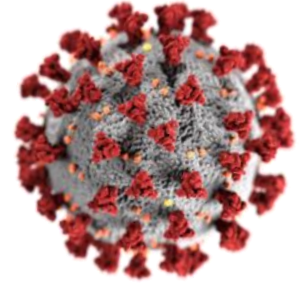


## AmoyDx® Coronavirus Testing Solution

Fast and sensitive, including viral RNA extraction and SARS-CoV-2 detection

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person, which is caused by a novel coronavirus named SARS-CoV-2.

**AmoyDx® Novel Coronavirus (2019-nCoV) Detection Kit** is a fast and sensitive real-time RT-PCR assay, which combines reverse transcription and PCR amplification in one-step procedure, intended use for qualitative detection of coronavirus SARS-CoV-2 with viral RNA extracted from human respiratory specimens. The kit simultaneously detects ORF1ab (open reading frame, ORF1ab) and N (Nucleoprotein) conserved regions of novel coronavirus, with an internal control system to monitor the whole PCR process.



SARS-CoV-2 virion

### Features and Benefits

- ✦ **Accurate**  
Simultaneous detection of two targets (ORF1ab & N gene)
- ✦ **Reliable**  
Negative, Positive, Internal controls in whole PCR process
- ✦ **Sensitive**  
LOD of 20 copies/ $\mu$ L armored RNA
- ✦ **Simple**  
One tube, one-step procedure, prevent cross contamination
- ✦ **Rapid**  
Quick results from sample to data in 3 hours
- ✦ **Extensive**  
Compatible with most common PCR instruments

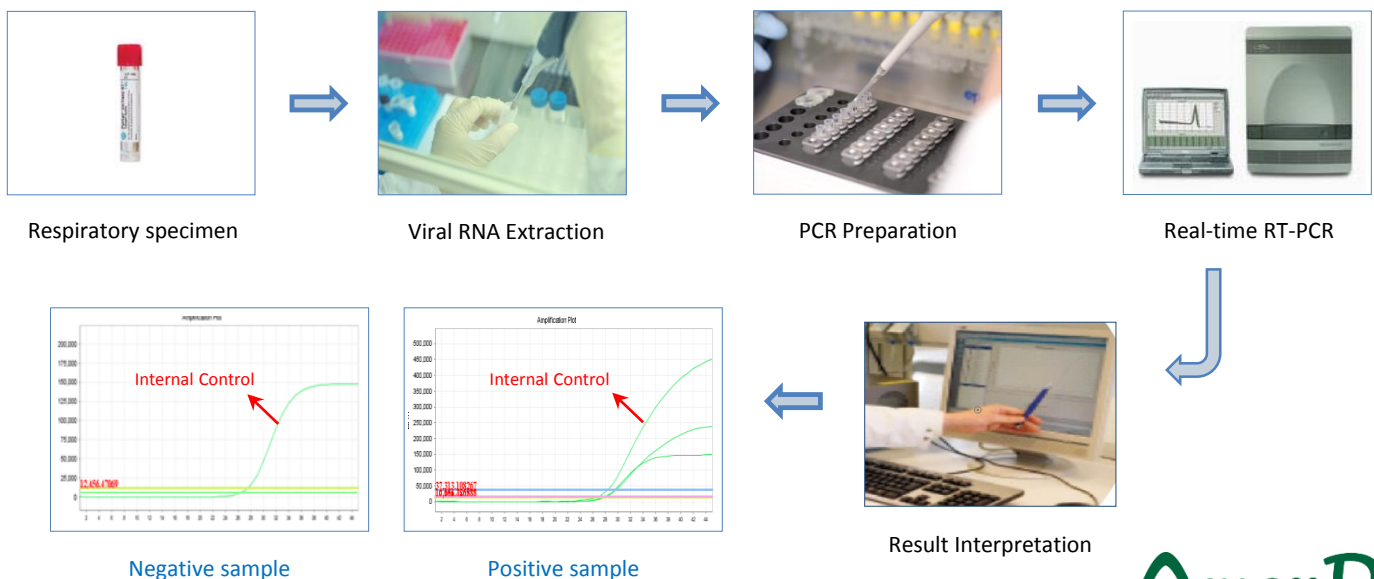
### Clinical Performance

(clinical data collected from hospitals)

AmoyDx nCoV	Patients		Total
	COVID-19 confirmed	COVID-19 unconfirmed	
+	24	0	24
-	1	460	461
<b>Total</b>	<b>25</b>	<b>460</b>	<b>485</b>
<b>NPV</b>	100%		
<b>PPV</b>	96%		

NPV: Negative predicate value, PPV: Positive predicate value.

### Workflow





## Specimen type

Upper respiratory specimen (nasopharyngeal/oropharyngeal extracts, washes or swabs)

Lower respiratory specimens (bronchoalveolar lavage samples, tracheal extracts or deep cough sputum)

## Testing Capabilities

Viral RNA Extraction (spin column)	nCoV RT-PCR Testing
96 samples in 1 hour	96 tests* per PCR run in 2 hours
 <p>2 centrifuges (48-place rotor)</p>	 <p>1 PCR instrument</p>
<p>✦ Turnaround time from sample to results: 3 hours.</p> <p>✦ 94 samples per instrument run, a total of 282 samples for 1 PCR instrument in 8 hours.</p>	

\* 1 negative control and 1 positive control are included in every PCR run.

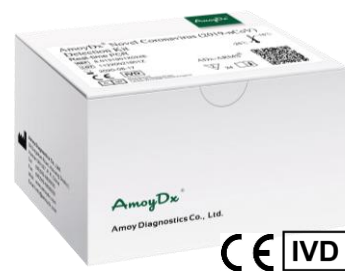
## Ordering Information

Product	Cat. No.	Size (tests/kit)	PCR Instrument**
AmoyDx® Novel Coronavirus (2019-nCoV) Detection Kit (CE-IVD)	8.0131901X024E	24 tests/kit	Mx3000P, ABI7500, LightCycler 480, II, SLAN-96S
AmoyDx® Virus/Cell RNA Kit	8.0250301X036G	36 tests/kit	/

\*\* The nCoV test has been validated on Rotor-Gene Q and QuantStudio 5.



AmoyDx® Virus/Cell RNA Kit



AmoyDx® 2019-nCoV RT-PCR Kit