Validation of a Viscous Fluid Preparation Protocol for Treating Whole Blood and Lower Respiratory Specimens Prior to Testing by the Luminex ARIES HSV 1&2 Assay

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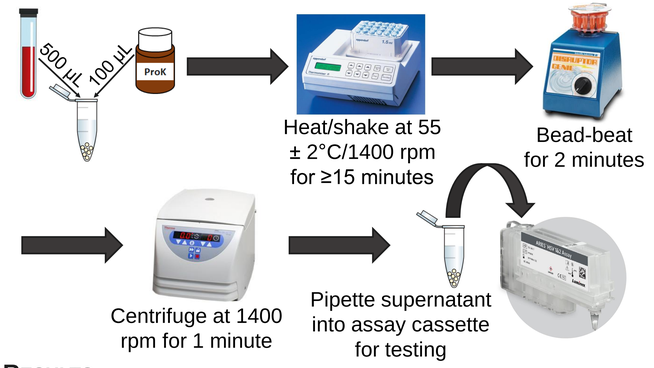
Background

- Diagnosis of herpes simplex virus (HSV) is routinely made based on clinical findings and supported by laboratory testing using polymerase chain reaction (PCR) or viral culture.
- The ARIES HSV 1&2 assay (Luminex) is a qualitative, real-time PCR test for the direct detection and differentiation of HSV-1/2 that is FDA-cleared for testing cutaneous and mucocutaneous specimens collected from symptomatic patients.

Methods

- Following implementation of the ARIES HSV 1&2 assay, high rates of invalid results were observed for two off-label, validated sources (38.5% for lower respiratory and 45.1% for whole blood).
- Six analyte-negative lower respiratory and whole blood specimens were spiked with positive control material (ZeptoMetrix) at the previously established limit of detection (LoD) for each respective analyte and source.
- These specimens were treated using the protocol illustrated below and tested by the ARIES.



Results

Average Change (Ct Value) Before *vs* After Treatment		
Specimen Source	**HSV-1**	**HSV-2**
Lower Respiratory	+0.1	0.0
Whole Blood	-1.8	-1.2

Implementation of a **viscous fluid protocol** led to a significant decrease in invalid rates for both **whole blood** and **lower respiratory** specimens tested on the **Luminex ARIES**.

Savings (time and $$$)

Turnaround time

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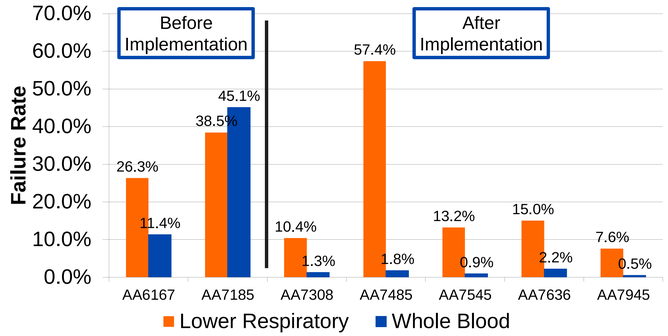
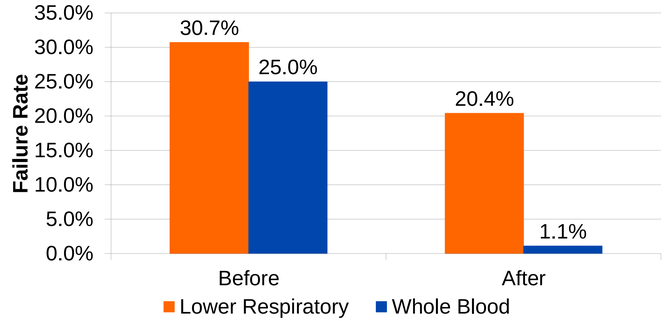
Results (Cont.)

- One lower respiratory specimen yielded a negative result prior to treatment, but was positive for HSV-2 following treatment with the viscous fluid protocol. The untreated specimen was positive on repeat testing.
- One lower respiratory specimen was invalid following the viscous fluid protocol, but yielded a positive HSV-1 result on repeat testing.

ARIES HSV 1&2 Assay Lot-to-Lot Failure Rates



Failure Rates – Before *vs* After Implementation



Conclusions

- Pretreatment of lower respiratory specimens using a viscous fluid protocol showed similar assay performance compared to non-treated specimens, with treated whole blood specimens exhibiting increased assay sensitivity compared to non-treated specimens.
- The LoD in both specimen types remained the same for both HSV-1 and HSV-2 following the viscous fluid protocol.
- Implementation of this process led to a significant decrease in the invalid rates for both specimen types, resulting in cost-savings for the laboratory and decreased assay turnaround time.