

Clinical Performance Evaluation of BZ COVID-19 Ag Test for detection of SARS-CoV-2 antigen from human nasopharyngeal and nasal swab.

- **In-vitro diagnostic device under clinical investigation:**

BZ COVID-19 Ag Test for detection of SARS-CoV-2 antigen from human nasopharyngeal and nasal swab.

- **Investigation Periods:** Oct 8, 2020~ Oct 28,2020

- **Sponsor:** Biozentech Co., Ltd.(#1805, 53, Gasan digital 2-ro, Geumcheon-gu, Seoul, 08588, Republic of Korea

- **Monitor:** Woo Sang Jung, Head of Research Division, Biozentech Co., Ltd..

- **Clinical Investigator:** Jeeyong Kim, M.D.

- **Location of the Clinical Investigation:** Korea University Ansan Hospital

Approved by



Oct 28, 2020

Professor of Korea University Ansan Hospital, 123, JeokGeum Ro, Danwon Gu, Ansan city,
Gyeonggi Do
Jeeyong Kim, M.D.

1 Purpose

This study is to determine the clinical sensitivity and clinical specificity of the BZ COVID-19 Ag Test compare to Allplex™ 2019-nCoV Assay.

2 Study design

Total One hundred ninety eight of nasopharyngeal swab, forty eight sputum and four nasal swab samples was evaluated.

Specimens collected from Korea University Guro Hospital and KCDC(2020-051). Sixty samples are COVID-19 positive and One hundred thirty eight samples are COVID-19 negative in nasopharyngeal swab. Also, Thirty eight samples are COVID-19 positive and ten samples are COVID-19 negative in sputum, two samples are COVID-19 positive and two samples are COVID-19 negative in nasal swab.

In the test of clinical sensitivity and clinical specificity, BZ COVID-19 Ag Test compared to comparator method (Allplex™ 2019-nCoV Assay [RP10243X,RP10244Y]).

3 Materials

3.1 Test device: BZ COVID-19 Ag Test (Lot # RCOV220A01, RCOV220A02)

3.2 Comparator : Allplex™ 2019-nCoV Assay [RP10243X,RP10244Y]; approved
Emergency Use Authorization from Korea Centers for Disease Control
and approval for export only (Seegene)

3.3 Specimens: Nasopharyngeal, nasal swab

3.3.1 Sixty positive nasopharyngeal samples

3.3.2 One hundred thirty eight negative nasopharyngeal samples

3.3.3 Thirty eight positive sputum samples

3.3.4 Ten negative sputum samples

3.3.5 Two positive nasal samples

3.3.6 Two negative nasal samples

4 Procedure

4.1 Test device – BZ COVID-19 Ag Test

Test procedure followed instruction manual of BZ COVID-19 Ag Test
(See Instructions For Use : IFU-COVID-19 Ag-EN(A))

4.2 Test procedure

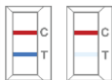
- 4.2.1 Place device on a clean, flat surface after removing from the pouch.
- 4.2.2 Write the patient's ID on the device.
- 4.2.3 Peel off aluminum foil seal.
- 4.2.4 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.
- 4.2.5 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.
- 4.2.6 Close the vial with the provided cap and push firmly onto the vial.
- 4.2.7 Mix thoroughly by flicking the bottom of the tube.
- 4.2.8 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.
- 4.2.9 Read and interpret the test result at 10 minutes. The test result should not be read and interpreted after 15 minutes.

4.3 Interpretation of results.

NOTE: The test results should be read and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes. The test results should not be interpreted using any instruments.

Positive: two distinct colored lines appear.

One red-colored line next to "C" and one blue-colored line next to "T" indicates COVID-19 positive result.



NOTE: The color intensity in the test region will vary depending on the amount of SARS-CoV-2 nucleocapsid protein antigen present in the sample. Any faint colored line(s) in the test region(s) should be considered as positive.

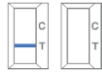
Negative:

One red-colored line only next to "C" indicates a negative result.



Invalid:

If the red-colored line in the control region "C" is not visible, the result is invalid. Re-run the test one time using the remaining specimen in the extraction vial if an invalid result is obtained during initial testing



5 Test conditions

5.1 Date: Oct 8, 2020 ~ Oct 21, 2020

5.2 Site: Korea University Ansan Hospital (15355, 123, JeokGeum Ro, Danwon Gu, Ansan city
Gyeonggi Do, Republic of Korea)

5.3 Operator: HyeonSeok Kim, Yeong Ran Choi

6. Results

6.1 Nasopharyngeal swab(NS), sputum(S), Nsalswab(NS) test

Specimen No.	BZ COVID-19 Ag Test	Comparator Method (RT-PCR)			
		Result	E gene	RdRP gene	Ngene
NPP-1	Positive	Positive	22.17	21.07	23.07
NPP-2	Positive	Positive	11.97	13.35	14.87
NPP-3	Positive	Positive	23.74	24.49	26.17
NPP-4	Positive	Positive	12.98	15.02	16.77
NPP-5	Positive	Positive	16.04	17.19	18.9
NPP-6	Positive	Positive	14.16	15.29	16.85
NPP-7	Positive	Positive	25.28	26.04	27.84
NPP-8	Positive	Positive	16.45	17.34	18.84
NPP-9	Positive	Positive	12.97	14.7	16.2
NPP-10	Positive	Positive	27.13	28.14	29.75
NPP-11	Positive	Positive	18.61	19.49	21.41
NPP-12	Positive	Positive	15.67	16.54	18.28
NPP-13	Positive	Positive	9.44	11.65	12.57
NPP-14	Positive	Positive	19.34	20.37	22.19
NPP-15	Negative	Positive	28.11	30.23	31.41
NPP-16	Positive	Positive	17.11	18.03	19.75
NPP-17	Positive	Positive	17.53	18.94	20.9
NPP-18	Positive	Positive	16.37	17.63	19.27
NPP-19	Positive	Positive	10.02	12.08	13.25
NPP-20	Positive	Positive	23.58	24.54	25.8
NPP-21	Positive	Positive	11.04	12.87	14.12
NPP-22	Positive	Positive	18.7	19.91	21.2

NPP-23	Positive	Positive	13.55	15	16.54
NPP-24	Positive	Positive	13.98	16.68	17.01
NPP-25	Positive	Positive	20.99	22.13	23.9
NPP-26	Positive	Positive	18.18	19.77	21.76
NPP-17	Positive	Positive	18.31	19.86	22.12
NPP-28	Positive	Positive	20.04	22.1	22.51
NPP-29	Positive	Positive	13.45	15.59	16.28
NPP-30	Positive	Positive	20.33	21.98	23.06
NPP-31	Positive	Positive	20.24	21.03	22.43
NPP-32	Positive	Positive	26.62	27.46	28.8
NPP-33	Positive	Positive	13.19	15.02	16.27
NPP-34	Positive	Positive	24.43	25.35	27.27
NPP-35	Positive	Positive	13.45	14.88	16.76
NPP-36	Positive	Positive	15.87	17.07	18.25
NPP-37	Positive	Positive	23.28	24.09	25.02
NPP-38	Positive	Positive	22.12	24.89	25.78
NPP-39	Positive	Positive	15.25	17.17	19.42
NPP-40	Positive	Positive	19.57	20.83	23.13
NPP-41	Positive	Positive	22.16	23.84	25.31
NPP-42	Positive	Positive	25.63	26.72	28.7
NPP-43	Positive	Positive	22.1	22.66	24.72
NPP-44	Positive	Positive	19.44	21.37	22.59
NPP-45	Positive	Positive	13.63	15.6	17.27
NPP-46	Positive	Positive	23.07	24.81	25.97
NPP-47	Positive	Positive	14.5	16.55	18.16
NPP-48	Positive	Positive	27.86	29.4	31.64
NPP-49	Positive	Positive	27.11	28.79	30.86
NPP-50	Positive	Positive	21.57	24.09	24.83
NPP-51	Positive	Positive	21.71	22.08	22.41
NPP-52	Positive	Positive	27.28	28.91	28.75
NPP-53	Positive	Positive	21.02	24.21	24.7
NPP-54	Positive	Positive	21.25	22.25	22.44
NPP-55	Positive	Positive	21.79	22.99	24.01
NPP-56	Positive	Positive	16.36	16.81	18.44
NPP-57	Positive	Positive	26.24	25.99	26.22
NPP-58	Positive	Positive	26.77	28.31	29.25

NPP-59	Positive	Positive	27.44	29.08	25.67
NPP-60	Positive	Positive	20.65	22.2	22.72
SP-61	Positive	Positive	20.45	20.77	21.4
SP-62	Positive	Positive	21.58	22.02	22.64
SP-62	Positive	Positive	22.27	24.84	23.79
SP-64	Positive	Positive	18.34	20.85	23
SP-65	Positive	Positive	21.82	25.21	24.83
SP-66	Positive	Positive	24.47	23.49	24.76
SP-67	Positive	Positive	32.2	33.52	34.98
SP-68	Positive	Positive	31.4	34.12	33.5
SP-69	Positive	Positive	27.5	29.64	29.2
SP-70	Positive	Positive	28.34	30.58	32.07
SP-71	Positive	Positive	28.96	30.84	31.25
SP-72	Positive	Positive	24.65	25.27	26.21
SP-73	Positive	Positive	24.38	26.69	25.88
SP-74	Positive	Positive	25.62	26.71	28.88
SP-75	Positive	Positive	18.24	15.99	16.12
SP-76	Positive	Positive	11.71	14.87	18.78
SP-77	Positive	Positive	15.22	14.12	14.64
SP-78	Positive	Positive	11.08	11.85	33.12
SP-79	Positive	Positive	17.01	16.4	18.77
SP-80	Negative	Positive	34.65	35.72	35.63
SP-81	Negative	Positive	33.66	33.9	35.38
SP-82	Positive	Positive	20.65	21.99	22.76
SP-83	Positive	Positive	18.77	20.09	22.31
SP-84	Positive	Positive	12.89	17.1	15.88
SP-85	Positive	Positive	10.89	11.96	12.85
SP-86	Positive	Positive	22.67	24.79	24.57
SP-87	Positive	Positive	27.23	28.49	31.17
SP-88	Positive	Positive	21.2	22.29	22.11
SP-89	Positive	Positive	22.25	27.7	27.47
SP-90	Positive	Positive	25.51	28.77	28.27
SP-91	Positive	Positive	28.21	30.67	31.45
SP-92	Positive	Positive	24.68	25.5	26.7
SP-93	Positive	Positive	21.96	23.13	25.55
SP-94	Positive	Positive	16.88	19.62	20.02

SP-95	Positive	Positive	24.26	24.89	25.18
SP-96	Positive	Positive	20.71	22.22	21.78
SP-97	Positive	Positive	19.48	21.48	20.67
SP-98	Positive	Positive	22.2	24.26	25.51
NSP-99	Positive	Positive	24.28	22.41	24.82
NSP-100	Positive	Positive	25.29	24.86	29.89
NPN-1	Negative	Negative	NA	NA	NA
NPN-2	Negative	Negative	NA	NA	NA
NPN-3	Negative	Negative	NA	NA	NA
NPN-4	Negative	Negative	NA	NA	NA
NPN-5	Negative	Negative	NA	NA	NA
NPN-6	Negative	Negative	NA	NA	NA
NPN-7	Negative	Negative	NA	NA	NA
NPN-8	Negative	Negative	NA	NA	NA
NPN-9	Negative	Negative	NA	NA	NA
NPN-10	Negative	Negative	NA	NA	NA
NPN-11	Negative	Negative	NA	NA	NA
NPN-12	Negative	Negative	NA	NA	NA
NPN-13	Negative	Negative	NA	NA	NA
NPN-14	Negative	Negative	NA	NA	NA
NPN-15	Negative	Negative	NA	NA	NA
NPN-16	Negative	Negative	NA	NA	NA
NPN-17	Negative	Negative	NA	NA	NA
NPN-18	Negative	Negative	NA	NA	NA
NPN-19	Negative	Negative	NA	NA	NA
NPN-20	Negative	Negative	NA	NA	NA
NPN-21	Negative	Negative	NA	NA	NA
NPN-22	Negative	Negative	NA	NA	NA
NPN-23	Negative	Negative	NA	NA	NA
NPN-24	Negative	Negative	NA	NA	NA
NPN-25	Negative	Negative	NA	NA	NA
NPN-26	Negative	Negative	NA	NA	NA
NPN-27	Negative	Negative	NA	NA	NA
NPN-28	Negative	Negative	NA	NA	NA
NPN-20	Negative	Negative	NA	NA	NA

NPN-21	Negative	Negative	NA	NA	NA
NPN-22	Negative	Negative	NA	NA	NA
NPN-23	Negative	Negative	NA	NA	NA
NPN-24	Negative	Negative	NA	NA	NA
NPN-25	Negative	Negative	NA	NA	NA
NPN-26	Negative	Negative	NA	NA	NA
NPN-27	Negative	Negative	NA	NA	NA
NPN-28	Negative	Negative	NA	NA	NA
NPN-29	Negative	Negative	NA	NA	NA
NPN-30	Negative	Negative	NA	NA	NA
NPN-31	Negative	Negative	NA	NA	NA
NPN-32	Negative	Negative	NA	NA	NA
NPN-33	Negative	Negative	NA	NA	NA
NPN-34	Negative	Negative	NA	NA	NA
NPN-35	Negative	Negative	NA	NA	NA
NPN-36	Negative	Negative	NA	NA	NA
NPN-37	Negative	Negative	NA	NA	NA
NPN-38	Negative	Negative	NA	NA	NA
NPN-39	Negative	Negative	NA	NA	NA
NPN-40	Negative	Negative	NA	NA	NA
NPN-41	Negative	Negative	NA	NA	NA
NPN-42	Negative	Negative	NA	NA	NA
NPN-43	Negative	Negative	NA	NA	NA
NPN-44	Negative	Negative	NA	NA	NA
NPN-45	Negative	Negative	NA	NA	NA
NPN-46	Negative	Negative	NA	NA	NA
NPN-47	Negative	Negative	NA	NA	NA
NPN-48	Negative	Negative	NA	NA	NA
NPN-49	Negative	Negative	NA	NA	NA
NPN-50	Negative	Negative	NA	NA	NA
NPN-51	Negative	Negative	NA	NA	NA
NPN-52	Negative	Negative	NA	NA	NA
NPN-53	Negative	Negative	NA	NA	NA
NPN-54	Negative	Negative	NA	NA	NA
NPN-55	Negative	Negative	NA	NA	NA
NPN-56	Negative	Negative	NA	NA	NA

NPN-57	Negative	Negative	NA	NA	NA
NPN-58	Negative	Negative	NA	NA	NA
NPN-59	Negative	Negative	NA	NA	NA
NPN-60	Negative	Negative	NA	NA	NA
NPN-61	Negative	Negative	NA	NA	NA
NPN-62	Negative	Negative	NA	NA	NA
NPN-63	Negative	Negative	NA	NA	NA
NPN-64	Negative	Negative	NA	NA	NA
NPN-65	Negative	Negative	NA	NA	NA
NPN-66	Negative	Negative	NA	NA	NA
NPN-67	Positive	Negative	NA	NA	NA
NPN-68	Negative	Negative	NA	NA	NA
NPN-69	Negative	Negative	NA	NA	NA
NPN-70	Negative	Negative	NA	NA	NA
NPN-71	Negative	Negative	NA	NA	NA
NPN-72	Negative	Negative	NA	NA	NA
NPN-73	Negative	Negative	NA	NA	NA
NPN-74	Negative	Negative	NA	NA	NA
NPN-75	Negative	Negative	NA	NA	NA
NPN-76	Negative	Negative	NA	NA	NA
NPN-77	Negative	Negative	NA	NA	NA
NPN-78	Negative	Negative	NA	NA	NA
NPN-79	Negative	Negative	NA	NA	NA
NPN-80	Negative	Negative	NA	NA	NA
NPN-81	Negative	Negative	NA	NA	NA
NPN-82	Negative	Negative	NA	NA	NA
NPN-83	Negative	Negative	NA	NA	NA
NPN-84	Negative	Negative	NA	NA	NA
NPN-85	Negative	Negative	NA	NA	NA
NPN-86	Negative	Negative	NA	NA	NA
NPN-87	Negative	Negative	NA	NA	NA
NPN-88	Negative	Negative	NA	NA	NA
NPN-89	Negative	Negative	NA	NA	NA
NPN-90	Negative	Negative	NA	NA	NA
NPN-91	Negative	Negative	NA	NA	NA
NPN-92	Negative	Negative	NA	NA	NA

NPN-93	Negative	Negative	NA	NA	NA
NPN-94	Negative	Negative	NA	NA	NA
NPN-95	Negative	Negative	NA	NA	NA
NPN-96	Negative	Negative	NA	NA	NA
NPN-97	Negative	Negative	NA	NA	NA
NPN-98	Negative	Negative	NA	NA	NA
NPN-99	Negative	Negative	NA	NA	NA
NPN-100	Negative	Negative	NA	NA	NA
NPN-101	Negative	Negative	NA	NA	NA
NPN-102	Negative	Negative	NA	NA	NA
NPN-103	Negative	Negative	NA	NA	NA
NPN-104	Negative	Negative	NA	NA	NA
NPN-105	Negative	Negative	NA	NA	NA
NPN-106	Negative	Negative	NA	NA	NA
NPN-107	Negative	Negative	NA	NA	NA
NPN-108	Negative	Negative	NA	NA	NA
NPN-109	Negative	Negative	NA	NA	NA
NPN-110	Negative	Negative	NA	NA	NA
NPN-111	Negative	Negative	NA	NA	NA
NPN-112	Negative	Negative	NA	NA	NA
NPN-113	Negative	Negative	NA	NA	NA
NPN-114	Negative	Negative	NA	NA	NA
NPN-115	Negative	Negative	NA	NA	NA
NPN-116	Negative	Negative	NA	NA	NA
NPN-117	Negative	Negative	NA	NA	NA
NPN-118	Negative	Negative	NA	NA	NA
NPN-119	Negative	Negative	NA	NA	NA
NPN-120	Negative	Negative	NA	NA	NA
NPN-121	Negative	Negative	NA	NA	NA
NPN-122	Negative	Negative	NA	NA	NA
NPN-123	Negative	Negative	NA	NA	NA
NPN-124	Negative	Negative	NA	NA	NA
NPN-125	Negative	Negative	NA	NA	NA
NPN-126	Negative	Negative	NA	NA	NA
NPN-127	Negative	Negative	NA	NA	NA
NPN-128	Negative	Negative	NA	NA	NA

NPN-120	Negative	Negative	NA	NA	NA
NPN-121	Negative	Negative	NA	NA	NA
NPN-122	Negative	Negative	NA	NA	NA
NPN-123	Negative	Negative	NA	NA	NA
NPN-124	Negative	Negative	NA	NA	NA
NPN-125	Negative	Negative	NA	NA	NA
NPN-126	Negative	Negative	NA	NA	NA
NPN-127	Negative	Negative	NA	NA	NA
NPN-128	Negative	Negative	NA	NA	NA
NPN-129	Negative	Negative	NA	NA	NA
NPN-130	Negative	Negative	NA	NA	NA
NPN-131	Negative	Negative	NA	NA	NA
NPN-132	Negative	Negative	NA	NA	NA
NPN-133	Negative	Negative	NA	NA	NA
NPN-134	Negative	Negative	NA	NA	NA
NPN-135	Negative	Negative	NA	NA	NA
NPN-136	Negative	Negative	NA	NA	NA
NPN-137	Negative	Negative	NA	NA	NA
NPN-138	Negative	Negative	NA	NA	NA
SN-139	Negative	Negative	NA	NA	NA
SN-140	Negative	Negative	NA	NA	NA
SN-141	Negative	Negative	NA	NA	NA
SN-142	Negative	Negative	NA	NA	NA
SN-143	Negative	Negative	NA	NA	NA
SN-144	Negative	Negative	NA	NA	NA
SN-145	Negative	Negative	NA	NA	NA
SN-146	Negative	Negative	NA	NA	NA
SN-147	Negative	Negative	NA	NA	NA
SN-148	Negative	Negative	NA	NA	NA
NSN-149	Negative	Negative	NA	NA	NA
NSN-150	Negative	Negative	NA	NA	NA

		PCR		
		Positive	Negative	Total
BZ COVID-19 Ag Test	Positive	97	1	98
	Negative	3	149	152
	Total	100	150	250
Sensitivity		97/100*100=97.0%		
Specificity		149/150*100=99.3%		

* Summary of the sensitivity and specificity of the BZ COVID-19 Ag Test compared to PCR.

7. Conclusion

Based on section 6, clinical sensitivity was 97.0% (97/100) and clinical specificity was 99.3% (149/150) comparing Allplex™ 2019-nCoV Assay in nasopharyngeal swab and nasal swab.

In conclusion, BZ COVID-19 Ag Test proved effective diagnosis for SARS-CoV-2 infection.