UTILITY OF A VIRAL VESICULAR PANEL MULTIPLEX PCR ASSAY FOR THE DIAGNOSIS OF MPOX

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BACKGROUND

The 2022 Mpox outbreak is notable for:
- Global reach
- Atypical presentations including overlap with common STIs
- High frequency of co-infections

The resulting diagnostic uncertainty has illustrated the need for improved diagnostic testing. We identified an existing commercially available research use only multiplex PCR panel with targets for Mpox as well as several mimics and evaluated its ability to detect Mpox from clinical specimens from the 2022 outbreak in Atlanta, GA.

Multiplex Panel Targets
Mpox virus Clade 1 (MPXV1)
Mpox virus Clade 2 (MPXV2)
Herpes simplex virus 1 (HSV1)
Herpes simplex virus 2 (HSV2)
Human Herpes virus 6 (HHV6)
Human Enterovirus (HEV)
Varicella Zoster virus (VZV)

METHODS

A convenience sample of residual specimens collected during routine clinical care were stored and later tested on the multiplex panel (Qiagen, Germantown, MD, USA). Reference testing was done by a commercial laboratory as part of routine care. Assay performance was measured by calculating positive percent agreement and negative percent agreement with 95% confidence intervals using the efficient-score method (vassarstats.net).

A **readily available**, **easy to use**, **multiplex PCR** assay reliably **detects MPOX** from clinical samples.

RESULTS

		Reference Standard		
		Positive	Negative	Total
QIAstat	Positive	36	0	36
	Negative	1	10	11
	Total	37	10	47
	Positive % Agreement	97.3% (84.2-99.9%)		
	Negative % Agreement	100 % (65.5-100%)		

A)

Sample ID	Target Detected	Reference Method	Co-Detection with Mpox
8	HSV 2	Culture (-), PCR (+)	Yes
11	HSV 2	Culture (+), PCR (+)	Yes
17	HSV 2	Culture (+), PCR (+)	Yes*
18	VZV	PCR (+)	No
24	HSV 2	PCR (+)	Yes
29	HSV 2	PCR (+)	Yes
40^	Enterovirus	PCR (+)	Yes
41^	Enterovirus	PCR (+)	Yes
43	HSV 2	ND	No
44	HSV 2	ND	No
48	HSV 2	Culture (-)	Yes

B)

Figure 1. **A)** Table showing performance of the QIAstat-Dx® Viral Vesicular panel in the detection of mpox (n= 47 samples from 40 patients). **B)** Description of non-mpox pathogens detected by the QIAstat-Dx® Viral Vesicular panel. * Mpox detected by reference method only. ^ Specimens from the same patient.

- The multiplex panel identified all but one case of Mpox detected by the reference method (PPA 97.3%, 95% CI 84.2-99.9%)
- Mpox was not detected in any sample where the reference method was negative (NPA 100%, 95% CI 65.5-100%)
- 11 non-Mpox viruses were detected, 8 of which represented co-infections
- No on-panel viruses other than Mpox were detected by a reference method but not by the multiplex assay

CONCLUSIONS

The commercial investigational panel was highly accurate for the detection of Mpox as compared to the reference method. It additionally offers several advantages over currently available testing strategies:
- Short turn around time
- Easy to use
- Safe
- Ability to detect other pathogens (mimics and co-infections)

These advantages make this panel a good candidate for evaluation as a tool for disease surveillance and outbreak response.

ADDITIONAL KEY INFORMATION

The authors declare no relevant conflicts of interest.

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