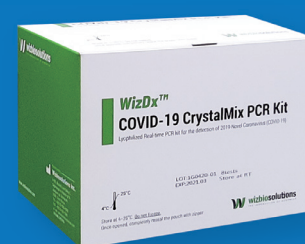


CE IVD

KFDA



WizDx™ COVID-19 CrystalMix PCR Kit

Point-of-care Real-time RT-PCR test for COVID-19

WizDx™ COVID-19 CrystalMix PCR Kit

WizDx™ COVID-19 CrystalMix PCR Kit provides a range of testing options for the real-time detection of 2019-Novel coronavirus (COVID-19) by fast real-time PCR. The Kit is a lyophilized real-time RT-PCR mix containing a specific primer and probe for the amplification of the 2019-Novel coronavirus.

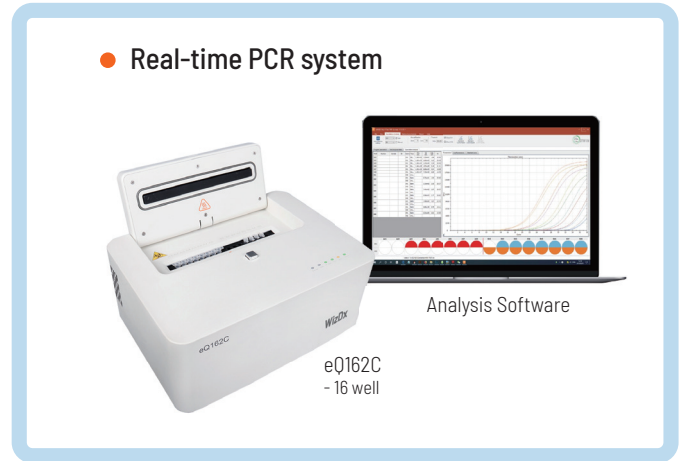
- Fast (80 min.)
- High Specificity & Sensitivity
- Lyophilized ready-to-use PCR kit
- Room temperature storage
- No need PCR preparation step
- Minimize human error & contamination



WizDx™ COVID-19 CrystalMix PCR Kit received an export license from MFDS
MFDS license No. : 20-301

Product Name	WizDx™ COVID-19 CrystalMix PCR Kit
Packaging Unit	96 tests/kit
Target	RdRP gene (COVID-19), E gene (Beta coronavirus)
Running Time	80 minutes, after RNA extraction
Storage	Room temperature (4~25°C)
Shelf-life	1 year from manufacturing date
Limit of Detection	RdRP gene : 20 copy/rxn, E gene : 20 copy/rxn
Manufacturing	ISO 13485:2016
PCR Machine	eQ162C Real-time PCR system
Guidance	Developed in accordance to the WHO guideline for 2019 novel coronavirus (SARS-CoV-2) testing

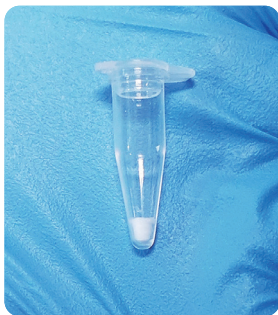
System Configuration



Features of WizDx™ Molecular Diagnostic Kit

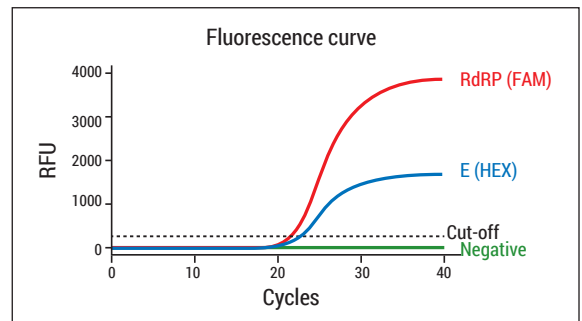
- **Carryover Protection Technology** applied to prevent cross-contamination
- **Hot-start technology** applied to minimize non-specific reactions and increase specificity
- **Special drying method and Ultra-Stability Technology** applied to long-term storage for 1 year at room temperature
- Mechanical dispense maximizes reproducibility and minimizes experimental errors
- As a dried type, it is convenient to store and ready-to-use, minimizing the experimental process.

Lyophilized PCR Kit

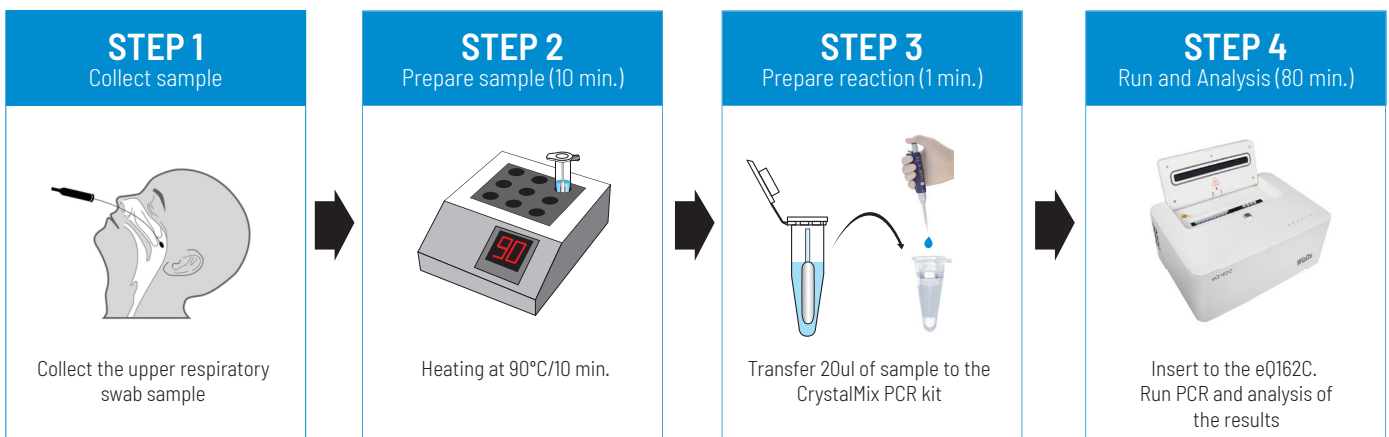


WizDx™ COVID-19 CrystalMix PCR kit is freeze-dried type, it contained all components for COVID-19 real-time RT-PCR, such as RT and PCR enzyme, COVID-19 specific primers and probe. So, it can use directly without any PCR mixture preparation step, therefore, easy-to-use, less contamination, less human error and, higher reproducibility.

Example of Test Results



Test Process



Comparison With Other Molecular Diagnostic Kits

Specifications	Competitor's COVID-19 Real-time PCR kit	WizDx™ COVID-19 CrystalMix PCR Kit
Principle	Real-time PCR	Real-time PCR
Accuracy	Depends on the manufacturer	100% specificity, LOD (RdRP :23 copy/rxn, E : 20 copy/rxn)
Kit type	Solution type (Prepare PCR mixture by mixing with PCR enzymes, primers and probes)	Dried (lyophilized) type, No need PCR mixture preparation step.
Storage/Shipping	Freezing / Dry ice	Room temperature / Room temperature
Specimen	Throat, nasopharyngeal, sputum	Throat, nasopharyngeal swab
Test time	Over 3 hours	80 minutes
User	Skilled & trained	Non-professional
RNA preparation step	30 minutes	10 minutes
Target gene	RdRP, E, (or N gene)	RdRP, E
Advantages / Disadvantages	Long test time, Complicate protocol, Laboratory use only, Need PCR mixture preparation step, Need cold chain, Freezing/thawing problem, Cross-contamination risk, Human error risk, Very expensive instrument	Short test time, Easy protocol, No PCR mixture preparation step, Room temperature storage, Less contamination, Point-of-care test available, Low human error, Competitive price.

Target gene



Amplicon Target on COVID-19 genome. ORF: open reading frame; E: envelope protein gene; M: membrane protein gene; N: nucleocapsid protein gene; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

Diagnostic Accuracy

Parameter	RdRP gene	E gene
Specificity	100%, no cross-reactivity to other respiratory virus	100%, no cross-reactivity to other respiratory virus
Detection	COVID-19 (SARS-CoV2-) specific	Beta coronavirus (SARS-related coronavirus)
Limit of detection	20 copy/rxn 	20 copy/rxn

Ordering Information

Product	Cat No.	Package
WizDx™ COVID-19 CrystalMix PCR Kit	DX1203A	96 tests
eQ162C Real-time PCR System	Q162C	1 system
WizPrep™ Viral DNA/RNA Mini Kit (V2)	W73052-100	100 prep