detection of HSV viremia.
- The assay has high sensitivity and rapid ease of use, and can provide for detection for diagnosis of HSV viremia in immunocompromised patients.
- Assay is qualitative, reflex testing by quantitative PCR may be necessary.



95% LoD = 500 cp/mL



95% LoD = 200 cp/mL