

Collection Kit Storage and Stability



Collection Device		# Ordernumber	Sample Type	CT, NG	HSV	MGen	TV	BV*	CV/TV*	HPV	APTIMA® CT/NG; CT, NG	APTIMA® HSV	APTIMA® MGen	APTIMA® TV	APTIMA® BV*	APTIMA® CV/TV*	APTIMA® HPV
Multitest		# PRD-03546 (50/bag)	Clinician Vaginal	✓		✓	✓	✓	✓		After collection store at 2 °C to 30 °C for up to 60 days. Freeze at –20°C to –70°C for up to 12 months.	After collection store at 2°C to 30°C for up to 60 days. Store at –20°C to –70°C for up to 90 days.	After collection store at 2°C to 30°C for up to 60 days. Store at –20°C or –70°C for up to an additional 90 days.	Physician Collected only After collection store at 2°C to 30°C for up to 60 days. Freeze at –20°C to –70°C for up to 12 months.	After collection store at 2°C to 30°C for up to 30 days.	After collection store at 2°C to 30°C for up to 30 days.	
			Self-Collected Vaginal**	✓		✓											
			Penile Meatal			✓											
			Clinician Throat	✓		✓											
			Self Collected Throat	✓		✓											
			Clinician Rectal	✓		✓											
			Self Collected Rectal	✓		✓											
			Oral Blister		✓												
			Genital Blister		✓												
Urine		# 301040 (50/bag)	Female Urine	✓		✓	✓				Transfer urine within 24 hours of collection. After collection store at 2°C to 30°C for up to 30 days. Freeze at –20°C to –70°C for up to 12 months.		Transfer urine within 24 hours of collection. After collection store at 2°C to 30°C for up to 30 days. Freeze at –20°C to –70°C for up to additional 90 days.	Female Urine only Transfer urine within 24 hours of collection. After transfer store at 2°C to 30°C for up to 30 days. Freeze at –20°C to –70°C for up to 12 months.			
			Male Urine	✓		✓											
Unisex		# 301041 (50/bag)	Male Urethral	✓		✓					After collection store at 2°C to 30°C for up to 60 days. Freeze at –20°C to –70°C for up to 12 months.		After collection store at 2°C to 30°C for up to 60 days. Freeze at –20°C to –70°C for up to additional 90 days.	Endocervical only After transfer store at 2°C to 30°C for up to 60 days. Freeze at –20°C to –70°C for up to 12 months.			
			Endocervical	✓		✓	✓										
Cervical		# 302657 (50/bag)	Cervical							✓							After collection store at 2°C to 30°C for up to 60 days. Freeze at –20°C to –70°C for up to 24 months.
Transfer		# PRD-05110 (100/bag)	ThinPrep®	✓		✓	✓			✓	Prior to transfer store at 2°C to 30°C for up to 30 days. After transfer store at 2°C to 8°C for up to 30 days. After transfer store at 15°C to 30°C for up to 14 days. Freeze at –20°C to –70°C for up to 12 months.			Prior to transfer store 2°C to 30°C for up to 30 days. After transfer: Store at 2°C to 8°C for up to 30 days. Store at 15°C to 30°C for up to 14 days. Freeze at ≤ –0°C for up to 12 months.			Prior to transfer store at 2°C to 8°C with not more than 30 days at temperatures up to 30°C for up to 105 days. After transfer store at 2°C to 8°C for up to 60 days. Freeze at –20°C to –70°C for up to 24 months.
			Surepath®							✓							

Specimen Type		APTIMA Combo 2®				Mycoplasma genitalium		APTIMA® Trichomonas vaginalis		APTIMA® HSV 1 & 2				APTIMA® HPV	
		Chlamydia¹		Gonorrhea¹		M. genitalium²		Trichomonas³		Herpes simplex virus⁴				Human Papilloma virus⁵	
		Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity		Specificity		Sensitivity	Specificity
Multitest		Multitest Swab Clinician Collected Vaginal Sample	97,2%	98,5%	97,7%	99,6%	92,0%	98,0%	100,0%	98,2%	*		*	*	*
		Multitest Swab Patient Collected Vaginal Sample	97,2%	98,5%	97,7%	99,6%	98,9%	98,5%	*	*	*		*	*	*
		Multitest Swab Penile Meatal Sample	*	*	*	*	88,4%	97,8%	*	*	*		*	*	*
		Multitest Swab Anogenital Skin Lesion Sample	*	*	*	*	*	*	*	*	HSV-1 94,7%	HSV-2 98,4%	HSV-1 99,6%	HSV-2 92,8%	*
Urine		Urine (Female)	PPA 98,9%	NPA 99,8%	PPA 96,6%	NPA 100,0%	77,8%	99,0%	95,5%	99,0%	*		*	*	*
		Urine (Male)	95,2%	99,8%	98,7%	99,7%	90,9%	99,4%	*	*	*		*	*	*
Unisex		Female Endocervical Swab	97,2%	99,3%	100,0%	99,8%	81,5%	98,3%	100,0%	98,1%	*		*	*	*
		Male Urethral Swab	100,0%	99,1%	100,0%	100,0%	98,2%	99,6%	*	*	*		*	*	*
Transfer		ThinPrep® Pap Test Vial	98,2%	100,0%	100,0%	100,0%	*	*	100,0%	98,6%	*		*	90,9% ⁶	67,9% ⁶

The Aptima Combo 2 assay demonstrates up to 100 % sensitivity and specificity in detecting CT/NG from throat and rectal swabs.¹
PPA=Positive Percentage Agreement, NPA=Negative Percentage Agreement
*: These sample types are not FDA-cleared for the specific assays listed.

References
1. Aptima Combo 2 Assay [package insert]. 502446-IFU-PI, San Diego, CA: Hologic, Inc; 2018.
2. Aptima Mycoplasma Genitalium Assay [package insert]. AW-17946, San Diego, CA: Hologic, Inc; 2019.
3. Aptima Trichomonas vaginalis Assay [package insert]. 503684-IFU-PI & 502536DE Rev. 005, San Diego, CA: Hologic, Inc; 2018.
4. Aptima HSV 1 & 2 Assay [package insert]. AW-15636-001, San Diego, CA: Hologic, Inc; 2018.
5. Aptima HPV Assay [package insert]. AW-14517-801 Rev. 005, San Diego, CA: Hologic, Inc; 2018.
6. NILM ≥30 Years Population. Performance of the Aptima HPV Assay for Detection of ≥CIN2 and ≥CIN3 (Unadjusted Estimates) at Baseline.