Extraction Free Portable COVID-19 RT-PCR Detection Solutions

MicroBioDx
MOLECULAR LAB SERVICES
Phone: 800-848-7240

Less than 90 minutes from sample to result
up to 16 sample a time

A New COVID-19 detection solution

RNA Extraction Free！ ！ ！

01

Sample Collection

Collect swab sample in VTM

02

Release viral RNA

Vortex or shake for 2 minutes

03

Transfer to PCR Tube

Pipette 17 uL VTM into 8 uL PCRmastermix
Make 25 uL PCR reaction mix

04

PCR Detection

Load the reaction mix onto Fast-16 real time PCR instrument, start experiment run. Complete the PCR thermal cycling, read the results.

Sample Collection

1-2 min

PCR Detection

55 min Fast Protocol
80 min Standard Protocol

Results

The new generation PCR technology

Accuracy And Safety

sensitivity

97.9%

Manufacturing Capacity

100,000 tests/day

sample

Detection limit

1000 copies/mL (Standard protocol)

1500 copies/mL (Fast protocol)

Sample volume

up to 17uL

specificity

95.7%

3 Gene

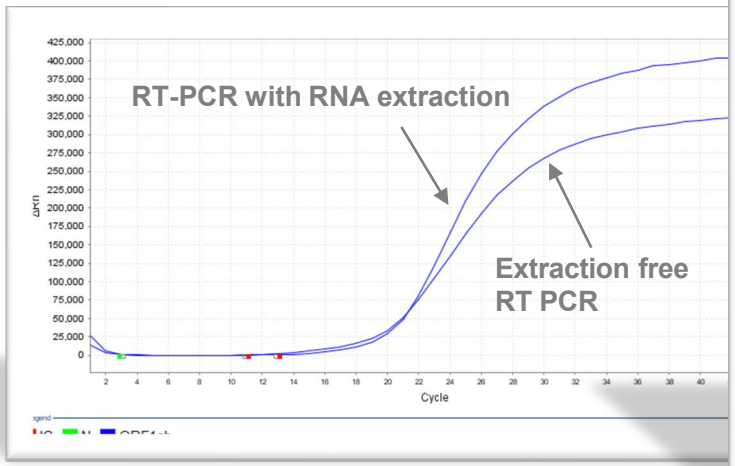
3 Gene Detected

ORF1ab(FAM)

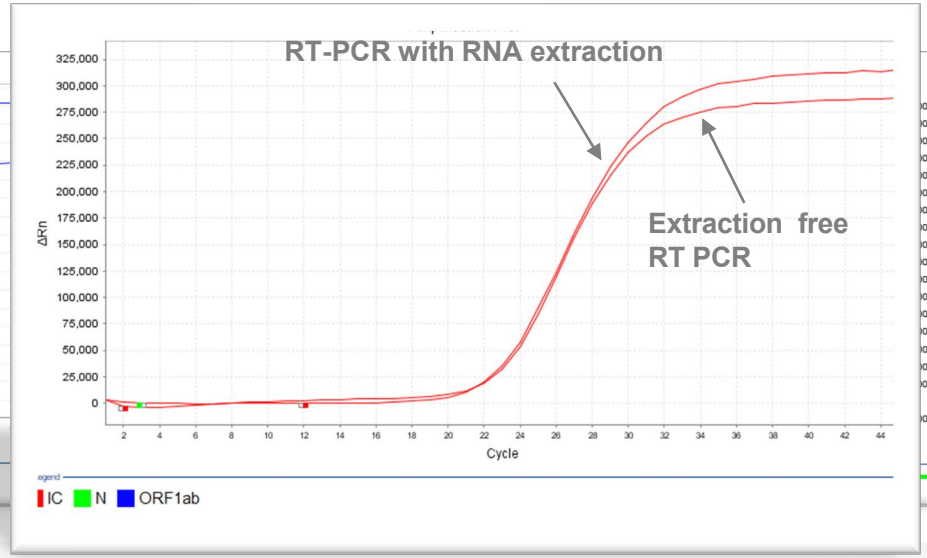
N gene (HEX)

Reference gene(Cy5)

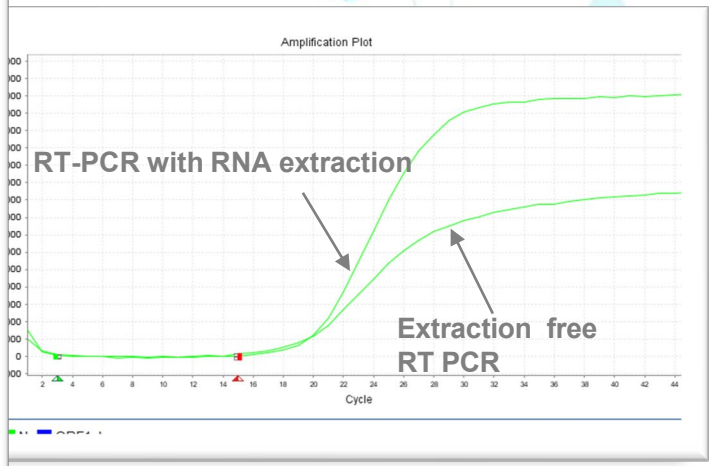
FAM channel
ORF1ab gene



Cy5 channel
Internal control gene



HEX channel
N gene



Faster, Lower Cost
Same Performance

01

Same Ct value

The Extraction free 1 step RT-PCR detection kit generates same Ct value as regular RT-PCR detection kit with RNA extraction step.

02

Viral RNA released completely

Without additional RNA extraction step and instrumentation, releasing agent is able to release viral RNA completely and generate results comparable with regular RNA extraction required RT-PCR reaction.

Portable Instrument Size

Adapt to Mobile or On-board Testing Environment

- ✓ Small footprint PCR instruments for high throughput or portable market needs.
- ✓ Portable "shoe box size" PCR instrument process 16 samples per run.
- ✓ Minimal hands on time, only simple vortex and pipetting required.
- ✓ Gold Standard RT-PCR Technology

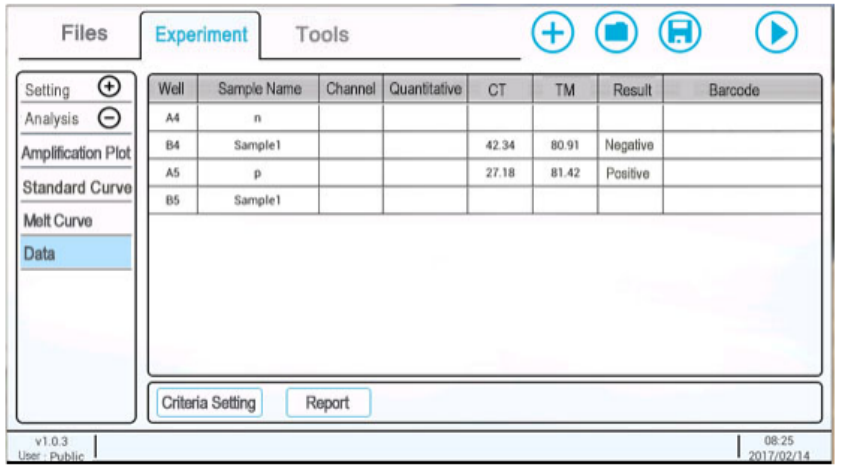
16 Sample per Run Portable RT PCR instrument

Total < 90 minutes for Processing 16 samples

Instrument Size:
(L x W x H) 320 x250 x 177mm
4.5 KG

Read Positive/Negative directly from the instrument touch screen. Actual unit physical design may vary slightly.

4.3.3.4 Data



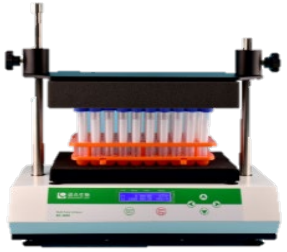
Criteria setting: choose qualitative in detection type. Enter the qualitative threshold and click ok to view the analysis results in the data interface after clicking the analysis button on the amplification plot interface.

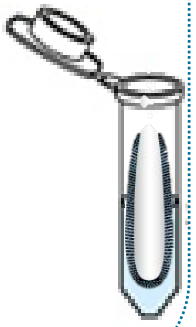
Extractionless COVID-19 RT-PCR Detection Kit Workflow

Step 1
Sample Collection

Rainamp™ VTM

Step 2
Release viral RNA
Load VTM vials on Vortexer
2 min up to 50 samples



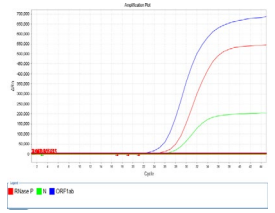


Step 3
Transfer swab 17µl VTM to PCR Tube

Add the VTM containing released SARS-COV-2 virus RNA to PCR mix

Step 4
Start PCR reaction
55 min for 16 samples.

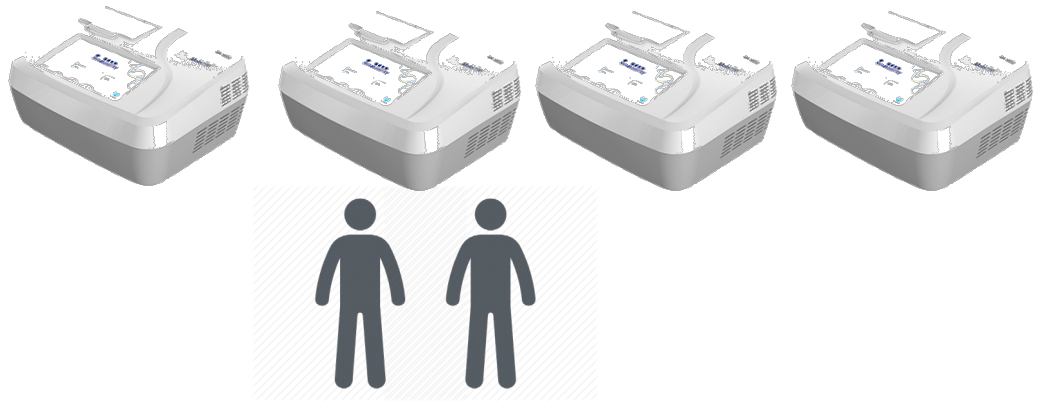
Read Results



1. Drop swab to VTM (virus transport medium) containing COVID-19 viral release reagent
2. Vortex or shake VTM tubes for 2 mins
3. Spin down solution, pipette 17 ul VTM solution to 8 ul PCR mix, prepare 25 ul reaction volume
4. Load reaction mix onto the Mini RT PCR instrument, start experiment run
5. Complete PCR thermal cycling and read results in 55 (Fast protocol) minutes or 81 (standard protocol) minutes for 16 samples
6. Generate reports of SARS-CoV-2 positive or SARS-CoV-2 negative
7. Reports can be generated via Excel or PFD files
8. Export reports using USB disk. Exported reports can be printed or store on labtop.

448Tests of Standard Process per day (2 shifts) just 4 PCR instrument + **2** Technicians

Standard Protocol



4 Mini 16 Well Plate RT PCR + 2 Technicians

X 2 Shifts (12 hours)

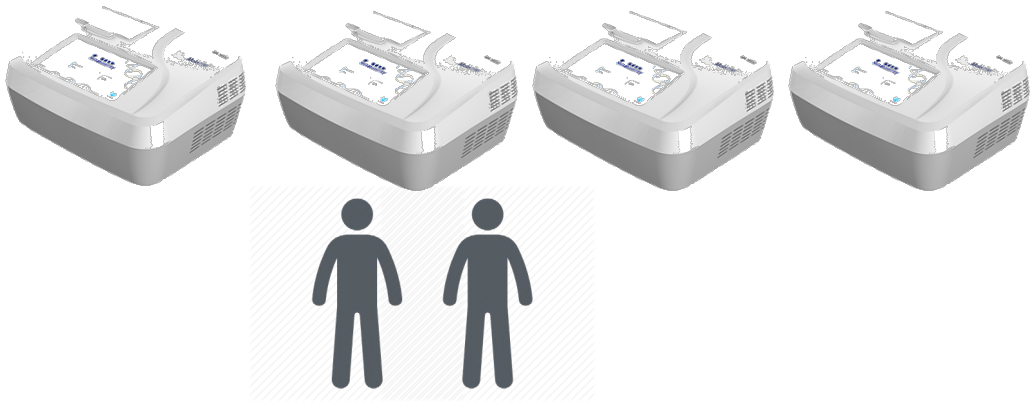
224 Samples in 6 hrs

448 Samples/ Day

			6 Hours		
	Time/Run	Tests/Run	No of Runs	No of Tests	*Note*
Fast-16 Portable PCR instrument	81 min	14	4	56	*16 well plate (14 specimens + 1Negative control + 1 positive control)*

672 Tests of Standard Process per day (2 shifts)
just 4 PCR instrument + **2** Technicians

Fast Protocol



X 2 Shifts (12 hours)

4 Mini 16 Well Plate RT PCR instruments + 2 Technicians

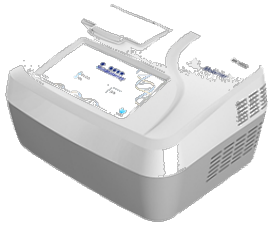
336 Samples in 6 hrs

672 Samples/Day

			6 Hours		
	Time/Run	Tests/Run	No of Runs	No of Tests	*Note*
Fast-16 Portable PCR instrument	55 min	14	6	84	*16 well plate (14 specimens + 1Negative control + 1 positive control)*

Order Information

Product Name



Fast-16 (Portable qPCR)

SARS-CoV-2 Detection
Kit (RT-PCR, RNA extraction free)
PCR assay+ Sample collection VTM

Sample Vortexer (50 samples throughput) (Optional)

Portable Power Station (Optional)

Manufacturing Compliance

ISO 13485 Certified