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KAIRA 2019-nCoV Detection Kit

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Technical Specification

NAME

Kaira 2019-nCov Detection Kit

STANDARD

ISO 13485: 2016
Directive 98/79/EC
ISO 14971: 2012
ISO 23640: 2011
EN 13612: 2002
ISO 17511: 2003
ISO 18113-2: 2009
ISO 18113-3: 2009
EN ISO 15223-1: 2016
EN 13975: 2003
IEC 62366-1: 2015

CERTIFICATION

CE (Regulation of the European Union) and FDA (Applied)

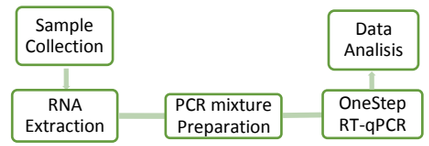
SUMMARY

The Kaira 2019-nCoV Detection Kit is an in vitro diagnostic kit designed for the qualitative detection of SARS-CoV-2 in human samples such as nasopharyngeal swap, oropharyngeal swap, or sputum samples through reverse transcription real-time polymerase chain reaction (rt Real-Time PCR).

CONTENTS

	Reagents	Unit	Quantity
1	2019-nCoV Primer & Probe Mixture	125μℓ / tube	2
2	2X OneStep RT qPCR Mixure	625 μℓ / tube	2
3	2019-nCoV Positive Control DNA	100 μℓ / tube	1
4	DEPC DW	200 μℓ / tube	1

WORKFLOW



- The Kaira 2019-nCoV Detection Kit is designed for use with QuantStudio 5 Real-Time PCR system, ABI 7500 Real-Time PCR system, or CFX96 Dx system.

PCR CONDITIONS FOR KAIRA 2019-NCOV

STEP	Temp	Running Time	Cycle Number
Reverse transcription	50°C	10 minutes	1 cycle
Pre-Denaturation	95°C	10 minutes	1 cycle
Denaturation	95°C	10 seconds	45 cycle
Annealing Extension *	60°C	30 seconds	

- This step scanned the fluorescence signal.

conc. (copies/ul)	positive	ratio (%)
11.20	24/24	100.0
3.73	22/24	91.7
1.24	14/24	58.3
0.41	8/24	33.3
0.14	0/24	0.0
0.05	0/24	0.0