



Lyra[®] Direct
Real-Time Results.
Ready-to-Use Assays.

HSV 1+2/VZV



For the qualitative detection and identification of Herpes simplex virus 1 and 2 and Varicella zoster virus using real time PCR

- One hour turn-around time from sample to answer.
- No vortexing or centrifugation.
- Validated on the Applied Biosystems[®] 7500 Fast Dx, QuantStudio[™] Dx Real-Time PCR Instrument and Cepheid Smartcycler[®] II.

Workflow benefits of Lyra Direct real-time PCR assays

Feature	Benefit
One step reagent set-up	Minimal hands-on time.
Speed	Results in less than 60 minutes.
Easy training	Simplified workflow with standard pipetting volumes.
Refrigerated storage	No freezer needed. 2°C to 8°C.
2-year shelf life	Reduce waste and reordering.
Room temperature set-up	No ice or cooling block required.
Flexible 96-test format	Avoid aliquoting and minimize reagent cost.

Clinical performance

Applied Biosystems® 7500 Fast Dx, refer to Package Insert for additional performance claims.

Cutaneous Lesions

HSV-1 Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS® HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	24	3*	27
Negative	0	252	252
Total	24	255	279
Sensitivity	24/24	100%	
Specificity	252/255	98.8%	

*One (1) of the three (3) positives was positive by an additional RT-PCR assay.

HSV-2 Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	34	8*	42
Negative	1**	236	237
Total	35	244	279
Sensitivity	34/35	97.1%	
Specificity	236/244	96.7%	

*Seven (7) of the eight (8) positives were positive by an additional RT-PCR assay.

**One (1) of the one (1) negative was positive by an additional RT-PCR assay.

VZV Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	26	7*	33
Negative	1**	189	190
Total	27	196	223
Sensitivity	26/27	96.3%	
Specificity	189/196	96.4%	

*Seven (7) of the seven (7) positives were positive by an additional RT-PCR assay.

**One (1) of the one (1) negative was positive by an additional RT-PCR assay.

Mucocutaneous Lesions

HSV-1 Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS® HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	98	10*	108
Negative	5**	531	536
Total	103	541	644
Sensitivity	98/103	95.1%	
Specificity	531/541	98.2%	

*Ten (10) of the ten (10) positives were positive by an additional RT-PCR assay.

**Five (5) of the five (5) negatives were positive by an additional RT-PCR assay.

HSV-2 Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	93	16*	109
Negative	2**	533	535
Total	95	549	644
Sensitivity	93/95	97.9%	
Specificity	533/549	97.1%	

*Sixteen (16) of the sixteen (16) positives were positive by an additional RT-PCR assay.

**Two (2) of the two (2) negatives were positive by an additional RT-PCR assay.

VZV Results

Lyra Direct HSV 1+2/VZV Assay	Comparator: ELVIS HSV ID and D ³ Typing Test		
	Positive	Negative	Total
Positive	4	3*	7
Negative	0	423	423
Total	4	426	430
Sensitivity	4/4	100%	
Specificity	423/426	99.3%	

*Three (3) of the three (3) positives were positive by an additional RT-PCR assay.

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Lyra Direct HSV 1+2/VZV Assay – 96-Reaction Kit: Cat. #M102
 Quidel Molecular HSV 1+2/VZV External Controls – 10-Reaction Kit: Cat. #M121

