

WizDx™

COVID-19

CrystalMix Multi PCR Kit

Fast Real-time PCR test for COVID-19 (SARS-CoV-2)

- Fast (60 min.)
- Easy-to-use Lyophilized PCR Kit
- High Sensitivity & Specificity
- Room temperature Storage/Shipping
- No need PCR preparation step
- Minimize human error & contamination



Easy & Fast



Accurate



Lyophilized
All-in-One



Room temp.
Storage/Shipping



No need PCR
preparaton step



Reduce human error
Prevent contamination



ISO13485:2016, GMP certified



WizDx™ COVID-19 CrystalMix Multi PCR Kit

WizDx™ COVID-19 CrystalMix™Multi 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.



www.wizbiosolution.com

Simple, Fast, Accurate

Key Features of **WizDx™ COVID-19 CrystalMix Multi PCR Kit**



Anti-Carryover Technology

Prevents cross-contamination



Hot-Start PCR Technology

Minimizes non-specific PCR reactions and increases specificity



Enhanced-stability technology

Sustains long-term storage at room temperature



Automated dispensing system

Maximizes reproducibility and minimizes experimental errors



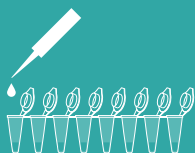
Ready-to-use, Freeze-dried form

Allows convenient storage and minimal experimental process

Easy & Fast **Molecular Diagnosis**

01 PCR set-up

WizDx™ CrystalMix offers freeze-dried, all-in-one tests. You may simply add prepped samples.



02 Run PCR test

With the CLEO™ Q16 PCR System, it takes less than 1 hour to be completed.

FAST



03 Results

CLEO™ Q16 makes it easy to view test results right on the instrument.



High **Sensitive**

Limit of detection (LoD) for the RdRP gene was 0.72 copies/μL and for the E gene was 0.77 copies/μL.

High **Specificity**

The specific probe design for the COVID-19 virus enables accurate inspection.

Convenience & Stable

Wizbiosolution's patented HNC(Heteromorphic Nanopolymer Coating) technology applied for WizDx™ COVID-19 CrystalMix Multi PCR Kit enables the reagents stored and transported at room temperature with the benefits of user-convenience and stabilization.

Easy & Accurate

Lyophilized PCR kits are very convenient to use because you can test immediately with the addition of sample RNA only, and provide more accurate results because you can drastically reduce experimental errors or contamination that may occur during the preparation process.

Perfect **Reproducibility**

WizDx™ COVID-19 CrystalMix Multi PCR Kits are precisely dispensed by fully automated dispensers in facilities certified with ISO13485 and GMP. They are supplied in lyophilized form with a single test quantity, so all the kits deliver exactly the same results.

Next-generation Molecular Diagnostic Technology

Target Gene

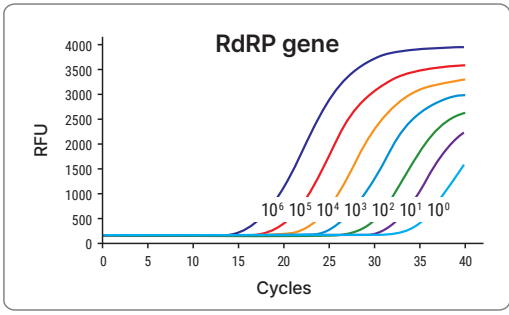
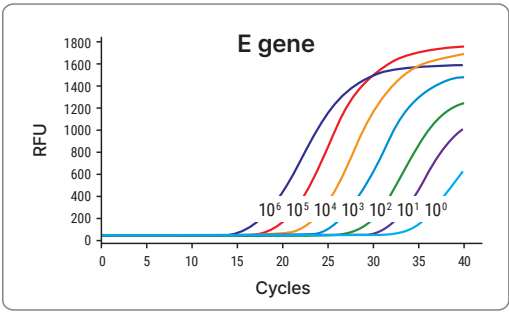


Amplicon Target on COVID-19 genome. ORF: open reading frame; E: envelope protein gene; M: membrane protein gene; N: nucleocapsid protein gene; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

Comparison With Other Molecular Diagnostic Kits

Specifications	Competitor's COVID-19 PCR kit	WizDx™ COVID-19 CrystalMix™ Multi PCR Kit
Principle	Real-time PCR	Real-time PCR
Accuracy	Depends on the manufacturer	100% specificity
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	Sputum, oropharyngeal swab, and nasopharyngeal swab	Sputum, oropharyngeal swab, and nasopharyngeal swab
Test time	2 ~ 3 hours	60 minutes
User	Skilled & trained	Non-professional
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.

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-CoV-2) specific	Beta coronavirus (SARS-related coronavirus)
Limit of detection	0.72 copies/μl 	0.77 copies/μl 



Specifications



Principle of Procedure	Multiplex Real-time PCR
Target	FAM (COVID-19 RdRp), HEX (COVID-19 N), Cy5 (Internal control)
Tests for Package	96 Tests/kit
Reagent Type	Lyophilized (Freeze-dried) in PCR tube
Limit of Detection (LoD)	COVID-19 RdRP gene (0.72 copies/μL), COVID-19 E gene (0.77 copies/μL).
Precision	Respectively detect the reference specimen of high and low concentrations in different time ranges-10 times, and the precision values of intra-assay and inter-assay Ct values were all <1.5%.
Specificity	Analytical specificity was evaluated for cross-reactivity by examining relevant pathogens and microorganisms likely to be present in the respiratory tract. The test was repeated three times and showed no cross-reactivity.
Sample Types	Sputum, Bronchial or Tracheal lavage
Shipping/Storage	Shipping and storage at room temperature for 12 months
Compatible Instruments	CLEO™ Q16 (Wizbiosolutions), CFX96 (Bio-Rad)

Ordering Information

Cat No.	Product	Package	Certification
DX1230A	WizDx™ COVID-19 CrystalMix Multi PCR Kit	96 T	CE IVD KFDA
CL0016	CLEO™ Q16 Real-time PCR	1 system	CE IVD KFDA
CL2016	CLEO™ AP16 Automated nucleic acid Extractor	1 system	IVD KFDA
W7020	WizMag™ Viral DNA/RNA	64 prep	IVD KFDA
W73052	WizPrep™ Viral DNA/RNA Mini Kit (V2)	100 prep	CE IVD KFDA

