Viga SARS COV-2 and Influenza A/B Molecular Diagnostic Kit

Store at -20 ºC in darkness

100 rxn

Cat NO: MD983007

By ROJE

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Kit content

Components	100 Preps
Q-ROMAX, 4X	500µl
Pro II Mix	400µl
RTase, Recombinant Reverse Transcriptase, RNase H-	100µl
Positive Control	150µl
Negative control	150µl

Description

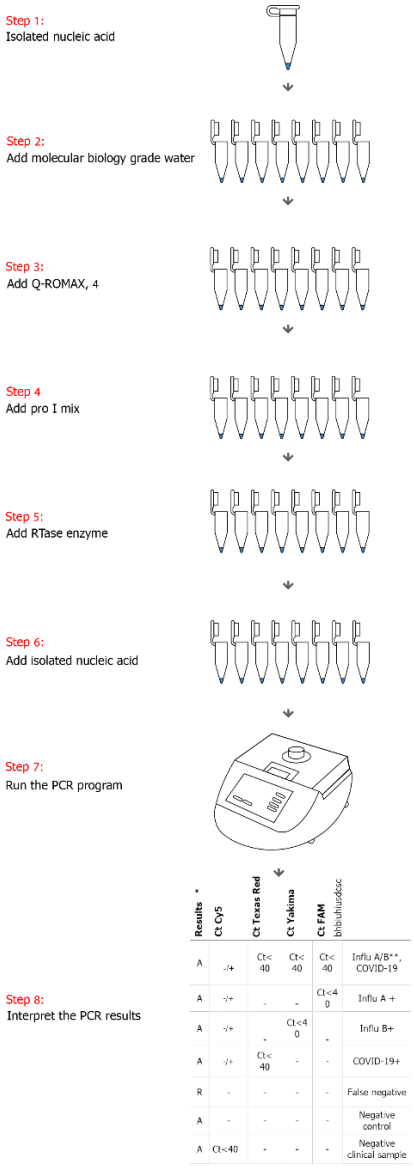
The Viga SARS COV-2 and Influenza A/B Molecular Diagnostic Kit are based on a one-step RT-PCR reverse transcriptase reaction. A part of the RNA sequence of Pathogen is converted to cDNA and then used as a PCR reaction template. The resulting PCR product is identified by an oligonucleotide probe labeled with fluorescent color. This Kit detects the *N* gene from SARS COV-2 and *M2* gene of the Influenza A virus and *NS1* gene of Influenza B virus. Other Coronaviruses and other strains of the Influenza virus are not identified with this Kit.

Specimen collection

Consider all samples potentially infectious and transfer them by precisely following the biosafety guidelines. The collection swab should have a synthetic tip, such as nylon or Dacron, and an aluminum or plastic shaft. A cotton swab with wooden shafts is not recommended. After sample collection, swabs should be stored at VTM (virus transfer medium) immediately.

Specimen isolation

For viral nucleic acid isolation use (REF: RN983072), RNJia Virus Kit or other kits approved by the ministry of health.



Process

Take out each component from the kit and place them on the benchtop. Allow the reagents to equilibrate to room temperature, then briefly vortex each tube for later use. The volume of the isolated sample in this test should be 10µl. Prepare PCR reaction to refer to Table 1 and then perform Real-time PCR refer to Table 2.

Table1: PCR reaction preparation

Components	volume
Q-ROMAX, 4X	5µl
Pro II Mix	4µl
RTase, Recombinant Reverse Transcriptase RNase H-	1µl
Isolated RNA	10µl

Table 2: One-step multiple Real time RT-PCR

Cycle #	Temp	time	Stage
1	50°C	20min	cDNA synthesis
1	95°C	3min	Polymerase activation
45	95°C	10s	Denaturation
	60°C	40s	Annealing and extension of nucleic acid and measurement of fluorescence in green, yellow and orange channels

Interpretation of results

- To analyze the PCR results, select the FAM channel for Influenza A, Yakima Yellow channel for Influenza B virus, Texas Red channel for SARS CoV-2, and cy5 channel for RNase P gene.
- Please check both amplification curves and Ct for each sample. The linear and logarithmic diagrams of the sample should both be checked and compared to the negative control.
- Evaluation of results should be done after reviewing positive and negative controls and confirming their acceptance. If the control result is not acceptable, the patient's result cannot be interpreted.
- Changes in Ct values in positive control may indicate partial inhibition of PCR.

Table 3: Valid control criteria

Results *	Ct Cy5	Ct Texas Red	Ct Yakima	Ct FAM	
A	-/+	Ct< 40	Ct< 40	Ct< 36	Influ A/B**, COVID-19
A	-+/	-	-	Ct<36	Influ A +
A	-+/	-	Ct< 40	-	Influ B+
A	/+-	Ct< 40	-	-	COVID-19+
R	-	-	-	-	False negative
A	-	-	-	-	Negative control
A	Ct< 40	-	-	-	Negative clinical sample

*A: Accept, R: Reject

**Influ A/B: Influenza A and B

limitation

- The optimal performance of this test also depends on how samples are collected, transferred, and stored.
- This kit is suitable for diagnosing target viruses in swab samples and respiratory sputum. A negative test does not reject the possibility of

SARS CoV-2, Influenza A or B virus, because test results may be affected by sample collection, user error, how the sample is mixed, or low virus titration that can be less than the sensitivity of the Kit.

- The presence of PCR inhibitors can cause false-negative results.
- Sequence diversity in the target area of unknown types of viruses may lead to false negative results or less Kit sensitivity. In these cases, the results should be interpreted based on clinical findings and other tests.
- The limit of detection in Viga SARS CoV-2 and Influenza A/B Molecular Diagnostic Kit is 200 copies per ml for COVID-19 and 150 copies per ml for Influenza A/B, respectively.