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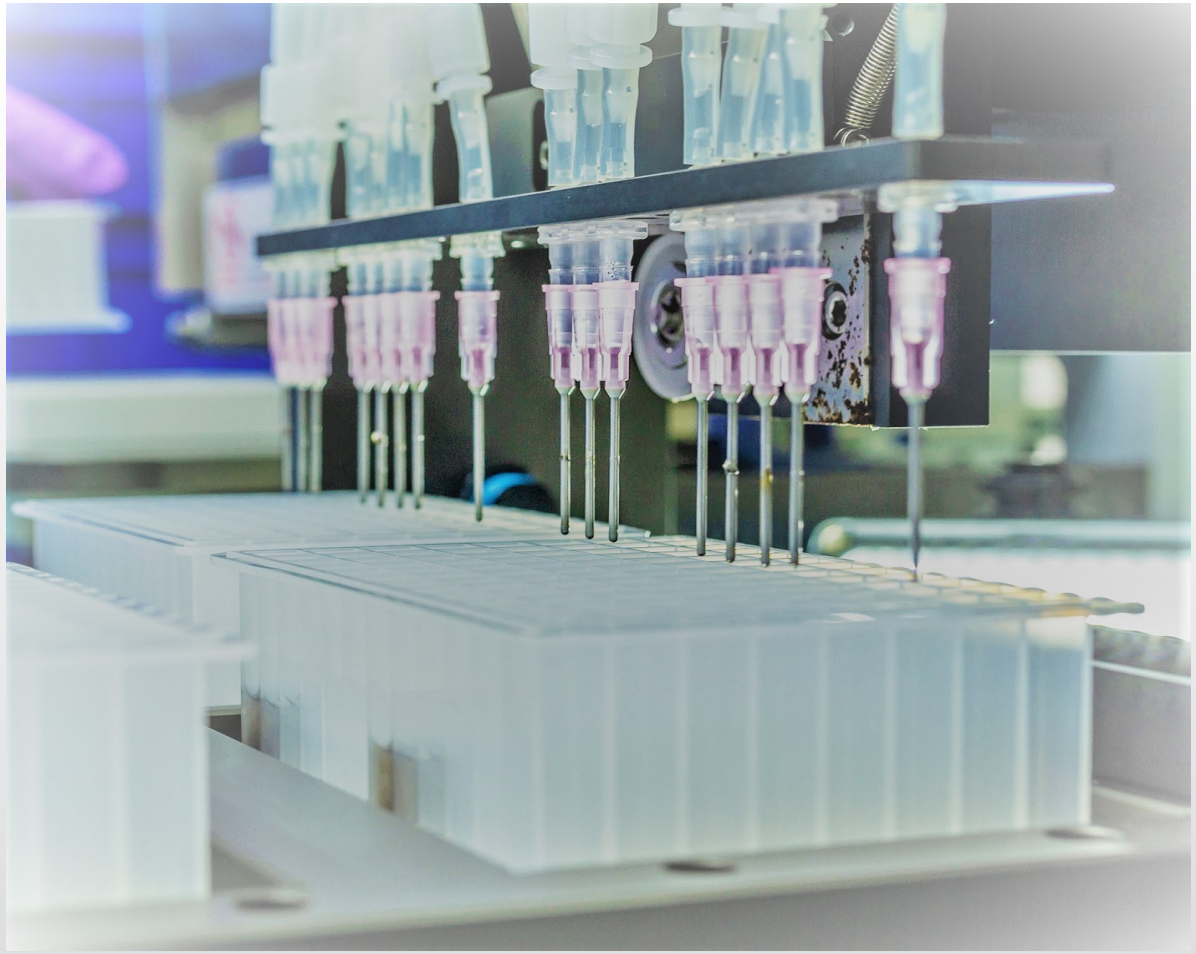
Katsura Biological Corp.

Solutions for COVID-19 Detection

July 2020



Workflow

Sample collection → Nucleic acid extraction → qPCR assay set-up → Detection & analysis

- Complete solution provided by Katsura

Sample Collection Kit

The Sample Collection Kit is designed for collection, transport, and storage of nasopharyngeal samples for downstream DNA/RNA analysis.

The transport medium provided with this kit is able to store and preserve specimen taken from the respiratory tract (e.g. throat, sputum), for subsequent use in nucleic acid analysis, like PCR, sequencing etc.

Product Name	KA Sample Collection Kit (50)
Kit Size	50 collection tubes & 50 swabs
Kit contents	Plastic collection tube with 1 ml transport medium
	Nasopharyngeal Dacron swab, length 154 ± 5 mm

Features of the Transport Medium

- Virus inactivation
- DNA/RNA preservation
- Growth suppression of potential contaminants (bacteria and fungi)
- Can be used for other respiratory samples as well (sputum, BAL…)

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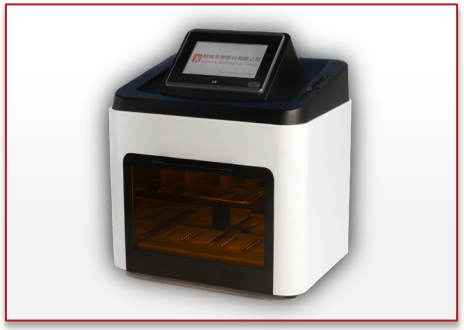
M32 Nucleic Acid Extractor

The M32 Nucleic Acid Extractor is a fully automated DNA/RNA purification instrument. It utilizes magnetic bead based extraction technology, and with its versatile and freely editable protocol options it provides a high level of flexibility in sample preparation for various downstream applications.

Product Name	M32 Nucleic Acid Extractor
Instrument Type	Benchtop automated NA extraction system
Technology	Magnetic bead based sample processing
Sample Capacity	1 – 32 samples / run
Throughput	Up to 750 samples / 8 hrs.
Control Interface	7-inch touch screen
Protocol Management	4 pre-set protocols, and up to 16 customized protocols

Features of the M32 Nucleic Acid Extractor

- Fast turn-around time for high throughput
  - Parallel sample processing
  - 20 – 50 minutes for up to 32 samples
- High yield & purity, excellent repeatability
  - More than 95% magnetic bead recovery
- Universal open platform
  - Usable with a wide range of magnetic bead based extraction reagents



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Viral DNA/RNA Respi Kit

The Viral DNA/RNA Respi Kit has been designed and optimized for automated isolation of viral DNA and/or RNA from respiratory samples, such as nasopharynx-geal & throat swabs, for use in downstream applica-tions like COVID-19 testing.

The extraction procedure is based on highly specific magnetic bead technology, and the prefilled 96-well deep well plates allow for fully automated NA puri-fication with excellent yields and quality.

Features of the Viral DNA/RNA Kit

- Fast extraction process (30 min. / run)
- High binding capacity
- Excellent recovery (>95%) and high yields
- All materials provided DNase/RNase free
- Easy adaptation to any 96-well plate based magnetic bead isolation platform

Product Name	Viral DNA/RNA Respi Kit (64)
Kit Size	For 64 extractions (4 plates for 16 samples each)
Kit Components	Lysis buffer JS-3 with magnetic beads
	W1A buffer (contains ethanol)
	W2B buffer (contains ethanol)
	Elution buffer (RNase-free water)
	8-rod comb (x 8)

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16S Real-Time PCR Cycler

The 16S Real-Time PCR Cycler is a compact PCR instrument that provides 3 channels for DNA target detection.

By using single PCR tubes it generates minimal waste while providing maximum flexibility in throughput, and the built-in software allows for set-up of a wide range of customized protocols.

Product Name	16S Real-Time PCR Cycler
Sample Capacity	1 – 16 samples / run
Sample Volume	25 – 120 µl
Supported Tubes	0.2 ml PCR single tubes, 0.2 ml PCR 8-well strip
Linear Dynamic Range	10 – 10^{10} copies (linearity R ≥ 0.99)
Excitation Wavelength	470 – 570 nm
Detection Wavelength	525 – 620 nm

Features of the 16S Real-Time PCR Cycler

- Fast and sensitive DNA analysis
  - Wide linear dynamic range
  - Provides relative & absolute quantitation results
- Built-in 7-inch touch screen, for fast and intuitive operation
  - Simple and quick set-up of customized protocols
- High temperature uniformity and accurate heating control

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qPCR Assay – abTES™ COVID-19 qPCR I Kit

The abTES™ COVID-19 qPCR I Kit is a qualitative Real-Time PCR kit which enables simultaneous detection of two COVID-19-specific regions from its non-structure polypeptide (ORF1a) in a single reaction.

The kit allows rapid, sensitive, and specific detection, and it has been validated on samples extracted from sputum, nasopharyngeal and throat swabs.

Features of the abTES™ COVID-19 qPCR I Kit

- Fast time to result, less than 1 hour
- Excellent clinical sensitivity and specificity
- Limit of detection 2 copies / µl
- Utilizes GAPDH as sample process control
- Validated for various sample extraction methods and PCR instruments

Product Name	abTES™ COVID-19 qPCR I Kit *
Kit Size	For 100 reactions (v1.1)
Kit Components	2 x RT-PCR reaction mix (1000 µl)
	RT/Taq enzyme mix (100 µl)
	Primer/probe mix (200 µl)
	COVID-19 positive control (50 µl)
	Nuclease-free water (450 µl)

* Produced by AITbiotech Pte. Ltd., Singapore

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qPCR Assay – Analytical Specificity

Table 15. Organisms that were tested for cross-reactivity.

Organism	Result
MERS Coronavirus	Not Detected
Coronavirus 229E	Not Detected
Coronavirus NL63	Not Detected
Coronavirus OC43	Not Detected
Influenza A	Not Detected
Influenza B	Not Detected
Respiratory Syncytial virus A	Not Detected
Respiratory Syncytial virus B	Not Detected

- No cross reactivity with other coronaviruses or common respiratory infectious pathogens

Source: Instructions for Use – abTES™ COVID-19 qPCR I Kit (Rev. 2020/6/24)

qPCR Assay – Clinical Performance

Table 18. Summary of the result of diagnostic sensitivity and specificity for COVID-19 as below.

Description	*ab*TES™ COVID-19 qPCR I Kit (*n*=112)		Sensitivity/ Specificity
	COVID-19 Positive	COVID-19 Negative	% (95% Confidence Internal)
COVID-19 Positive	65	2*	97 % sensitivity
COVID-19 Negative	0	45	100 % specificity
Total	65	47	

**The Ct values of these two specimens in its original runs was very high, implying the virus load was very low and reported as negative in this evaluation. Moreover, the RNA samples have since then been freeze/thawed repeatedly, possibly causing degradation.*

- Excellent clinical sensitivity and optimal specificity

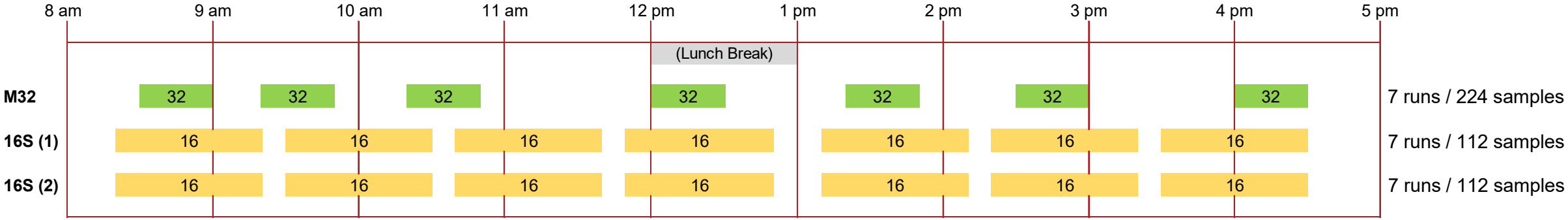
Source: Instructions for Use – abTES™ COVID-19 qPCR I Kit (Rev. 2020/6/24)

Workflow Set-Up for High Throughput

Instrument	Samples / run	No. instruments*	Results / 8.5 hrs.	Results / 12 hrs.
M32 Nucleic Acid Extractor	32	1	224	320
16S Real-Time PCR Cycler	16	2		

* One back-up instrument each recommended for peak hours

Work schedule example:



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