TAN Bead

Taiwan
Advanced
Nanotech

Maelstrom™ 9600

REVOLUTIONIZING MAGNETIC BEAD HANDLING

Maximize Throughput and Eliminate Cross-contamination

ISO 13485 CE IVD FDA TFDA CFDA

Product Video

Maelstrom™ 9600 Series Features

Patented Maelstrom Spin Mixing Technology

TANBead Maelstrom product embodies this novel technology and delivers improved performance for applications in molecular diagnostics and life sciences. Maelstrom Series are FDA and CE approved, and the patents are granted in the Canada, China, EU, Korea, Japan, Taiwan, and USA.

Fully Automated

- Simultaneous processing and purification of DNA,RNA samples
- Automation of complicated manual steps
- Independent temperature control modules ensure stability of purification performance

Patented Whirl Stirring Mixing Technology

- Processing volume up to 1,600µl
- Spin tips stir magnetic beads at speeds up to 3000 rpm
- Effective prevention of aerosol cross contamination

Easy Operation

- Intuitive user interface and easy menu navigation
- Parameters can be fine-tuned based on experimental requirements

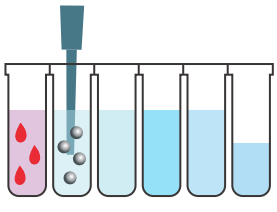
Time Saving

- High-throughput: 96 samples can be processed simultaneously
- High stirring efficiency with variable speeds for considerable time savings

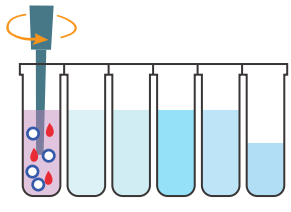
Principle of Nucleic Acid Extraction

Sample Bead DNA

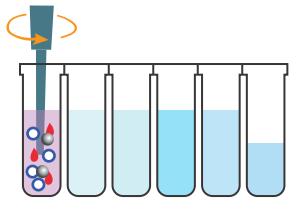
Step 1
Activate beads



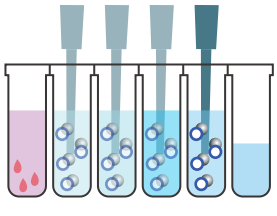
Step 2
Mix sample with Lysis Buffer



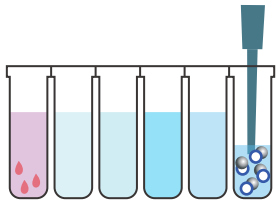
Step 3
Mix sample with beads



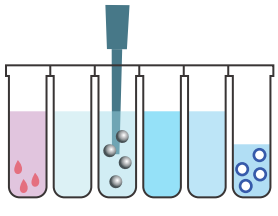
Step 4
Wash bead-DNA from #2 ~ #5 well



Step 5
Elute DNA



Step 6
Release beads



Maelstrom™ 9600 Series Features

Performance

- The coefficient of variation of nucleic acid extraction concentration is less than 5%
- High consistency
- No Cross-contamination to neighbor well Experimental results

Specification

Model	Maelstrom™ 9600
Run Time	25~60 min
Samples per run	Max 96 samples
Weight (NW)	130kg
Dimensions (WxDxH)	87x57.5x70cm
Power Supply	AC 220-240 V
Processing volume	50µl - 1,600µl
Magnetic Rod	>3,000 gauss
Spin Speed	up to 3,000 rpm
Temp control	4 set
Heating Block	Yes (4 pcs)
Heating	RT~130°C
UV Lamp	Yes
Display	7" touch screen

Patents

USA	US09616398B2
EU	EP2937136
Canada	CA2862946
Japan	JP6151735B2
Korea	10-1696517
China	CN104971638B
Taiwan	TWI526245B

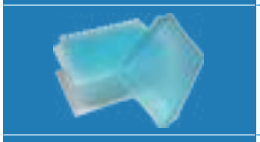
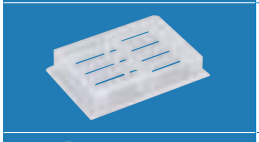
Reagent kits

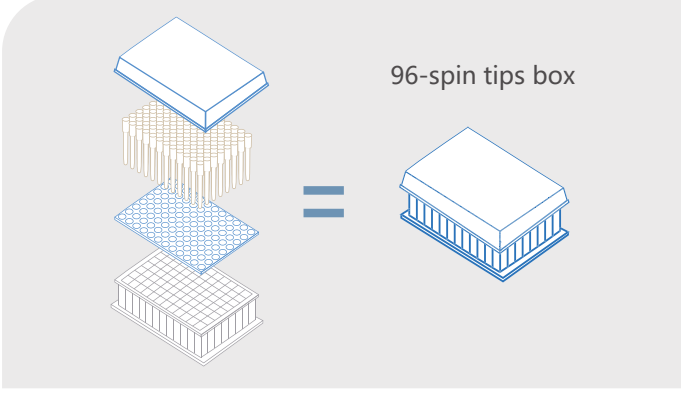
Scan QR code for more reagents

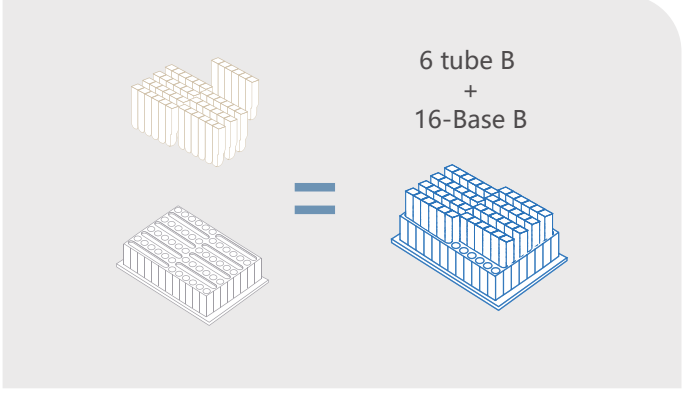
Sample	Target	Test	Kits Format	Ordering No.
Blood	Total DNA	96	Auto Plate	301188
Viral	Viral DNA / RNA	96	Auto Plate	301206
Tissue	Total DNA	96	Auto Plate	301192
Gram Bacteria	Bacteria Total DNA	96	Auto Plate	301198

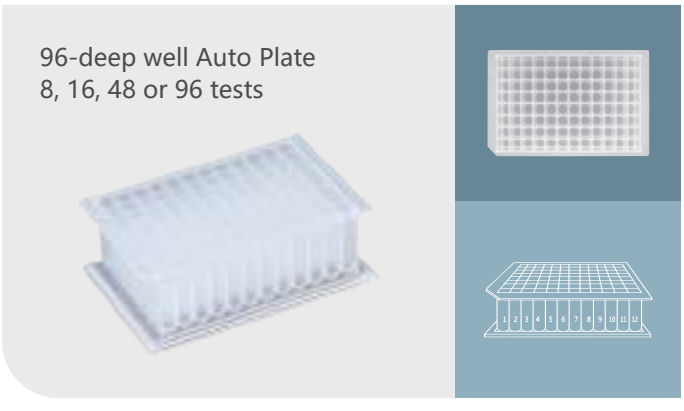
Maelstrom™ 9600 Series Features

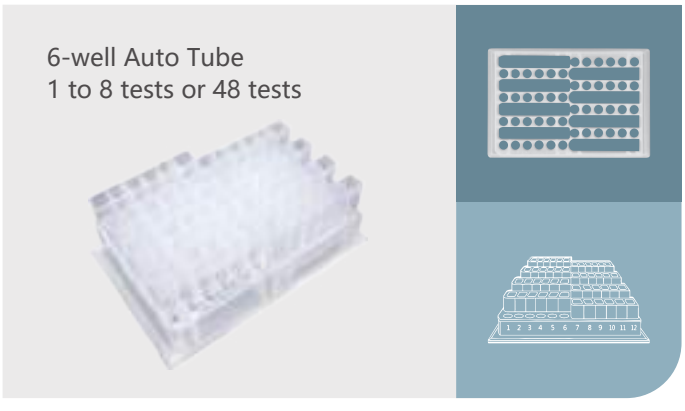
Consumables

Images	Product Name	Format	Description	Ordering No.
	96 deep well plate	Auto Plate	• Processing volume 50µl-1,600µl • Widely use for molecular diagnostics	083.MWP01.20X
	96-spin tips box	Auto Plate	• 96 pcs of Medium(pen-shape) spin tips in one box	083.MSP01.20X
	6 tube B	Auto Tube	• Special Package for single or small number of tests • Minimal consumable waste • No reagent loss	104143
	16-Base B	Auto Tube	• Incorporate with 6 tube B for small number of tests	104026
	Spin tips	Auto Plate Auto Tube	• A unique design to maximum mixing efficiency	104157









TAN Bead

Taiwan Advanced Nanotech

www.tanbead.com

6F., No. 188, Wenhe Rd., Guishan Dist., Taoyuan City 333, Taiwan
T. +886-3-3167568 F. +886-3-3173369 E. success@tanbead.com

2021-02

Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	TANBead Magnetic Rotary Mixer; TANBead Nucleic Acid Extraction Kit; TANBead Nucleic Acid Extraction System Maelstrom 8 Autostage; TANBead Nucleic Acid Extractor; TANBead Nucleic Acid Extractor Maelstrom 4800; TANBead Nucleic Acid Extractor Maelstrom 4810; TANBead Nucleic Acid Extractor Maelstrom 9600; TANBead Nucleic Acid Extractor Maelstrom 9610
Classification Name:	CLINICAL SAMPLE CONCENTRATOR
Product Code:	JJH[6]
Device Class:	1
Regulation Number:	862.2310[7]
Medical Specialty:	Clinical Chemistry
Registered Establishment Name:	TAIWAN ADVANCED NANOTECH INC.[8]
Registered Establishment Number:	3013548521
Owner/Operator:	Taiwan Advanced Nanotech Inc.[9]
Owner/Operator Number:	10054412
Establishment Operations:	Manufacturer

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Page Last Updated: 01/25/2021

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9. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=10054412

MACHEREY-NAGEL

NucleoMag® Pathogen

Automated purification of SARS-CoV-2 RNA from respiratory samples on the Maelstrom 9600

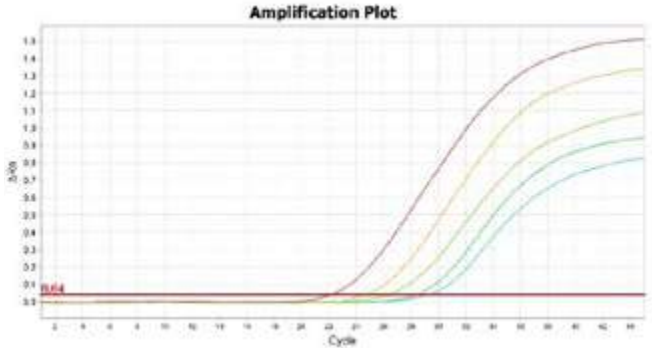
Introduction

Isolation of pathogen nucleic acids (e.g. viral RNA & DNA, bacterial DNA) from clinical samples is the basis for a large variety of molecular tests that have become standard methodology in research and diagnostic laboratories.

Due to the diversity of clinical sample material the isolation procedure often poses challenges to laboratory workflows. The purification process needs to be suitable for a wide variety of sample materials. In addition, the molecular diagnostic market demands automatable and reliable extraction methods.

To meet these requirements MACHEREY-NAGEL developed the NucleoMag® Pathogen kit allowing the automated isolation of nucleic acids from various starting materials using magnetic bead technology.

Here, we demonstrate the purification of SARS-CoV-2 viral RNA from respiratory secrete samples using the TANBead Maelstrom 9600 instrument and downstream detection by qRT-PCR.



NucleoMag® Pathogen	
Technology	Magnetic beads
Sample material	≤ 200 µL whole blood, serum, plasma, ≤ 200 µL swab wash solution ≤ 25 mg tissue (e.g., ear notches), ≤ 200 µL feces
Elution volume	50–200 µL
Fragment size	300 bp–approx. 50 kbp
Preparation time	30–40 min (excl. lysis) / 96 samples

TANBead Maelstrom 9600	
Description	Automated nucleic acid extraction instrument
Technology	Magnetic rods; mixing by whirl stirring
Capacity	6–96 samples/run
Footprint	87 x 70 x 57.5 cm

Highly sensitive detection of SARS-CoV-2 RNA in respiratory samples

A dilution series of inactivated SARS-CoV-2 RNA was spiked into respiratory secrete samples and subjected to the automated NucleoMag® Pathogen extraction procedure on the Maelstrom 9600 instrument. Viral RNA was detected reliably via qRT-PCR on an Applied Biosystems Real-Time PCR Cycler (red = 1:1 dilution, yellow = 1:3, light green = 1:10, green = 1:30, light blue = 1:100).

Data was kindly provided by Dr. Stefan Mustafa (Labor Dr. Mustafa, Vienna, Austria). The method was developed by Michael Zechner (LabConsulting, Vienna, Austria).

For more information please contact MACHEREY-NAGEL Bioanalysis technical support: bio-tech@mn-net.com

Your advantages at a glance

- Proven NucleoMag® lysis and purification procedure suitable for diverse clinical samples
- High speed nucleic acid purification by the Maelstrom 9600 instrument
- Highly pure nucleic acids ready to be used in the downstream application of your choice

Product	Specifications	Pack of	REF
NucleoMag® Pathogen	Magnetic bead-based kit for the isolation of viral RNA / DNA, and microbial DNA from clinical samples; including NucleoMag® B-Beads, buffers, Carrier RNA and Proteinase K	96 preps 384 preps	744210.1 744210.4
NucleoMag® Dx Pathogen (CE-IVD)	CE-IVD certified, magnetic bead-based kit for the isolation of viral RNA from respiratory samples; including NucleoMag® B-Beads, buffers, Carrier RNA and Proteinase K	384 preps	744215.4

TANBead Maelstrom™ 9600: Extraction system for diagnostic of SARS-COV-2

Comparative study with a commercial reference extraction system

MAIN FEATURES

TANBead Maelstrom™ 9600 is a novel technology for applications in molecular diagnostics. The fully automated magnetic bead operating platforms use the magnetic rods within the equipment for nucleic acid isolation. The magnetic beads with nucleic acids adsorbed are automatically transferred from well to well for cell lysis, nucleic acid adsorption, washing, and elution. In contrast to laborious and prone to erros manual Spin Column operations, TANBead's automated extraction devices provide you a walk-away solution and effort-saving approach for processing multiple samples at the same time. Features of the system can be summarized as follows:

Fully Automated

- Temperature control modules to ensure the stability of the purification process.
- Simultaneous processing and purification of DNA and RNA samples.
- Automation of complicated manual steps.
- Pre-dispensed plates with all reagents ready to use.

Patented Whirl Stirring Mixing Technology

- Processing volume of 300 µl.
- Effective prevention of aerosol cross contamination.

Easy Operation

- Intuitive user interface and easy menu navigation.
- Lysis buffer included for SARS CoV-2 virus inactivation (15 minutes at room temperature).

Time Saving

- High-throughput: 96 samples can be processed simultaneously, 40 min after inactivation.

Maelstrom™ 9600

CE IVD FDA

DIRECT SARS-COV-2 REALTIME PCR KIT is a product from Vircell to detect nucleic acid from SARS-CoV-2 in human respiratory samples. The TANBead's automated extraction process of SARS-COV-2 RNA in respiratory samples can be combined with the amplification kit from Vircell. The features of this REAL TIME PCR kit can be summarized as follow:

- **Double target assay**: specific for COVID-19 (*N* gene) and other SARS- related coronavirus (*E* gene).
- **Multiplex PCR- one single reaction tube** per sample.
- Suitable for **FAM/Cy5/HEX (VIC) qPCR cycler**.
- **Endogenous human *RNAse P* control**- for detecting improper sample collection or degradation.
- **Lyophilized** master mix and positive control to ensure stability and reduce transportation costs.
- Fast and reliable **results in less than 2 hours**.

DIRECT SARS-COV-2 REALTIME PCR KIT

CE IVD

VIRCELL Molecular

TANBead Maelstrom™ 9600: Extraction system for diagnostic of SARS-COV-2

COMPARATIVE RESULTS

This study compared the results of 24 positive and 30 negative respiratory samples for SARS-CoV-2, extracted with OptiPure Viral AutoPlate (TANBead), run on Maelstrom M9600 instrument, and QIAamp Viral RNA Mini Kit (Qiagen) (used as a reference method). The samples were nasopharyngeal swabs collected in different transport media. Viral RNA was extracted according to manufacturer protocol, with the modification of an initial 15 minutes incubation protocol at room temperature. The lysis buffer was provided with the kit, in order to inactivate the samples.

The extraction efficiency from these two different extraction platforms was evaluated using RTPCR002-LP DIRECT SARS-COV-2 REALTIME PCR KIT (Vircell) on a CFX96 thermocycler (Bio-Rad). Results expressed as Ct values were plotted in figures on the right for each positive sample.

Detection of SARS-CoV-2 was determined by the detection of gene target E and N according to the RT-PCR kit instructions. Additionally, the internal human control (human RNase P) was reported in a comparative graph, and also as a correlation (dispersion graph).

The figures action methods was noticeable, showing linearity values of R2 > 0.99 for the correlations in all targets.

Results for negative samples showed no reactivity with any of the two extraction methods, showing a similar correlation for the internal human control (data not shown).

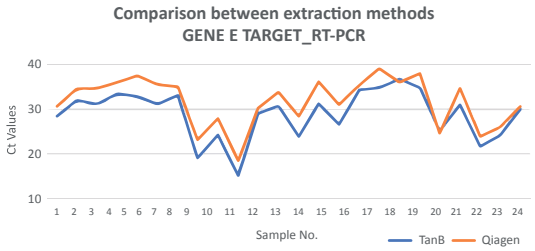
CONCLUSIONS

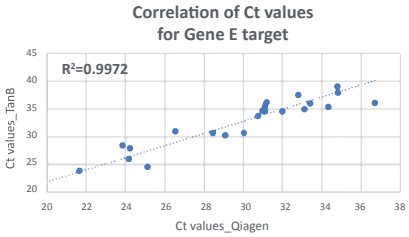
TANBead OptiPure Viral Auto Plate system showed comparable results to the Qiagen commercial Spin Column reference kit considered as the gold standard for virus purification. Average earlier Ct values for TanBead kit could be explained by the different input and output volume used.

The advantages of the TANBead automated system, easy to use, and time saving, exceeded the features of a manual purification kit, preserving the accuracy and reliability of an RNA extraction kit.

The combination of DIRECT SARS-COV-2 REALTIME PCR KIT (96-well plate format, ref: RTPCR002-LPP) and Tanbead system can be used to run 96 samples in less than 3 hours, with a minimum manual manipulation of respiratory samples.

A





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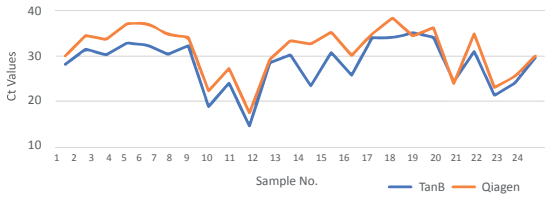

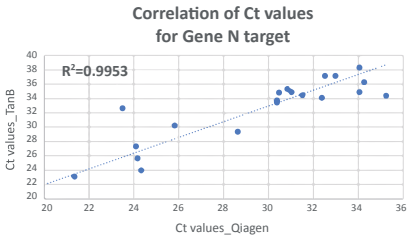

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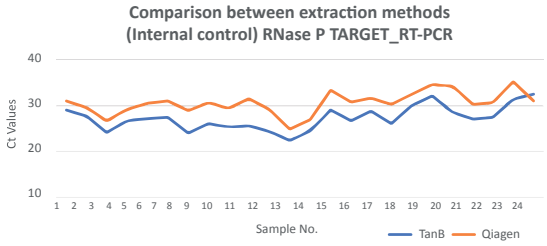

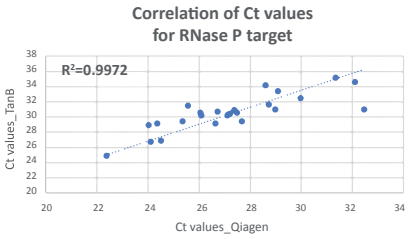

Figures: Comparison and correlations between extraction methods. The graph shows the values of Ct obtained after Real time RT-PCR. A for target E, B for target N and C for Human RNase P.

Vircell, S.L.
Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, Spain
+34 958 441 264 customerservice@vircell.com www.vircell.com

VIRCELL Molecular

Verification of Seegene AllplexTM 2019-nCoV Assay

Start date: 200408

Background/goal

A new Coronavirus SARS-CoV-2 has been discovered in China and is beginning to spread around the world. If there is a risk of or established spread in society, we must be able to monitor possible spread of infection and be able to quickly analyze samples from suspected cases of disease. This increased need for virus diagnostics due to the Covid-19 pandemic has led to an increased workload, where both clinical samples and staff screenings are to be performed with rapid response times. For this we need to evaluate an alternative work flow of the routine diagnostics, using another kit, Seegene Allplex™ 2019-nCoV Assay (Seegene). The same genes that FOHM (the Swedish CDC) recommends are used in Allplex™ 2019-nCoV Assay, Egene and RdRp. These genes are also used in the in-house real-time PCR that we use since 27/2 2020 for the detection of the SARS-CoV-2. Yet another gene, the Ngene, is used as a target in Allplex, but here we have no method to compare with.

This kit will be run mainly on the personnel screening tests but also serve as backup to existing routine diagnostics with a SARS-CoV-2 screening inhouse PCR. The kit is CE-IVD marked.

Measurement principle

RT-PCR (Reverse Transcriptas - Polymerase Chain Reaction) methodology. Virus RNA is converted in a first step to cDNA in PCR and detected with a TaqMan hydrolysprobe. The Allplex 2019-nCoV assay is a CE-IVD kit with multiplex real-time RT-PCR that detects 3 different genes: the Egene from *Sarbecovirus* in the FAM channel, the RdRP gene (SARS-CoV-2) in the Cal Red 610 channel and the N gene (SARS-CoV-2) in the Quasar 670 channel.

Materials and method

Test system

Nasopharyngeal test in UTM, Virocult and Amies transport medium

RNA from all samples was extracted using the Maelstrom 9600 instrument (TANBead) with the TANBead Nucleic Acid Extraction Optipure Viral 665 Kit unless otherwise stated.

Allplex™ 2019-nCoV Assay has been verified according to:

IC added to PCR mix

A clinical sample (No 1) was tested in dilution 1/10-1/1000 in Virocult where dilution 1/10 and 1/100 were prepared in parallel on the MagLead instrument (PSS), see Table 1.

A clinical sample (No 2) was tested in 1/10 and 1/100 in UTM-RT medium and Virocult, see Table 1.

IC added to the extraction

Allplex™ 2019-nCoV Assay was also verified with IC added to the extraction according to the manufacturer's instructions and ran in parallel with SARS-CoV-2 screening inhouse PCR routine diagnostics. A total of 48 clinical samples were tested here, of which 19 positive, see Tables 3 and 4. In the first round, IC was tested after the samples were transferred to the Maelstrom plate. Also the samples were run both with and without added IC in the extraction on our SARS-CoV-2 screening inhouse PCR routine diagnostics (Table 3). In the second round, IC was added together with Proteinas K to the Maelstrom plate before the samples were added (Table 4).

For description of RT-PCR see document: *SARS-CoV-2 screening inhouse PCR No. 636262.*

Controls and control material

An IC control is included in the kit consisting of an MS2 fag and its function is to detect/detect inhibition or failure of PCR or extraction. It is detected in the HEX channel. As positive PCR control, SARS-CoV-2 RNA (included in the kit) is used. A positive preparation control consisting of a positive patient sample diluted in virocult medium to 1/1000 as well as negative preparation controls consisting of Milli-Q water (5 in 96 samples) is used in each run.

Results

To test Allplex sensitivity, a clinical sample (A) was tested in dilution 1/10-1/1000 in Virocult where dilution 1/10 and 1/100 were also prepared in parallel on MagLead, see Table 1. The results of these tests showed good consistency between the PCRs with regrd to the dilution series. Extraction with MagLead provides a slightly higher yield of RNA. An additional clinical sample (B) was tested in 1/10 and 1/100 in both UTM-RT medium and Virocult. As for the UTM-RT medium, the PCR curves shows a little later, <1.5 cycles, compared to Virocult.

Table 1. Detection of SARS-CoV-2 with Seegene Allplex vs SARS-CoV-2 screening inhouse PCR on Maelstrom extractions with dilution of two clinical samples A and B, ct-value.

Clinical specimen	SARS-CoV-2 In-house	Seegene Egene	Seegene RdRP	Seegene Ngene	Seegene IC
A: 1/10	23,99	21,63	23,03	24,28	23,59
A: 1/100	27,50	25,42	26,83	27,90	23,61
A: 1/1000	30,58	28,38	29,49	30,88	23,89
A: 1/10000	33,68	31,68	32,87	33,97	23,70
A: 1/10*	22,13	19,67	21,40	23,00	22,38
A: 1/100*	25,94	23,51	24,96	26,91	23,99
B: UTM 1/10	31,21	29,49	29,43	32,08	30,52
B: UTM 1/100	36,38	34,03	34,93	36,09	36,08
B: Virocult 1/10	30,70	28,73	28,73	31,83	30,10
B: Virocult 1/100	34,84	33,27	33,27	36,36	34,14

*Samples extracted on MagLead

IC added to the extraction

Allplex™ 2019-nCoV Assay was also validated according to the manufacturer's instructions with IC added to the extraction. Detection was performed in parallel with SARS-CoV-2 screening inhouse PCR routine diagnostics. Table 2 shows the results where ic was added to the Maelstrom plate after the samples were added and Table 3 shows the results when IC was added with Proteinase K before the samples were added to the Mealstrom plate. Out of a total of 48 clinical samples tested, all 19 positive with the SARS-CoV-2 screening inhouse PCR also became positive with Allplex in all three genes, the E gene, the RdRP, N gene. Two additional samples only became positive in the N gene, see Tables 3 and 4. A strong positive sample gives a negative IC value, which is absolutely correct when amplification of this gene is set to be competed out. No impact was seen on SARS-CoV-2 screening inhouse PCR when Allplex IC was added to extraction, see Table 3. One negative sample is indicated as Negative Control(Invalid) because Type was listed as NC instead of SAMPLE as it should be done with negative preparation controls with water, see Table 3.

Table 2. Clinical samples run in parallel with Seegene Allplex and SARS-CoV-2 screening inhouse PCR (200417).

Name	Type	FAM		Cal Red 610		Quasar 670		HEX		Auto Interpretation	Ct inhouse
		E gene	C(t)	RdRP gene	C(t)	N gene	C(t)	IC	C(t)		IC
Neg K H2O	NC	-	N/A	-	N/A	-	N/A	+	29.22	Negative	e.u.
Kliniskt prov 1	SAMPLE	+	28.24	+	31.17	+	29.62	+	28.32	2019-nCoV Detected	32,98
Kliniskt prov 2	SAMPLE	+	32.61	+	35.41	+	34.55	+	30.18	2019-nCoV Detected	35,14
Kliniskt prov 3	SAMPLE	+	33.80	-	N/A	+	34.41	+	28.71	2019-nCoV Detected	35,34
Kliniskt prov 4	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.31	Negative	37,86/neg*
Kliniskt prov 5	SAMPLE	+	24.36	+	26.45	+	26.15	+	27.66	2019-nCoV Detected	25,33
Kliniskt prov 6	SAMPLE	+	23.50	+	26.58	+	26.60	-	N/A	2019-nCoV Detected	25,86
Kliniskt prov 7	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.39	Negative	neg
Kliniskt prov 8	SAMPLE	-	N/A	-	N/A	-	N/A	+	30.57	Negative	neg
Kliniskt prov 9	SAMPLE	-	N/A	-	N/A	-	N/A	+	29.63	Negative	neg
Kliniskt prov 10	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.52	Negative	neg
Kliniskt prov 11	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.44	Negative	neg
Kliniskt prov 12	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.63	Negative	neg
Kliniskt prov 13	SAMPLE	-	N/A	-	N/A	-	N/A	+	29.05	Negative	neg
Kliniskt prov 14	SAMPLE	-	N/A	-	N/A	-	N/A	+	29.05	Negative	neg
Kliniskt prov 15	SAMPLE	+	12.41	+	16.10	+	16.74	-	N/A	2019-nCoV Detected	15,95
Kliniskt prov 16	SAMPLE	+	32.13	+	33.96	+	33.22	+	30.76	2019-nCoV Detected	35,34
Kliniskt prov 17	SAMPLE	-	N/A	-	N/A	-	N/A	+	30.63	Negative	neg
Kliniskt prov 18	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.56	Negative	neg
Prepk-CoV-2	PC	+	27.91	+	29.53	+	29.22	+	27.65	Positive Control(+)	33,5
Neg PCR K H2O	NC	-	N/A	-	N/A	-	N/A	-	N/A	Negative Control(-)	e.u.
Pos PCR K	PC	+	20.63	+	20.25	+	18.70	+	19.27	Positive Control(+)	e.u.

*Negative when rerun and interpreted as negative ; e.u. = not performed

Table 3. Clinical samples run in parallel with Seegene Allplex and SARS-CoV-2 screening inhouse PCR (200421).

Name	Type	FAM		Cal Red 610		Quasar 670		HEX		Auto Interpretation	Ct Inhouse Egene
		E gene	C(t)	RdRP gene	C(t)	N gene	C(t)	IC	C(t)		
Kliniskt prov 1	SAMPLE	+	27.61	+	29.64	+	29.58	+	26.76	2019-nCoV Detected	30,68
Kliniskt prov 2	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.28	Negative	neg
Kliniskt prov 3	SAMPLE	-	N/A	-	N/A	-	N/A	+	28.64	Negative	41,53*
Kliniskt prov 4	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.58	Negative	neg
Kliniskt prov 5	SAMPLE	-	N/A	-	N/A	+	36.26	+	27.06	2019-nCoV Detected	38,11/41,23*
Kliniskt prov 6	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.71	Negative	neg
Kliniskt prov 7	SAMPLE	+	17.64	+	20.45	+	21.27	-	N/A	2019-nCoV Detected	21,1
Kliniskt prov 8	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.08	Negative	neg
Kliniskt prov 9	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.37	Negative	neg
Kliniskt prov 10	SAMPLE	-	N/A	-	N/A	-	N/A	+	26.59	Negative	neg
Kliniskt prov 11	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.28	Negative	neg
Kliniskt prov 12	SAMPLE	+	21.14	+	23.01	+	23.99	+	28.68	2019-nCoV Detected	24,02
Kliniskt prov 13	SAMPLE	+	17.71	+	19.62	+	20.43	-	N/A	2019-nCoV Detected	20,7
Kliniskt prov 14	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.09	Negative	neg
Kliniskt prov 15	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.45	Negative	neg
Kliniskt prov 16	SAMPLE	+	20.92	+	23.22	+	23.85	+	27.21	2019-nCoV Detected	24,13
Kliniskt prov 17	SAMPLE	+	21.90	+	24.19	+	24.37	+	24.44	2019-nCoV Detected	25,03
Kliniskt prov 18	SAMPLE	+	28.28	+	31.17	+	30.81	+	27.80	2019-nCoV Detected	31,55
Kliniskt prov 19	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.39	Negative	neg
Kliniskt prov 20	SAMPLE	-	N/A	-	N/A	-	N/A	+	26.66	Negative	neg
Kliniskt prov 21	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.53	Negative	neg
Kliniskt prov 22	SAMPLE	+	26.37	+	30.17	+	29.18	+	27.64	2019-nCoV Detected	30
Kliniskt prov 23	SAMPLE	-	N/A	-	N/A	-	N/A	+	26.70	Negative	neg
Kliniskt prov 24	SAMPLE	-	N/A	-	N/A	-	N/A	+	26.89	Negative	neg
Kliniskt prov 25	SAMPLE	+	21.43	+	23.78	+	24.19	+	28.90	2019-nCoV Detected	24,36
Kliniskt prov 26	SAMPLE	-	N/A	-	N/A	+	37.33	+	26.76	2019-nCoV Detected	40,41*
Kliniskt prov 27	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.23	Negative	neg
Kliniskt prov 28	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.15	Negative	neg
Kliniskt prov 29	SAMPLE	-	N/A	-	N/A	-	N/A	+	37.26	Negative	neg
Kliniskt prov 30	SAMPLE	+	29.38	+	31.84	+	31.32	+	27.10	2019-nCoV Detected	32,66
Neg Prek-H2O	SAMPLE	-	N/A	-	N/A	-	N/A	+	27.82	Negative	41,70 neg
Prepk-CoV-2	SAMPLE	+	26.28	+	28.77	+	28.50	+	28.14	2019-nCoV Detected	29,06
PCR Pos K	PC	+	19.94	+	20.27	+	18.08	+	23.27	Positive Control(+)	e.u.
PCR Neg K	NC	-	N/A	-	N/A	-	N/A	-	N/A	Negative Control(-)	e.u.

*Ct >40 in first run or when rerun and interpreted as negative; e.u. = not performed

Conclusion/assessment

Allplex™ 2019-nCoV Assay shows a good consistency with SARS-CoV-2 screening inhouse PCR and a high sensitivity if not better since two more samples became positive with the Allplex assay. However, these two additional positive samples could not be verified. Both Virocult and UTM medium and extraction with Maelstrom or MagLead work with Allplex assay. This validation shows that AllplexTM 2019-nCoV Assay can be used as an alternative to the routine diagnostics, mainly for the personnel samples but also as backup to existing routine diagnostics with a SARS-CoV-2 screening inhouse PCR.

Author: Paula Mölling, Molecular Biologist, Associate Professor, Clinical Microbiology, Örebro University Hospital, Sweden

Taiwan Advanced Nanotech

Kit Reference

● **Recommended:** Internally Validated kit with proven extraction efficiency on the sample type and target.

○ **Compatible:** Can be used on the sample type and target. Not internally validated - Extraction efficiency and results may differ.

Sample	Target	Blood DNA (611)	OptiPure Blood DNA (61E)	Dried Blood Spot DNA (61E-BS)	Blood RNA (621)	OptiPure cfDNA (61C)	FFPE DNA (61P)	HBV (615)	OptiPure Viral (665)	Plant DNA (613)	Plant RNA (6K3)	Tissue DNA (6T2)	Tissue RNA (6K2)	Stool DNA (6SC)	Fungi (61F)	Bacteria DNA (61G)
Blood	gDNA	●	●													
	Total RNA				●											
Buffy coat	gDNA	●	●													
	Total RNA				○											
Leukocyte	gDNA	○	●[2]													
	Total RNA				○											
Clotted, Dried blood	gDNA			●												
Plasma / Serum	Virus							●	●							
	Bacteria															○
	cfDNA					●										
Bone marrow	gDNA		●													
Body fluids	Virus		○						○							
	Virus+Bacteria		○						○							
	Bacteria		○						○							○
Cell culture supernatant	Virus								○							
	Bacteria+Virus								○							
	Bacteria								○							○
BAL, Aspirates	gDNA								●							
Liquid sample transport media	Virus								●[1]							
	Bacteria								○							○
	Bacteria+Virus								○							
Bacteria culture	Bacteria															●
Sputum	Bacteria															○
	Virus								●[1]							
Saliva	gDNA		○													
	Virus								●							
	Bacteria															○
Culture cells	gDNA											●				
	Total RNA												●			
	Bacteria															○
Solid tissue	gDNA											●				
	Total RNA												●			
	Virus											○				
	Bacteria											○				
Rodent tails	gDNA											○				
	Total RNA												○			
FFPE	gDNA						●									
Swab	gDNA		●						●							
	Bacteria															○
	Virus								●							
Stool	gDNA													●		
	Bacteria													●		
	Virus													○		
Fish	gDNA											●				
	Total RNA												●			
Yeast	gDNA														●	
Plant, Seed	gDNA									●						
	Total RNA										●					
Water	Bacteria															○

Note. 1. Comparing the yield of oropharyngeal swabs and sputum for detection of 11 common pathogens in hospitalized children with lower respiratory tract infection.
2. Interactions of COMT and ALDH2 Genetic Polymorphisms on Symptoms of Parkinson's Disease.

TANBead Forensic DNA

Sample	Blood stain	Chewing gum	Cigarette butts	Sperm	Stamps, Envelopes	Fingernails	Hair, Hair roots
gDNA	●	●	●	●	○	●	○
mitochondria DNA	●	●	●	●	○	●	●

Taiwan Advanced Nanotech Inc. 6F., No. 188, Wenhe Rd., Guishan Dist., Taoyuan City 333, Taiwan
+886-3-3167568 +886-3-3173369 success@tanbead.com www.tanbead.com

2021-07_V1.0

Certificate TW15/10220

The management system of

Taiwan Advanced Nanotech Inc.

No.2, Aly.12, Lane.81, Longshou St., Taoyuan Dist.,
Taoyuan City 330, Taiwan (R.O.C.)

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 03 March 2021 until 03 March 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 December 2023
Issue 5. Certified since 03 March 2015

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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HC SGS 13485 2016 0118 M2

Taiwan Advanced Nanotech Inc.

ISO 13485:2016
EN ISO 13485:2016

Issue 5

Detailed scope

Design and Manufacture of Nucleic Acid Extraction Kit.
Design and Manufacture of Nucleic Acid Extractor

Additional facilities

1~4F, No.8, lane 10, Sec. 2, Zhongfu Rd., Zhongli Dist., Taoyuan City 320, Taiwan (R.O.C.)

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