

Test Report of the New Variants

COVID-19 assay (LFA method)

1. **Experiment purpose:** The COVID-19 has produced a series of mutations during the pandemic. COVID-19 detection reagent (lateral flow chromatography) is now used to detect nucleocapsid protein (NP) recombinant proteins of variants from the UK, South Africa, the United States and Brazil, to verify the performance of the LFA assay on the variants.
2. **Experiment materials**
 - 2.1. COVID-19 NP assay reagent (LFA), Batch No. 2101K402, the test results of NP recombinant protein was positive at 31.25pg/ mL and its result was weak positive at 20pg/mL.
 - 2.2. NP recombinant protein of UK variant B.1.1.7, including mutation: D3L, S235F, expressed in HEK293 cell.
 - 2.3. NP recombinant protein of South African variant B.1.351, including mutation: R203K, G204R, expressed in HEK293 cell.
 - 2.4. NP recombinant protein of US variant B.1.2, including mutation: P67S, P199L, expressed in HEK293 cell.
 - 2.5. NP recombinant protein of U Brazil variant B.1.1.28, including mutation: P80R, S235F, expressed in HEK293 cell.
3. **Experiment method**
 - 3.1. The NP recombinant proteins of the four variants were diluted with sample diluent. The dilution ratio is as follows: 1/1K, 1/200K, 1/400K, 1/800K, 1/1600K, 1/3200K, 1/6400K, 1/12800K, 1/25800K
 - 3.2. Use COVID-19 assay reagent (LFA) to detect the above diluted specimens. Each specimen is tested twice.
 - 3.3. Add samples and interpret the results according to the operation methods in the instructions.
 - 3.4. Record the results.
4. **Experiment result**

The experimental record results are shown as follows

Variant Dilution ratio	UK variant	South Africa variant	US variant	Brazilian variant
Sample diluent	-	-	-	-
	-	-	-	-
1/1K	+	+	+	+
	+	+	+	+
1/200K	+	+	+	+
	+	+	+	+
1/400K	+	+	+	+
	+	+	+	+
1/800K	+	+	+	+
	+	+	+	+
1/1600K	+	+	+	+
	+	+	+	+

1/3200K	+	+	+	+
	+	+	+	+
1/6400K	+	+	+-	+
	+	+	+-	+
1/12800K	+	+-	-	+-
	+	+-	-	+-
1/25600K	+-	-	/	-
	+-	-	/	-

From the above table, the test result of NP recomb. protein of the UK variant was positive at dilution of 1/12800K and while it was slightly positive at dilution of 1/25600K. The test result of NP recombinant protein of the South African variant was positive at 1/6400K dilution and slightly positive at 1/12800K dilution, while it was negative at 1/25600K. The test result of NP recombinant protein of the American variant was positive at 1/3200K dilution and slightly positive at 1/6400K dilution, while it was negative at 1/12800K. The test result of NP recombinant protein of the Brazilian variant was positive at dilution of 1/6400K and slightly positive at dilution of 1/12800K, while it was negative at 1/25600K.

5. Experiment conclusion:

The NP recombinant protein of the variant from the United Kingdom, South Africa, the United States and Brazil was detectable by the COVID-19 assay (LFA).

The NP recombinant protein of UK variant is detectable at the dilution ratio of 1/12800K.

The NP recombinant protein of US variant is detectable at the dilution ratio of 1/3200K.

The NP recombinant protein of Brazilian variant is detectable at the dilution ratio of 1/6400K.

The NP recombinant protein of South Africa variant is detectable at the dilution ratio of 1/6400K.