



Performance evaluation of Microbix HPV swabs on the Alinity m HR HPV

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BACKGROUND

Human Papillomavirus (HPV) testing is a critical component in the early detection and prevention of cervical cancer. With increasing adoption of HPV vaginal self collection as an alternative screening approach, particularly for improving access and patient acceptability, the need for well characterized positive materials has grown. As labs perform verification testing for implementation of self-collection, a reliable source of positive sample for different genotypes of HPV is necessary. In this study, we evaluated dry swab samples prepared by Microbix for five HPV genotypes for use in verification studies.

METHODS

- Microbix HPV dry swab samples positive for HPV16, HPV18, HPV45, HPV31, and HPV51 and negative swab samples were prepared by placing them into Alinity m Transport Tubes with 2.5 mL of Alinity m Specimen Buffer Kit II (09Ro43-050). The swab samples were vortexed 3 times for 10 seconds prior to loading them on to the Alinity m for testing with the Alinity m HR HPV assay.
- Swab reproducibility was evaluated by testing the neat samples across 3 days. To determine sensitivity, samples were diluted with the Alinity m Specimen Buffer Kit II and tested six replicates each at 1:10, 1:50, 1:100. Swab sample stability was investigated for samples stored at room temperature for 1, 4, 7, and 12 days post sample preparation.
- Detection rate, average cycle number (CN) and standard deviation (SD) were evaluated.

CONCLUSION

This study demonstrates the utility of the Microbix HPV dry-swabs for use in preparing samples and panels during verification of HPV vaginal self-collection and the respective molecular HPV assays.

RESULTS

Reproducibility

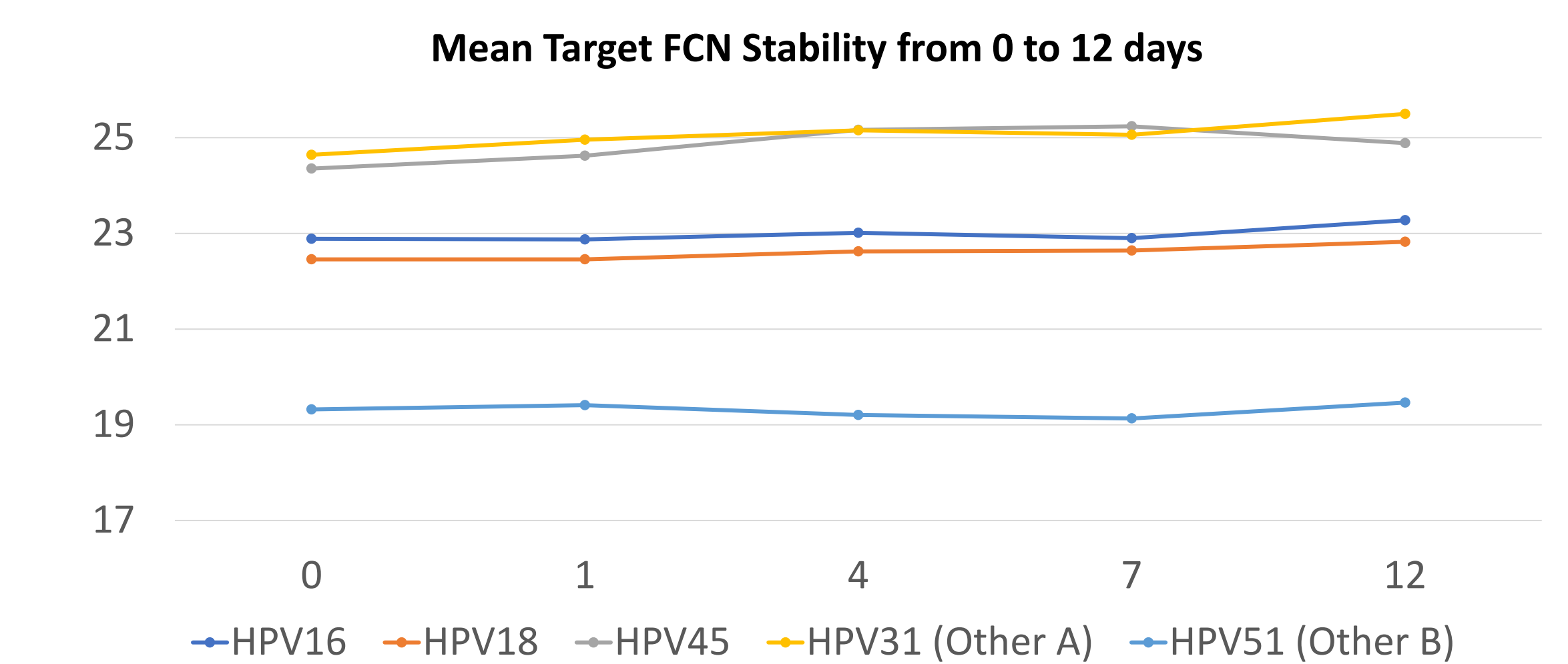
HPV Genotype	Alinity m Interpretation	Detection	Mean Target FCN	SD
HPV16	HPV16	6/6	22.89	0.27
HPV18	HPV18	6/6	22.46	0.38
HPV45	HPV45	6/6	24.35	0.31
HPV31	HPV Other A	6/6	24.64	0.50
HPV51	HPV Other B	6/6	19.32	0.43

Sensitivity

Genotype	Dilution	Detected	Target FCN		Cellular Control FCN	
			Mean FCN	SD	Mean FCN	SD
HPV16	Neat	4/4	22.60	0.37	22.29	0.30
	1:10	6/6	26.43	0.35	26.32	0.25
	1:50	6/6	29.24	0.53	29.05	0.23
	1:100	6/6	30.29	0.66	30.26	0.42
HPV18	Neat	3/3	22.14	0.37	22.28	0.29
	1:10	6/6	26.05	0.39	26.40	0.30
	1:50	6/6	28.67	0.64	29.07	0.48
	1:100	6/6	30.15	0.93	30.29	0.37
HPV45	Neat	3/3	24.32	0.24	22.80	0.27
	1:10	6/6	27.78	0.18	26.56	0.29
	1:50	6/6	30.11	0.54	29.32	0.38
	1:100	5/6	31.36	0.43	30.62	0.27
HPV31 (Other A)	Neat	3/3	24.89	0.14	22.24	0.06
	1:10	6/6	28.36	0.51	26.18	0.08
	1:50	4/6	31.15	0.75	29.61	0.52
	1:100	1/6	31.88	.	30.92	0.62
HPV51 (Other B)	Neat	3/3	18.69	0.49	21.43	0.39
	1:10	6/6	23.30	0.42	25.52	0.41
	1:50	6/6	25.88	0.40	28.50	0.22
	1:100	6/6	27.08	0.70	29.79	0.59

Stability

Genotype	Day	Detected	Target FCN		Cellular Control FCN	
			Mean CN	SD	Mean CN	SD
HPV16	0	6/6	22.89	0.27	22.60	0.19
	1	3/3	22.87	0.20	22.53	0.13
	4	3/3	23.01	0.12	22.71	0.29
	7	6/6	22.90	0.38	22.51	0.36
	12	3/3	23.27	0.20	22.93	0.17
HPV18	0	6/6	22.46	0.38	22.11	0.30
	1	3/3	22.46	0.65	22.18	0.50
	4	3/3	22.62	0.66	22.38	0.42
	7	6/6	22.64	0.34	22.27	0.38
	12	3/3	22.82	0.33	22.09	0.43
HPV45	0	6/6	24.35	0.31	22.69	0.25
	1	3/3	24.62	0.28	22.80	0.13
	4	3/3	25.16	0.14	23.14	0.24
	7	6/6	25.24	0.54	22.31	0.51
	12	3/3	24.88	0.52	22.78	0.73
HPV31 (Other A)	0	6/6	24.64	0.50	22.29	0.41
	1	3/3	24.96	0.62	22.31	0.64
	4	3/3	25.15	0.73	22.44	0.57
	7	6/6	25.06	0.35	22.89	0.34
	12	3/3	25.50	0.44	22.50	0.44
HPV51 (Other B)	0	6/6	19.32	0.43	21.82	0.53
	1	3/3	19.41	0.40	21.40	0.10
	4	3/3	19.21	0.53	21.70	0.29
	7	6/6	19.13	0.42	21.59	0.33
	12	3/3	19.46	0.61	21.60	0.31



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