

Classification: Clinical performance test
 Test name: Clinical performance test
 Test period : 2020. 02. 24~26.
 Tester : MFDS(KOREA Ministry Food and Drug Safety)



LabGun™ COVID-19 Assay Clinical performance test

Clinical sample		upper respiratory tract, lower respiratory tract
Used kits	Lot No.	COV20B002
Number of test		246
Test period		2020. 02. 24~26

Clinical performance comparison test result

5-1 Clinical performance test specimens and test results

The number of clinical specimens using the residual specimens provided by the LabGenomics Diagnostic Laboratory is as shown in Table 10 and the results are shown in Table 11.

[Table 10] Type and number of samples used for clinical performance testing

Number of examiners	Specimen Type	Sample	Total
123	upper respiratory tract	123	246
	lower respiratory tract	123	

Classification: Clinical performance test
 Test name: Clinical performance test
 Test period : 2020. 02. 24~26.
 Tester : MFDS(KOREA Ministry Food and Drug Safety)



5-2 Concordance analysis

Analyze the agreement between the results of the test product and the comparative product.

5-2-1 Test result between test product and comparative product

Tester	Specimen	Comparison products	Test Product	Result
U001	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U002	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U003	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U004	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U005	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U006	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U007	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U008	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U009	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U010	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U011	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U012	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U013	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U014	nasopharyngeal/throat swab	Negative	Positive	Not matched
	Sputum	Positive	Positive	Matched
U015	nasopharyngeal/throat	Negative	Negative	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



	swab			
	Sputum	Negative	Negative	Matched
U016	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U017	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U018	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U019	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U020	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U021	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U022	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U023	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U024	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U025	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U026	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U027	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U028	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U029	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U030	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U031	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U032	nasopharyngeal/throat swab	Negative	Negative	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



	Sputum	Negative	Negative	Matched
U033	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U034	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U035	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U036	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U037	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U038	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U039	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U040	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U041	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U042	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U043	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U044	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U045	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U046	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U047	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U048	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U049	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



U050	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U051	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U052	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U053	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U054	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U055	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U056	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U057	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U058	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U059	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U060	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U061	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U062	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U063	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U064	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U065	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U066	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U067	nasopharyngeal/throat	Negative	Negative	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



	swab			
	Sputum	Negative	Negative	Matched
U068	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U069	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U070	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U071	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U072	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U073	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U074	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U075	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U076	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U077	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U078	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U079	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U080	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U081	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U082	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U083	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U084	nasopharyngeal/throat swab	Negative	Negative	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



	Sputum	Negative	Negative	Matched
U085	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U086	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U087	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U088	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U089	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U090	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U091	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U092	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U093	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U094	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U095	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U096	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U097	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U098	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U099	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Positive	Positive	Matched
U100	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U101	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched

Classification: Clinical performance test

Test name: Clinical performance test

Test period : 2020. 02. 24~26.

Tester : MFDS(KOREA Ministry Food and Drug Safety)



U102	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U103	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U104	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U105	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Positive	Positive	Matched
U106	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U107	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U108	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U109	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U110	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Negative	Negative	Matched
U111	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U112	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U113	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U114	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U115	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U116	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U117	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U118	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U119	nasopharyngeal/throat	Negative	Negative	Matched

Classification: Clinical performance test
 Test name: Clinical performance test
 Test period : 2020. 02. 24~26.
 Tester : MFDS(KOREA Ministry Food and Drug Safety)



	swab			
		Sputum	Negative	Negative
U120	nasopharyngeal/throat swab	Positive	Positive	Matched
	Sputum	Negative	Negative	Matched
U121	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U122	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched
U123	nasopharyngeal/throat swab	Negative	Negative	Matched
	Sputum	Negative	Negative	Matched

* U014 The result of the comparative product was negative, but the test results of two products of the same person's lower respiratory tract were positive. Therefore, the negative result is the same in both products.

5-2-2 Analysis of correspondence between test product and comparative product

The test results between the test product and the comparative product are summarized (Table 11) and the positive and negative result agreement rate and 95% confidence interval value are calculated (Table 12).

[Table 11] Judgment table of test products and comparative products

		PowerCheck 2019-nCoV Real-time PCR Kit		Total
		Positive	Negative	
LabGun™ COVID-19 Assay	Positive	18	-	18
	Negative	-	105	105
Total		18	105	123

Determine Cohen's Kappa coefficient using the following formula

- TP(True positive), TN(True negative), FP(False positive), FN(False negative), n(recruitment)
 - Total matched(%) = $100 \cdot (TP + TN)/n$
 - Cohen's Kappa value: $\frac{\{(TP+TN)/n\} - [\{(TP+FN)/n\} \cdot \{(TP+FP)/n\}] + [\{(FP+TN)/n\} \cdot \{(FN+TN)/n\}]}{1 - [\{(TP+FN)/n\} \cdot \{(TP+FP)/n\}] + [\{(FP+TN)/n\} \cdot \{(FN+TN)/n\}]}$
- => 1.7074/1.7074 = 1

Classification: Clinical performance test
 Test name: Clinical performance test
 Test period : 2020. 02. 24~26.
 Tester : MFDS(KOREA Ministry Food and Drug Safety)



The calculated negative matched rate and 95% confidence Interval between the Test Product and the comparative product are as follows.

	value	95% CI
Positive matched rate	100%	82.4% - 100%
Negative matched rate	100%	96.5% - 100%

6. 결론

Comparison between LabGun™ COVID-19 Assay (Test Product) and comparative product PowerCheck 2019-nCoV Real-time PCR Kit (Control) which is total of 123 clinical residual samples showed 100% agreement between the positive and negative results. Cohen's kappa coefficient was also calculated as 1. Therefore, LabGun™ COVID-19 Assay (test product) can be seen to be clinically equivalent to PowerCheck 2019-nCoV Real-time PCR Kit (control product) of cogen Biotech.

7. Positive sample clinical test raw data

Tester	Specimen	Comparison products		Test Product	
		RdRp	E	RdRp	E
U008	nasopharyngeal/throat swab	21.8	18.7	22.7	22.7
	Sputum	22.4	19.2	22.6	23.3
U014	nasopharyngeal/throat swab	0.0	34.5	38.3	40.0
	Sputum	33.1	28.5	31.9	32.6
U027	nasopharyngeal/throat swab	15.5	14.6	18.1	18.1
	Sputum	16.8	16.0	19.5	19.9
U029	nasopharyngeal/throat swab	29.6	29.0	32.5	33.2
	Sputum	24.6	24.0	27.4	27.9
U054	nasopharyngeal/throat swab	20.4	19.2	23.0	23.1
	Sputum	19.9	18.7	23.0	23.2
U060	nasopharyngeal/throat swab	24.4	23.8	27.4	28.1
	Sputum	34.3	33.0	36.3	38.2
U062	nasopharyngeal/throat swab	32.4	31.7	34.9	35.9
	Sputum	27.8	27.1	30.8	31.6
U072	nasopharyngeal/throat swab	18.8	17.9	21.9	21.8

Classification: Clinical performance test
 Test name: Clinical performance test
 Test period : 2020. 02. 24~26.
 Tester : MFDS(KOREA Ministry Food and Drug Safety)



	Sputum	26.9	25.7	29.9	30.3
U080	nasopharyngeal/throat swab	17.7	17.2	20.7	21.1
	Sputum	16.6	16.2	19.3	19.9
U081	nasopharyngeal/throat swab	25.8	25.2	28.6	29.3
	Sputum	19.3	18.6	22.0	22.4
U085	nasopharyngeal/throat swab	32.2	31.5	34.5	37.9
	Sputum	37.5	0.0	39.1	0.0
U089	nasopharyngeal/throat swab	24.9	24.6	27.0	29.7
	Sputum	24.8	24.4	27.3	30.1
U091	nasopharyngeal/throat swab	25.7	25.4	28.1	30.9
	Sputum	21.0	20.2	23.4	25.8
U099	nasopharyngeal/throat swab	0.0	0.0	0.0	0.0
	Sputum	35.3	34.2	36.8	39.1
U101	nasopharyngeal/throat swab	21.6	21.3	24.6	27.1
	Sputum	17.0	16.4	19.3	21.7
U105	nasopharyngeal/throat swab	27.5	26.9	30.1	33.0
	Sputum	32.4	31.8	34.2	38.0
U110	nasopharyngeal/throat swab	36.4	34.3	39.4	42.1
	Sputum	0.0	0.0	0.0	0.0
U120	nasopharyngeal/throat swab	31.6	31.0	33.0	36.2
	Sputum	0.0	0.0	0.0	0.0