

TANBead®HPV DNA Extraction Kit (61H series)

1st Edition, Nov 2022



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Introduction



The TANBead® Nucleic Acid Extraction Kit is a nucleic acid purification kit based on magnetic bead technology by using with corresponding TANBead® Nucleic Acid Extractor, which is suitable for extracting human papillomavirus (HPV) DNA in cervical swab or liquid-based cytology samples. The purified DNA can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays. The kit is intended for use by technicians, physicians, and biologists with well-trained in molecular biological techniques, the techniques of magnetic bead purification, in vitro diagnostic procedures and academic researshes. Any results generated by using the sample preparation procedure in conjunction with any downstream diagnostic assay should be interpreted related to other clinical or laboratory findings. The kit is not limited to any specific disorder, condition, or other additional accompanying diagnostics. It is applicable for all population.



Reagent Kits and Instrument

Inotrument	REF	Cat NO.		Toot
Instrument	KEF	IVD	RUO	Test
Maelstrom 8 /	M61HA46	301589	301431	96
Maelstrom 4800 series	M61HS46	301590	301432	96
Manlatrana 0000 agrica	W61HA46	301591	301433	96
Maelstrom 9600 series	W61HS66	301592	301434	72

Specification

Feature	Specif	ication	
Downstream application	PCR, qPCR analysis, hui genotyping	man papillom	avirus (HPV)
Starting material	300 µL cervical swab or lic samples	quid-based cy	tology
Processing mode	Automated, magnetic prod	cessing	
	Instrument	Auto Plate	Auto Tube
Throughput	Maelstrom 8 series	8	4
(Max tests/ run)	Maelstrom 4800 series	48	24
	Maelstrom 9600 series	96	48
Nucleic acid binding technology	Magnetic beads		
Elution Volume	50-80 μL		

Kit Contents

Maelstrom 8 / Maelstrom 4800 series

M61HA46	96 tests	Pre-filled plate for use
Auto Plate	6 PCS	Pre-filled with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-free water
Spin Tip	96 PCS x 1 box	Spin tip assembled box
Protocol	1	Instruction guides for user

M61HS46	96 tests	Pre-filled tube for use
Auto Tube	8 Trays	Pre-filled with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-free water
Base	2	A rack for 8 Auto Tubes
Spin Tip	48 PCS x 2 box	Spin tip assembled box
Protocol	1	Instruction guide for user



Kit Contents

Maelstrom 9600 series

W61HA46	96 tests	Pre-filled plate for use
Auto Plate	6 PCS	Pre-filled with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-free water
Spin Tip	96 PCS x 1 box	Spin tip assembled box
Protocol	1	Instruction guides for user

W61HS66	72 tests	Pre-filled tube for use
Auto Tube	6 Tray	Pre-filled with reagent buffers
Proteinase K	1.0 mL x 2	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-free water
Base	2 PCS	A rack for 8 Auto Tubes
Spin Tip	48 tips x 2 boxes	Spin tip assembled box
Protocol	1	Instruction guides for user

Pre-filled Plate or Tube Contents

M61HA46, M61HS46			
Well Buffer		Volume (μL)	
1/7	Lysis Buffer	400	
2/8	Washing Buffer 1 800		
3/9	Magnetic Beads	800	
4/10	Washing Buffer 2 800		
5/11	Washing Buffer 2 800		
6/12	Elution Buffer	80	

W61HA46, W61HS66			
Position	Plate	Volume (μL)	
1	Lysis Buffer	400	
2	Washing Buffer 1	800	
3	Magnetic Beads	800	
4	Washing Buffer 2	800	
5	Washing Buffer 2	800	
6	Elution Buffer	80	
7	-	-	
8	Spin Tip	-	

Precautions

- **01** Avoid using expired reagents.
- When the temperature is below 20°C, place the Auto Plates / Auto Tubes in an oven (preheated 42~60°C) 5 to 10 minutes.
- **03** Avoid vigorous shaking, to avoid excessive formation of foam.
- O4 Carefully remove aluminum foil to avoid splashing.
- Do not expose the opened reagents or Auto Plates / Auto Tubes to
 air. The evaporation may cause pH change and affect the extraction effectiveness.
- Please check the integrity of the Auto Plates / Auto Tubes and remember to insert the strips or spin tip into the appropriate position of the suitable instrument before operating them.
- 07 Please wear a mask and disposable gloves when handling.
- **08** Use sterile consumables to avoid nuclease contamination.
- Reagent solution contains guanidine salt, avoid using bleach containing detergent.
- Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
- If any serious incident occurs, please report to the manufacturer and the competent authority of the member state in which the user and / or the patient is established.

Materials Required but not Provided



- TANBead®Nucleic Acid Extraction System (non-sterile)
 Maelstrom 8/ Maelstrom 4800 series , Maelstrom 9600 series
- 02 1M Dithiothreitol (DTT, molecular grade)
- **03** Disposable gloves
- **04** Scissors, utility knives
- **05** Micropipette, disposable tips (10 μL / 200 μL / 1000 μL)
- **06** 1.5 mL microcentrifuge tube
- 07 15 mL / 50 mL conical tube

Kit Storage

- TANBead® HPV DNA extraction kit could be stored at 15-35°C for 12 months and please find the expiration date labeled on the box of each reagent kit.
- The proteinase K would be transported at room temperature. Upon received the reagent kit, please keep the proteinase K at 2-8°C for long-tern storage. The room temperature delivery of proteinase K has been validated that does not affect its performance.
- The pre-filled plate, tube, and solution provided with the reagent kit can be stored at room temperature and are stable for at least 18 months after production.

Safety Information

When you are working with chemicals, must wear a suitable lab coat, disposable gloves, and safety goggles. For more information, please consult TANBead Inc. for the appropriate safety data sheets (SDSs).

Quality Control

In accordance with TANBead Inc. certificated Quality Management System (QMS and ISO13485), the product must be tested against intended specifications to ensure the consistence of product performance and quality.

Sample Storage

The sampling should follow the guidance of collection container provided by the supplier. Samples storage in ThinPrep[®] PreservCyt[®]

Solution (Hologic) or SurePath[™] Preservative Fluid (BD) are suggested for HPV DNA extraction by using 61H series reagent kits.

Samples stored in ThinPrep[®] PreservCyt[®] Solution could be kept at 4-37°C for up to three weeks and in SurePath™ Preservative Fluid could be kept at 2-10°C for up to six months or at 15-30°C for up to 4 weeks.

13 The storage and transportation condition, such as temperature, time and container may cause the variation of yield and quality of purified nucleic acids. In general, fresh prepared samples are recommended.

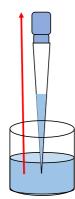
Procedure and Description



TANBead® HPV DNA extraction kit is applicable for non-mucus and mucus samples:

- **01** Sample pretreatment (bypass this step for non-mucus sample):
 - (1) Transfer 300 µL mucus sample into the 1.5 mL microcentrifuge tube.
 - (2) Add 20 μL 1M DTT and vortex thoroughly for 10 sec.
 - (3) Briefly spin the sample down and incubate at 37°C for 10-20 mins until the sample is liquidized.
 - (4) Transfer the mixture (sample) to Auto Plate/Tube for HPV DNA purification.
- O2 Automation: transfer sample to Auto Plate/Tube to proceed lysis, residues washing and elution step for DNA purification.

Non-mucus sample





STEP







STEP 2

14

Add 10 µL Proteinase K into each well and then go on the automatic process



Mucus sample



STEP 1

Take 300 μ L cervical swab or liquid based cytology sample, then add 20 μ L 1M DTT







Briefly spin down sample, incubate at 37°C for 10 - 20 mins

TIPS

Incubate the sample until it is liquidized



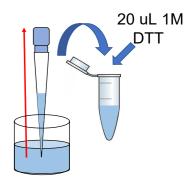
STEP3

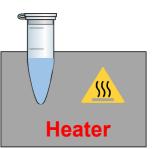
Transfer 320 μ L mixture sample into each well



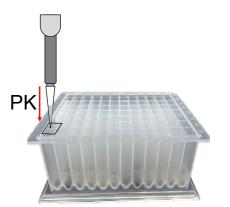
STEP4

Add 10 μ L Proteinase K into each well and then go on the automatic process









Instrument Description



Maelstrom 8 (up to 8 tests per run)

Maelstrom 4810 (up to 48 tests per run)

Maelstrom 9610 (up to 96 tests per run)

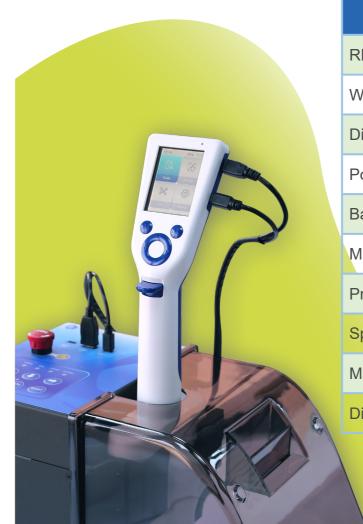
- 2 Instrument Operation Guide
- 3 Instrument Maintenance

Automatic Nucleic Acid Extraction System



Maelstrom 8 (up to 8 tests per run)

aelstrom 8 handler is a magnetic bead handling device with high-speed stirring function, which can spin up to 3000 rpm. With eight magnetic rods, intuitive interface, and simple operation, it can accomplish any nucleic acid extraction application. It works alone or with Autostage to form an automated solution, called Maelstrom 8 Autostage.



Feature	Specification
REF	Maelstrom 8 handler
Weight (NW)	600 g
Dimensions	11.2(W)x6.3(L)x32.7(H) cm
Power rating	5 Vac, 2A
Battery	3.7 Vac, 2,850 mAh
Max. Throughput	8 samples per run
Process. volume	50 - 1,500 μL
Spin speed	up to 3,000 rpm
Magnetic rod	> 3,000 gauss
Display	2.4" LCD, 240 x 320 pixels





aelstrom 4810 is a 48-throughput instrument, combined with our patented technology, the entire run can be completed in about 15-60 minutes, depending on the reagent kit. Maelstrom 4810 can operate 1 to 48 samples, which offers great flexibility to customers.

Feature	Specification
REF	Maelstrom 4810
Weight (NW)	Approx. 45 kg
Dimensions	58(W) x43(L) x47(H) cm
Power rating	AC 100-AC 240 V 50/60 Hz, 5-2.5 A
Fuse	250 V, 5A
Max. Throughput	48 samples per run
Process. volume	50 - 1,600 μL
Spin speed	up to 3,000 rpm
Heater	12 independent heating blocks
Magnetic rod	> 3,900 gauss
Display	7-inch touchscreen
UV	UV-C type, 8 W
HEPA	E 10 class

Maelstrom 9610 (up to 96 tests per run)



aelstrom 9610 is a 96-throughput instrument, With the patented technology which can improve the mixing efficiency of magnetic beads and increase the processing sample volume, M9610 has become one of the most competitive automated DNA/RNA extraction instruments. Combined with TANBead extraction reagents, our system is highly affirmed by many medical institutions as it can contribute to large scale sample screening request.

Feature	Specification
REF	Maelstrom 9610
Weight (NW)	Approx. 95 kg
Dimensions	87(W)x57.5(L)70(H) cm
Power rating	AC 220-240 V, 50/60 Hz, 3.5 A AC 100-120 V, 50/60 Hz, 8 A
Fuse	250 V, 5 A
Max. Throughput	96 samples per run
Process. volume	50 - 1,600 μL
Spin speed	up to 3,000 rpm
Heater	4 independent heating blocks
Magnetic rod	> 3,900 gauss
Display	7-inch touchscreen
UV	UV-C type, 4 W
HEPA	E 10 class



Instrument Operation Guide

Maelstrom 4800 series (Herein represented by Maelstrom 4810)





Press the power button in the back of Maelstrom 4800 series instrument



2-1

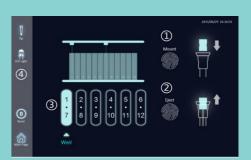
Assemble the spin tip assemble box and select the "Tip" on the panel.



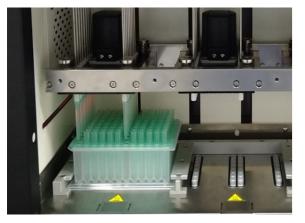
2

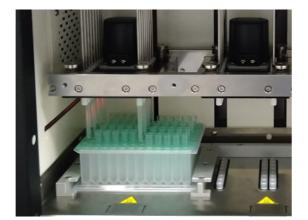
2-2

Choose the intended position, such as 1/7, 2/8, 3/9, 4/10, 5/11, 6/12 and press "Mount".









Mounting tips (Auto Plate)

Mounting tips (Auto Tube)



Add samples to wells of Auto Plate/ Tube, then put it into the extractor.

Back to the homepage and choose "Run"



Select the corresponding program (program name: 61H)



Press "Run" to start the automatic extraction process



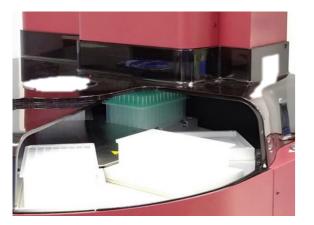
Instrument Operation Guide

Maelstrom 9600 series (Herein represented by Maelstrom 9610)

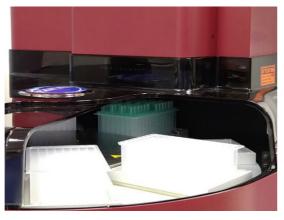


Press the power button in the back of Maelstrom 9600 series instrument

Press "Run" and choose the corresponding program (program name: 61H)







Mounting tips (Auto Tube)

3









Carefully remove the aluminum foil on the Auto Plates/Tubes.

4

4-1

Add samples to wells of Auto Plate/ Tube.

4

Follow the guide on the screen and assemble the required Auto Plate/ Auto Tubes and the assembled spin tip assembled box (NO.8 plate position) to intended plate position.

5

After placing all plates at right positions, press "Run" to start the automatic extraction process





Instrument Maintenance

It is important to clean the device after every use If samples or reagents have been spilled, it is important to clean the device immediately to avoid damage or contamination of samples

- Wear gloves and appropriate personal protective equipment.
- If the device is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.
- The device may go through a run with the magnetic rods unprotected If this happens, the magnetic rod needs to be cleaned immediately.
- To clean the magnetic rods, wipe with a soft cloth dampened with pure water. Do not use alcohol solvent.

Service Information



Supporting Info



Technical Support

Troubleshooting

2 Ordering Information

Technical Support

- Taiwan Advance Nanotech Inc. provides post sales service and technical support in case of any questions, please try to contact our authorized distributor nearest to you or our company for more help.
- If there is a need to contact us, you can call our rep number at +886-3-3167568 or email us at service@tanbead.com for further assistance.
- To efficiently solve the problems and answer your questions, please provide us at least the serial number (for instruments), REF and lot number (for reagent kits) when you talk to our technician personnel.



Troubleshooting

Troubleshooting



Less or no nucleic acid yield in the elute

Improper pretreatment

Mucus samples directly used for DNA extraction may cause less DNA yield and has a negative effect on qPCR analysis. Please operate the reagent kit according to the workflow shown as page 14 and 15.

Improper program

Please make sure the extraction program shown on the instrument panel is the same with that shown in IFU, especially in temperature settings.

Sample type and status

The long storage time of sample would have negative effect on its nucleic acid yield, length, and quality. Please use samples for HPV DNA extraction according to the description shown as page 13. Moreover, extraction efficiency would be variable among different individuals' samples.

• Magnetic beads remain on the column wall

Improper delivery

This phenomenon is usually caused by transportation and the extraction performance is unaffected. If required, you could centrifuge the plate/tube at 3000 rpm for 1 min or wash them by using the pipetman to make magnetic beads return to the storage buffer.

Less magnetic beads remain in the elute

Elution contamination

Once magnetic beads remain in all elutes, it may be due to the contaminants in elution buffers, such as microorganism.

Please contact our field application engineer (FAE) by phone (+886-3-3167568) or email (service@tanbead.com) for further assistance immediately.

Improper sample input

If this issue appeared in certain samples, please initiate a new extraction again and check whether the issue is still occurred.

In most cases of few magnetic beads found in elutes, you could still use the elute for downstream molecular analyses with unaffected extraction performance.

Amplification failure or unexpected results are found by PCR analysis

Long amplicon size

Generally, the fragment size of purified Mucus DNA is ranging from 100-1000 bp. For PCR analysis, keep amplicons less than 500 bp is recommended.

Crosscontamination between samples

This issue may be caused by sample overloading. Make sure that the amount of sample and elution buffer keeps within the processing volume.

Ordering Information

Maelstrom 8 / Maelstrom 4800 series

Sample	Description	Test	REF	Cat No.
	Blood DNA Auto Plate	96	M611A46	301126
	Blood DNA Auto Tube	96	M611S46	301127
	OptiPure Blood DNA Auto Plate	96	M61EA46	301128
Blood	OptiPure Blood DNA Bulk Plate	960	M61EA10	301307
	OptiPure Blood DNA Auto Tube	96	M61ES46	301129
	Blood RNA Auto Plate	96	M621A46	301400
	Blood RNA Auto Tube	96	M621S46	301401
	Dignt DNA Auto Digto	96	M613A46*	301134
	Plant DNA Auto Plate	96	M613A46-SE*	301371
Dlant		96	M613S46*	301135
Plant	Plant DNA Auto Tube	96	M613S46-SE*	301372
	Plant RNA Auto Plate	96	M6K3A46*	301383
	Plant RNA Auto Tube	96	M6K3S46*	301384
ofDNIA	OptiPure cfDNA Auto Plate	96	M61CA46	301385
cfDNA	OptiPure cfDNA Auto Tube	96	M61CS46	301389
FFDF	OptiPure FFPE DNA Auto Plate	96	M61PA46	301152
FFPE	OptiPure FFPE DNA Auto Tube	96	M61PS46	301153
	OptiPure Viral Auto Plate	96	M665A46	301148
Virus	OptiPure Viral Auto Tube	96	M665S46	301149
	OptiPure Viral Bulk Plate	960	M665A10	301346
	Virapid Virus Auto Plate	96	M685A46	301572
	Virapid Virus Auto Tube	96	M685S46	301573
LIDV/	HPV Auto Plate	96	M61HA46	301589
HPV	HPV Auto Tube	96	M61HS46	301590

Note: black font = IVD and RUO available, blue font = RUO available

Ordering Information



Maelstrom 8 / Maelstrom 4800 series

Sample	Description	Test	REF	Cat No.
	Tissue DNA Auto Plate	96	M612A46	301130
Tissue	Tissue DNA Auto Tube	96	M612S46	301131
	Tissue Total DNA Auto Plate	96	M6T2A46	301132
	Tissue Total DNA Bulk Plate	960	M6T2A10	301306
	Tissue Total DNA Auto Tube	96	M6T2S46	301133
	Tissue Total DNA Auto Kit	96	M6T2046	301260
	Tissue RNA Auto Plate	96	M6K2A46	301366
	Tissue RNA Auto Tube	96	M6K2S46	301367
Fundi	Fungi DNA Auto Plate	96	M61FA46	301585
Fungi	Fungi DNA Auto Tube	96	M61FS46	301586
Farancia	Forensic DNA Auto Plate	96	M6TFA46	301424
Forensic	Forensic DNA Auto Tube	96	M6TFS46	301425
	Gram Bacteria DNA Auto Kit	96	M61G046	301257
	Gram Bacteria DNA Auto Plate	96	M61GA46	301138
Bacteria		96	M61GA46-SE	301294
		96	M61GS46	301139
	Gram Bacteria DNA Auto Tube	96	M61GS46-SE	301295
Disamid	Plasmid Extraction Auto Plate	96	M6PEA46*	301578
Plasmid	Plasmid Extraction Auto Tube	96	M6PES46*	301579
F1 F1	Food and Feed DNA Auto Plate	96	M6GMA46*	301635
Food Feed	Food and Feed DNA Auto Tube	96	M6GMS46*	301636
Environmental	Environmental Microbiome DNA Auto Plate	96	M6EMA46*	301641
Microbiome	Environmental Microbiome DNA Auto Tube	96 M6EMS46*		301642
Stool	Stool Cell DNA Auto Plate	96	M6SCA46	301387
0.001	Stool Cell DNA Auto Tube	96	M6SCS46	301388

Note: black font = IVD and RUO available, blue font = RUO available

Ordering Information

Maelstrom 9600 series

Sample	Description	Test	REF	Cat No.
Blood	Blood DNA Auto Plate	96	W611A46	301186
	Blood DNA Auto Tube	72	W611S66	301187
	OptiPure Blood DNA Auto Plate	96	W61EA46	301188
	OptiPure Blood DNA Auto Tube	72	W61ES66	301189
	Blood RNA Auto Plate	96	W621A46	301402
	Blood RNA Auto Tube	72	W621S66	301403
	Plant DNA Auto Plate	96	W613A46*	301194
		96	W613A46-SE*	301379
Plant	Plant DNA Auto Tube	72	W613S66*	301259
Гіапі		72	W613S66-SE*	301378
	Plant RNA Auto Plate	96	W6K3A46*	301406
	Plant RNA Auto Tube	72	W6K3S66*	301407
cfDNA -	OptiPure cfDNA Auto Plate	96	W61CA46	301377
	OptiPure cfDNA Auto Tube	72	W61CS66	301386
EEDE	OptiPure FFPE DNA Auto Plate	96	W61PA46	301629
FFPE	OptiPure FFPE DNA Auto Tube	72	W61PS66	301630
	OptiPure Viral Auto Plate	96	W665A46	301224
Virus	OptiPure Viral Bulk Plate	960	W665A10	301345
	OptiPure Viral Auto Tube	72	W665S66	301209
	Virapid Virus Auto Plate	96	W685A46	301574
	Virapid Virus Auto Tube	72	W685S66	301575
HPV	HPV DNA Auto Plate	96	W61HA46	301591
пг۷	HPV DNA Auto Tube	72	W61HS66	301592

Note: black font = IVD and RUO available, blue font = RUO available

Ordering Information



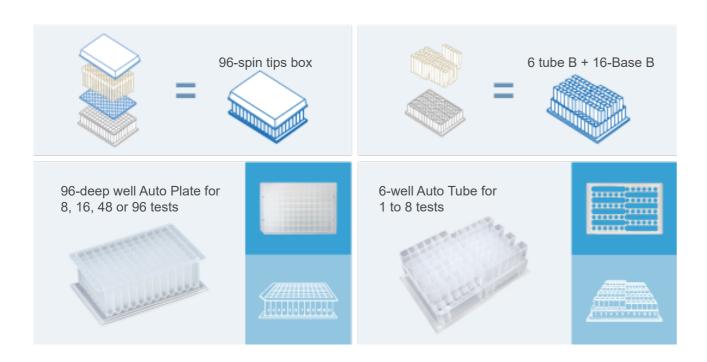
Maelstrom 9600 series

Sample	Description	Test	REF	Cat No.
_	Tissue DNA Auto Plate	96	W612A46	301190
	Tissue DNA Auto Tube	72	W612S66	301191
	Tissue Total DNA Auto Plate	96	W6T2A46	301192
Tissue	Tissue Total DNA Auto Tube	72	W6T2S66	301193
	Tissue RNA Auto Plate	96	W6K2A46	301404
	Tissue RNA Auto Tube	72	W6K2S66	301405
Caranaia	Forensic DNA Auto Plate	96	W6TFA46	301291
Forensic	Forensic DNA Auto Tube	72	W6TFS66	301426
Bacteria	Gram Bacteria DNA Auto Plate	96	W61GA46	301198
	Gram Bacteria DNA Auto Tube	72	W61GS66	301199
Plasmid	Plasmid Extraction Auto Plate	96	W6PEA46*	301580
	Plasmid Extraction Auto Tube	72	W6PES66*	301581
Food Feed	Food and Feed DNA Auto Plate	96	W6GMA46*	301637
	Food and Feed DNA Auto Tube	72	W6GMS66*	301638
Environmental Microbiome	Environmental Microbiome DNA Auto Plate	96	W6EMA46*	301643
	Environmental Microbiome DNA Auto Tube	72	W6EMS66*	301644
	Stool Cell DNA Auto Plate	96	W6SCA46	301392
Stool	Stool Cell DNA Auto Tube	72	W6SCS66	301391

Note: black font = IVD and RUO available, blue font = RUO available

Consumables

	Sample	Description	Test	REF
			100 pcs/carton	083.
	96 deep well plate	Auto Plate	Processing volume 50-1,600 μL	MWP01.20X
			For molecular diagnostics100 pcs/carton	
	96 deep well plate (Unique hook design)	Auto Plate	Processing volume 50-1,600 μL	083. MWP02.20X
- costillia			For molecular diagnostics	
	Spin Tips Assembled Box (Unique hook design)	Auto Plate	80 pcs/carton96 pcs of spin tips in one box	083.MSP09.10X
***************************************	Spin Tips Assembled Box (Unique hook design)	Auto Tube	80 pcs/carton48 pcs of spin tips in one box	083.MSP10.10X
	6 tube B	Auto Tube	96 pcs/bag, 16 bags/ cartonmeMinimal consumable waste	104143
	16-Base B	Auto Tube	 300 pcs/carton Integrate with 6 tube B for small number of tests 	104026
	Spin tips	Auto Plate Auto Tube	2,000 pcs/bag, 10 bags /cartonA unique design for maximum mixing efficiency	056.CSM03.111





Taiwan Advanced Nanotech Inc.









