TEST ACCURACY OF HUMAN PAPILLOMAVIRUS IN URINE FOR DETECTION OF CERVICAL INTRA-EPITHELIAL NEOPLASIA

SUPPLEMENTARY MATERIAL

Supplementary Table S1: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ in 243 colposcopy patients with triple matched samples, using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

Supplementary Table S2: Agreement between Onclarity hrHPV testing in urine and in self-collected cervico-vaginal or provider-collected cervical samples among 243 colposcopy patients with triple matched samples.

Supplementary Table S3: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ in 64 “research only” participants with triple matched samples, using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

Supplementary Table S4: Agreement between Onclarity hrHPV testing in urine and in self-collected cervico-vaginal or provider-collected cervical samples among 64 “research only” participants with triple matched samples.

Supplementary Table S5: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ including all valid results for a given sample type and using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

Supplementary Table S6: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN3+, using the established Onclarity cycle threshold for provider-collected samples on all sample types.

Supplementary Table S1: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ in 243 colposcopy patients with triple matched samples, using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

Type of sample	hrHPV assay	Histology		Sensitivity (95% CI)	Specificity (95% CI)
		CIN2+ N = 81	<CIN2 N = 162		
Urine	Positive	65	94	80.3% (71.6-88.9%)	42.0% (34.4-49.6%)
	Negative	16	68		
Self-collected cervico-vaginal	Positive	77	108	95.1% (90.3-99.8%)	33.3% (26.1-40.6%)
	Negative	4	54		
Provider-collected cervical	Positive	77	104	95.1% (90.3-99.8%)	35.8% (28.4-43.2%)
	Negative	4	58		

CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

* Cycle threshold of ≤34.2 for all hrHPV subtypes, except HPV16 with cycle threshold set at ≤38.3 as per FDA-approved thresholds for provider-collected specimens.

Supplementary Table S2: Agreement between Onclarity hrHPV testing in urine and in self-collected cervico-vaginal or provider-collected cervical samples among 243 colposcopy patients with triple matched samples.

		Urine samples (N)		Overall agreement (95% CI)	Positive agreement (95% CI)	Negative agreement (95% CI)	Cohen's κappa (95% CI)
		Positive	Negative				
Self-collected cervico-vaginal samples	**Positive**	150 (62%)	35 (14%)	82%	87%	69%	0.56
	Negative	9 (4%)	49 (20%)	(77-87%)	(83-91%)	(60-78%)	(0.46-0.68)
Provider-collected cervical samples	**Positive**	147 (61%)	34 (14%)	81%	86%	68%	0.55
	Negative	12 (5%)	50 (21%)	(76-86%)	(83-90%)	(60-77%)	(0.44-0.67)

CI, confidence interval; CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

Supplementary Table S3: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ in 64 "research only" participants with triple matched samples, using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

Type of sample	hrHPV assay	Histology		Sensitivity (95% CI)	Specificity (95% CI)
		CIN2+ N = 2	<CIN2 N = 62		
Urine	Positive	1	44	50.0% (0.0-100%)	29.0% (17.7-40.3%)
	Negative	1	18		
Self-collected cervico-vaginal	Positive	1	49	50.0% (0.0-100%)	21.0% (10.8-31.1%)
	Negative	1	13		
Provider-collected cervical	Positive	1	34	50.0% (0.0-100%)	45.2% (32.8-57.6%)
	Negative	1	28		

CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

* Cycle threshold of ≤34.2 for all hrHPV subtypes, except HPV16 with cycle threshold set at ≤38.3 as per FDA-approved thresholds for provider-collected specimens.

Supplementary Table S4: Agreement between Onclarity hrHPV testing in urine and in self-collected cervico-vaginal or provider-collected cervical samples among 64 "research only" participants with triple matched samples.

		Urine samples (N)		Overall agreement (95% CI)	Positive agreement (95% CI)	Negative agreement (95% CI)	Cohen's κappa (95% CI)
		Positive	**Negative**				
Self-collected cervico-vaginal samples	**Positive**	43 (67%)	7 (11%)	86%	91%	73%	0.63
	Negative	2 (3%)	12 (19%)	(77-94%)	(84-97%)	(56-90%)	(0.42-0.85)
Provider-collected cervical samples	**Positive**	32 (50%)	3 (5%)	75%	80%	67%	0.48
	Negative	13 (20%)	16 (25%)	(64-86%)	(70-90%)	(51-82%)	(0.27-0.69)

CI, confidence interval; CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

Supplementary Table S5: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN2+ including all valid results for a given sample type and using the established Onclarity cycle threshold* for provider-collected samples on all sample types.

		Histology			
Type of sample	**hrHPV assay**	**CIN2+**	**<CIN2**	**Sensitivity (95% CI)**	**Specificity (95% CI)**
Urine (N = 403)	Positive	92	170	80.0% (72.7-87.3%)	41.0% (35.3-46.7%)
	Negative	23	118		
Self-collected cervico-vaginal (N = 380)	Positive	95	183	92.2% (87.1-97.4%)	33.9% (28.3-39.5%)
	Negative	8	94		
Provider-collected cervical (N = 343)	Positive	93	148	94.9% (90.5-99.3%)	39.6% (33.5-45.7%)
	Negative	5	97		

CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

* Cycle threshold of ≤34.2 for all hrHPV subtypes, except HPV16 with cycle threshold set at ≤38.3 as per FDA-approved thresholds for provider-collected specimens.

Supplementary Table S6: Test accuracy of Onclarity hrHPV assay on different samples for the detection of CIN3+*, using the established Onclarity cycle threshold† for provider-collected samples on all sample types.

Type of sample	hrHPV assay	Histology		Sensitivity (95% CI)	Specificity (95% CI)
		CIN3+ N = 49	<CIN3 N = 258		
Urine	Positive	47	169	83.7 (73.3-94.0)	36.8 (30.9-42.7)
	Negative	2	89		
Self-collected cervico-vaginal	Positive	47	188	95.9 (90.4-100.0)	27.1 (21.7-32.6)
	Negative	2	70		
Provider-collected cervical	Positive	41	163	95.9 (90.4-100.0)	34.5 (28.7-40.3)
	Negative	8	95		

CIN, cervical intraepithelial neoplasia; hrHPV, high-risk human papillomavirus.

* CIN2/3 cases were categorized as CIN3+ for this analysis.

† Cycle threshold of ≤34.2 for all hrHPV subtypes, except HPV16 with cycle threshold set at ≤38.3 as per FDA-approved thresholds for provider-collected specimens.