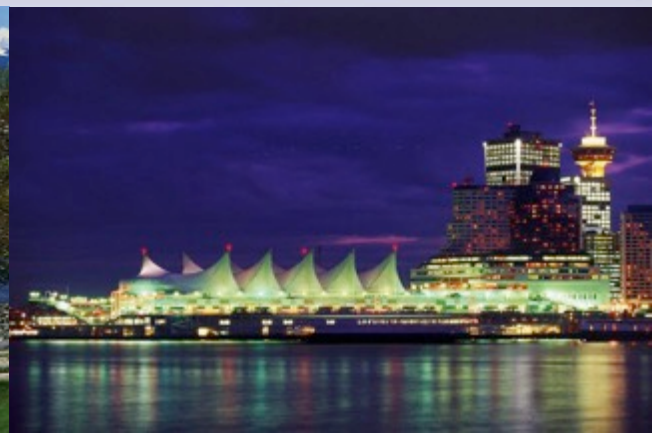
Aurora
ILLUMINATING SOLUTIONS

COVID-19 Solutions

Company overview



Aurora's Comprehensive Solutions

- Instrumentation
  - Elemental Analysis
  - Automated Liquid Handling
  - Ion Channel Screening Technology
  - OEM Solutions
- Reagent Kits and Consumables
- Contract Research Services
- Precision Medicine &Ion Channel Retreat - Conferences

Precision Medicine & ION CHANNEL RETREAT
Share Knowledge. Exchange Ideas. Establish Partnerships

Aurora
ILLUMINATING SOLUTIONS

Coronavirus Detection Solutions

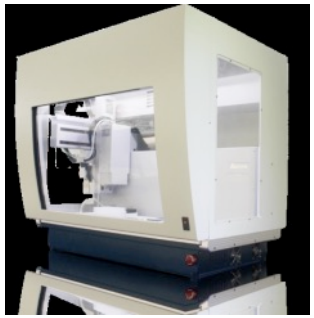
- COVID-19 Viral Detection Kits
- 200 copies per mL detection limit
- Target genes: ORF1ab and N gene
- Compatible with sputum, alveolar wash and pharyngeal swab samples
- Positive, negative and internal controls to monitor test accuracy
- CE and CFDA certified qPCR detection kits
- Currently under US FDA review
- Currently used in several countries in Europe, Asia, and Africa (including 40 health institutions in China)

- Automated Liquid Handling Workstation
- These workstations can streamline both viral RNA extraction workflows and qPCR reaction setup.
- Compatible with: VERSA 1100 Gene Workstation

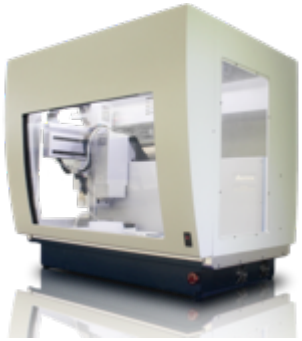
- Commercially available COVID-19 detection kits
- Aurora Biomed's AB MagPure Viral RNA Kit
- CE and CFDA certified qPCR detection kits

- Benefits :
- Reduces staff exposure risk
- Increases sample throughput
- Reduces the risk of human-introduced error
- Minimizes the risk of cross-contamination

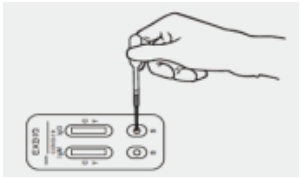
- COVID-19 Antibody-Response Rapid Test Kit
- Qualitative detection of COVID-19 IgM/IgG antibodies in human serum, plasma, or whole blood
- Rapid finger-prick test for coronavirus
- Screen patients and isolate carriers immediately
- Four simple steps with results in under 20 minutes



AB MagPure Viral RNA isolation kit



Automated Liquid Handling Workstation



AB COVID-19 Antibody-Response Rapid Test

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AB COVID-19 2-step detection Kit

AB COVID-19 2-step detection Kit

Kits supplied by Aurora: overview

- Sample source: sputum, pharyngeal swab
  - Sample Collection Kit
  - AB COVID-19 2-step detection Kit (Magnetic Bead COVID-19 Viral Isolation/COVID-19 PCR amplification kit)

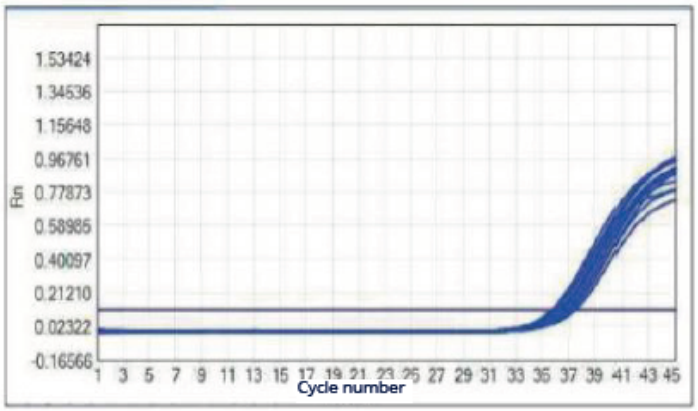
- Kits specifications:
  - Sensitivity: 200 copies per mL
  - 24 tests per kit
  - Target genes: ORF1ab and N gene
  - Positive control and an internal standard to monitor test accuracy is included with each kit

2-Step test

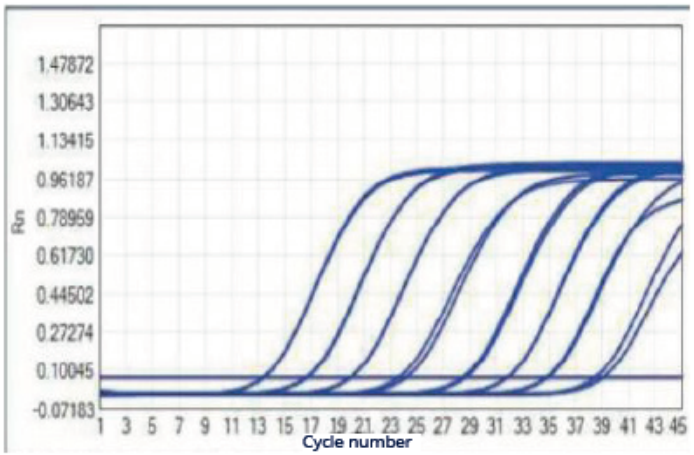
- First step: Nucleic Acid is isolated from sample in separate workflow
- Second Step: qPCR reaction is used to detect presence of Coronavirus-19
  - Isolated nucleic acid is template
- Benefits
  - High precision
  - Reduced chance of false negative (failing to detect COVID infection)
  - Removal on qPCR reaction inhibitors (leading to failure of test)
- Automation options
  - VERSA 1100 (1000 uL pump) – walk away automation
  - VERSA 1100 (NAP, 1000uL pump) + VERSA 10 PCR (250uL pump)

Sample data

- Detection limit:
  - 200 copies per mL
- Wide testing range
  - 10^2 – 10^9 copies per mL



Detection limit: 200 copies per mL



Plasmid test linear range: 10^2-10^9 copies per mL

CE IVD Certificate

Obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF IVD NOTIFICATION

Ref. No.: CMB [redacted] 2020
Order No.:CMB [redacted] 2020

BELGIUM

Date: 04/03/2020

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: [redacted] BIOTECH INC.

ADDRESS: [redacted] BIOTECH INC.
NO. [redacted] ROAD, [redacted] DISTRICT
[redacted] PEOPLE'S REPUBLIC OF CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 02/03/2020 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (3 PAGES, 10 DEVICES)

As of the 03/03/2020, and as long as the manufacturer will continue complying with the hereabove mentioned requirements" he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and/or the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

Mr. G. Elkayam CEO
Obelis sa

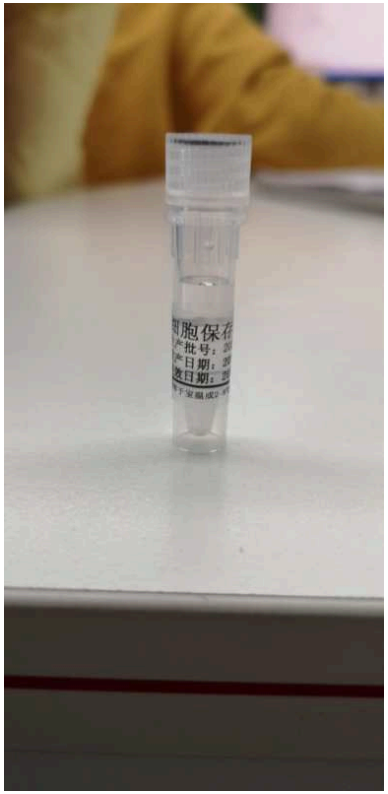
Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

Registered Address: Bd. Général Wahis 53- 1030 Brussels | Registered Office Address: Bd Brand Whitlock 10, B – 1210 Brussels- Belgium
T : + 32 (0) 2 732 5804 | F : + 32 (0) 2 732 6033 | Email: mail@obelis.net | Website: www.obelis.net
VA – ID: 0044116 – 22/03/2018

Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Coronavirus - NA Reagents	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood and feces from suspected pneumonia cases with novel coronavirus infection, patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection. For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: 2019-nCoV-PCR Mix 2019-nCoV-PCR-Enzyme Mix 2019-nCoV-PCR-Positive Control 2019-nCoV-PCR-Negative Control	15.04.40.19	Others

Kit Components – Sample Collection



Kit users in China

Province	Institutions	Province	Institutions
Hubei	Wuhan dean medical laboratory co. LTD	Hunan	The 53rd hospital of the people's liberation army of China
	Wuhan kang shengda medical laboratory co. LTD		Hunan provincial people's hospital
	PLA 990 central hospital		Hunan center for disease control and prevention
	Wuhan blood center		Xiangya hospital, central south university
	Tianyou hospital affiliated to wuhan university of science and technology		Hunan province CDC
Beijing	China CDC	Henan	Henan provincial center for disease control and prevention
	China Inspectorate		Henan provincial center for disease control and prevention
	Institute of military medicine	Jiangsu	Jiangsu center for disease control and prevention
	Beijing hospital		Jiangsu provincial people's hospital
	Peking union medical college hospital		Jiangsu center for disease control and prevention
	Beijing center for disease control and prevention	Shaanxi	Disease control in shaanxi province
	China-japan friendship hospital		Ningxia for disease control and prevention
Shanghai	Wuhan lanwei medical laboratory co. LTD	Gansu	Gansu provincial center for disease control and prevention
	Wuhan ping 'an good medical laboratory co. LTD		Gansu jinyu medical laboratory co. LTD
	Shanghai public health center	Hebei	Hebei hospital of traditional Chinese medicine
	Zhongshan hospital affiliated to fudan university	Jiangxi	Jiangxi jinyu medical laboratory co. LTD
	Shanghai jinyu medical laboratory co. LTD	Sichuan	The Chinese Academy of Sciences
Guangdong	Guangzhou jinyu medical examination center co. LTD	Shanxi	Shanxi provincial people's hospital
	Disease control in guangdong province	Guizhou	Guizhou jinyu medical examination center co. LTD
Yunnan	Gansu jinyu medical laboratory co. LTD	Tianjin	Institute of military medicine
	Disease control in yunnan province	Shandong	971 hospital of the people's liberation army of China
	First people's hospital of yunnan province	Zhejiang	Zhejiang provincial people's hospital

COVID 19 kit used in Wuhan's Hospital

COVID 19 kit used in Wuhan CDC

COVID 19 kit used in Vulcan Mountain Hospital

COVID 19 kit used in Laos

COVID 19 kit used in Ethiopia

Automated Liquid Handling System

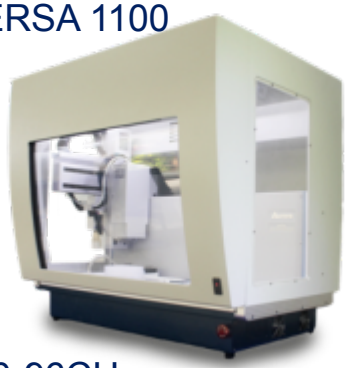
Versa Series
Automated Liquid Handling

VERSA Series and Reagents: Total Solution For Life Science/Molecular Diagnosis & Drug Discovery

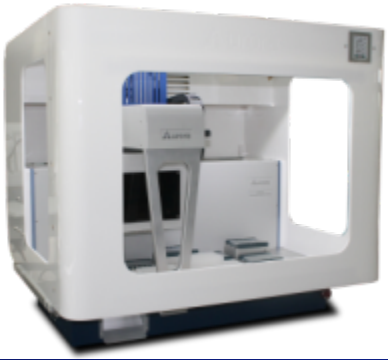
VERSA 110

VERSA 10

VERSA 1100



VERSA 1100-96CH



VERSA HT

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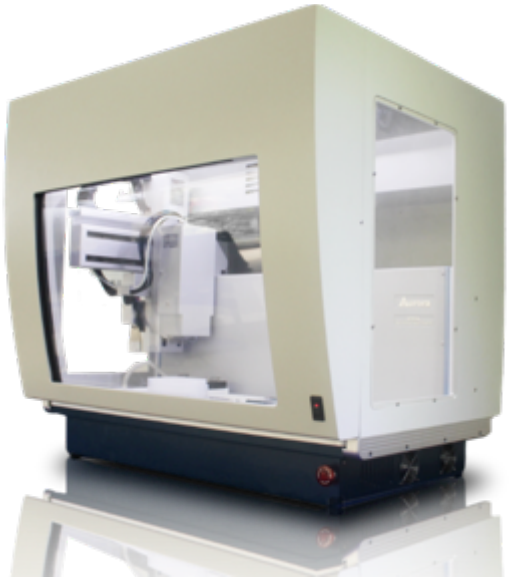
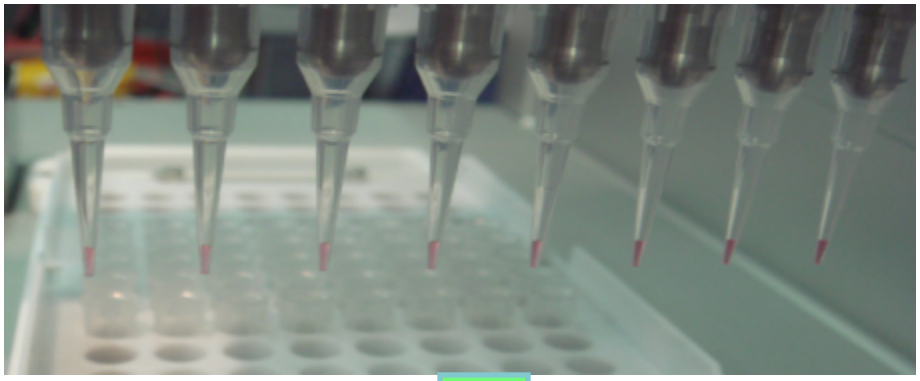
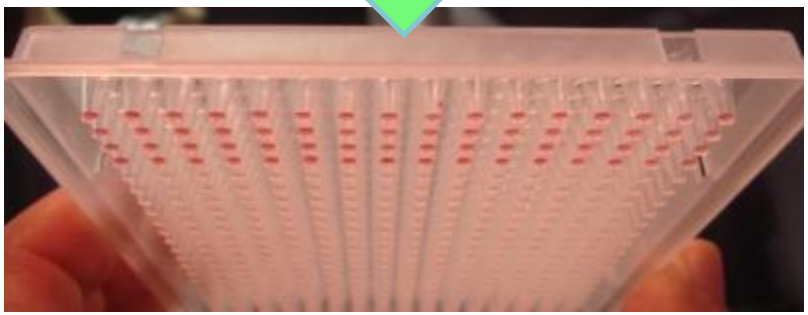
Automated COVID-19 Viral Workstation

- Higher Throughput
- Reduces chance of human error
  - e.g. mixing up samples
- Reduces risk of cross-contamination
- Reduce exposure time of laboratory staff to potentially infected samples
- Free up staff to analyze data and generate reports



Dispensing Accuracy at Low Volume





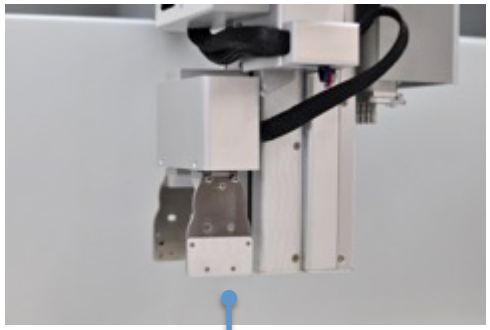
250µL syringe pipettor

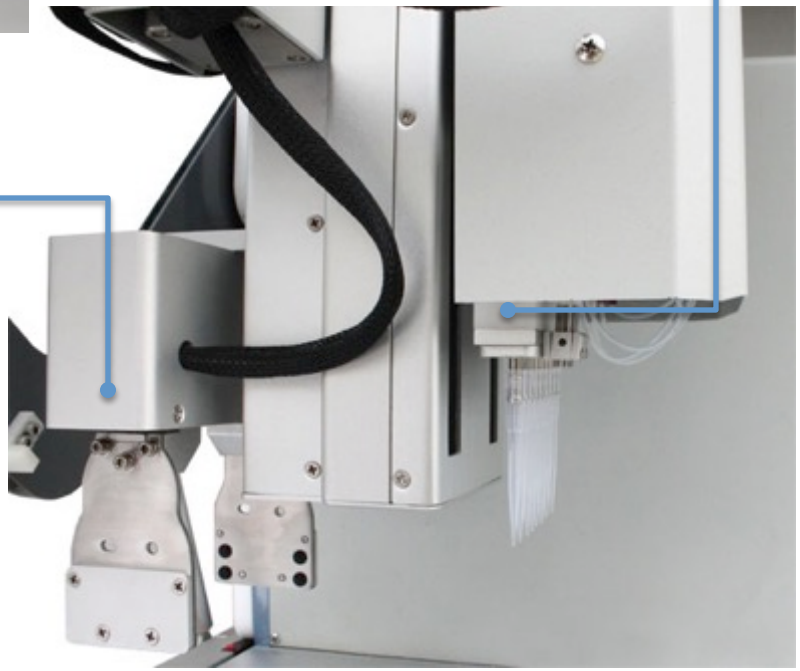
Dispensing range: **1µL - 200µL**

100µL	**CV < 0.2%**
20 µL	**CV < 0.5%**
10 µL	**CV < 2%**
1µL	**CV < 3%**

Transferring 1 µL liquid to 384-well plate

VERSA 3 in 1 Robotic Arm

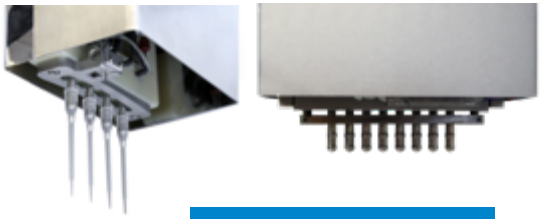




Gripper

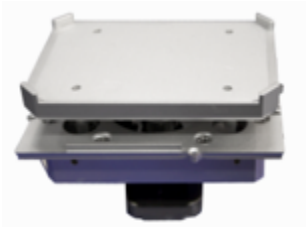
RD Channels &
4 or 8 Channel
Pipetting Head

VERSA Functional Modules



Pipetting Heads

Sample & Reagent Cooling/Heating

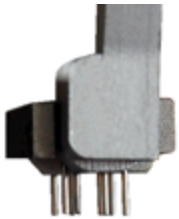


Shaker/Heater

Plate Gripper

VERSA workstations can be equipped with diverse modular accessories for optimal configuration

Aspirator



ReagentDrop

Magnetic Bead Modules

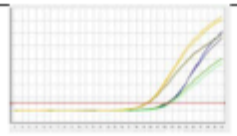
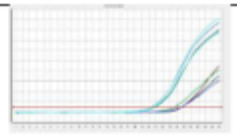
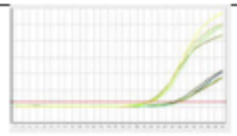
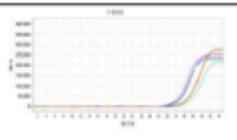
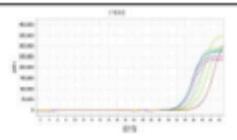
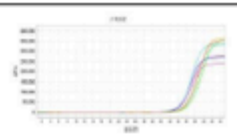
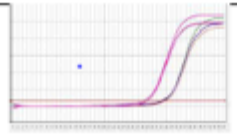
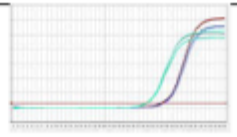
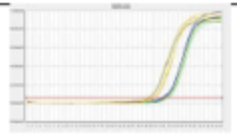
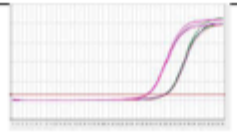
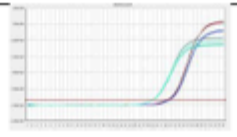
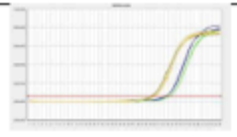
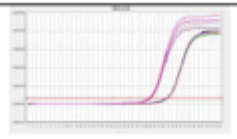
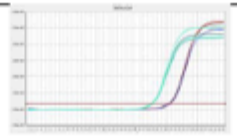
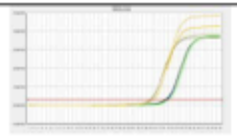
Positive Pressure Module

Nitrogen Dryer

AB Magpure COVID-19 Extraction Kit

Item NO.	CE5412	Contents
MagPure Particles MPN	5ml	Magnetic Bead/NaCl/ NaN_3
Proteinase K	100 mg	Proteinase K
Protease Dissolve Buffer	6 ml	glycerol/Tris/CaCl2
Buffer MLB	150 ml	Guanidine Salt/Isopropano/EDTA
Buffer MW1	53 ml	Guanidine Salt/Tris/EDTA
Buffer MW2	50 ml	Tris/NaCl
Buffer AVE	30 ml	10mm Tris,pH8.0

Performance Comparison between AB Magpure Isolation kit and two other brands

Virus	AB MagPure Viral RNA Isolation Kit	Company C Viral RNA Isolation Kit	Company D Viral RNA Isolation Kit
HBV			
HCV			
SARS-CoV-2 (FAM Channel)			
SARS-CoV-2 (VIC Channel)			
SARS-CoV-2 (CY5 Channel)			

Conclusion: By comparing the results from HBV, HCV and SARS-CoV-2 tests, Aurora Biomed's AB MagPure Viral RNA Isolation Kit performs better than the kits from Company A, B, C and D. Ct values are similar.

qPCR instrument requirements

qPCR instrument

- Required detection channels
  - HEX, FAM & ROX
- Compatible with
  - 0.2ml PCR tubes
  - 8-strips of 0.2ml PCR tubes
  - 96-well PCR plates

Validation data and Applications

Precision and Repeatability

No.	Medium concentration positive		Critical concentration positive		negative	
	ORF 1ab	N	ORF 1ab	N	ORF 1ab	N
Positive detection rate	100%	100%	100%	100%	0%	0%
CV（%）	2.21%	0.22 %	/	/	/	/

Table Ct value statistics of inter-batch unprecision detection results (sample 2)

No.	Medium concentration positive		Critical concentration positive		negative	
	ORF 1ab	N	ORF 1ab	N	ORF 1ab	N
Positive detection rate	100%	100%	100%	100 %	0%	0%
CV（%）	1.42%	1.57%	/	/	/	/

Table Ct value statistics of inter-batch unprecision detection results (sample 3)

No.	Medium concentration positive		Critical concentration positive		negative	
	ORF 1ab	N	ORF 1ab	N	ORF 1ab	N
Positive detection rate	100%	100%	100%	100%	0%	0%
CV（%）	1.57%	1.46%	/	/	/	/

Medium Concentration - 4.0E4 copies/mL
Critical Concentration - 4.0E2 copies/mL

The experiment was conducted in 3 batches - the range of Ct CV detected in these batches and between batches was less than 5%.

Therefore, it can be considered that this kit has good testing repeatability and precision both in and between batches.

Verification of minimum detection limit

Seven clinical samples of 2019-ncov from different sources were diluted to 2.0E2 copies/mL, and three batches of reagents were used for detection. Each sample was tested for 20 times.

Conclusion: as can be seen from the above results, 9 samples of nucleic acid from different sources were diluted to 2.0E2 copies/mL, and the positive detection rate of two target genes of the three batches of reagents was above 95%, so 2.0E2 copies/mL could be used as the minimum detection limit of this kit.

Repeatability

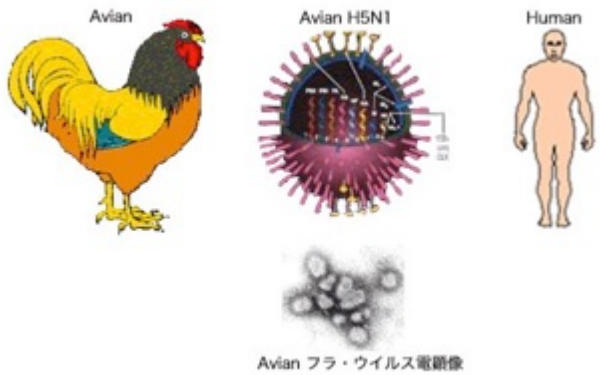
Twelve nucleic acids from different sources of 2019-nCoV clinical samples were added to the negative samples for simulation and diluted to 4.0E3 copies/mL, three batches of reagents were used for detection. Each sample was repeatedly detected for 10 times, and CV% of Ct value was calculated.

Conclusion: as can be seen from the above results, 12 samples from different sources were diluted to 4.0E3 copies/mL, and the Ct CV% of the two target genes of the three batches of reagents was less than 5%, indicating that the detection repeatability of this kit was good.

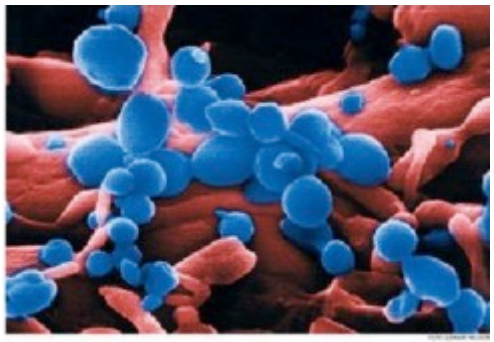
VERSA Applications – Disease Control

- Major Application Sections

- Disease Control
  - Detection of Avian Flu (H5N1 Virus)
  - Detection of HIV, Hepatitis, etc
  - Detection of bacteria and other organisms that may pollute air, water, soil and food

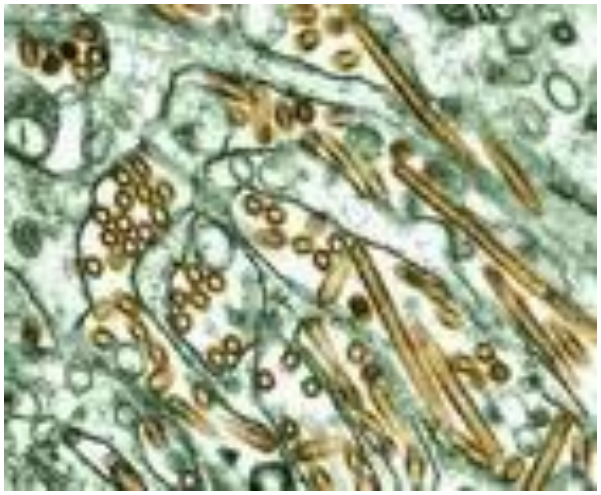


H5N1 Detection

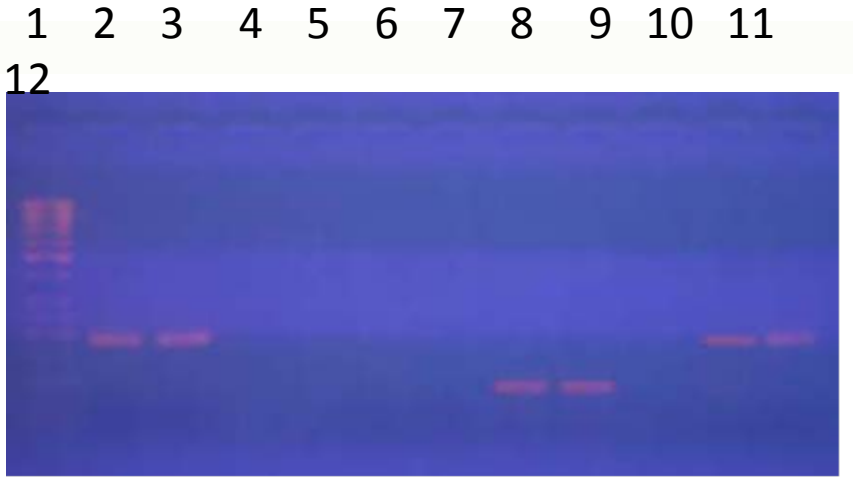


Avian Influenza

- As an example: The USDA has set up a network of labs to monitor migratory birds for the spread of avian influenza and Aurora is working with the Utah Veterinary Diagnostic Laboratory to adopt our VERSA mini PCR workstation to automate the screening procedure. The plan is to standardize the methodology for the 40+ labs involved in the National program

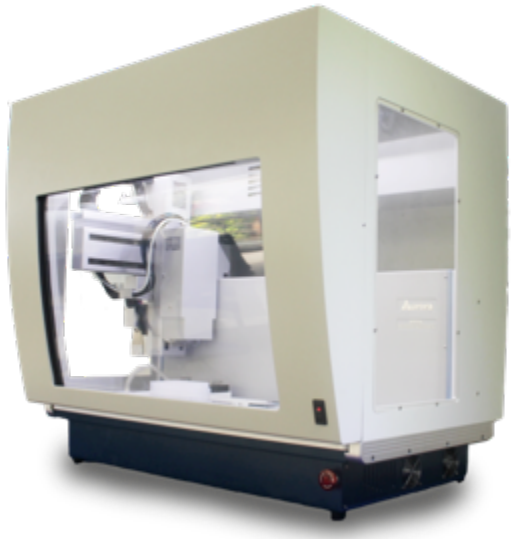


Avian Influenza Virus(H5N1)



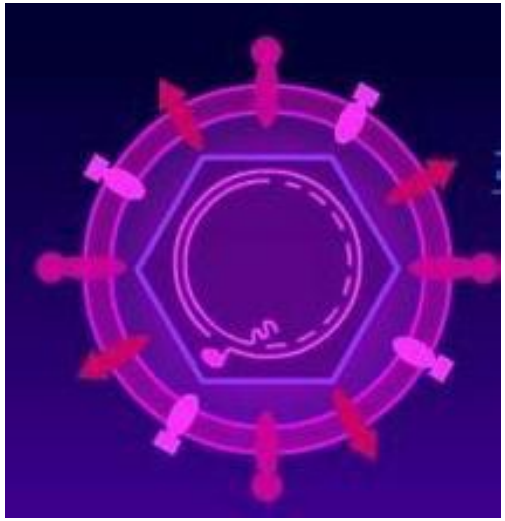
Agarose (3%) Gel, lane # 1 (DNA Ladder, 50bp-1 kb), lane 2-3 (Influenza type A amplicon 191bp), lane 4-5 (Negative control for A), lane 6-7 (Negative control for N1), lane 8-9 (N1 amplicon, 107bp), lane 10 (Negative control for H5), and lane 11-12 (H5 amplicon, 192bp).

DNA extraction of African swine fever virus from Zaozhuang Animal Husbandry Bureau



Hepatitis B Virus (HBV)

Hepatitis B is a disease caused by hepatitis B virus (HBV), which is mainly caused by liver disease, and can cause multiple organ damage. Hepatitis B is widely popular in the world, mainly in children and young adults, a small number of patients can be converted to liver cirrhosis or liver cancer. As a result, it has become a serious threat to human health, and is also the most popular and most serious disease in our country. Hepatitis B has not a certain epidemic period, all the four seasons can be onset, but is always sporadic. In recent years, the incidence of hepatitis B increased significantly.



Hepatitis B Virus (HBV) detection method

Specific serum etiological tests including HBsAg, anti-HBs, HBeAg, anti-HBe, anti-HBc, anti-HBcIgM, or HBV-DNADNA-p, Pre-S1, Pre-S2 etc. if eligible. *in situ* hybridization was used to detect intrahepatic HBV-DNA.

1-step Infectious disease Workflow automation

Life Science

by Sikander Gill, Li Wenji, Fan Xu, Rajwant Gill, He Bin, Nick Bandy and Dong Liang

Automation of a One-Step, Real-Time PCR-Based DNA Quantitative Kit for the Diagnosis of HBV

Automation of one-tube or one-step real-time PCR-based molecular diagnostics has distinct advantages for sample processing in preparative work. It saves time and effort, improves processing capacity, eliminates human error and ensures batch consistency of reagents and samples in the detection and diagnostic process of clinical samples. The VERSA 10 workstation (Aurora Biomed, Inc., Vancouver, B.C.) was validated for automated use for a Hepatitis B viral (HBV) DNA quantitative fluorescent diagnostic kit (Sansure Biotech, Changsha, Hunan, China).

Results show that the automated operation

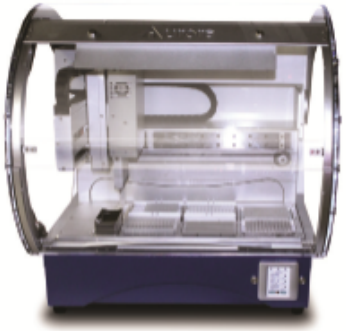
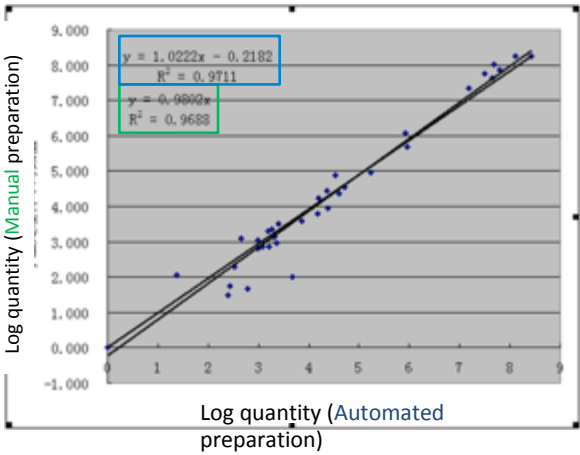


Figure 1 – VERSA 10 workstation with HEPA/UV enclosure.

Figure 2 – Hepatitis B viral DNA quantitative fluorescent diagnostic kit.



Comparison of **VERSA 10 data** and manual data

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Sensitivity Tests

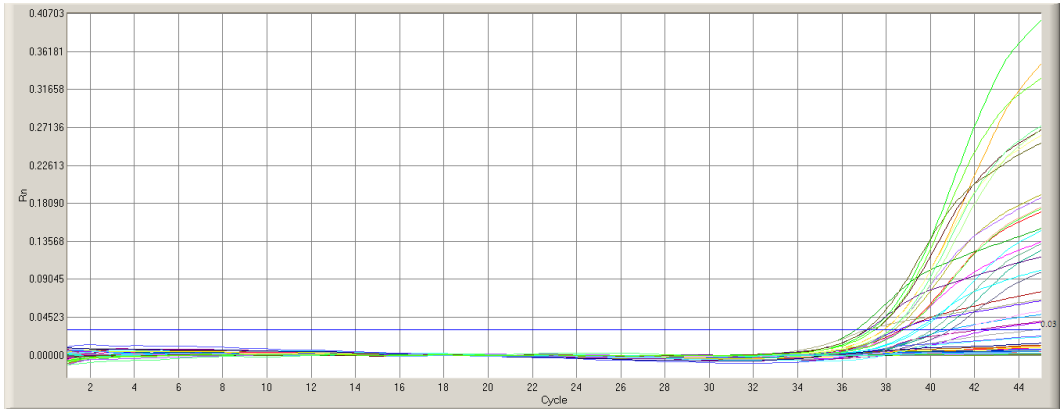


Figure1 Manual preparation

Take the target value of 1.96 1.96 e+05 IU/ml of hepatitis B sample, diluted to 1.96 e+02 IU/ml, for low concentration samples used in the experiment.

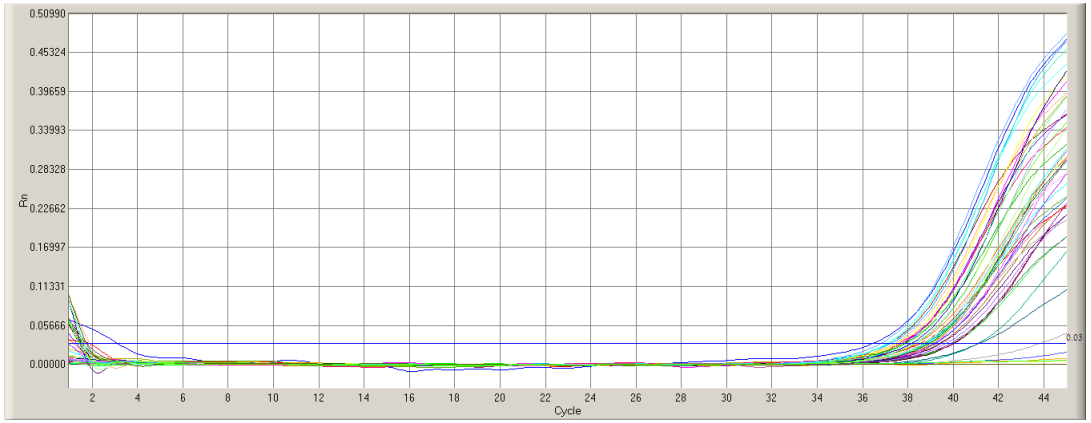


Figure2 VERSA automation

From figure 1 and figure 2 amplification curves,
VERSA10 can meet the performance requirements of the kit when dealing with low concentration samples and even produce better results than manual operation, fully meet the requirements of automation test application.

Cross contamination tests

	1	2	3	4	5	6
A	H	NTC	H	NTC	H	NTC
B	NTC	H	NTC	H	NTC	H
C	H	NTC	H	NTC	H	NTC
D	NTC	H	NTC	H	NTC	H
E	H	NTC	H	NTC	H	NTC
F	NTC	H	NTC	H	NTC	H
G	H	NTC	H	NTC	H	NTC
H	NTC	H	NTC	H	NTC	H

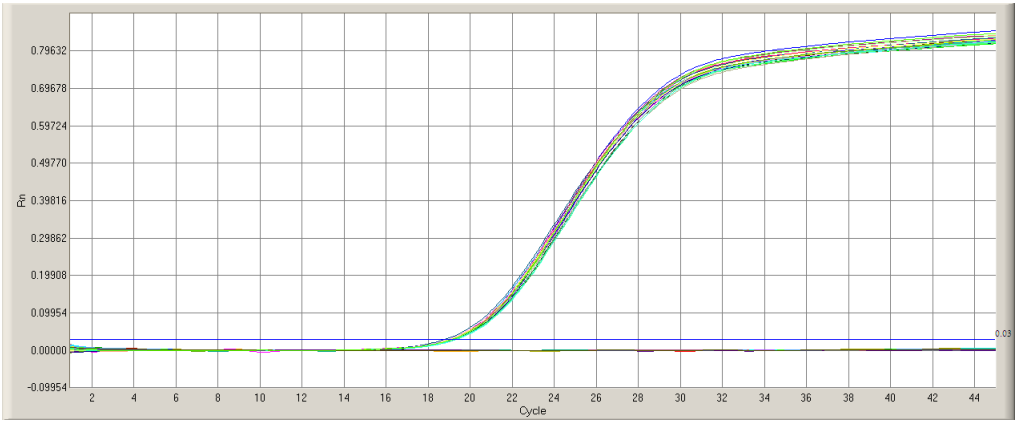
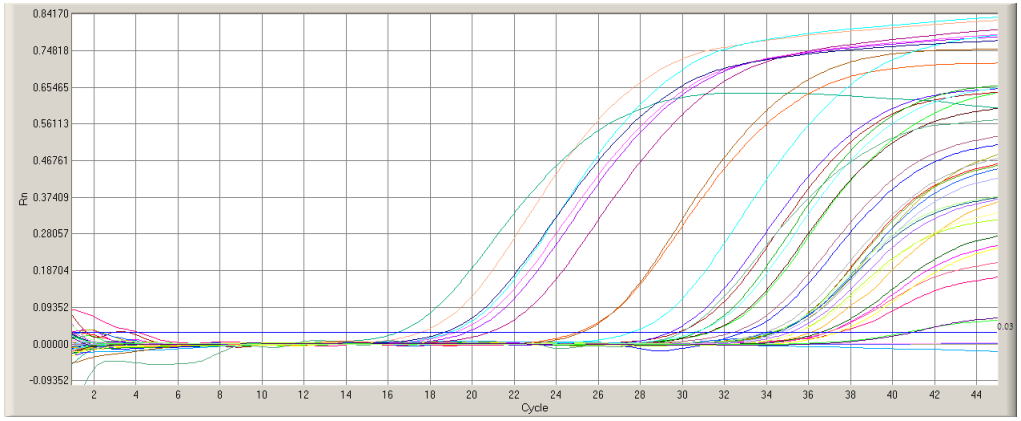


Figure 3 VERSA10 cross-contamination sample amplification curve

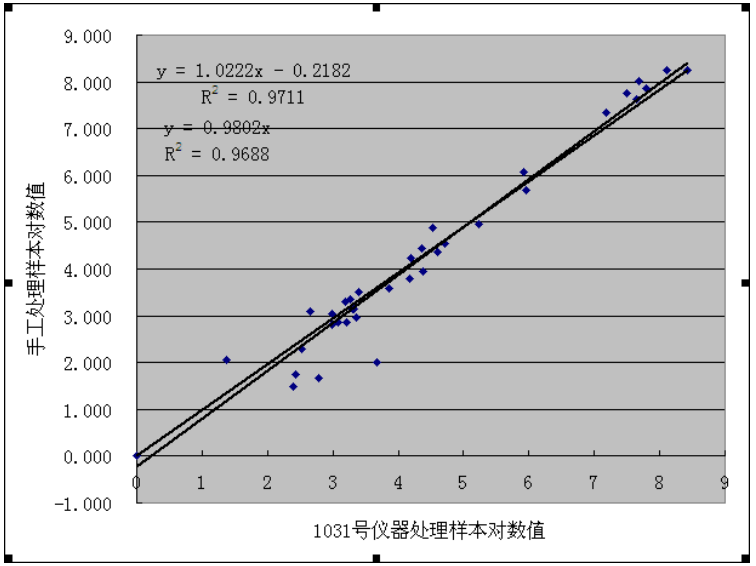
From the results figure 3 amplification curve, VERSA10 can effectively avoid cross-contamination, and high concentration sample reproducibility is very good.

Results of Clinical Samples



Amplification curve of Clinical samples by **VERSA 10**

Versa data and manual data are similar. However, for low concentration samples, Versa data is better.



The relationship between **VERSA 10 data** and Manual data

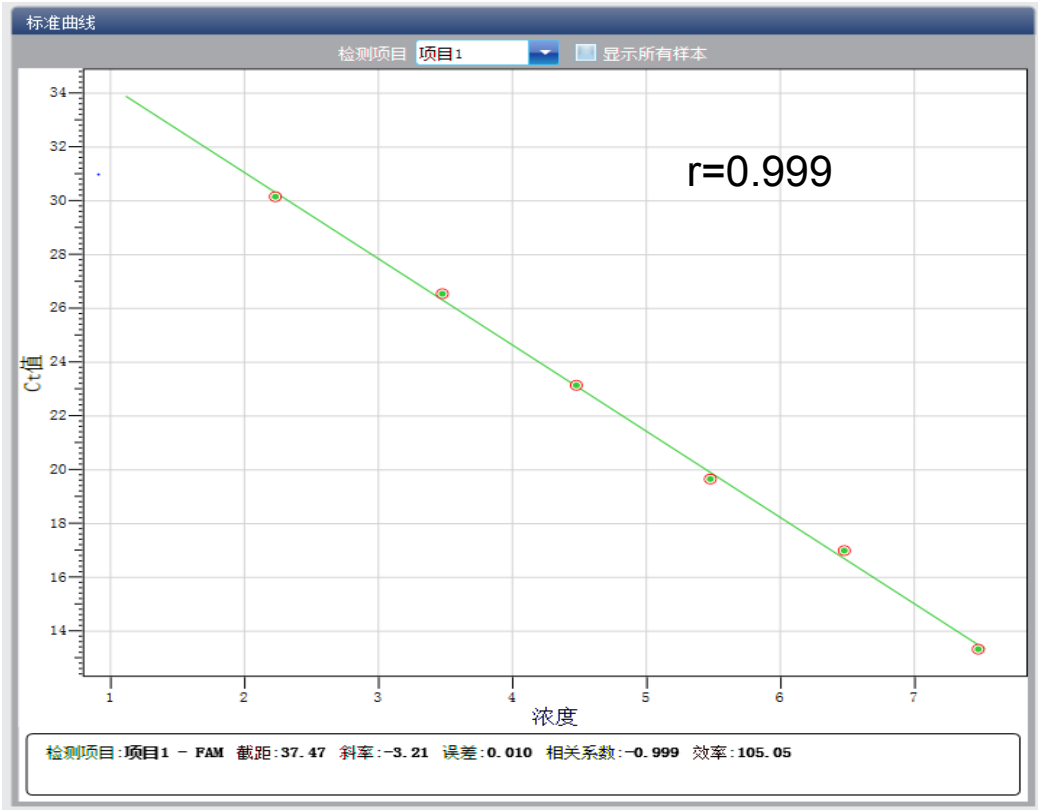
VERSA 10 Automation of HBV Testing

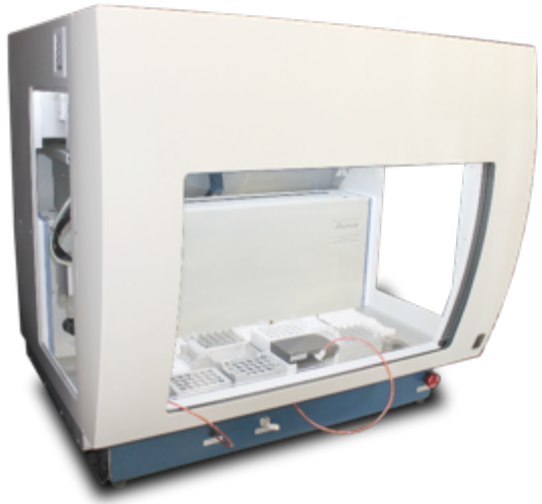
北京地坛医院
BEIJING DITAN HOSPITAL

Beijing Ditan Hospital is formerly known as Beijing NO.1 Infectious Diseases Hospital, which is Beijing Municipal Center for Infectious Disease Virus Prevention, affiliated hospitals of Beijing Municipal Health Bureau. It has extensive experiences on various liver diseases, A, B, C, D, E all types of acute and chronic hepatitis. What's more, it comes top in the fields on the treatment of severe hepatitis, chronic hepatitis, cirrhosis, liver cirrhosis and hepatorenal syndrome and other severe liver disease in China.

HBV Test Result Analysis

1. Calibration Curve



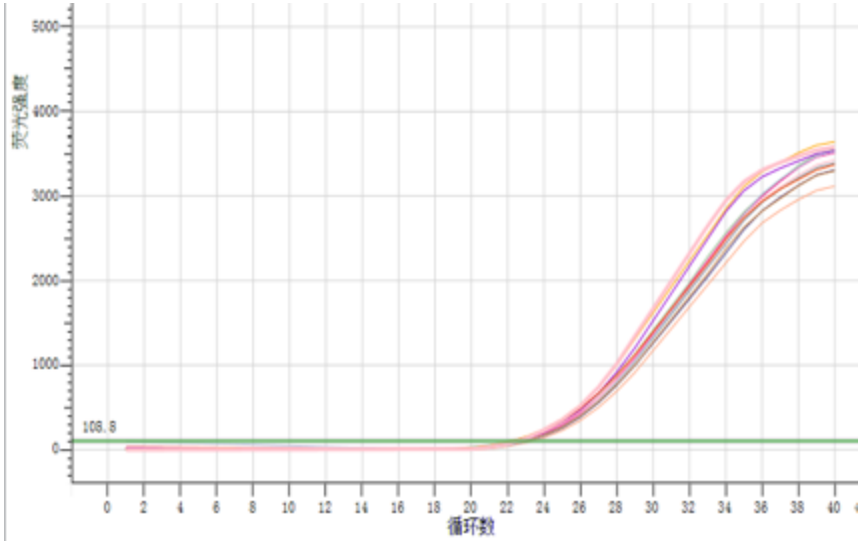


VERSA 1100 4-Channel

r=0.999,
PCR CV values of less than 3%

HBV Test result analysis

3. HBV low concentration sample (E3) amplification curve



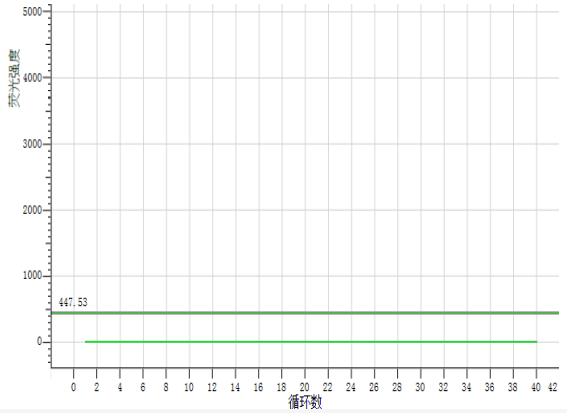
Statistical analysis of Ct value
(12 samples) **CV 1.6%**

Sample	Dye	Ct	SD	Ave.Ct	CV.Ct	Concentration
A0(1/10^4)	FAM	22.4	0.37	22.88		5.23E+03
A0(1/10^4)	FAM	23.25	0.37	22.88		3.43E+03
A0(1/10^4)	FAM	22.96	0.37	22.88		5.00E+03
A0(1/10^4)	FAM	22.9	0.37	22.88		4.25E+03
A0(1/10^4)	FAM	22.61	0.37	22.88		4.60E+03
A0(1/10^4)	FAM	23.53	0.37	22.88		2.79E+03
A0(1/10^4)	FAM	23.18	0.37	22.88	1.60%	3.71E+03
A0(1/10^4)	FAM	23.13	0.37	22.88		3.72E+03
A0(1/10^4)	FAM	22.34	0.37	22.88		6.33E+03
A0(1/10^4)	FAM	22.51	0.37	22.88		5.44E+03
A0(1/10^4)	FAM	23.06	0.37	22.88		3.66E+03
A0(1/10^4)	FAM	22.74	0.37	22.88		5.99E+03

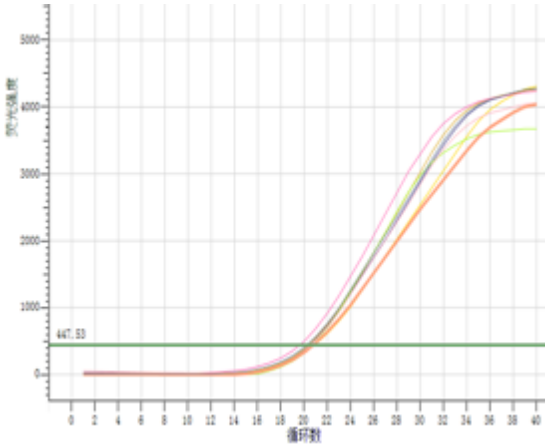
HBV Cross-Contamination Test

Statistical analysis of Ct value
8 samples (E5) **CV 1.9%**

Sample	Dye	Ct	SD	Ave.Ct	CV.Ct	Concentration
A0(1/100)	FAM	20.51	20.52	0.4	1.94%	2.38E+05
A0(1/100)	FAM	20.94	20.52	0.4		1.80E+05
A0(1/100)	FAM	20.45	20.52	0.4		2.49E+05
A0(1/100)	FAM	20.8	20.52	0.4		1.89E+05
A0(1/100)	FAM	19.7	20.52	0.4		4.33E+05
A0(1/100)	FAM	20.63	20.52	0.4		2.17E+05
A0(1/100)	FAM	20.86	20.52	0.4		1.86E+05
A0(1/100)	FAM	20.29	20.52	0.4		2.84E+05



Amplification curves of 8 negative samples



Amplification curves of 8 positive samples

- Negative samples produce no amplification curve, indicating no cross contamination.
- CV value of positive samples is 1.94%, indicating the good reproducibility

Compatible to Any Thermocyclers

Rotor-Gene Rings

RocheTM
Light Cycler Carousel

micropcr

A new way to look at Real Time PCR

COVID-19 IgM/IgG Antibody Rapid Test Kit

- Sample source: human serum, plasma, or whole blood
- Detection upon onset of Symptoms – Day 0 – Day 14

- Kits specifications:
  - Sample Volume – 50uL of Whole blood/peripheral blood or 20uL serum/plasma
  - 10 tests per kit
  - Target antibodies: Specific IgM and IgG antibodies
  - Time Detection – 15-20 minutes
  - No cross reaction

COVID-19 IgM/IgG Antibody Rapid Test Kit

- Sample Volume: 50µL whole or peripheral blood or 20µL Serum and Plasma
- Detection Time: 10 – 15 minutes
- Separate Reaction: no cross-reaction
- Suitable for Point of Care Testing. No need for extra equipment.

Protocol Description

To stimulate blood flow, massage the finger tip from which blood will be collected.

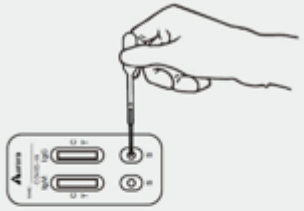
Wipe the finger tip with cotton alcohol towlet and let it dry naturally

Prick ventral side finger tip with the supplied disposable needle

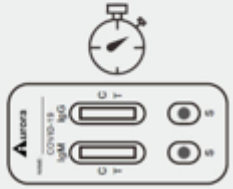
Wipe off the first drop of blood with a sterile dry cotton ball

Use a dropper to suck up about 50 µL of blood

Add 50µl of whole blood to the supplied Sample Diluent tube and mix thoroughly

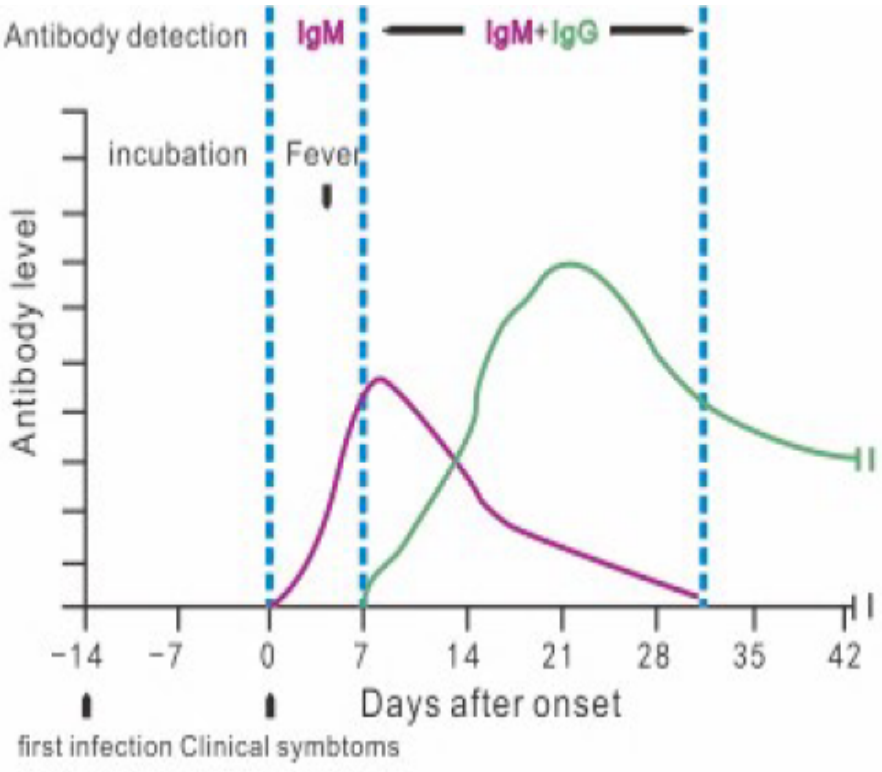


Place 4 drops diluted sample into each of the two sample holes (S) in the test casstte



Leave test casstte at room temperature for 10 minutes to observe the results.

Principle

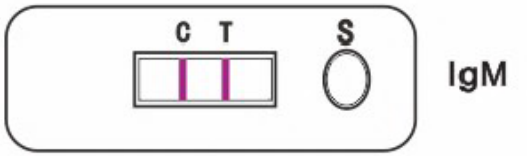


- IgM and IgG expressed with response to exposure to COVID-19
- Peaks during acute or recovery phase
- IgM peaks from day 7 to 14
- IgM + IgG peaks from days 14 to 21

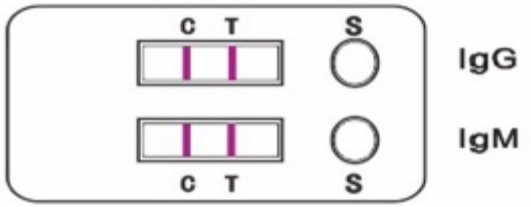
- Based on the capture immunoassay
- Antibodies binds to antigen- dye conjugate in the test region (T), which produces a colored test band that indicates a positive result.

Interpretation of the Results

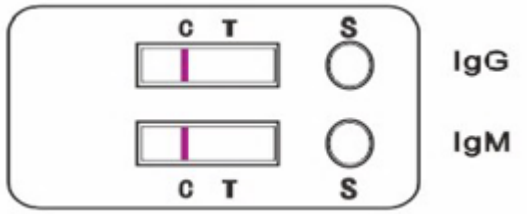
Coloured line in (T) region indicates **positive** for SARS-CoV-2 Specific IgG antibodies



Coloured line in (T) region indicates **positive** for SARS-CoV-2 Specific IgM antibodies



Coloured line in (T) region indicates **positive** for SARS-CoV-2 Specific IgG antibodies and IgM antibodies



No coloured line in (T) region indicates **negaetive** for SARS-CoV-2 Specific IgG antibodies and IgM antibodies

Validation

IgM and IgG test Results

Table 1. (IgM + IgG) test results of 58 early positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	49	0	49
Negative (-)	9	0	9
Total	58	0	58

Table 2. (IgM + IgG) test results of 45 middle and late positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	44	0	44
Negative (-)	1	0	1
Total	45	0	45

IgM test Results

Table 3. IgM test results of 58 early positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	49	0	49
Negative (-)	9	0	9
Total	58	0	58

Table 4. IgM test results of 45 middle and late positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	44	0	44
Negative (-)	1	0	1
Total	45	0	45

IgG test Results

Table 5. IgG test results of 58 early positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	19	0	19
Negative (-)	39	0	39
Total	58	0	58

Table 6 . IgG test results of 45 middle and late positive samples

Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	42	0	42
Negative (-)	3	0	3
Total	45	0	45

IgM and IgG (Negative samples) Results

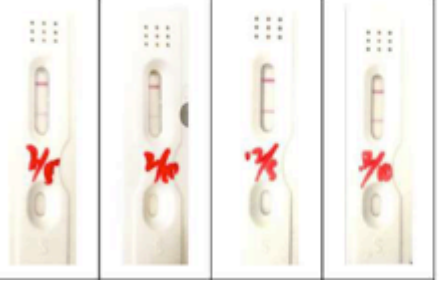
Table 7. (IgM + IgG) test results of 100 negative samples

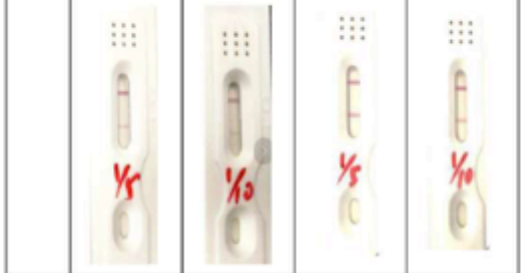
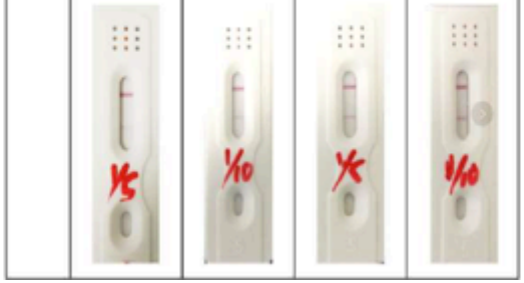
Assessment reagent	Control group		Total
	Positive (+)	Negative (-)	
Positive (+)	0	0	0
Negative (-)	0	100	100
Total	0	100	100

There were 103 positive samples and 100 negative samples tested.

- Positive Coincidence Rate is 90.29%,
- Negative Coincidence Rate is 100.00%,
- Total coincidence rate is 92.18%.

COVID-19 IgM Antibody Validation

Sample	Test Group			
	5x Dilution C	10x Dilution D	5x Diluted E	10x Diluted F
A1	Chemiluminescence Data 1.227		Negative	
				
A2	Chemiluminescence Data 9.69		Positive	
				

Sample	Test Group			
	5x Dilution C	10x Dilution D	5x Diluted E	10x Diluted F
A3	Chemiluminescence Data 16.03		Positive	
				
A4	Chemiluminescence Data 8.11		Positive	
				

Sample	Test Group			
	5x Dilution C	10x Dilution D	5x Diluted E	10x Diluted F
A6	Chemiluminescence Data 0.337		Negative	
				
A7	Chemiluminescence Data 0.718		Negative	
				

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COVID-19 IgG Antibody Validation

Sample	Test Group			
	5x Dilution C	10x Dilution D	5x Diluted E	10x Diluted F
	IgM 8.11 (+) IgG>30(+) Chemiluminescence			
				
	IgM 0.114 (-) IgG>30(+) Chemiluminescence			
				

Sample	Test Group			
	5x Dilution C	10x Dilution D	5x Diluted E	10x Diluted F
	IgM 0.337 (-) IgG>30(+) Chemiluminescence			
				
	IgM 0.716 (-) IgG>30(+) Chemiluminescence			
				

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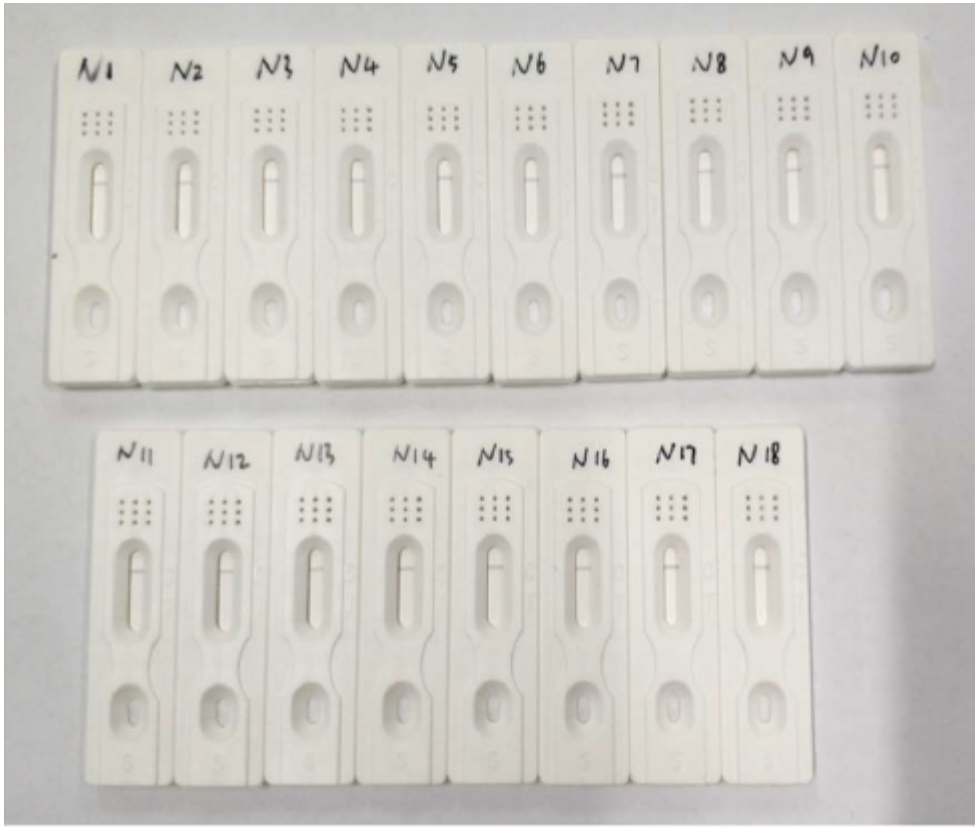
False Negative Results

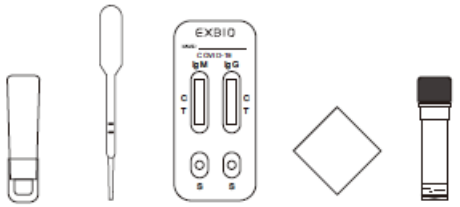


Advantages

- timesaver during the pandemic
- cost-efficient
- Qualitative rapid finger-prick test for COVID-19
- Identify COVID-19 infection before symptoms appear
- Screen workforce and isolate carriers immediately

Kit Details

KIT COMPONENTS



Component	Quantity
COVID-19 IgM/IgG AntibodyTest strip	10
Sample diluent tube	10
Dropper	10
Blood taking needle	10
Alcohol pad	10
Manual	1

Quality Certification

CERTIFICATE OF REGISTRATION

This is to certify that

Aurora Instruments Ltd. and Aurora Biomed Inc. (Aurora Group)

1001 East Pender Street, Vancouver, British Columbia V6A 1W2 Canada

operates a

Quality Management System

which complies with the requirements of

ISO 9001:2008

for the following scope of registration

The registration covers the Quality Management System for the manufacture and distribution of spectrometer equipment, automated liquid handling workstation, accessories and OEM equipment and all instrument servicing performed by AURORA group.

Certificate No.:	CERT-0059231	Original Certification Date:	December 2, 2011
File No.:	800032	Current Certification Date:	December 2, 2011
Issue Date:	December 5, 2011	Certificate Expiry Date:	December 1, 2014

Chris Jouppi
President,
QMI-SAI Canada Limited

Alex Ezrakhovich
General Manager,
SAI Global Certification Services Pty Ltd

ISO 9001

SAI GLOBAL

EBO

Certificate of Conformity

NO.: CE11-IVD110045

The following product has been tested by us with the listed standards and found in conformity with the European directive 98/79/EC, EMC 2004/108/EC and LVD 2006/95/EC. It is possible to use CE marking to demonstrate the conformity with the IVD, EMC and LVD Directive

Applicant:	Aurora Biomed Inc.
Address:	1001E, Pender Street, Vancouver BC, Canada
Manufacturer:	Aurora Biomed Inc.
Address:	1001E, Pender Street, Vancouver BC, Canada
EUT:	Automated Liquid Handling
Brand Name:	Versa
M/N:	1100, 110, 10

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards: EN 61326-1:2006
EN 61326-2-6:2006
EN 61010-1:2010
EN 61010-2-101:2002

Kevin Yi
Laboratory Manager

Date: November 14, 2011

The test report was carried out from submitted type samples of a product in conformity with the specification of the respective standards. The certificate holder has the right to fix the CE-mark for IVD, EMC and LVD directive on the product complying with the inspection samples.

Shenzhen EBO Technology Co., Ltd.
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Service Center in China

Our China Service Center is conveniently located in Daliang, Shunde, Guangdong, half hour drive from Guangzhou city.

GIBH-Aurora Joint Life Science Lab

VERSA for Avian Flu Detection

Dr. Dong Liang (Aurora CEO)
Visiting PI at the Chinese Academy of Science

SCIENCE FEATURE

CAPITALIZING ON CHINA-BASED RESEARCH AND DEVELOPMENT

MICHELE ARDUENGO, PH.D., PROMEGA CORPORATION

Here we profile the Guangzhou Institute of Biomedicine and Health (GIBH), which was created to improve public health by promoting technology-driven innovation and international collaboration in biomedical research. GIBH is designed to be a "translational highway from bench to clinic", focusing on the early stages of pharmaceutical discovery and development and partnering with other entities to bring lab discoveries to the clinic.

An Urgent Call to Action

The first major infectious disease of the 21st century arose in February 2003. Originally identified as an "atypical pneumonia", it originated in Guangdong Province, China. In March 2003, the disease was renamed Severe Acute Respiratory Syndrome or SARS (1). Although SARS claimed 812 lives, unprecedented international cooperation enabled containment of SARS in less than four months.

SARS illustrated the importance of international cooperation and responsive research efforts in containing newly emerging infectious diseases. Furthermore, scientists and officials in the Peoples Republic of China realized that China needed to become an integral part of these international efforts. This involvement would require creating modern facilities for handling dangerous disease agents, building state-of-the-art laboratories, and producing well trained scientists to contribute to the continued improvement of human health (2). The Chinese Academy of Sciences and the governments of Guangdong Province and its capital city, Guangzhou, organized to raise the equivalent of 36 million U.S. dollars to establish the Ghangzhou Institute of Biomedicine and Health (GIBH) to serve as a base of international cooperation in health research.

The Guangzhou Institute of Biomedicine and Health (GIBH)

GIBH is charged with taking disease-focused research discoveries from the lab bench directly to the improvement of human health and social wealth worldwide. According to Dr. Ling Chen, Director General of GIBH, his job comes with huge responsibility, and he states that he is continually mindful of his responsibility to the Chinese taxpayer. He also recognizes the opportunity that GIBH has to contribute to human health beyond China through collaborations with public and private research efforts around the world.

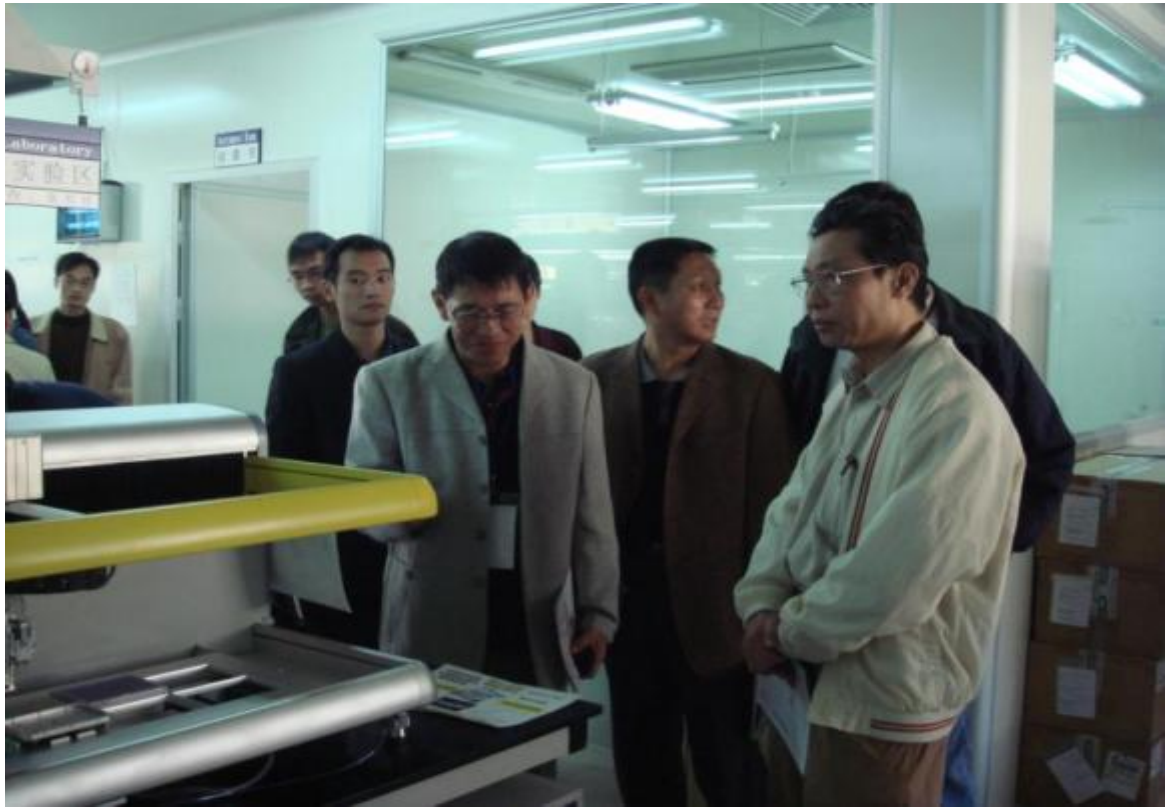
The work at GIBH will focus on the early stages of drug discovery, elucidating disease mechanisms, validating targets for new therapeutics and identifying lead compounds. GIBH hopes to partner with international biotechnology and pharmaceutical companies to take these lead compounds into preclinical and clinical studies. Currently the center is working in four disease-focused research areas. In the area

The Guangzhou Institute of Biomedicine and Health in Guangdong Province. GIBH is located in the city of Guangzhou (formerly known as Canton) in Guangdong Province of southern China. Guangzhou is a city of 10 million people and will be home to the 2010 Asia Games.

of infectious disease, the center is working on an adenovirus vaccine for HIV. They are also investigating influenza, hepatitis and SARS. In the area of cancer, they are investigating kinase targets and small-molecule kinase inhibitors that have therapeutic potential. GIBH is investigating natural product drugs for the treatment of metabolic (obesity, diabetes) and cardiovascular (thrombosis, atherosclerosis) diseases.

Aurora
ILLUMINATING SOLUTIONS

State Key Laboratory of Respiratory Disease



State Key Laboratory of Respiratory Disease - **Dr. Nanshan Zhong**

Aurora's CEO Dr. Dong Liang and the VERSA Gene liquid handler were recognized by Dr. Nanshan Zhong.
Dr. Zhong has earned international fame for managing the SARS outbreak in 2003 and the COVID-19 pandemic in 2020 in China.

Corporate Culture

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