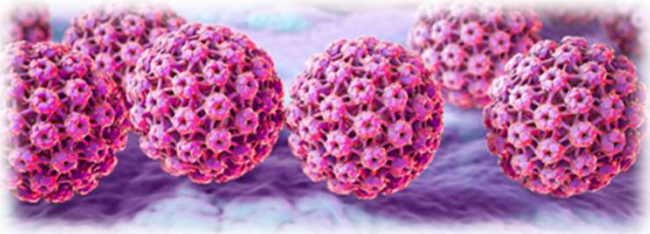
UroGene Easy HPV Test Kit

TBA、Talenome社、ｺﾝｹﾝ大学で共同開発された、尿からのHPV検査キット。

Human Papillomavirus

detection and identification



Features of the Kit

1. Specimen

標準法のような膣の拭い液でなく、尿からのHPV検査が可能



This kit utilizes urine, allowing for easy sample collection.

2. Simple testing process

検査操作は非常に簡単。専門技術不要。

Simple 4-step : Urine Filtration → DNA Extraction → PCR Amp. → LFA Detection

3. Detection categorized by cancer risk level

がん化リスクの高いHPVの検査が可能。

Types 16/18, high-risk types, and low-risk types are each detected on a separate line.

4. High detection performance despite multiplex capability

標準法と非常に高い一致率。
しかも、感染の見逃し無し。

Overall clinical trial concordance rate : 94% (342 samples. Absolutely no false negatives.)
(The presence of the target HPV gene was confirmed in almost all false-positive specimens.)

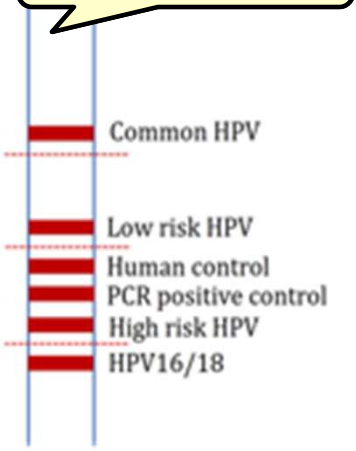
5. Compatible with low-cost thermal cyclers

高価な機器が不要

No need for expensive RT-PCR instruments or high-cost centrifuges

The testing process for the kit

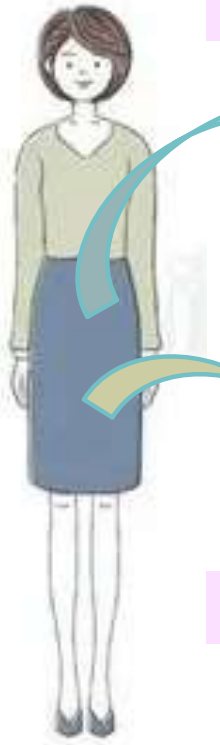
少し時間はかかるが、非常に簡単で安価に検査が可能

Process	Cell collection	DNA Extraction	PCR Amplification	Strip Detection
Image	尿20ccを特殊なろ紙で簡単にろ過 	ろ紙を回収し、試薬で煮てHPV遺伝子回収 	PCR反応で増幅 	C-PASで検出 
Input / Sample	Urine x 20m ℓ	the special filter with the leaking cells	Target DNA Extract (Solution in the 1.5 ml tube)	C-PAS with latex solution
Procedure	Collecting leaking cells from urine by Special Filter Gravity filtration	Immerse the filter in 0.5ml of DNA extraction reagent in a 1.5ml tube Heat with a Heatblock	The solution(1 μl) is putted into a PCR tube with primers and enzyme Amplify by *miniPCR*	Insert C-PAS into the PCR tube with latex solution Lateral flow assay
Condition and Time	5 min. or less	95℃ x 15min	60 min.	10 min.

Clinical trial procedures

同じ患者

タイで薬事承認されている標準法と比較する臨床試験を実施した。



Allplex™ HPV28 Detection

Gold Standard



Cervical lavage → DNA Extraction (Beads Extraction) → qPCR Allplex™ HPV28 / HPV → qPCR results (Cervical lavage)

膣の拭い液を採取し、標準法のキット(韓国SeeGene社製)で、HPVの感染有無判定

UroGene Easy HPV Test Kit

同じ患者の尿を検体として、我々の製品でその患者のHPV感染有無を判定

Urine 20mℓ → Collection (Using Filter) → DNA Extraction 250μℓ → PCR (Mongkol HPV Kit) → Detection (C-PAS) → Strip results (Using Urine)

◆ For reference, we also conducted AllePlex kit testing on the same urine samples in parallel.

Report of the Clinical trials

confidential

Gold Standard

UroGene Easy HPV Test kit

がん疑い検体の検査結果比較表

	qPCR by All plex HPV detection		HPV Strip test					
ID	Urine (Reference)	Cervical larvage (Gold Standerd)	Common HI	HPV 16-1	High Ris	Low Ris	Human	Amp cont
CP001	39	39	Detected	ND	Detected	ND		
CP002	42, 51, 52, 58, 59, 66, 69	42, 51, 52, 58, 66, 69	Detected	ND	Detected	Detected		
CP003	Neg	Neg	ND	ND	ND	ND		
CP004	16, 61	16	Detected	Detected	Detected	Detected		
CP005	51, 68		Detected	ND	Detected	Detected		
CP006					Detected	ND		
CP007					Detected	ND		
CP008					ND	ND		
CP009					Detected	Detected		
CP010	18, 61, 66, 68, 70	61, 66, 68	Detected	Detected	Detected	Detected		
CP011	Neg	Neg	ND	ND	ND	ND		
CP012	51, 53, 54, 58, 68, 73	18, 54, 58, 68, 73	Detected	Detected	Detected	Detected		
CP013	53	18, 53	Detected	Detected	Detected	ND		
CP014	16, 52, 59, 66, 73	52, 59, 66, 73	Detected	Detected	Detected	ND		
CP015	39, 58, 66, 68	39, 58, 66, 68	Detected	ND	Detected	Detected		
CP016	Neg	Neg	ND	ND	ND	ND		
CP017	44, 56, 70	44, 56, 70	Detected	ND	Detected	Detected		
CP018	42, 51, 54	54	Detected	ND	Detected	Detected		
CP019	61	Neg	Detected	ND	ND	Detected		
CP020	40, 42, 51, 52, 54	42, 51, 52, 54	Detected	ND	Detected	Detected		
CP021	18, 52	18, 52	Detected	Detected	Detected	ND		
CP022	31, 33, 39, 53, 56	31, 33, 39, 53, 56	Detected	ND	Detected	ND		
CP023	58	58	Detected	ND	Detected	ND		
CP024	11, 6, 73	11, 6, 73	Detected	ND	Detected	Detected		
CP025	39	39	Detected	ND	Detected	ND		
CP026	18, 51, 53	18, 31, 51	Detected	Detected	Detected	Detected		
CP027	43	43, 68	Detected	ND	Detected	Detected		
CP028	Neg	Neg	ND	ND	ND	ND		
CP029	53, 58	53, 58	Detected	ND	Detected	ND		
CP030	16, 39, 58	39, 58	Detected	Detected	Detected	ND		
CP031	58	58	Detected	ND	Detected	ND		
CP032	Neg	52, 58	Detected	ND	Detected	ND		
CP033	52	52	Detected	ND	Detected	ND		
CP034	6	6	Detected	ND	ND	Detected		
CP035	16	16	Detected	Detected	Detected	Detected		
CP036	Neg	Neg	ND	ND	ND	ND		
CP037	Neg							
CP038	66							
CP039	Neg							
CP040	52, 58							
CP041	59							
CP042	58							
CP043	58							
CP044	16							
CP045	42							
CP046	39							
CP047	16, 52	52	Detected	Detected	Detected	Detected		
CP048	18, 26, 52, 68	18, 26, 52	Detected	Detected	Detected	Detected		
CP049	58	58	Detected	ND	Detected	ND		
CP050	58	58	Detected	ND	Detected	ND		
CP051	53, 54	Neg	Detected	ND	Detected	Detected		
CP052	16, 52, 58, 66	52	Detected	Detected	Detected	Detected		
CP053	52, 58, 66	40, 52, 58, 66	Detected	ND	Detected	Detected		
CP054	Neg	Neg	ND	ND	ND	ND		
CP055	Neg	Neg	ND	ND	ND	ND		
CP056	18	18	Detected	Detected	Detected	ND		
CP057	16, 61	16, 61	Detected	Detected	Detected	Detected		
CP058	44, 52	44, 51, 52	Detected	Detected	Detected	Detected		
CP059	16	16	Detected	Detected	Detected	ND		
CP060	45, 59	45, 68	Detected	ND	Detected	ND		

通常検体の検査結果比較表

	PCR by All plex HPV detecti		HPV Strip test					
ID	Urine (reference	Cervical larvage (Gold Standen	Common HF	HPV 16-1	High Ris	Low Ris	Human	Amp cont
SC001	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC002	58	58	Detected	ND	Detected	ND	Detected	Detected
SC003	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC004	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC005	Neg	Neg	Detected	ND	ND	Detected	Detected	Detected
SC006	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC007	45, 68	45, 51, 68	Detected	ND	Detected	Detected	Detected	Detected
SC008	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC009	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC010	52	61	Detected	ND	Detected	Detected	Detected	Detected
SC011	68	68	Detected	ND	Detected	ND	Detected	Detected
SC012	11	11	Detected	ND	ND	Detected	Detected	Detected
SC013	Neg	Neg	Detected	ND	ND	Detected	Detected	Detected
SC014	61	61	Detected	ND	ND	Detected	Detected	Detected
SC015	68	68	Detected		Detected	Detected	Detected	Detected
SC016							Detected	Detected
SC017							Detected	Detected
SC018							Detected	Detected
SC019							Detected	Detected
SC020							Detected	Detected
SC021	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC022	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC023	Neg	Neg	Detected	ND	ND	Detected	Detected	Detected
SC024	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC025	Neg	Neg	Detected	ND	ND	Detected	Detected	Detected
SC026	42, 54	42	Detected	ND	ND	Detected	Detected	Detected
SC027	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC028	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC029	42	Neg	Detected	ND	Detected	Detected	Detected	Detected
SC030	Neg	Neg	ND	ND	ND	ND	Detected	Detected
SC031	Neg	Neg	Detected	ND	ND	Detected	Detected	Detected
SC032	58, 70	58, 70	Detected	ND		Detected	Detected	Detected
SC033	43	Neg	Detected		Detected	Detected	Detected	Detected
SC034	Neg	Neg			ND	ND	Detected	Detected
SC035	Neg					ND		
SC036	43				ected	ND		
						ND		
						ected		
						D		
						D		
						D		
						D		
						D		
						D		
						D		
						D		
						ND		
SC050	39	39	Detected	ND				
SC051	Neg	Neg	ND	ND				
SC052	Neg	Neg	ND	ND				
SC053	Neg	Neg	ND	ND				
SC055	66	66	Detected	ND				
SC056	Neg	Neg	ND	ND				
SC057	Neg	Neg	ND	ND				
SC058	Neg	53	Detected	ND				
SC059	Neg	Neg	ND	ND				
SC060	66	Neg	ND	ND				
SC061	Neg	Neg	ND	ND				
SC062	Neg	Neg	ND	ND				
SC063	Neg	54	Detected	ND				
SC064	Neg	Neg	ND	ND				
SC065	70	70	Detected	ND				

・標準法と非常に高い一致率が得られた。
・取り逃がし誤診断は無し。

このキットの高い検査性能が証明された.

Evaluation of Clinical Trial Results

◆Very high concordance with the standard

◆No false negatives.

Overall Match Rate with the standard	
Number of Samples	342
Number of Test Lines	1368
Match	1287
Mismatch(F.P)	81
Mismatch(F.N)	0
Match rate	94%

◆ Absolutely excellent test results!

- ✓ This kit showed a very good correlation with the standard method
- ✓ There were no false negatives at all.
- ✓ Additional testing confirmed the presence of the target HPV in the false-positive samples.

◆ This kit has **Very high testing capacity**