

Frequently Asked Questions (FAQs)

Rapid Identification Kit for B.1.1.7 Lineage of SARS-CoV-2

Rapid Identification Kit for B.1.1.7 Lineage and B.1.351 Lineage of SARS-CoV-2 Detection Kit for 6 Mutations in S Gene of SARS-CoV-2

1) What real-time PCR systems are validated with this assay?

Rapid Identification Kit for B.1.1.7 Lineage of SARS-CoV-2

- Applied Biosystems™ QuantStudio 5 Real-Time PCR System
- Roche LightCycler® 480 Real time PCR System

Rapid Identification Kit for B.1.1.7 Lineage and B.1.351 Lineage of SARS-CoV-2

- Applied Biosystems™ QuantStudio 5 Real-Time PCR System
- Applied Biosystems™ 7500 Fast Real-Time PCR System
- Roche LightCycler® 480 Real time PCR System

Detection Kit for 6 Mutations in S Gene of SARS-CoV-2

- Applied Biosystems™ QuantStudio 5 Real-Time PCR System
- Roche LightCycler® 480 Real time PCR System

2) What specimen type is validated with your kit?

- Oropharyngeal swabs
- Sputum

3) What comes in this kit? Can I buy some of the vials in your kit?

Rapid Identification Kit for B.1.1.7 Lineage of SARS-CoV-2

Rapid Identification Kit for B.1.1.7 Lineage and B.1.351 Lineage of SARS-CoV-2

- Reaction Mix for Wild Strain
- Reaction Mix for Mutant Strain
- Enzyme Mix
- Positive Control
- Blank Control

Detection Kit for 6 Mutations in S Gene of SARS-CoV-2

- Reaction Mix A (Amplification of ORF1ab, internal reference, N501Y and K417N mutations)
- Reaction Mix B (Amplification of A570D, HV69-70del, K417T and E484K mutations)
- Enzyme Mix
- Positive Control
- Blank Control

Customers need to order the whole kit during transactions. We are unable to sell some of the vials in the kit.

4) What are the advantages of your test over other tests on the market?

- Highly compatible – Bundled kits require very similar lab settings and procedure
- Highly sensitive – Superior limit of detection for oropharyngeal swabs or sputum
- Fast TAT – Sample to result in 2.8 hours with automated sample preparation system (RT-PCR only takes 1 hour)
- High-throughput – Ramp up labs for large-scale, community-based testing
- Ease of use – All-inclusive with pre-mixed reaction reagents
- Easy interpretation – Analysis of each allele with well-defined controls

5) What gene target is used in your assay?

Rapid Identification Kit for B.1.1.7 Lineage of SARS-CoV-2

Spike protein mutations N501Y and P681H of SARS-CoV-2.

Rapid Identification Kit for B.1.1.7 Lineage and B.1.351 Lineage of SARS-CoV-2

Spike protein mutations N501Y, P681H, K417N, and HV69-70del of SARS-CoV-2.

Detection Kit for 6 Mutations in S Gene of SARS-CoV-2

Spike protein mutations N501Y, A570D, HV69-70del, K417N, K417T and E484K of SARS-CoV-2.

6) What is the turnaround time (TAT) of your test when sample and reagent preparation is handled manually? What about the TAT when sample and reagent preparation is handled by the MGISP-960RS automated sample preparation system?

The TAT below is valid for both of assays when 36 to 96 samples are processed:

TAT (Hour)	Manual	Automation
RNA extraction	1.5	1.3
RT-PCR master mix prep	0.25	
RT-PCR setup	0.25	
RT-PCR	1	1
Data analysis	0.5	0.5
Total	3.5	2.8

7) Does your test include an internal control, and if so, what is it?

Yes. An internal reference control is included. This control targets human beta-actin gene.

8) Is positive control provided in your kit?

Yes. A positive control is provided in the kit. This control contains “pseudo-virus” or virus-like particle in which the synthetic viral RNA target and human beta-actin target in protein are coated separately.

9) What extraction control shall I use with the assay?

The positive control provided in the kit can serve as an extraction control.

10) Which viral RNA extraction methods are recommended for your kit?

- MGIEasy Nucleic Acid Extraction Kit, (MGI, catalog# 1000020261 or 1000020471)
- QIAamp Viral RNA Mini Kit, (Qiagen, catalog# 52904 or 52906)

11) How many controls should I use for each experiment?

At least two controls: one positive control and one blank control should be run in each experiment.

12) How do I interpret the control results?

Rapid Identification Kit for B.1.1.7 Lineage of SARS-CoV-2:

Quality Control Metrics	VIC / HEX (Observation)	FAM (Observation)	CY5 (Observation)	Interpretation
Blank Control	No amplification or Ct value is > 38.	No amplification	No amplification	Pass. Proceed to sample analysis.
Postive Control	Sigmoidal amplification curve and Ct value is ≤ 32.	Sigmoidal amplification curve and Ct value is ≤ 32.	Sigmoidal amplification curve and Ct value is ≤ 32.	
Blank Control	Sigmoidal amplification curve and Ct value is ≤ 38.	Sigmoidal amplification curve and Ct value is ≤ 41.	Sigmoidal amplification curve and Ct value is ≤ 41.	Failed. Repeat the run.
Postive Control	No amplification or Ct value is > 32.	No amplification or Ct value is > 32.	No amplification or Ct value is > 32.	

Rapid Identification Kit for B.1.1.7 Lineage and B.1.351 Lineage of SARS-CoV-2:

Quality Control Metrics		FAM (Observation)	CY5 (Observation)	VIC / HEX (Observation)	ROX (Observation)	Interpretation
Blank Control	PCR-Mix 1	No amplification	No amplification	No amplification	No amplification or Ct value is > 38.	Pass. Proceed to sample analysis.
	PCR-Mix 2				No amplification	
Positive Control	PCR-Mix 1	Sigmoidal amplification curve and Ct value is ≤ 35.	Sigmoidal amplification curve and Ct value is ≤ 35.	Sigmoidal amplification curve and Ct value is ≤ 35.	Sigmoidal amplification curve and Ct value is ≤ 35.	
	PCR-Mix 2				Sigmoidal amplification curve and Ct value is ≤ 35.	
Blank Control	PCR-Mix 1	Sigmoidal amplification curve and Ct value is ≤ 41.	Sigmoidal amplification curve and Ct value is ≤ 41.	Sigmoidal amplification curve and Ct value is ≤ 41.	Sigmoidal amplification curve and Ct value is ≤ 38.	Failed. Repeat the run.
	PCR-Mix 2				Sigmoidal amplification curve and Ct value is ≤ 41.	
Positive Control	PCR-Mix 1	No amplification or Ct value is > 35.	No amplification or Ct value is > 35.	No amplification or Ct value is > 35.	No amplification or Ct value is > 35.	
	PCR-Mix 2				No amplification or Ct value is > 35.	

Detection Kit for 6 Mutations in S Gene of SARS-CoV-2:

Blank Control

PCR-Mix1

- Ct values at FAM, VIC/HEX and ROX channels are 0 or no data available.
- Ct value at CY5 channel is 0, no data available or higher than 38.

PCR-Mix2

- Ct values at FAM, CY5, ROX and VIC/HEX channels are 0 or no data available.

Positive Control

PCR-Mix1&2

- Ct values at FAM, CY5, ROX and VIC/HEX channels are all in S-shape with Ct values not higher than 35 in both PCR-Mix1 and Mix2.

Above requirements should be met in a single test. Otherwise, the test is invalid and may be retested in line with the package insert.

13) What Ct cutoff values should be used when interpreting the assay data?

Ct Cutoff	PCR Machine Detection Channel		
	FAM, CY5	VIC	ROX
Mutation Detection Kit			
B.1.1.7 lineage	41	38	N/A
B.1.1.7 & B.1.351 lineages	41	41	38 or 41 (only for internal reference)
6 mutations in S gene	41 or 38 (only for internal reference)	41	41

14) How does your kit inventory look like in US?

BGI stocks the kits at our local warehouses in US. We frequently replenish our inventory to meet our customer demand.

15) At what temperature is the kit maintained during shipping?

The kit is shipped with dry ice where the temperature is maintained at approximately -80°C.

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