

# **TANBead<sup>®</sup>cell-free DNA Extraction Kit (61C series)**

1<sup>st</sup> Edition, Nov 2022



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### Automatic Nucleic Acid E

Maelstrom 8 (up to 8 tests pe

Maelstrom 4810 (up to 48 test

Maelstrom 9610 (up to 96 test

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# Introduction

The TANBead<sup>®</sup> Nucleic Acid Extraction Kit is a nucleic acid purification kit based on magnetic bead technology by using with corresponding TANBead<sup>®</sup> Nucleic Acid Extractor, which can automatically isolate and purify cell-free DNA (cfDNA) from human serum and plasma. The purified cfDNA can be used with many downstream applications employing PCRbased qualitative, semi-quantitative, quantitative assays and capillary electrophoresis. The kit is intended for use by technicians, physicians, and biologists with well-trained in molecular biological techniques, the techniques of magnetic bead purification and in vitro diagnostic procedures. Any diagnostic 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.

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# **Reagent Kits and Instrument**

Instrument	DEE	Cat NO.		Teet
Instrument	KEF	IVD	RUO	Test
Maelstrom 8 / Maelstrom 4800 series	M61CA46	301385	301508	96
	M61CS46	301389	301509	96
Maelstrom 9600 series	W61CA46	301377	301510	96
	W61CS66	301386	301511	72

# **Specification**

Feature	Specif	ication	
Downstream application	PCR, qPCR and NGS analysis		
Starting material	500-1,000 μL plasma / se	rum	
Processing mode	Automated, magnetic proc	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	70-100 μL		
Typical yield	1-100 ng/ per mL plasma or serum		
Typical DNA size	100-300 bp		

# **Kit Contents**

### Maelstrom 8 / Maelstrom 4800 series

M61PA46	96 tests	
Auto Plate	6 PCS	Pre-fille
Proteinase K	1.2 mL x 2	Protein
Elution Buffer	1.5 mL x 1	Nuclea
Spin Tip	96 PCS x 1 box	Spin tip
Protocol	1	Instruc

M61PS46	96 tests	
Auto Tube	8 Trays	Pre
Proteinase K	1.2 mL x 2	Prot
Elution Buffer	1.5 mL x 1	Nuc
Base	2 PCS	A ra
Spin Tip	48 PCS x 2 box	Spir
Protocol	1	Inst



Pre-filled plate for use
filled with reagent buffers
einase K
ease-free water
tip assembled box
uction guides for user

### Pre-filled tube for use

- e-filled with reagent buffers
- teinase K
- clease-free water
- ack for 8 Auto Tubes
- n tip assembled box
- truction guides for user

# **Kit Contents**

### Maelstrom 9600 series

M61PA46	96 tests	Pre-filled plate for use
Auto Plate	7 PCS	Pre-filled with reagent buffers
Proteinase K	1.2 mL x 3	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

W61CS66	72 tests	Pre-filled tube for use
Auto Tube	7 Trays	Pre-filled with reagent buffers
Proteinase K	1.2 mL x 3	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-free water
Base	2 PCS	A rack for 8 Auto Tubes
Spin Tip	48 PCS x 2 box	Spin tip assembled box
Protocol	1	Instruction guides for user

# **Pre-filled Plate or Tube Contents**

M61CA46, M61CS46				
Well	Buffer	Volume (µL)		
1/7	Lysis Buffer	800		
2/8	Washing Buffer 1	1000		
3/9	Washing Buffer 2	1000		
4/10	Washing Buffer 2	1000		
5/11	Magnetic Beads	500		
6/12	Elution Buffer	100		

W61PC46, W61CS66			
Position	Plate	Volume (µL)	
1	Lysis Buffer	800	
2	Lysis Buffer	800	
3	Washing Buffer 1	1000	
4	Washing Buffer 2	1000	
5	Washing Buffer 2	1000	
6	Magnetic Beads	500	
7	Elution Buffer	100	
8	Spin Tip	-	



## **Precautions**

**01** Avoid using expired reagents.

When the temperature is below 20°C, place the Auto Plates / Auto 02 Tubes in an oven (preheated 42~60°C) 5 to 10 minutes.

- **03** Avoid vigorous shaking, to avoid excessive formation of foam.
- **04** Carefully remove aluminum foil to avoid splashing.

Do not expose the opened reagents or Auto Plates / Auto Tubes to 05 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 09 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 11 patient is established.

## **Materials Required but not Provided**

01	TANBead <sup>®</sup> Nucleic Acid Extraction Maelstrom 8/ Maelstrom 4800 ser
02	Disposable gloves
03	Scissors, utility knives
04	Micropipette, disposable tips (10 µ
05	1.5 mL microcentrifuge tube
06	15 mL / 50 mL conical tube
07	20% SDS (Sodium dodecyl sulfate
08	Streck Cell-Free DNA BCT tubes

## **Kit Storage**

01 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-02 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 03 after production.



System (non-sterile) ries, Maelstrom 9600 series

μL / 200 μL / 1000 μL)

e)

or compatible ones

TANBead<sup>®</sup> cell-free DNA extraction kit could be stored at 15-35°C for 18 months and please find the expiration date labeled on the box of each

# **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 Transportation and Storage**

For short-term storage (up to 7 days), plasma and serum sample should 01 be stored at 2-8°C. For long-term storage, please store samples at -20°C or even -80°C.

The storage and transportation condition, such as temperature, time and container may cause the variation of yield and quality of purified 02 nucleic acids. In general, fresh prepared serum and plasma samples are recommended.

The transportation of blood samples should follow transportation-related laws and were kept at 2-25°C. Blood samples should be separated for serum or plasma within 6 hrs. The plasma or serum should be transported at 2-8°C or by frozen.

## **Procedure and Description**

### TANBead® cell-free DNA extraction procedure containing 3 steps:

**01** Sample preparation:

(1) Plasma separation:

- **a.** The blood sample collected in Streck Cell-Free DNA BCT tubes is stable at 6-37 °C up to 14 days.
- **b.** Centrifuge at 1,600 x g for 10 minutes.
- c. Transfer the upper layer (plasma) to a new conical tube.
- **d.** Centrifuge at 16,000 x g for 10 minutes.
- e. Transfer the supernatant (sample) to a new conical tube for cfDNA purification.

(2) Prepare the serum sample:

- a. The blood sample collected in anticoagulant-free collection tubes or serum separator ones.
- **b.** Keep at room temperature for at appropriate 30 minutes to let clot form.
- **c.** Centrifuge at 1,600 x g for 10 minutes.
- **d.** Transfer the upper layer (serum) to a new conical tube.
- e. Centrifuge at 16,000 x g for 10 minutes.
- f. Transfer the supernatant (sample) to a new conical tube for cfDNA purification
- treating with 20% SDS and proteinase K.
- 03 residues washing and elution step for DNA purification.





Sample lysis: Proteins, DNase and RNase can be lysed (inactive) by

Automation: transfer sample to Auto Plate/Tube to proceed lysis,

# Plasma sample











# Serum sample







# Add 500 $\mu$ L supernatant with 30 $\mu$ L 20% SDS and 20 $\mu$ L Proteinase K (PK)



TIPS

Large sample input (9600 series only)

Sample Volume(µL)	PK (µL)	20% SDS(μL)	Plate Position
500	20	30	Plate 1
1000	40	60	Divide the mixture evenly and add to Plate 1 and 2





Incubate at 60 °C for





20 min

Add the total mixture into the well



# Instrument Description

1 Automatic Nucleic Acid Extraction System

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.







ature	Specification		
	Maelstrom 8 handler		
W)	600 g		
าร	11.2(W)x6.3(L)x32.7(H) cm		
ng	5 Vac, 2A		
	3.7 Vac, 2,850 mAh		
ughput	8 samples per run		
volume	50 - 1,500 μL		
d	up to 3,000 rpm		
rod	> 3,000 gauss		
	2.4" LCD, 240 x 320 pixels		

# Maelstrom 4810 (up to 48 tests per run)

aelstrom 4810 is a 48-throughput instrument, combined with our patented N 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 Μ 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	Specificatio
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 H AC 100-120 V, 50/60 H
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
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)





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)







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# Instrument Operation Guide

# Maelstrom 9600 series (Herein represented by Maelstrom 9610)

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2

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

Press "Run" and choos (program name: 61C)







### Press "Run" and choose the corresponding program



### Mounting tips (Auto Plate)



Mounting tips (Auto Tube)



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

3

### 3-1

Add samples to wells of Auto Plate/ Tube.

### 3-2

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.

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.

4

To clean the magnetic rods, wipe with a soft cloth dampened with pure water. Do not use alcohol solvent.



# Supporting Info

# **Service Information**

### **Technical Support**

- Taiwan Advance Nanotech Inc. provides post sales service and
- assistance.

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Service Information

**Technical Support** 

Troubleshooting

Ordering Information 2





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

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

of proteinase K.

### • 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.

### Improper pretreatment

Insufficient

sample lysis

Please operate the reagent kit according to the workflow shown as page 14 and 15.

Please check the lysis condition (temperature, reagent

concentration...etc.) in step (6) shown as page 14 and 15.

Also, please check the expiry date and storage condition

### • Less magnetic beads remain in the elute

Improper program

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

Sample type and status

The long storage time of sample would have negative effect on its nucleic acid yield, length, quality and integrity. Please find the complete recommendation of storage and transportation shown in section "Sample Transportation and Storage" at page 12. Elution contamination

Improper

sample input

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.

If this issue appea a new extraction a still occurred. In most cases of you could still use analyses with unaf



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

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

# Troubleshooting

# **Ordering Information**

### Maelstrom 8 / Maelstrom 4800 series

		Sample	Description	Test	REF	Cat No.
Amplification failure or unexpected			Blood DNA Auto Plate	96	M611A46	301126
			Blood DNA Auto Tube	96	M611S46	301127
• results are fou	results are found by PCR analysis			96	M61EA46	301128
recure are reality of entanalycie			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
	Please collect separated plasma or serum from		Plant DNA Auto Plate	96	M613A46*	301134
Genomic DNA	blood sample carefully after centrifugation, avoid taking the buffy coat or the clot.	Plant		96	M613A46-SE*	301371
contamination			Plant DNA Auto Tube	96	M613S46*	301135
				96	M613S46-SE*	301372
			Plant RNA Auto Plate	96	M6K3A46*	301383
	Since cfDNA typically shows a length of about 166 bp, for PCR analysis, keep amplicons less than 250 bp is recommended.		Plant RNA Auto Tube	96	M6K3S46*	301384
Long amplicon size		cfDNA	OptiPure cfDNA Auto Plate	96	M61CA46	301385
			OptiPure cfDNA Auto Tube	96	M61CS46	301389
		EEDE	OptiPure FFPE DNA Auto Plate	96	M61PA46	301152
			OptiPure FFPE DNA Auto Tube	96	M61PS46	301153
•	This issue may be caused by sample		OptiPure Viral Auto Plate	96	M665A46	301148
Cross-contamination	overloading. Make sure that the amount of		OptiPure Viral Auto Tube	96	M665S46	301149
between samples	sample and elution buffer keeps within the	Virus	OptiPure Viral Bulk Plate	960	M665A10	301346
1	processing volume.		Virapid Virus Auto Plate	96	M685A46	301572
			Virapid Virus Auto Tube	96	M685S46	301573
		НР//	HPV Auto Plate	96	M61HA46	301589
			HPV Auto Tube	96	M61HS46	301590





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# **Ordering Information**

### Maelstrom 8 / Maelstrom 4800 series

Sample	Imple Description		REF	Cat No.
	Tissue DNA Auto Plate	96	M612A46	301130
	Tissue DNA Auto Tube	96	M612S46	301131
	Tissue Total DNA Auto Plate	96	M6T2A46	301132
Tiaqua	Tissue Total DNA Bulk Plate	960	M6T2A10	301306
lissue	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
Funci	Fungi DNA Auto Plate	96	M61FA46	301585
Fungi	Fungi DNA Auto Tube	96	M61FS46	301586
Forencia	Forensic DNA Auto Plate	96	M6TFA46	301424
Forensic	Forensic DNA Auto Tube	96	M6TFS46	301425
	Gram Bacteria DNA Auto Kit	96	M61G046	301257
	Cram Destaria DNA Auto Dista	96	M61GA46	301138
Bacteria	Gram Bacieria Dina Auto Plate	96	M61GA46-SE	301294
	Crem Destaria DNA Auto Tuba	96	M61GS46	301139
	Gram Baciena DNA Auto Tube	96	M61GS46-SE	301295
Dleamid	Plasmid Extraction Auto Plate	96	M6PEA46*	301578
Plasmid	Plasmid Extraction Auto Tube	96	M6PES46*	301579
	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
51001	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	e Description		REF	Cat No.
	Blood DNA Auto Plate	96	W611A46	301186
	Blood DNA Auto Tube	72	W611S66	301187
Plead	OptiPure Blood DNA Auto Plate	96	W61EA46	301188
DIOOU	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 Plata	96	W613A46*	301194
	Plant DNA Auto Plate	96	W613A46-SE*	301379
Dlant	Plant DNA Auto Tubo	72	W613S66*	301259
Piant	Plant DNA Auto Tupe	72	W613S66-SE*	301378
	Plant RNA Auto Plate	96	W6K3A46*	301406
	Plant RNA Auto Tube	72	W6K3S66*	301407
	OptiPure cfDNA Auto Plate	96	W61CA46	301377
CIDINA	OptiPure cfDNAAuto Tube	72	W61CS66	301386
FEDE	OptiPure FFPE DNA Auto Plate	96	W61PA46	301629
FFPE	OptiPure FFPE DNA Auto Tube	72	W61PS66	301630
	OptiPure Viral Auto Plate	96	W665A46	301224
	OptiPure Viral Bulk Plate	960	W665A10	301345
Virus	OptiPure Viral Auto Tube	72	W665S66	301209
	Virapid Virus Auto Plate	96	W685A46	301574
	Virapid Virus Auto Tube	72	W685S66	301575
	HPV DNA Auto Plate	96	W61HA46	301591
HPV	HPV DNA Auto Tube	72	W61HS66	301592

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





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# **Ordering Information**

# Consumables

### **Maelstrom 9600 series**

Sample	Description	Test	REF	Cat No.
	Tissue DNA Auto Plate	96	W612A46	301190
	Tissue DNA Auto Tube	72	W612S66	301191
Tiaqua	Tissue Total DNA Auto Plate	96	W6T2A46	301192
lissue	Tissue Total DNA Auto Tube	72	W6T2S66	301193
	Tissue RNA Auto Plate	96	W6K2A46	301404
	Tissue RNA Auto Tube	72	W6K2S66	301405
Forencia	Forensic DNA Auto Plate	96	W6TFA46	301291
Forensic	Forensic DNA Auto Tube	72	W6TFS66	301426
Destaria	Gram Bacteria DNA Auto Plate	96	W61GA46	301198
Baclena	Gram Bacteria DNA Auto Tube	72	W61GS66	301199
Dloomid	Plasmid Extraction Auto Plate	96	W6PEA46*	301580
Plasmid	Plasmid Extraction Auto Tube	72	W6PES66*	301581
	Food and Feed DNA Auto Plate	96	W6GMA46*	301637
Food Feed	Food and Feed DNA Auto Tube	72	W6GMS66*	301638
Environmental	Environmental Microbiome DNA Auto Plate	96	W6EMA46*	301643
Microbiome	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

Sample	Description	Test	REF
96 deep well plate	Auto Plate	<ul> <li>100 pcs/carton</li> <li>Processing volume 50-1,600 µL</li> <li>For molecular diagnostics</li> </ul>	083. MWP01.20X
96 deep well plate (Unique hook design)	Auto Plate	<ul> <li>100 pcs/carton</li> <li>Processing volume 50-1,600 µL</li> <li>For molecular diagnostics</li> </ul>	083. MWP02.20X
Spin Tips Assembled Box (Unique hook design)	Auto Plate	<ul><li>80 pcs/carton</li><li>96 pcs of spin tips in one box</li></ul>	083.MSP09.10X
Spin Tips Assembled Box (Unique hook design)	Auto Tube	<ul> <li>80 pcs/carton</li> <li>48 pcs of spin tips in one box</li> </ul>	083.MSP10.10X
6 tube B	Auto Tube	<ul><li>96 pcs/bag, 16 bags/ cartonme</li><li>Minimal consumable waste</li></ul>	104143
16-Base B	Auto Tube	<ul> <li>300 pcs/carton</li> <li>Integrate with 6 tube B for small number of tests</li> </ul>	104026
Spin tips	Auto Plate Auto Tube	<ul> <li>2,000 pcs/bag, 10 bags /carton</li> <li>A unique design for maximum mixing efficiency</li> </ul>	056.CSM03.111







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### $\bigoplus$ https://www.tanbead.com

success@tanbead.com