PROJECT CODE	PRODUCT DESIGNATION	REFERENCE
NA	BIOSYNEX® COVID-19 Ag BSS	SW40006
NA	BIOSYNEX® COVID-19 Ag BSX	SW40006_BSX

Content

I. CLINICAL STUDY 1: Clinical samples study report

Date of the report: 09/09/2020

➢ Objective

Evaluate the performance of BIOSYNEX COVID-19 Ag BSS on clinical samples.

➢ Material

✓ Description of component

COVID-19 Antigen Rapid Test Cassette (Swab)
Lot: 20200313, Exp: 02-2022

Commercial PCR assay: DAAN GENE CO. LTD, Detection kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence probing)

✓ Description of samples

Clinical samples: 203 patients exhibiting pneumonia or respiratory symptoms were sequentially enrolled and nasopharyngeal (NP) swab samples were collected for testing, two swab samples from each patient were taken at the same time.

➢ Method

○ Study design

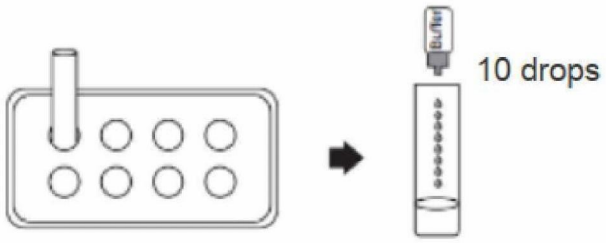
Clinical samples: 203 patients exhibiting pneumonia or respiratory symptoms were sequentially enrolled and nasopharyngeal (NP) swab samples were collected for testing, two swab samples from each patient were taken at the same time. One swab sample was used for COVID-19 Antigen Rapid Test Cassette (Swab) testing, the other swab sample was used for commercial PCR assay testing. The swab samples were tested in single with COVID-19 Antigen Rapid Test Cassette (Swab), the results were compared to PCR assay results.
Note: the tests were performed using fresh samples

○ Test procedure

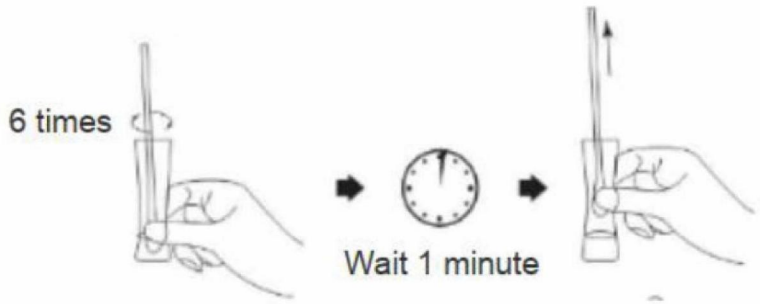
According to the package insert:

SAMPLE PREPARATION PROCEDURE

1.Insert the extraction tube into the workstation. Make sure that the tube is standing firm and reaches the bottom of the workstation.
2.Add 0.3 mL (about 10 drops) of the sample extraction buffer into the extraction tube.



3.Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
4.Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5.Leave the swab in the extraction tube for 1 minute.
6.Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.



TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2.Insert a nozzle with filter into the sample extraction tube tightly.
3.Reverse the sample extraction tube, and add 4 drops (about 100 µL) of test sample by squeezing the extracted solution tube into the sample window.
4.Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

➢ Results

LINE DATA:

S/N	Specimen ID	Gender	Age	Specimen Type	Specimen collection date	Days since symptoms onset	COVID-19 Ag test result	PCR result	PCR result (Ct)		Clinical diagnosis background information
									ORF	N	
1	00074886	female	46	nasopharyngeal (NP) swab	2020-03-02	2	-	-	no Ct	no Ct	Dry cough for 2 days, sore throat
2	00074907	male	49	nasopharyngeal (NP) swab	2020-03-02	1	+	+	24.45	21.91	Headache, diarrhea 1 days, chest CT double lung inferior lobe pleural diffuse in infection, novel Coronavirus 2 targets PCR is positive
3	00074922	male	33	nasopharyngeal (NP) swab	2020-03-02	3	+	+	29.40	27.01	Cough, shortness of breath for 3 days, infectious lesions in both lungs, positive nucleic acid test for COVID-19
4	00074990	male	39	nasopharyngeal (NP) swab	2020-03-02	4	+	+	29.77	27.57	Fever and dry cough for 4 days. Chest CT showed multiple height-density shadows in both lungs, some of which were ground glass, nasopharyngeal swab sample PCR is positive
5	00075018	female	61	nasopharyngeal (NP) swab	2020-03-02	1	+	+	26.45	24.13	Cough, sore throat for 1 days, nucleic acid is positive
6	00075020	male	34	nasopharyngeal (NP) swab	2020-03-02	2	+	+	27.75	26.00	Cough, nasal obstruction for 1 day, chest CT bronchovascular bundle of both lungs thickened and increased, the upper lobe of both lungs showed a little pulmonary balloon cavity shadow under pleura
7	00075056	female	74	nasopharyngeal (NP) swab	2020-03-02	2	+	+	29.34	27.16	Headache and abdominal pain for 2 days. Chest CT showed a little inflammatory lesions in the dorsal pleura of the right lower lobe of the lung, and the nucleic acid test of COVID-19 is positive
8	00075057	female	65	nasopharyngeal (NP) swab	2020-03-02	4	-	-	no Ct	no Ct	Cough 4 days,
9	00075060	male	28	nasopharyngeal (NP) swab	2020-03-02	5	-	-	no Ct	no Ct	Fever 5 days, chest CT in both lungs

											a little scattered inflammation
10	00075061	male	52	nasopharyngeal (NP) swab	2020-03-02	6	-	-	no Ct	no Ct	Fever, cough, chills, headache
11	00075065	female	35	nasopharyngeal (NP) swab	2020-03-02	1	+	+	24.36	21.76	Fever 1 days
12	00075076	male	51	nasopharyngeal (NP) swab	2020-03-02	7	-	-	no Ct	no Ct	Fever, cough, expectoration for 1 week, chills, headache
13	00075091	male	77	nasopharyngeal (NP) swab	2020-03-03	7	+	+	27.88	25.72	Fever, cough, sputum accompanied by shortness of breath for 1 week, and ground glass shadows scattered in both lungs on chest CT, nucleic acid is positive
14	00075095	female	49	nasopharyngeal (NP) swab	2020-03-03	3	+	+	26.98	24.79	Cough for 3 days, chest CT was considered to be infectious lesions in both lungs, nucleic acid is positive
15	00075103	female	40	nasopharyngeal (NP) swab	2020-03-03	2	+	+	29.02	25.56	Cough, nucleic acid is positive
16	00075105	female	45	nasopharyngeal (NP) swab	2020-03-03	1	+	+	23.27	20.81	The nucleic acid test of COVID-19 is positive
17	00075109	female	74	nasopharyngeal (NP) swab	2020-03-03	5	+	+	26.64	23.38	Fever, headache for 5 days, chest tightness for 1 day, cough double lung infection, PCR positive test for COVID-19 nucleic acid
18	00075134	male	46	nasopharyngeal (NP) swab	2020-03-03	2	+	+	29.64	27.73	The nucleic acid test of COVID-19 is positive and chest CT showed patchy ground vitreous lesions in both lungs
19	00075136	female	51	nasopharyngeal (NP) swab	2020-03-03	4	+	+	25.81	23.16	Fever 4 days, COVID-19 nucleic acid test is positive , chest CT double down pneumonia
20	00075137	female	72	nasopharyngeal (NP) swab	2020-03-03	4	-	-	no Ct	no Ct	Fever, cough
21	00075142	female	63	nasopharyngeal (NP) swab	2020-03-03	3	+	+	29.88	26.58	The nucleic acid test of COVID-19 is positive
22	00075148	female	72	nasopharyngeal (NP) swab	2020-03-04	2	+	+	27.88	24.54	The nucleic acid test of COVID-19 is positive, and chest CT showed multiple lobes and segments of ground glass lesions in both lungs
23	00075149	female	55	nasopharyngeal (NP) swab	2020-03-04	3	-	-	no Ct	no Ct	Cough and sore throat for 3 days
24	00075151	female	45	nasopharyngeal (NP) swab	2020-03-04	3	+	+	29.84	29.82	Nucleic acid is positive for COVID-19. Chest CT showed many ground-glass lesions in both lungs, mainly external lung

25	00075153	female	47	nasopharyngeal (NP) swab	2020-03-04	3	+	+	28.03	25.54	Cough, wheezing for 3 days, fever for 1 day, infectious lesions in both lungs, nucleic acid is positive
26	00075165	female	15	nasopharyngeal (NP) swab	2020-03-04	5	+	+	29.77	26.92	Dry cough for 5 days, headache, chest CT scan of the anterior lobe of the right upper lobe, patchy ground glass shadow of the dorsal lobe of the lower lobe, considered inflammation, COVID-19 nucleic acid test is positive
27	00075179	female	55	nasopharyngeal (NP) swab	2020-03-04	3	+	+	29.84	28.20	Cough, sputum for 3 days, chest CT, right lung and left lower lung blade shaped, patchy high-density blur
28	00075183	female	57	nasopharyngeal (NP) swab	2020-03-04	2	+	+	23.56	21.93	Cough for 2 days, wheezing for 2 days, chest CT double pneumonia
29	00075193	male	71	nasopharyngeal (NP) swab	2020-03-04	3	-	-	no Ct	no Ct	Cough and sore throat for 3 days
30	00075196	male	49	nasopharyngeal (NP) swab	2020-03-04	1	+	+	26.17	24.35	Cough, sputum for 1 days, fever for 1 days, chest CT, infectious lesions in both lungs, nucleic acid test is positive
31	00075198	female	41	nasopharyngeal (NP) swab	2020-03-05	2	-	-	no Ct	no Ct	Cough and sore throat for 2 days
32	00075225	male	63	nasopharyngeal (NP) swab	2020-03-05	2	-	-	no Ct	no Ct	Fever 1 day, pharyngeal pain 2 days
33	00075231	male	51	nasopharyngeal (NP) swab	2020-03-05	3	+	+	29.93	27.60	Fever, cough for 3 day, chest CT in both lungs scattered patchy ground glass shadow, nucleic acid is positive
34	00075240	male	57	nasopharyngeal (NP) swab	2020-03-05	5	-	-	no Ct	no Ct	Fever and cough for 5 days. Chest CT scan of the lower lobe of the left lung showed round and slightly high-density shadow, patchy upper lobe and upper lobe of the right lung showed small nodular high-density shadow
35	00075253	male	78	nasopharyngeal (NP) swab	2020-03-05	4	+	+	29.92	30.33	The nucleic acid test of COVID-19 was positive, the chest CT showed multiple lobe infectious lesions in both lungs, and the small nodules in the middle lobe of the right lung

											showed COVID-19 positive
36	00075262	female	63	nasopharyngeal (NP) swab	2020-03-05	2	+	+	28.34	26.21	Cough, expectoration for 2 days, CT infection of both lungs
37	00075275	male	25	nasopharyngeal (NP) swab	2020-03-05	2	-	-	no Ct	no Ct	Diarrhea 1 day, chest CT right middle lobe pleural, minute nodules
38	00075278	male	34	nasopharyngeal (NP) swab	2020-03-05	1	+	+	26.48	24.59	Cough, chest pain for 1 day, chest CT findings of the lower lobe of both lungs were considered infectious lesions, there were a few fibrous bands in the medial middle lobe of the right lung and the anterior inner base of the lower lobe of the left lung.Nucleic acid is positive
39	00075279	male	58	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	Cough and runny nose for 4 days
40	00075293	male	60	nasopharyngeal (NP) swab	2020-03-05	2	+	+	22.58	20.90	Cough for 2 days, chest CT scan of the left upper lobe and lower tongue, the middle lobe of the right lung, and the lower lobe of each segment of the patchy ground glass shadow
41	00075295	female	2	nasopharyngeal (NP) swab	2020-03-06	2	-	-	no Ct	no Ct	Cough and runny nose for 2 days
42	00075298	female	33	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	Cough and runny nose for 4 days
43	00075320	male	63	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	Cough and sore throat for 3 days
44	00075367	female	32	nasopharyngeal (NP) swab	2020-03-06	1	+	+	25.75	23.77	Nucleic acid positive, CT infection of lower lobe of both lungs, right upper lobe tip, posterior segment, left upper lobe lingual nodules, nucleic acid is positive
45	00075375	male	35	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	Cough and sputum for 3 days
46	00077579	female	44	nasopharyngeal (NP) swab	2020-03-07	2	-	-	no Ct	no Ct	Cough and sputum for 2 days
47	00078768	male	27	nasopharyngeal (NP) swab	2020-03-09	2	+	+	28.53	26.10	COVID-19 Nucleic acid is positive

Investigational site 2:

S/N	Specimen ID	Gender	Age	Specimen type	Specimen collection date	Days since symptom onset	COVID-19 Ag result	PCR result	PCR result (Ct)		Clinical Diagnosis Background Information
									ORF	N	
1	6609515	male	25	nasopharyngeal (NP) swab	2020-03-02	4	-	-	no Ct	no Ct	fever
2	6609573	male	51	nasopharyngeal (NP) swab	2020-03-02	10	+	+	31.79	30.54	Novel Coronavirus infectious pneumonia
3	6609620	female	46	nasopharyngeal (NP) swab	2020-03-02	7	+	+	31.72	29.69	Novel Coronavirus infectious pneumonia
4	6610889	female	53	nasopharyngeal (NP) swab	2020-03-02	2	+	+	27.87	25.76	Novel Coronavirus infectious pneumonia
5	6610830	female	47	nasopharyngeal (NP) swab	2020-03-02	2	+	+	28.31	26.48	Novel Coronavirus infectious pneumonia
6	6610814	male	48	nasopharyngeal (NP) swab	2020-03-02	4	+	+	31.51	29.48	Novel Coronavirus infectious pneumonia
7	6610849	female	26	nasopharyngeal (NP) swab	2020-03-02	3	+	+	30.79	28.42	Novel Coronavirus infectious pneumonia
8	6610807	male	57	nasopharyngeal (NP) swab	2020-03-02	5	+	+	30.19	27.90	Novel Coronavirus infectious pneumonia
9	6610823	male	56	nasopharyngeal (NP) swab	2020-03-02	4	+	+	30.96	28.17	Novel Coronavirus infectious pneumonia
10	6610827	male	66	nasopharyngeal (NP) swab	2020-03-02	6	-	+	32.34	32.83	Novel Coronavirus infectious pneumonia
11	6610865	female	47	nasopharyngeal (NP) swab	2020-03-02	7	+	+	31.55	29.15	Novel Coronavirus infectious pneumonia
12	6610825	female	57	nasopharyngeal (NP) swab	2020-03-02	9	+	+	31.33	30.44	Novel Coronavirus infectious pneumonia
13	6610847	male	62	nasopharyngeal (NP) swab	2020-03-02	7	-	-	no Ct	no Ct	cough
14	6610871	female	31	nasopharyngeal (NP) swab	2020-03-02	5	-	-	no Ct	no Ct	fever
15	6610886	male	40	nasopharyngeal (NP) swab	2020-03-02	5	-	-	no Ct	no Ct	fever
16	6610896	female	28	nasopharyngeal (NP) swab	2020-03-02	8	+	+	31.98	30.87	Novel Coronavirus infectious pneumonia
17	6610906	female	63	nasopharyngeal (NP) swab	2020-03-02	7	-	-	no Ct	no Ct	fever
18	6610908	female	81	nasopharyngeal (NP) swab	2020-03-02	3	+	+	30.52	27.77	Novel Coronavirus infectious pneumonia
19	6610921	female	45	nasopharyngeal (NP) swab	2020-03-03	4	-	-	no Ct	no Ct	diarrhea

20	6610929	male	71	nasopharyngeal (NP) swab	2020-03-03	7	-	-	no Ct	no Ct	fever
21	6610971	female	19	nasopharyngeal (NP) swab	2020-03-03	5	-	-	no Ct	no Ct	fever
22	6610981	female	18	nasopharyngeal (NP) swab	2020-03-03	8	-	-	no Ct	no Ct	fever
23	6611010	female	42	nasopharyngeal (NP) swab	2020-03-03	5	-	-	no Ct	no Ct	fever
24	6611016	male	15	nasopharyngeal (NP) swab	2020-03-03	6	-	-	no Ct	no Ct	fever
25	6611027	male	25	nasopharyngeal (NP) swab	2020-03-03	4	-	-	no Ct	no Ct	fever
26	6611030	male	25	nasopharyngeal (NP) swab	2020-03-03	7	-	-	no Ct	no Ct	fever
27	6611034	female	39	nasopharyngeal (NP) swab	2020-03-03	7	-	-	no Ct	no Ct	fever
28	6611048	male	76	nasopharyngeal (NP) swab	2020-03-03	7	+	+	30.98	29.71	Novel Coronavirus infectious pneumonia
29	6611043	female	29	nasopharyngeal (NP) swab	2020-03-03	6	-	-	no Ct	no Ct	fever
30	6611040	female	43	nasopharyngeal (NP) swab	2020-03-03	5	-	-	no Ct	no Ct	fever
31	6611063	female	81	nasopharyngeal (NP) swab	2020-03-03	4	+	+	31.75	27.01	Novel Coronavirus infectious pneumonia
32	6611067	female	48	nasopharyngeal (NP) swab	2020-03-03	6	+	+	31.00	28.49	Novel Coronavirus infectious pneumonia
33	6611081	male	48	nasopharyngeal (NP) swab	2020-03-03	6	-	-	no Ct	no Ct	fever
34	6611094	male	80	nasopharyngeal (NP) swab	2020-03-03	5	-	-	no Ct	no Ct	fever
35	6611100	male	46	nasopharyngeal (NP) swab	2020-03-03	7	-	-	no Ct	no Ct	cough
36	6611122	male	26	nasopharyngeal (NP) swab	2020-03-03	5	-	-	no Ct	no Ct	fever
37	6611124	male	34	nasopharyngeal (NP) swab	2020-03-03	4	-	-	no Ct	no Ct	fever
38	6611128	male	16	nasopharyngeal (NP) swab	2020-03-03	6	-	-	no Ct	no Ct	fever
39	6611198	female	34	nasopharyngeal (NP) swab	2020-03-04	5	-	-	no Ct	no Ct	diarrhea
40	6611210	female	38	nasopharyngeal (NP) swab	2020-03-04	4	+	+	30.52	29.43	Novel Coronavirus infectious pneumonia
41	6611227	male	22	nasopharyngeal (NP) swab	2020-03-04	6	-	-	no Ct	no Ct	fever
42	6611234	female	27	nasopharyngeal (NP) swab	2020-03-04	5	-	-	no Ct	no Ct	fever
43	6611259	female	33	nasopharyngeal (NP) swab	2020-03-04	5	-	-	no Ct	no Ct	fever

44	6611260	male	2	nasopharyngeal (NP) swab	2020-03-04	5	+	+	31.11	30.64	Novel Coronavirus infectious pneumonia
45	6611263	female	41	nasopharyngeal (NP) swab	2020-03-04	6	-	-	no Ct	no Ct	fever
46	6611265	female	50	nasopharyngeal (NP) swab	2020-03-04	4	+	+	29.79	27.64	Novel Coronavirus infectious pneumonia
47	6611268	male	66	nasopharyngeal (NP) swab	2020-03-04	3	+	+	28.13	25.29	Novel Coronavirus infectious pneumonia
48	6611270	male	43	nasopharyngeal (NP) swab	2020-03-04	5	+	+	30.58	28.56	Novel Coronavirus infectious pneumonia
49	6611273	male	42	nasopharyngeal (NP) swab	2020-03-04	3	-	-	no Ct	no Ct	Lung infection
50	6611278	male	41	nasopharyngeal (NP) swab	2020-03-04	5	+	+	31.54	29.27	Novel Coronavirus infectious pneumonia
51	6611282	male	57	nasopharyngeal (NP) swab	2020-03-04	4	+	+	29.45	27.42	Novel Coronavirus infectious pneumonia
52	6611284	female	53	nasopharyngeal (NP) swab	2020-03-04	6	+	+	30.66	28.14	Novel Coronavirus infectious pneumonia
53	6611286	male	57	nasopharyngeal (NP) swab	2020-03-04	4	+	+	30.19	27.65	Novel Coronavirus infectious pneumonia
54	6611292	female	50	nasopharyngeal (NP) swab	2020-03-04	7	+	+	31.06	29.14	Novel Coronavirus infectious pneumonia
55	6611293	female	56	nasopharyngeal (NP) swab	2020-03-04	5	+	+	29.13	29.18	Novel Coronavirus infectious pneumonia
56	6612294	female	31	nasopharyngeal (NP) swab	2020-03-04	4	-	-	no Ct	no Ct	fever
57	6612298	male	55	nasopharyngeal (NP) swab	2020-03-04	5	+	+	31.35	28.53	Novel Coronavirus infectious pneumonia
58	6613295	female	29	nasopharyngeal (NP) swab	2020-03-04	4	-	-	no Ct	no Ct	fever
59	6613315	female	54	nasopharyngeal (NP) swab	2020-03-05	7	+	+	32.37	30.19	Novel Coronavirus infectious pneumonia
60	6613318	female	29	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	fever
61	6613320	male	55	nasopharyngeal (NP) swab	2020-03-05	5	-	+	32.11	32.05	Novel Coronavirus infectious pneumonia
62	6613321	male	45	nasopharyngeal (NP) swab	2020-03-05	4	+	+	30.60	27.93	Novel Coronavirus infectious pneumonia
63	6613323	female	52	nasopharyngeal (NP) swab	2020-03-05	5	+	+	29.60	26.87	Novel Coronavirus infectious pneumonia

64	6613324	female	52	nasopharyngeal (NP) swab	2020-03-05	4	+	+	29.79	27.64	Novel Coronavirus infectious pneumonia
65	6613326	male	41	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	fever
66	6613327	male	35	nasopharyngeal (NP) swab	2020-03-05	5	+	+	31.68	28.55	Novel Coronavirus infectious pneumonia
67	6613329	female	44	nasopharyngeal (NP) swab	2020-03-05	5	-	-	no Ct	no Ct	fever
68	6613319	male	27	nasopharyngeal (NP) swab	2020-03-05	3	+	+	29.19	27.77	Novel Coronavirus infectious pneumonia
69	6613330	female	28	nasopharyngeal (NP) swab	2020-03-05	5	+	+	31.59	29.48	Novel Coronavirus infectious pneumonia
70	6613332	female	22	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	fever
71	6613333	female	48	nasopharyngeal (NP) swab	2020-03-05	5	+	+	31.31	28.85	Novel Coronavirus infectious pneumonia
72	6613334	female	36	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	fever
73	6613336	female	26	nasopharyngeal (NP) swab	2020-03-05	4	+	+	30.85	28.94	Novel Coronavirus infectious pneumonia
74	6613341	male	33	nasopharyngeal (NP) swab	2020-03-05	5	-	-	no Ct	no Ct	cough
75	6613343	female	48	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	Acute upper respiratory infection
76	6613346	male	69	nasopharyngeal (NP) swab	2020-03-05	5	-	-	no Ct	no Ct	cough
77	6613350	male	45	nasopharyngeal (NP) swab	2020-03-05	4	-	-	no Ct	no Ct	chest distress
78	6613394	female	54	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	cough
79	6613397	male	23	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	fever
80	6614104	female	45	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	fever
81	6614102	male	27	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	Acute upper respiratory infection
82	6614106	female	40	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	cough
83	6614107	male	21	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
84	6614109	male	56	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	fever
85	6614111	female	40	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
86	6614114	male	41	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	fever
87	6614119	female	44	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	Acute respiratory infection

88	6614124	female	46	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
89	6614129	female	24	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	fever
90	6614137	female	38	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
91	6614140	male	19	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
92	6614149	female	50	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	diarrhea
93	6614152	male	51	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	diarrhea
94	6614159	male	53	nasopharyngeal (NP) swab	2020-03-06	3	-	-	no Ct	no Ct	fever
95	6614162	female	20	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	fever
96	6614168	male	46	nasopharyngeal (NP) swab	2020-03-06	7	+	+	32.25	31.19	Novel Coronavirus infectious pneumonia
97	6614175	female	56	nasopharyngeal (NP) swab	2020-03-06	5	-	-	no Ct	no Ct	cough
98	6614178	female	27	nasopharyngeal (NP) swab	2020-03-06	4	-	-	no Ct	no Ct	fever
99	6614208	female	43	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	cough
100	6614205	female	38	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	cough
101	6614240	male	3	nasopharyngeal (NP) swab	2020-03-07	4	-	-	no Ct	no Ct	Acute upper respiratory infection
102	6614247	male	55	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	Upper respiratory disease
103	6614255	male	26	nasopharyngeal (NP) swab	2020-03-07	6	-	-	no Ct	no Ct	Upper respiratory disease
104	6614253	male	59	nasopharyngeal (NP) swab	2020-03-07	6	-	-	no Ct	no Ct	cough
105	6614264	female	43	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	fever
106	6614262	female	35	nasopharyngeal (NP) swab	2020-03-07	3	-	-	no Ct	no Ct	fever
107	6614260	female	44	nasopharyngeal (NP) swab	2020-03-07	4	-	-	no Ct	no Ct	fever
108	6614269	male	48	nasopharyngeal (NP) swab	2020-03-07	7	+	+	31.41	28.66	Novel Coronavirus infectious pneumonia
109	6614273	male	42	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	fever
110	6614275	male	27	nasopharyngeal (NP) swab	2020-03-07	4	-	-	no Ct	no Ct	fever
111	6614483	male	39	nasopharyngeal (NP) swab	2020-03-07	7	-	-	no Ct	no Ct	cough
112	6614484	female	47	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	fever

113	6614494	male	57	nasopharyngeal (NP) swab	2020-03-07	4	+	+	29.36	26.20	Novel Coronavirus infectious pneumonia
114	6614496	male	42	nasopharyngeal (NP) swab	2020-03-07	4	-	-	no Ct	no Ct	fever
115	6615510	male	57	nasopharyngeal (NP) swab	2020-03-07	5	-	-	no Ct	no Ct	cough
116	6615515	male	43	nasopharyngeal (NP) swab	2020-03-07	5	+	+	31.74	29.33	Novel Coronavirus infectious pneumonia
117	6615526	female	41	nasopharyngeal (NP) swab	2020-03-07	6	-	-	no Ct	no Ct	cough
118	6615549	male	35	nasopharyngeal (NP) swab	2020-03-07	4	-	-	no Ct	no Ct	fever
119	6616665	female	42	nasopharyngeal (NP) swab	2020-03-08	5	-	-	no Ct	no Ct	fever
120	6616683	female	62	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	fever
121	6616672	female	32	nasopharyngeal (NP)	2020-03-08	4	-	-	no Ct	no Ct	fever
122	6616643	female	49	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	fever
123	6616642	female	35	nasopharyngeal (NP) swab	2020-03-08	5	-	-	no Ct	no Ct	Acute pharyngitis
124	6616688	female	42	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	Acute upper respiratory infection
125	6616654	male	36	nasopharyngeal (NP) swab	2020-03-08	6	-	-	no Ct	no Ct	cough
126	6617700	female	37	nasopharyngeal (NP) swab	2020-03-08	3	-	-	no Ct	no Ct	fever
127	6617715	male	64	nasopharyngeal (NP) swab	2020-03-08	5	-	-	no Ct	no Ct	Acute upper respiratory infection
128	6617723	female	31	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	fever
129	6617717	female	61	nasopharyngeal (NP) swab	2020-03-08	5	-	-	no Ct	no Ct	fever
130	6617711	male	16	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	fever
131	6617737	female	28	nasopharyngeal (NP) swab	2020-03-08	3	-	-	no Ct	no Ct	fever
132	6617749	male	32	nasopharyngeal (NP) swab	2020-03-08	5	-	-	no Ct	no Ct	fever
133	6617751	male	61	nasopharyngeal (NP) swab	2020-03-08	7	-	-	no Ct	no Ct	cough
134	6617764	male	27	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	fever
135	6617768	male	52	nasopharyngeal (NP) swab	2020-03-08	3	-	-	no Ct	no Ct	fever
136	6617779	female	48	nasopharyngeal (NP) swab	2020-03-08	7	-	-	no Ct	no Ct	cough
137	6617784	male	21	nasopharyngeal (NP) swab	2020-03-08	4	-	-	no Ct	no Ct	diarrhea

138	6617807	female	43	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	fever
139	6617820	female	26	nasopharyngeal (NP) swab	2020-03-09	3	-	-	no Ct	no Ct	fever
140	6617814	male	58	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	fever
141	6617825	male	42	nasopharyngeal (NP) swab	2020-03-09	5	+	+	30.8	33.26	Novel Coronavirus infectious pneumonia
142	6617824	male	62	nasopharyngeal (NP) swab	2020-03-09	5	-	-	no Ct	no Ct	cough
143	6617836	male	23	nasopharyngeal (NP) swab	2020-03-09	3	-	-	no Ct	no Ct	fever
144	6617842	male	61	nasopharyngeal (NP) swab	2020-03-09	5	-	-	no Ct	no Ct	pneumonia
145	6617848	female	27	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	fever
146	6617852	male	29	nasopharyngeal (NP) swab	2020-03-09	3	-	-	no Ct	no Ct	fever
147	6617858	female	35	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	Lung infection
148	6617861	male	85	nasopharyngeal (NP) swab	2020-03-09	3	-	-	no Ct	no Ct	fever
149	6617870	male	19	nasopharyngeal (NP) swab	2020-03-09	5	-	-	no Ct	no Ct	Acute pharyngitis
150	6617878	male	61	nasopharyngeal (NP) swab	2020-03-09	3	+	+	29.74	32.03	Novel Coronavirus infectious pneumonia
151	6617886	male	32	nasopharyngeal (NP) swab	2020-03-09	3	-	-	no Ct	no Ct	fever
152	6617899	male	36	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	diarrhea
153	6617882	male	64	nasopharyngeal (NP) swab	2020-03-09	4	-	-	no Ct	no Ct	fever
154	6617917	male	28	nasopharyngeal (NP) swab	2020-03-10	3	-	-	no Ct	no Ct	fever
155	6617924	male	70	nasopharyngeal (NP) swab	2020-03-10	3	-	-	no Ct	no Ct	fever
156	6617953	male	43	nasopharyngeal (NP) swab	2020-03-10	6	-	-	no Ct	no Ct	cough

INTERPRETATION:

Tableau 1: COVID-19 Antigen Rapid Test vs PCR

Method		PCR		Total Results
COVID-19 Ag Rapid Test	Results	Positive	Negative	
	Positive	71	0	71
	Negative	2	130	132
Total Results		73	130	203

Relative Sensitivity: 97.3% (71/73)

Relative Specificity: 100% (130/130)

Accuracy: 99.0% (201/203)

Tableau 2: Positive results broken down by days since symptom onset

Days Since Symptom Onset	Cumulative PCR Positive(+)	Cumulative COVID-19 Ag Rapid Test Cassette Positive(+)	PPA
1	7	7	100%
2	18	18	100%
3	30	30	100%
4	44	44	100%
5	59	58	98.3%
6	62	60	96.8%
7	70	68	97.1%
8	71	69	97.2%
9	72	70	97.2%
10	73	71	97.3%

Tableau 3: COVID-19 Ag Rapid Test performance against the comparative method - by Cycle Threshold Counts

COVID-19 Ag Rapid Test	PCR results (Ct) of nucleoprotein (N) gene	
	Positive (Ct<30)	Positive (Ct≥30)
Positive	62	9
Negative	0	2
Total	62	11
Sensitivity	100%	82%
COVID-19 Ag Rapid Test	PCR results (Ct) of open reading frame (ORF) gene	
	Positive (Ct<30)	Positive (Ct≥30)
Positive	40	31
Negative	0	2
Total	40	33
Sensitivity	100%	94%

Compiled data (N gene and ORF gene):

PCR results (Ct)	COVID-19 Ag Rapid Test sensitivity
Ct<30	100%
Ct≥30	91%

➢ Conclusion

The above results show that:
The Relative Sensitivity of BIOSYNEX COVID-19 Ag BSS rapid test is 97.3% (71/73), Relative Specificity is 100% (130/130) in comparison to PCR.

Discussion:
If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

II. CLINICAL STUDY 2: Supplemental study

Completion date: 02/09/2020
Date of the report: 07/10/2020

➢ Objective

To enhance the performances data of the Biosynex COVID-19 Ag BSS product with:
-1: dry positive or negative nasal swabs confirmed by Life River 2019-nCov RT-PCR®
-2: positive nasal swabs unloaded in 1mL of saline buffer confirmed by Life River 2019-nCov RT-PCR®

➢ Material

✓ Description of component

Product name	Biosynex COVID-19 Ag BSS
Reference	SW40006
Batch	2008124
Charte de Lecture	Gold color Card Biosynex G1012

✓ Description of samples

Code	Origin	Sampling types*	T° stockage	RT-PCR
				Life River ® SARS-COV-2
D0820-282	CCN Lab	1	- 20 °C	NEGATIVE
D0820-283	CCN Lab	1	- 20 °C	NEGATIVE
D0820-284	CCN Lab	1	- 20 °C	NEGATIVE
D0820-285	CCN Lab	1	- 20 °C	NEGATIVE
D0820-286	CCN Lab	1	- 20 °C	NEGATIVE
D0820-287	CCN Lab	1	- 20 °C	POSITIVE
D0820-288	CCN Lab	1	- 20 °C	NEGATIVE
D0820-289	CCN Lab	1	- 20 °C	NEGATIVE
D0820-290	CCN Lab	1	- 20 °C	NEGATIVE
D0820-291	CCN Lab	1	- 20 °C	NEGATIVE
D0820-292	CCN Lab	1	- 20 °C	NEGATIVE
D0820-293	CCN Lab	1	- 20 °C	NEGATIVE
D0820-294	CCN Lab	1	- 20 °C	NEGATIVE
E0820-37	CCN Lab	1	- 20 °C	NEGATIVE
E0820-38	CCN Lab	1	- 20 °C	POSITIVE
E0820-40	CCN Lab	1	- 20 °C	NEGATIVE
E0820-41	CCN Lab	1	- 20 °C	NEGATIVE
E0820-9	CCN Lab	2	- 20 °C	POSITIVE
E0820-15	CCN Lab	2	- 20 °C	POSITIVE
E0820-20	CCN Lab	2	- 20 °C	POSITIVE

E0820-21	CCN Lab	2	- 20 °C	POSITIVE
E0820-26	CCN Lab	2	- 20 °C	POSITIVE
E0820-27	CCN Lab	2	- 20 °C	POSITIVE
E0820-28	CCN Lab	2	- 20 °C	POSITIVE
E0820-33	CCN Lab	2	- 20 °C	POSITIVE
E0820-34	CCN Lab	2	- 20 °C	POSITIVE
E0820-45	CCN Lab	2	- 20 °C	POSITIVE
E0820-47	CCN Lab	2	- 20 °C	POSITIVE
E0820-48	CCN Lab	2	- 20 °C	POSITIVE
E0820-49	CCN Lab	2	- 20 °C	POSITIVE
E0820-50	CCN Lab	2	- 20 °C	POSITIVE
E0820-54	CCN Lab	2	- 20 °C	POSITIVE
E0820-55	CCN Lab	2	- 20 °C	POSITIVE
E0820-56	CCN Lab	2	- 20 °C	POSITIVE
E0820-57	CCN Lab	2	- 20 °C	POSITIVE
E0820-58	CCN Lab	2	- 20 °C	POSITIVE
E0820-59	CCN Lab	2	- 20 °C	POSITIVE
E0820-61	CCN Lab	2	- 20 °C	POSITIVE
E0820-62	CCN Lab	2	- 20 °C	POSITIVE
E0820-65	CCN Lab	2	- 20 °C	POSITIVE
E0820-67	CCN Lab	2	- 20 °C	POSITIVE
E0820-69	CCN Lab	2	- 20 °C	POSITIVE
E0820-72	CCN Lab	2	- 20 °C	POSITIVE
E0920-001	CCN Lab	2	-20 °C	POSITIVE
E0920-105	CCN Lab	2	-20 °C	POSITIVE

**Sampling types described in « 1. Objective »*

- Method
  - Study protocol

The aim of this study is to enhance the performances data of the Biosynex COVID-19 Ag BSS product with nasals swabs or nasals swabs unloads in 1mL of physiological saline from patient tested positive for SARS COV-2 gene by RT-PCR.

The study is realized with samples from patient tested by RT-PCR for SARS COV-2 by the CCN lab: 15 Negative samples and 30 Positive samples.

  - Protocol of the test

Different protocols have been used for this study:

If the samples are nasal swabs: add 0,3mL (about 10 drops) of the sample extraction buffer into the extraction tube. Insert the swab into the extraction tube and unload the swab by rolling the swab at least 6 times. Leave it in the extraction tube during 1 min and squeeze the tube to immerse the swab. Finally, remove the swab, mix it by vortexing and use the extraction solution as test sample.

If samples are nasal swabs unloads in 1mL of physiological saline for Life River®: Add 150µL (about 5 drops) of the sample extraction buffer into the extraction tube. Take 30µL of the sample and put it on the 150µL. Mix it by vortexing. Use the extraction solution as test sample.

Add 4 drops of the sample into the sample well. Read the result after 15 minutes with the Gold color Card Biosynex G1012. Intensities from 3 to 10 are considered as positive. Intensities strictly below 3 are considered as negative.

- Results
  - Raw data:

N°	RT-PCR	RT-PCR			TDR	
		ORFAB	N	E	C line	Test line
D0820-282	NEGATIVE	NA	NA	NA	10	1
D0820-283	NEGATIVE	NA	NA	NA	10	1
D0820-284	NEGATIVE	NA	NA	NA	10	1
D0820-285	NEGATIVE	NA	NA	NA	10	1
D0820-286	NEGATIVE	NA	NA	NA	10	1
D0820-287	POSITIVE	21	19	21	10	10
D0820-288	NEGATIVE	NA	NA	NA	10	1
D0820-289	NEGATIVE	NA	NA	NA	10	1
D0820-290	NEGATIVE	NA	NA	NA	10	1
D0820-291	NEGATIVE	NA	NA	NA	10	1
D0820-292	NEGATIVE	NA	NA	NA	10	1
D0820-293	NEGATIVE	NA	NA	NA	10	1
D0820-294	NEGATIVE	NA	NA	NA	10	1
E0820-37	NEGATIVE	NA	NA	NA	10	1
E0820-38	POSITIVE	14	12	13	10	10
E0820-40	NEGATIVE	NA	NA	NA	10	1
E0820-41	NEGATIVE	NA	NA	NA	10	1
E0820-9	POSITIVE	17	15	17	10	10
E0820-15	POSITIVE	14	12	13	10	10
E0820-20	POSITIVE	25	23	24	10	3
E0820-21	POSITIVE	19	18	19	10	9
E0820-26	POSITIVE	16	14	15	10	10
E0820-27	POSITIVE	20	19	19	10	7
E0820-28	POSITIVE	18	17	17	10	10
E0820-33	POSITIVE	17	16	18	10	10
E0820-34	POSITIVE	20	17	18	10	6
E0820-45	POSITIVE	14	13	13	10	10
E0820-47	POSITIVE	17	16	17	10	9
E0820-48	POSITIVE	14	13	13	10	10
E0820-49	POSITIVE	22	21	22	10	6
E0820-50	POSITIVE	12	11	11	10	10
E0820-54	POSITIVE	10	10	11	10	1
E0820-55	POSITIVE	20	17	19	10	8
E0820-56	POSITIVE	16	16	16	10	10
E0820-57	POSITIVE	17	15	16	10	10

E0820-58	POSITIVE	15	14	14	10	10
E0820-59	POSITIVE	16	14	19	10	10
E0820-61	POSITIVE	19	18	19	10	8
E0820-62	POSITIVE	14	10	12	10	10
E0820-65	POSITIVE	20	19	20	10	9
E0820-67	POSITIVE	15	14	15	10	10
E0820-69	POSITIVE	15	13	14	10	10
E0820-72	POSITIVE	22	22	22	10	6
E0920-001	POSITIVE	17	16	17	10	10
E0920-105	POSITIVE	29	27	28	10	2

- Correlation:

		Biosynex COVID-19 Ag BSS		
		Positive	Negative	
Life River (RT-PCR)	Positive	28	2	**30**
	Négative	0	15	**15**
		28	**17**	**45**

Relative Sensitivity: 28/(28+2)*100 = 93,3%

Relative Specificity: 15/(15+0)*100 = 100%

Accuracy: (28+15)/(28+2+15+0)*100 = 95,6%

➢ Conclusion

According to the results we obtained, we can conclude that the Biosynex COVID-19 Ag BSS test gives 95,6% of correlation with the RT-PCR (Life River®) test.

III. Claimed performances

Biosynex calculated performances on the test (sensitivity, specificity, reliability and sensitivity according to Ct) based on the compilation of the data on the of the data of the two carried out studies (see §I and §II).

Results from both studies were compiled to generate the following data:

1. Sensitivity, Specificity, Accuracy

		PCR		
		Positive	Negative	
BIOSYNEX COVID-19 Ag BSS	Positive	99	0	**99**
	Negative	4	145	**149**
		103	**145**	**248**

Based on this data: the sensitivity, specificity, accuracy were calculated:

Sensitivity : 96% (95%CI*: 93,6-98,4%) *Confidence interval
Specificity: 100% (95%CI*: 100%-100%)
Accuracy: 98% (95%CI*: 96,4-99,6%)

➢ Conclusion

Based on data from studies documented in §I and II, the sensitivity of the test is 96%, the specificity is 100%, and the accuracy is 98%.

2. Sensitivity according to Ct

The sensitivity of the test according to the Ct of the samples (resulting from the RT-PCR test) was calculated.

Samples were divided into 3 categories, according to the Ct:

- $0 < Ct \leq 20$
- $21 \leq Ct \leq 30$
- $31 \leq Ct \leq 35$

For one given sample, the highest Ct (among the Ct for the different searched genes) determines the category in which the sample is placed.
Sensitivity was calculated for each of these 3 categories.

➢ Raw data

S/N	Days since symptoms onset	COVID Ag test result	PCR Result	Ct ORF	Ct N	Ct E		PCR used
1	2	NEG	NEG	NA	NA	NA		DAAN GENE
2	1	POS	POS	24	22	NA		DAAN GENE
3	3	POS	POS	29	27	NA		DAAN GENE
4	4	POS	POS	30	28	NA		DAAN GENE
5	1	POS	POS	26	24	NA		DAAN GENE
6	2	POS	POS	28	26	NA		DAAN GENE
7	2	POS	POS	29	27	NA		DAAN GENE
8	4	NEG	NEG	NA	NA	NA		DAAN GENE
9	5	NEG	NEG	NA	NA	NA		DAAN GENE
10	6	NEG	NEG	NA	NA	NA		DAAN GENE
11	1	POS	POS	24	22	NA		DAAN GENE
12	7	NEG	NEG	NA	NA	NA		DAAN GENE
13	7	POS	POS	28	26	NA		DAAN GENE
14	3	POS	POS	27	25	NA		DAAN GENE
15	2	POS	POS	29	26	NA		DAAN GENE
16	1	POS	POS	23	21	NA		DAAN GENE
17	5	POS	POS	27	23	NA		DAAN GENE
18	2	POS	POS	30	28	NA		DAAN GENE
19	4	POS	POS	26	23	NA		DAAN GENE
20	4	NEG	NEG	NA	NA	NA		DAAN GENE
21	3	POS	POS	30	27	NA		DAAN GENE
22	2	POS	POS	28	25	NA		DAAN GENE
23	3	NEG	NEG	NA	NA	NA		DAAN GENE
24	3	POS	POS	30	30	NA		DAAN GENE
25	3	POS	POS	28	26	NA		DAAN GENE
26	5	POS	POS	30	27	NA		DAAN GENE
27	3	POS	POS	30	28	NA		DAAN GENE
28	2	POS	POS	24	22	NA		DAAN GENE
29	3	NEG	NEG	NA	NA	NA		DAAN GENE
30	1	POS	POS	26	24	NA		DAAN GENE
31	2	NEG	NEG	NA	NA	NA		DAAN GENE
32	2	NEG	NEG	NA	NA	NA		DAAN GENE
33	3	POS	POS	30	28	NA		DAAN GENE
34	5	NEG	NEG	NA	NA	NA		DAAN GENE
35	4	POS	POS	30	30	NA		DAAN GENE
36	2	POS	POS	28	26	NA		DAAN GENE
37	2	NEG	NEG	NA	NA	NA		DAAN GENE
38	1	POS	POS	26	25	NA		DAAN GENE
39	4	NEG	NEG	NA	NA	NA		DAAN GENE
40	2	POS	POS	23	21	NA		DAAN GENE
41	2	NEG	NEG	NA	NA	NA		DAAN GENE

42	4	NEG	NEG	NA	NA	NA		DAAN GENE
43	3	NEG	NEG	NA	NA	NA		DAAN GENE
44	1	POS	POS	26	24	NA		DAAN GENE
45	3	NEG	NEG	NA	NA	NA		DAAN GENE
46	2	NEG	NEG	NA	NA	NA		DAAN GENE
47	2	POS	POS	29	26	NA		DAAN GENE
1	4	NEG	NEG	NA	NA	NA		DAAN GENE
2	10	POS	POS	32	31	NA		DAAN GENE
3	7	POS	POS	32	30	NA		DAAN GENE
4	2	POS	POS	28	26	NA		DAAN GENE
5	2	POS	POS	28	26	NA		DAAN GENE
6	4	POS	POS	32	29	NA		DAAN GENE
7	3	POS	POS	31	28	NA		DAAN GENE
8	5	POS	POS	30	28	NA		DAAN GENE
9	4	POS	POS	31	28	NA		DAAN GENE
10	6	NEG	POS	32	33	NA		DAAN GENE
11	7	POS	POS	32	29	NA		DAAN GENE
12	9	POS	POS	31	30	NA		DAAN GENE
13	7	NEG	NEG	NA	NA	NA		DAAN GENE
14	5	NEG	NEG	NA	NA	NA		DAAN GENE
15	5	NEG	NEG	NA	NA	NA		DAAN GENE
16	8	POS	POS	32	31	NA		DAAN GENE
17	7	NEG	NEG	NA	NA	NA		DAAN GENE
18	3	POS	POS	31	28	NA		DAAN GENE
19	4	NEG	NEG	NA	NA	NA		DAAN GENE
20	7	NEG	NEG	NA	NA	NA		DAAN GENE
21	5	NEG	NEG	NA	NA	NA		DAAN GENE
22	8	NEG	NEG	NA	NA	NA		DAAN GENE
23	5	NEG	NEG	NA	NA	NA		DAAN GENE
24	6	NEG	NEG	NA	NA	NA		DAAN GENE
25	4	NEG	NEG	NA	NA	NA		DAAN GENE
26	7	NEG	NEG	NA	NA	NA		DAAN GENE
27	7	NEG	NEG	NA	NA	NA		DAAN GENE
28	7	POS	POS	31	30	NA		DAAN GENE
29	6	NEG	NEG	NA	NA	NA		DAAN GENE
30	5	NEG	NEG	NA	NA	NA		DAAN GENE
31	4	POS	POS	32	27	NA		DAAN GENE
32	6	POS	POS	31	28	NA		DAAN GENE
33	6	NEG	NEG	NA	NA	NA		DAAN GENE
34	5	NEG	NEG	NA	NA	NA		DAAN GENE
35	7	NEG	NEG	NA	NA	NA		DAAN GENE
36	5	NEG	NEG	NA	NA	NA		DAAN GENE
37	4	NEG	NEG	NA	NA	NA		DAAN GENE
38	6	NEG	NEG	NA	NA	NA		DAAN GENE
39	5	NEG	NEG	NA	NA	NA		DAAN GENE

40	4	POS	POS	31	29	NA		DAAN GENE
41	6	NEG	NEG	NA	NA	NA		DAAN GENE
42	5	NEG	NEG	NA	NA	NA		DAAN GENE
43	5	NEG	NEG	NA	NA	NA		DAAN GENE
44	5	POS	POS	31	31	NA		DAAN GENE
45	6	NEG	NEG	NA	NA	NA		DAAN GENE
46	4	POS	POS	30	28	NA		DAAN GENE
47	3	POS	POS	28	25	NA		DAAN GENE
48	5	POS	POS	31	29	NA		DAAN GENE
49	3	NEG	NEG	NA	NA	NA		DAAN GENE
50	5	POS	POS	32	29	NA		DAAN GENE
51	4	POS	POS	29	27	NA		DAAN GENE
52	3	POS	POS	31	28	NA		DAAN GENE
53	4	POS	POS	30	28	NA		DAAN GENE
54	7	POS	POS	31	29	NA		DAAN GENE
55	5	POS	POS	29	29	NA		DAAN GENE
56	4	NEG	NEG	NA	NA	NA		DAAN GENE
57	5	POS	POS	31	29	NA		DAAN GENE
58	4	NEG	NEG	NA	NA	NA		DAAN GENE
59	7	POS	POS	32	30	NA		DAAN GENE
60	4	NEG	NEG	NA	NA	NA		DAAN GENE
61	5	NEG	POS	32	32	NA		DAAN GENE
62	4	POS	POS	31	28	NA		DAAN GENE
63	5	POS	POS	30	27	NA		DAAN GENE
64	4	POS	POS	30	28	NA		DAAN GENE
65	4	NEG	NEG	NA	NA	NA		DAAN GENE
66	5	POS	POS	32	29	NA		DAAN GENE
67	5	NEG	NEG	NA	NA	NA		DAAN GENE
68	3	POS	POS	29	28	NA		DAAN GENE
69	5	POS	POS	32	29	NA		DAAN GENE
70	4	NEG	NEG	NA	NA	NA		DAAN GENE
71	5	POS	POS	31	29	NA		DAAN GENE
72	4	NEG	NEG	NA	NA	NA		DAAN GENE
73	4	POS	POS	31	29	NA		DAAN GENE
74	5	NEG	NEG	NA	NA	NA		DAAN GENE
75	4	NEG	NEG	NA	NA	NA		DAAN GENE
76	5	NEG	NEG	NA	NA	NA		DAAN GENE
77	4	NEG	NEG	NA	NA	NA		DAAN GENE
78	5	NEG	NEG	NA	NA	NA		DAAN GENE
79	4	NEG	NEG	NA	NA	NA		DAAN GENE
80	5	NEG	NEG	NA	NA	NA		DAAN GENE
81	5	NEG	NEG	NA	NA	NA		DAAN GENE
82	5	NEG	NEG	NA	NA	NA		DAAN GENE
83	3	NEG	NEG	NA	NA	NA		DAAN GENE
84	4	NEG	NEG	NA	NA	NA		DAAN GENE

85	3	NEG	NEG	NA	NA	NA		DAAN GENE
86	5	NEG	NEG	NA	NA	NA		DAAN GENE
87	4	NEG	NEG	NA	NA	NA		DAAN GENE
88	3	NEG	NEG	NA	NA	NA		DAAN GENE
89	4	NEG	NEG	NA	NA	NA		DAAN GENE
90	3	NEG	NEG	NA	NA	NA		DAAN GENE
91	3	NEG	NEG	NA	NA	NA		DAAN GENE
92	4	NEG	NEG	NA	NA	NA		DAAN GENE
93	4	NEG	NEG	NA	NA	NA		DAAN GENE
94	3	NEG	NEG	NA	NA	NA		DAAN GENE
95	4	NEG	NEG	NA	NA	NA		DAAN GENE
96	7	POS	POS	32	31	NA		DAAN GENE
97	5	NEG	NEG	NA	NA	NA		DAAN GENE
98	4	NEG	NEG	NA	NA	NA		DAAN GENE
99	5	NEG	NEG	NA	NA	NA		DAAN GENE
100	5	NEG	NEG	NA	NA	NA		DAAN GENE
101	4	NEG	NEG	NA	NA	NA		DAAN GENE
102	5	NEG	NEG	NA	NA	NA		DAAN GENE
103	6	NEG	NEG	NA	NA	NA		DAAN GENE
104	6	NEG	NEG	NA	NA	NA		DAAN GENE
105	5	NEG	NEG	NA	NA	NA		DAAN GENE
106	3	NEG	NEG	NA	NA	NA		DAAN GENE
107	4	NEG	NEG	NA	NA	NA		DAAN GENE
108	7	POS	POS	31	29	NA		DAAN GENE
109	5	NEG	NEG	NA	NA	NA		DAAN GENE
110	4	NEG	NEG	NA	NA	NA		DAAN GENE
111	7	NEG	NEG	NA	NA	NA		DAAN GENE
112	5	NEG	NEG	NA	NA	NA		DAAN GENE
113	4	POS	POS	29	26	NA		DAAN GENE
114	4	NEG	NEG	NA	NA	NA		DAAN GENE
115	5	NEG	NEG	NA	NA	NA		DAAN GENE
116	5	POS	POS	32	29	NA		DAAN GENE
117	6	NEG	NEG	NA	NA	NA		DAAN GENE
118	4	NEG	NEG	NA	NA	NA		DAAN GENE
119	5	NEG	NEG	NA	NA	NA		DAAN GENE
120	4	NEG	NEG	NA	NA	NA		DAAN GENE
121	4	NEG	NEG	NA	NA	NA		DAAN GENE
122	4	NEG	NEG	NA	NA	NA		DAAN GENE
123	5	NEG	NEG	NA	NA	NA		DAAN GENE
124	4	NEG	NEG	NA	NA	NA		DAAN GENE
125	6	NEG	NEG	NA	NA	NA		DAAN GENE
126	3	NEG	NEG	NA	NA	NA		DAAN GENE
127	5	NEG	NEG	NA	NA	NA		DAAN GENE
128	4	NEG	NEG	NA	NA	NA		DAAN GENE
129	5	NEG	NEG	NA	NA	NA		DAAN GENE

130	4	NEG	NEG	NA	NA	NA		DAAN GENE
131	3	NEG	NEG	NA	NA	NA		DAAN GENE
132	5	NEG	NEG	NA	NA	NA		DAAN GENE
133	7	NEG	NEG	NA	NA	NA		DAAN GENE
134	4	NEG	NEG	NA	NA	NA		DAAN GENE
135	3	NEG	NEG	NA	NA	NA		DAAN GENE
136	7	NEG	NEG	NA	NA	NA		DAAN GENE
137	4	NEG	NEG	NA	NA	NA		DAAN GENE
138	4	NEG	NEG	NA	NA	NA		DAAN GENE
139	3	NEG	NEG	NA	NA	NA		DAAN GENE
140	4	NEG	NEG	NA	NA	NA		DAAN GENE
141	5	POS	POS	31	33	NA		DAAN GENE
142	5	NEG	NEG	NA	NA	NA		DAAN GENE
143	3	NEG	NEG	NA	NA	NA		DAAN GENE
144	5	NEG	NEG	NA	NA	NA		DAAN GENE
145	4	NEG	NEG	NA	NA	NA		DAAN GENE
146	3	NEG	NEG	NA	NA	NA		DAAN GENE
147	4	NEG	NEG	NA	NA	NA		DAAN GENE
148	3	NEG	NEG	NA	NA	NA		DAAN GENE
149	5	NEG	NEG	NA	NA	NA		DAAN GENE
150	3	POS	POS	30	32	NA		DAAN GENE
151	3	NEG	NEG	NA	NA	NA		DAAN GENE
152	4	NEG	NEG	NA	NA	NA		DAAN GENE
153	4	NEG	NEG	NA	NA	NA		DAAN GENE
154	3	NEG	NEG	NA	NA	NA		DAAN GENE
155	3	NEG	NEG	NA	NA	NA		DAAN GENE
156	6	NEG	NEG	NA	NA	NA		DAAN GENE
E0920-54		POS	POS	17	16	17		LifeRiver
E0920-105		NEG	POS	29	27	28		LifeRiver
D0820-282		NEG	NEG	NA	NA	NA		LifeRiver
D0820-283		NEG	NEG	NA	NA	NA		LifeRiver
D0820-284		NEG	NEG	NA	NA	NA		LifeRiver
D0820-285		NEG	NEG	NA	NA	NA		LifeRiver
D0820-286		NEG	NEG	NA	NA	NA		LifeRiver
D0820-287		POS	POS	21	19	21		LifeRiver
D0820-288		NEG	NEG	NA	NA	NA		LifeRiver
D0820-289		NEG	NEG	NA	NA	NA		LifeRiver

D0820-290		NEG	NEG	NA	NA	NA		LifeRiver
D0820-291		NEG	NEG	NA	NA	NA		LifeRiver
D0820-292		NEG	NEG	NA	NA	NA		LifeRiver
D0820-293		NEG	NEG	NA	NA	NA		LifeRiver
D0820-294		NEG	NEG	NA	NA	NA		LifeRiver
E0820-37		NEG	NEG	NA	NA	NA		LifeRiver
E0820-38		POS	POS	14	12	13		LifeRiver
E0820-40		NEG	NEG	NA	NA	NA		LifeRiver
E0820-41		NEG	NEG	NA	NA	NA		LifeRiver
E0820-9		POS	POS	17	15	17		LifeRiver
E0820-15		POS	POS	14	12	13		LifeRiver
E0820-20		POS	POS	25	23	24		LifeRiver
E0820-21		POS	POS	19	18	19		LifeRiver
E0820-26		POS	POS	16	14	15		LifeRiver
E0820-27		POS	POS	20	19	19		LifeRiver
E0820-28		POS	POS	18	17	17		LifeRiver
E0820-33		POS	POS	17	16	18		LifeRiver
E0820-34		POS	POS	20	17	18		LifeRiver
E0820-45		POS	POS	15	13	13		LifeRiver
E0820-47		POS	POS	17	16	17		LifeRiver
E0820-48		POS	POS	14	13	13		LifeRiver
E0820-49		POS	POS	22	21	22		LifeRiver
E0820-50		POS	POS	12	11	11		LifeRiver
E0820-54		NEG	POS	10	10	11		LifeRiver
E0820-55		POS	POS	20	17	19		LifeRiver
E0820-56		POS	POS	16	16	16		LifeRiver
E0820-57		POS	POS	17	15	16		LifeRiver
E0820-58		POS	POS	15	14	14		LifeRiver
E0820-59		POS	POS	16	14	19		LifeRiver
E0820-61		POS	POS	19	18	19		LifeRiver
E0820-62		POS	POS	14	10	12		LifeRiver
E0820-65		POS	POS	20	19	20		LifeRiver
E0820-67		POS	POS	15	14	15		LifeRiver
E0820-69		POS	POS	15	13	14		LifeRiver
E0820-72		POS	POS	22	22	22		LifeRiver

Legend :

Ct 0 to 20
Ct 21 to 30
Ct 31 to 35
➢ The highest Ct determines the Ct category of the sample

➢ Interpretation

Number of positive / negative BIOSYNEX COVID-19 Ag BSS test by category of Ct:

			BIOSYNEX COVID-19 Ag BSS		Total
			Positive	Negative	
RT-PCR	Positive	0 < Ct ≤ 20	24	1	25
	Positive	21 ≤ Ct ≤ 30	45	1	46
	Positive	31 ≤ Ct ≤ 35	30	2	32
	Negative		0	145	145
Total			99	149	248

Sensitivity = number of positive results with BIOSYNEX COVID-19 Ag BSS / Number of positive results with RT-PCR

Ct	Sensitivity
0 < Ct ≤ 20	96%
21 ≤ Ct ≤ 30	98%
31 ≤ Ct ≤ 35	94%
0 < Ct ≤ 30	97%

Global Sensitivity : 96%

➢ Conclusion

The sensitivity of BIOSYNEX COVID-19 Ag BSS is 96% for samples with Ct between 0 and 20, 98% for samples with Ct between 21 and 30, and 94% for samples with Ct between 31 and 35. The sensitivity is 97% for samples with Ct between 0 and 30.

The overall sensitivity of BIOSYNEX COVID-19 Ag BSS is 96%.

IV. Performances according to criteria established by the 'Haute Autorité de Santé' in FRANCE

In France, the test has to comply with criteria established by the 'Haute Autorité de Santé' (HAS) for clinical performances.

The clinical study carried documented in §I of this document is used to demonstrate the conformity with HAS criteria. Some of the data of this study are excluded because they do not meet with the requested delay between sample collection and testing, see reworked data in the Raw data section below.

➢ Summary of the protocol according to HAS criteria:

- Study design: prospective comparative clinical study.
- Population included: patients with moderate symptoms; randomized enrollment. Nasopharyngeal samples, utilization of fresh samples.
  Note: in the raw data below, patients where delay between symptoms onset and testing was superior to 4 days are excluded. This brings the number of included subjects to 116, comparing to 203 originally enrolled in the study.
- Comparator: RT-PCR targeting ORF1ab and N genes: Detection kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence probing) manufactured by DAAN GENE.

➢ Raw data

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
1	2	NEG	NEG
2	1	POS	POS
3	3	POS	POS
4	4	POS	POS
5	1	POS	POS
6	2	POS	POS
7	2	POS	POS
8	4	NEG	NEG
9	5	NEG	NEG
10	6	NEG	NEG
11	1	POS	POS
12	7	NEG	NEG
13	7	POS	POS
14	3	POS	POS
15	2	POS	POS
16	1	POS	POS
17	5	POS	POS
18	2	POS	POS
19	4	POS	POS

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
20	4	NEG	NEG
21	3	POS	POS
22	2	POS	POS
23	3	NEG	NEG
24	3	POS	POS
25	3	POS	POS
26	5	POS	POS
27	3	POS	POS
28	2	POS	POS
29	3	NEG	NEG
30	1	POS	POS
31	2	NEG	NEG
32	2	NEG	NEG
33	3	POS	POS
34	5	NEG	NEG
35	4	POS	POS
36	2	POS	POS
37	2	NEG	NEG
38	1	POS	POS
39	4	NEG	NEG
40	2	POS	POS
41	2	NEG	NEG
42	4	NEG	NEG
43	3	NEG	NEG
44	1	POS	POS
45	3	NEG	NEG
46	2	NEG	NEG
47	2	POS	POS
1	4	NEG	NEG
2	10	POS	POS
3	7	POS	POS
4	2	POS	POS
5	2	POS	POS
6	4	POS	POS
7	3	POS	POS
8	5	POS	POS
9	4	POS	POS
10	6	NEG	POS
11	7	POS	POS
12	9	POS	POS
13	7	NEG	NEG
14	5	NEG	NEG

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
15	5	NEG	NEG
16	8	POS	POS
17	7	NEG	NEG
18	3	POS	POS
19	4	NEG	NEG
20	7	NEG	NEG
21	5	NEG	NEG
22	8	NEG	NEG
23	5	NEG	NEG
24	6	NEG	NEG
25	4	NEG	NEG
26	7	NEG	NEG
27	7	NEG	NEG
28	7	POS	POS
29	6	NEG	NEG
30	5	NEG	NEG
31	4	POS	POS
32	6	POS	POS
33	6	NEG	NEG
34	5	NEG	NEG
35	7	NEG	NEG
36	5	NEG	NEG
37	4	NEG	NEG
38	6	NEG	NEG
39	5	NEG	NEG
40	4	POS	POS
41	6	NEG	NEG
42	5	NEG	NEG
43	5	NEG	NEG
44	5	POS	POS
45	6	NEG	NEG
46	4	POS	POS
47	3	POS	POS
48	5	POS	POS
49	3	NEG	NEG
50	5	POS	POS
51	4	POS	POS
52	3	POS	POS
53	4	POS	POS
54	7	POS	POS
55	5	POS	POS
56	4	NEG	NEG

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
57	5	POS	POS
58	4	NEG	NEG
59	7	POS	POS
60	4	NEG	NEG
61	5	NEG	POS
62	4	POS	POS
63	5	POS	POS
64	4	POS	POS
65	4	NEG	NEG
66	5	POS	POS
67	5	NEG	NEG
68	3	POS	POS
69	5	POS	POS
70	4	NEG	NEG
71	5	POS	POS
72	4	NEG	NEG
73	4	POS	POS
74	5	NEG	NEG
75	4	NEG	NEG
76	5	NEG	NEG
77	4	NEG	NEG
78	5	NEG	NEG
79	4	NEG	NEG
80	5	NEG	NEG
81	5	NEG	NEG
82	5	NEG	NEG
83	3	NEG	NEG
84	4	NEG	NEG
85	3	NEG	NEG
86	5	NEG	NEG
87	4	NEG	NEG
88	3	NEG	NEG
89	4	NEG	NEG
90	3	NEG	NEG
91	3	NEG	NEG
92	4	NEG	NEG
93	4	NEG	NEG
94	3	NEG	NEG
95	4	NEG	NEG
96	7	POS	POS
97	5	NEG	NEG
98	4	NEG	NEG

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
99	5	NEG	NEG
100	5	NEG	NEG
101	4	NEG	NEG
102	5	NEG	NEG
103	6	NEG	NEG
104	6	NEG	NEG
105	5	NEG	NEG
106	3	NEG	NEG
107	4	NEG	NEG
108	7	POS	POS
109	5	NEG	NEG
110	4	NEG	NEG
111	7	NEG	NEG
112	5	NEG	NEG
113	4	POS	POS
114	4	NEG	NEG
115	5	NEG	NEG
116	5	POS	POS
117	6	NEG	NEG
118	4	NEG	NEG
119	5	NEG	NEG
120	4	NEG	NEG
121	4	NEG	NEG
122	4	NEG	NEG
123	5	NEG	NEG
124	4	NEG	NEG
125	6	NEG	NEG
126	3	NEG	NEG
127	5	NEG	NEG
128	4	NEG	NEG
129	5	NEG	NEG
130	4	NEG	NEG
131	3	NEG	NEG
132	5	NEG	NEG
133	7	NEG	NEG
134	4	NEG	NEG
135	3	NEG	NEG
136	7	NEG	NEG
137	4	NEG	NEG
138	4	NEG	NEG
139	3	NEG	NEG
140	4	NEG	NEG

S/N	Days since symptoms onset	COVID Ag test result	PCR Result
141	5	POS	POS
142	5	NEG	NEG
143	3	NEG	NEG
144	5	NEG	NEG
145	4	NEG	NEG
146	3	NEG	NEG
147	4	NEG	NEG
148	3	NEG	NEG
149	5	NEG	NEG
150	3	POS	POS
151	3	NEG	NEG
152	4	NEG	NEG
153	4	NEG	NEG
154	3	NEG	NEG
155	3	NEG	NEG
156	6	NEG	NEG

Legend:

Excluded: delay since symptoms onset is superior to 4 days

➢ Results

		PCR		Total results
		Positive	Negative	
Total results	Positive	45	0	45
	Negative	0	71	71
Total results		45	71	116

Sensitivity with 95% confidence interval: 90.2% - 100%

Specificity with 95% confidential interval: 93.6% - 100%

V. Technical Validation report Covid-19 Ag BSS - Federal Office of Public Health (Switzerland)

Date of the report: 23/12/2020

➢ Objective

Evaluation of the BIOSYNEX COVID-19 Ag BSS test against the validation criteria established by the Swiss Society of Microbiology (performed for the Federal Office of Public Health (Switzerland))

➢ Summary

The BIOSYNEX COVID-19 Ag BSS Test has passed the validation criteria as described by the Swiss Society of Microbiology. At a Ct-value of 26 and 29, the BIOSYNEX COVID-19 Ag BSS assay showed a technical sensitivity of 98.4% and 96.3% compared to a reference standard showing a technical sensitivity of 98.4% and 96.3%, respectively. The technical specificity was 100% versus 99% for the reference assay.

➢ Material

✓ Description of component

Assay name: BIOSYNEX COVID-19 Ag BSS
Assay lot number: 2011282 (exp. 2022-10)

➢ Method

The technical performance was validated in (i) 100 PCR-positive and 200 PCRnegative samples and (ii) in a serial dilution against a reference standard in order to determine and compare the diagnostic limits of detection. In general samples were used from the routine diagnostic of the validating laboratory. To allow for a cross-laboratory comparison, 5 SARS-CoV-2 PCR-positive samples were used from aliquoted samples of one single laboratory and distributed to all laboratories. In addition, 50 SARS-CoV-2 PCR negative samples with other respiratory viruses were used and tested by all laboratories. These samples included the following viruses: Coronaviruses (229, HKU1, OC43, NL63, n=3 each), Parainfluenza 1-4 (n=3 each), Rhino/Enteroviruses (n=5 each), Influenza A and B (n=6 each), RSV (n=6 each), and human Metapneumovirus (n=3).

Reference standard: Standard Q COVID-19 Rapid Antigen Test from SD Biosensor/Roche
Reference Lot number: QCO3020112 (exp 2022.10.16)
PCR System: Cobas 6800, Roche, E-Gene was considered for Ct-values

Minimal acceptance criteria to successfully pass the validation:

- Sensitivity at Ct 23 (corresponding to approx. 10'000'000 c/mL), at least 95%
- Sensitivity at Ct 26 (corresponding to approx. 1'000'000 c/mL), at least 90%
- Sensitivity at Ct 29 (corresponding to approx. 100'000 c/mL), at least 80%
- Overall specificity, at least 99%
- Serial dilution has to detect up to Ct 23.3 and 23.1, respectively.

➢ Interpretation of technical sensitivity and specificity

Technical sensitivities at Ct 26 and Ct 29, as well as the overall specificity is shown in Table 1. Figure 1 shows the percentage of antigen positivity in relation to Ct values over a range of 100 PCR-positive clinical samples. In order to detect 80% and 90% of PCR positive samples, the BIOSYNEX COVID-19 Ag BSS test requires a minimum Ct of 34.8 and 31.4, respectively; in contrast, the reference standard requires a minimum Ct of 34.8 and 31.4.

	Sensitivity			Specificity
	Ct 23	Ct 26	Ct 29	
Reference	100%	98.4%	96.3%	99%
BIOSYNEX	100%	98.4%	96.3%	100%

Table 1. Technical sensitivity and specificity, expressed in percentage. For sensitivities at Ct 26 and Ct29 a threshold of 90% and 80% has to be reached. Overall specificity needed to be at least 99%

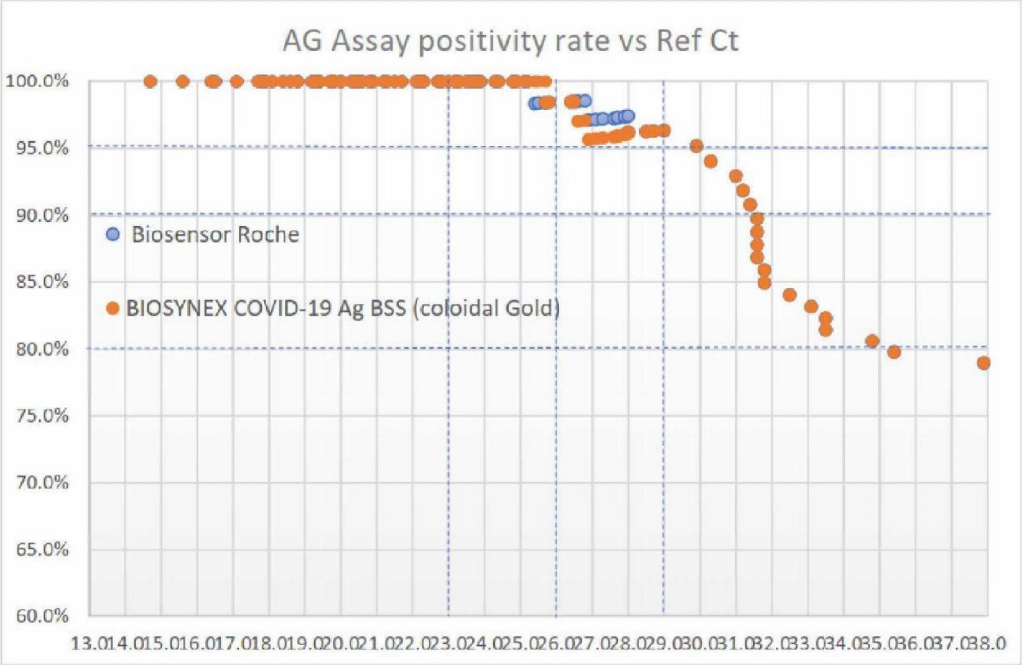


Figure1. Percentage of antigen positivity compared to Ct values of samples.

The median Ct values in antigen positive samples were 22.7for the BIOSYNEX COVID-19 Ag BSS Assay and 22.7 for the reference standard (Figure 2).

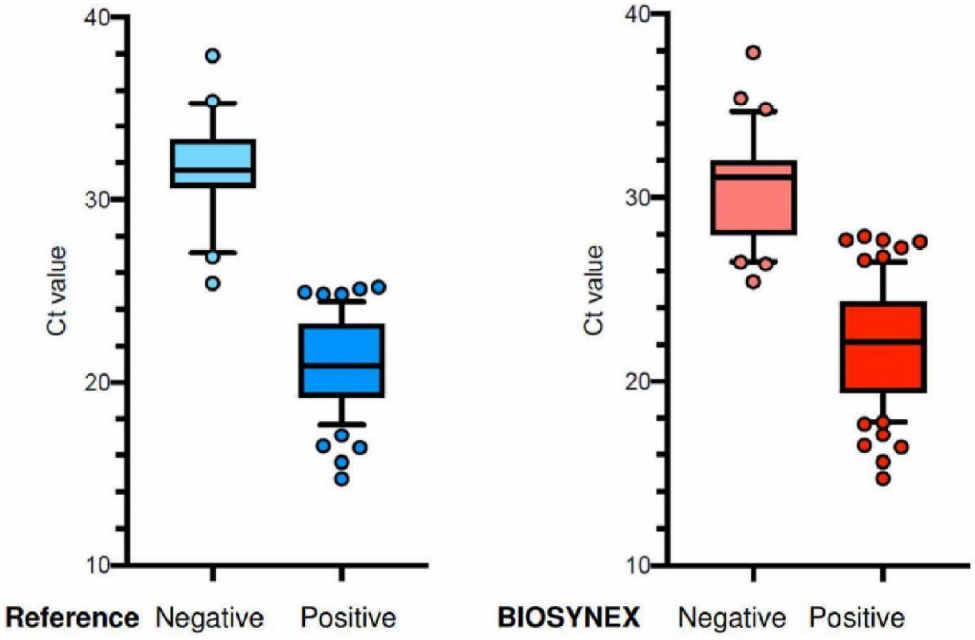


Figure 2. ct values of antigen positive and negative tested samples from routine diagnostics. Boxes show median and interquartile range, whiskers show 10-90th percentile.

➢ Samples tested from serial dilution

The serial dilution from positive samples indicates that the BIOSYNEX COVID-19 Ag BSS assay had a 1-titer higher sensitivity. The minimal positivity of 23.3 and 23.1 has been reached.

	Ct	21.1	21.9	23.3	24.4	25.1	26.1	27.7
Cell culture supernatant	BIOSYNEX	+	+	+	+	-	-	-
	Reference	+	+	+	+	-	-	-
	Ct	**21.4**	**22.3**	**23.1**	**24.1**	**25.5**	**26.4**	**27.3**
Clinical sample	BIOSYNEX	+	+	+	+	+	(+)	(+)
	Reference	+	+	+	+	+	-	-

Table 2. Serial dilution of 2 highly positive sample in a back-to-back comparison. +, clear positive reaction, (+) faint band, and – negative. Green shade indicates the range within a test has to be positive.

VI. CLINICAL STUDY 3: Clinical study report on nasal + nasopharyngeal swabs

Date of the report: 2021/01/15

➢ Abstract

Performance of a rapid antigen test (Rapid COVID-19 Antigen test) was evaluated in a clinical study across 7 US sites. The test performance compared to a variety of RT-PCR results suggests that it has high applicability in testing for the presence of SARS-COV-2 in both symptomatic and asymptomatic populations, especially when viral load is high. The test is applicable for samples taken from either the anterior nares or the nasopharynx.

Couples with the rapid turnaround time and ease of use, this test can provide a significant advantage in the testing strategies required for limiting the spread of SARS-COV-2 in communities.

➢ Background

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses (229E, OC43, NL63, and HKU1) are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains (SARS-CoV, MERS-CoV, SARS-CoV-2) are zoonotic in origin and have sometimes been linked to fatalities.

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

➢ Materials and Methods

The primary objective is to determine the sensitivity and specificity of the Coronavirus Ag Rapid Test Cassette when testing intended use populations who meet the criteria of having COVID-19 infection by Centers for Disease Control and Prevention (CDC). The test is to be performed by healthcare

professionals at clinical settings. In this study, the test is evaluated with two sample collection methods: Sampling from anterior nares, or nasopharynx.

✓ Principle

The BIOSYNEX COVID-19 Ag BSS is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab and nasal swab. The test strip shown in Figure 1 is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device.

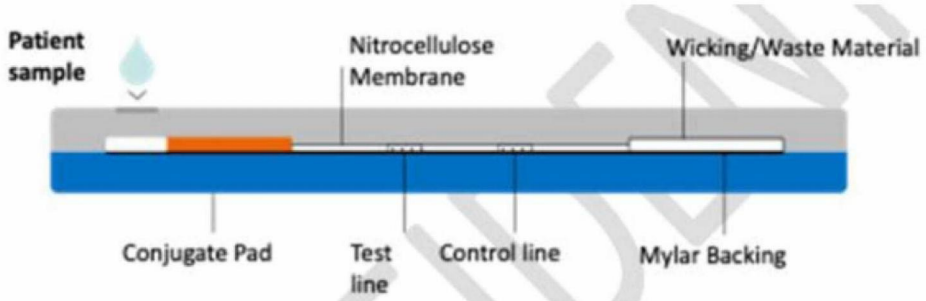


Figure 1: Test strip design

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

✓ Study design

Clinical evaluations were conducted at an actual user site with "real-world" patients as the study population. Clinical specimens were from test subjects in a randomized, blinded fashion. Consent was received from all subjects to be simultaneously sampled for a COVID-19 RT-PCR test and for an antigen test at the clinical site.

Samples were collected from subjects where the healthcare provider suspects the individual may have COVID-19 infection based on the CDC description of COVID-19 symptoms or may been exposed. The paired samples were subsequently confirmed by an EUA approved RT-PCR assay and were under the Principal Investigator's care. Subjects with known RT-PCR results in the prior 14 days could waive the RT-PCR sampling requirement.

Various RT-PCR assay were used as the comparator, which was determined on site specific availability and allowed the clinical evaluation to be part of the normal workflow at the sites. Performance relative to individual PCR comparators is shown in the result section below. Each of the selected RT-PCR methods was approved by the USFDA under Emergency Use Authorization.

✓ Study locations, settings, operators

The study was carried out at 7 sites across the USA. Study sites included the settings of: Emergency Room, Hospital Ward, Homeless Shelter in cooperation with Red Cross, Drive-Through testing, contact Tracing Teams, Community Clinic, College Campus, General Clinic with emergency and elective procedures. The study included only non-trained operators. The total number of operators working with the test in this study was 26.

✓ Inclusion and Exclusion Criteria

Inclusion criteria

1. Must be 21 years old or older.
2. Has symptoms that lead the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection.
3. Was exposed to a COVID-19 patient within 14 days that leads the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection
4. Has an immediate need to determine COVID-19 status for occupational purposes.
5. Must be willing to provide a sample for COVID-19 RT-PCR testing if the subject has not been previous tested for COVID-19 RT-PCR within 14 days.
6. Must be willing to provide a sample for additional tests required by the study site (antigen test or RT-PCR).
7. Must be able to sign a consent form.
8. Must be able to provide nasopharyngeal or nasal swab samples.

Exclusion criteria

1. Is receiving treatment with infusion of convalescent plasma or other antibody therapy related to SARS-CoV-2 infections.
2. Is participating in a SARS-CoV-2 vaccine study.
3. Tested positive for COVID-19 positive more than 14 days ago.

✓ Description of component

Coronavirus Ag Rapid Test Cassette (Swab)
Lot: 2008139

➢ Test procedure for Nasopharyngeal Swab

The test was performed according to the Instructions for use (IFU) in the package insert. For the antigen test device, the sample was collected from one side of the nasopharynx with the swab included with the kit. Fresh specimens were tested immediately on the rapid antigen test. Viral Transport Media (VTM) was not used for shipping the samples to a different location for testing, as this is not

recommended in the instructions for use. USFDA EUA listed PCR assay was used as the comparator; its samples were collected from the opposite side of the Nasopharynx and processes as per the instructions for use.

➢ Results - Nasopharyngeal Swab

A total of 865 fresh nasopharyngeal swab samples were collected and tested, which included 119 positive samples and 746 negative samples.

✓ Raw data

Not available

✓ Overall study results for nasopharyngeal swab

Overall study results are shown in Table 1

Method		**PCR (Nasopharynx)**		**Total Results**
Rapid COVID-19 Antigen Test (Nasopharynx)	Results	Positive	Negative	
	Positive	117	3	120
	Negative	2	743	745
Total		119	746	865

Table 1: Rapid COVID-19 Antigen Test (Nasopharyngeal Swab) vs PCR (Nasopharyngeal Swab)

Relative Sensitivity: 98.32% (95% Confidence Interval: 94.06% to 99.80%)
Relative Specificity: 99.60% (95% Confidence Interval: 98.83% to 99.92%)
Accuracy: 99.42% (95% Confidence Interval: 98.66% to 99.81%)

✓ Days post-symptom onset demographics

During enrollment patients were screened for evidence of symptoms and the onset of symptoms. Aggregated test performance as a function of the days post symptom onset is presented in Table 2. Of note is that the test demonstrates high sensitivity even in the case of asymptomatic patients (38 of 38). This is a critical requirement for population screening.

Analysis of positive patients experiencing symptom onset within 11 days were recorded. Correlation between the Rapid COVID-19 Antigen Test and the PCR comparator stratified by days post symptom onset are shown in Table 2.

Days post symptom onset	Samples tested	Antigen positive results	PPA	95% CI
Asymptomatic	38	38	100%	92.42% - 100%
0	0	0	N/A	N/A
1	8	7	88%	47.35% - 99.68%
2	10	10	100%	69.15% – 100%
3	12	12	100%	73.54% - 100%

4	15	15	100%	78.19% - 100%
5	12	12	100%	73.54% - 100%
6	5	5	100%	47.82% - 100%
7	11	10	91%	58.72% - 99.77%
8	0	0	N/A	N/A
9	1	1	100%	2.50% - 100%
10	1	1	100%	2.50% - 100%
11	5	5	100%	47.82% - 100%
>11	1	1	100%	2.50 - 100%
Total	**119**	**117**	**98%**	**94.06% – 99.80%**

Table 2: Positive result stratified by days post symptom onset

✓ Cycle threshold (Ct) Analysis

For the positive test results, the cycle threshold counts were recorded and compared against the rapid antigen results, presented in table 3. Literature suggests that Ct values greater than 30 are generally non-infectious, corresponding to a viral load of >1E6 copies per mL. The test performance in table 3 is separated for samples below Ct<30 and for those where Ct≥30. For Ct<30 the test is highly sensitive and false negatives were observed only in cases where Ct≥30. This suggests the rapid antigen test could be an effective method of screening for infectious, asymptomatic patients which is a key requirement in the high- volume population screening that is critical to limit the spread of the disease.
The performance of the Rapid COVID-19 antigen test with positive results stratified by the comparator PCR method cycle threshold (Ct) counts in table 3.

Rapid COVID-19 Antigen test (Nasopharynx)	**RT-PCR comparator positive result cycle threshold (Ct)**	
	Ct<30	**Ct≥30**
Positive	101	16
Negative	0	2
Total	101	18
Positive Agreement (95% CI)	**100% (96.41% - 100%)**	**88.89% (65.29% - 98.63%)**

Table 3: Positive Result Stratified by Cycle Threshold (Ct) Value

➢ Test procedure for nasal swab

The test was performed according to the Instructions for Use (IFUB22056-02) in the package insert.
For the antigen test device, the sample was collected from anterior nares with the swab included with the kit. Fresh specimens were tested immediately on the rapid antigen test.
Viral Transport Media (VTM) was not used for shipping the samples to a different location for testing, as this is not recommended in the instructions. A USFDA EUA listed PCR assay was used as the comparator; its samples were then collected from the opposite side of the nasopharynx and processed as per the instructions for use.

➢ Results - nasal swab

A total of 237 fresh nasal swab samples was collected and tested, which included 109 positive samples and 128 negative samples. The Rapid COVID-19 Antigen Test results were compared to results of USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in nasopharyngeal swab specimens.

✓ Raw data

Not available

Method		**PCR (Nasopharynx)**		**Total Results**
Rapid COVID-19 Antigen Test (Anterior nares)	Results	Positive	Negative	
	Positive	106	0	106
	Negative	3	128	131
Total results		109	128	237

Table 4: Rapid COVID-19 Antigen Test (nasal swab) vs PCR (nasopharyngeal swab)

Relative Sensitivity: 97.25% (95% CI*: 92.17% to 99.43%)
Relative Specificity: 100% (95% CI*: 97.16% to 100%)
Accuracy: 98.73% (95%CI*: 96.35% to 99.74%)

➢ Conclusion

Performance of a rapid Antigen test (Rapid COVID-19 antigen test) was evaluated in a clinical study across multiple US sites. The comparative method was USFDA Emergency use Authorized RT-PCR Assay with samples taken from the Nasopharynx.

For nasopharyngeal sampling with the Rapid COVID-19 Antigen Test, the overall test accuracy over 865 samples was 99.42% with a sensitivity of 98.32% and a specificity of 99.60% relative to RT-PCR and relatively uniform across all 7 sites. Performance relative to symptom onset days indicated that the test performs very well even in the case of asymptomatic patients (38 of 38 positives) and at Ct <30 (101 of 101 positives), indicating its applicability in screening in patients that may or may not present with symptoms, but could be infectious.

For nasal sampling with the Rapid COVID-19 Antigen Test, the overall test accuracy over 237 samples was 98.73% with a sensitivity of 97.25% and a specificity of 100% relative to RT-PCR. For this sampling method, analysis relative to symptom onset was not performed.

The overall test performance coupled with the fast turnaround time and high sensitivity with asymptomatic patients with high viral load suggests that this test would have significant impact in screening for the presence of SARS-CoV-2 in communities.

VII. CLINICAL STUDY 4: Supplemental study for nasal samples

Completion date: 2021/02/11
Date of the report: 2021/02/11

➢ Objective

To enhance the performances data of the Biosynex COVID-19 Ag BSS product with negative nasal swabs confirmed by Life River 2019-nCov RT-PCR®.

➢ Material

✓ Description of component

Product name	Biosynex COVID-19 Ag BSS
Reference	SW40006
Batch	2009146
Charte de Lecture	Gold color Card Biosynex G1012

✓ Description of tested samples

Code	Origin	Samples types	T° stockage	RT-PCR
				Life River ® SARS-COV-2
C0221-01	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-02	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-03	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-04	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-05	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-06	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-07	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-08	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-09	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-10	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-11	CCN Lab	Nasal	- 20 °C	NEGATIVE
C0221-12	CCN Lab	Nasal	- 20 °C	NEGATIVE

➢ Method

✓ Study protocol

The aim of this study is to enhance the performances data of the Biosynex COVID-19 Ag BSS product with nasals swabs from patient tested negative for SARS COV-2 gene by RT-PCR.

The study is realized with samples from patient tested by RT-PCR for SARS COV-2 by the CCN lab: 12 Negative samples.

✓ Test protocol

Add 0,3mL (about 10 drops) of the sample extraction buffer into the extraction tube. Insert the swab into the extraction tube and unload the swab by rolling the swab at least 6 times. Leave it in the extraction tube during 1 min and squeeze the tube to immerse the swab. Finally, remove the swab, mix it by vortexing and use the extraction solution as test sample.

Add 4 drops of the sample into the sample well. Read the result after 15 minutes with the Gold color Card Biosynex G1012. Intensities from 3 to 10 are considered as positive. Intensities strictly below 3 are considered as negative.

➢ Results

✓ Raw data

N°	RT-PCR	RT-PCR			TDR	
		ORFAB	N	E	C line	Test line
C0221-01	NEGATIVE	NA	NA	NA	10	1
C0221-02	NEGATIVE	NA	NA	NA	10	1
C0221-03	NEGATIVE	NA	NA	NA	10	1
C0221-04	NEGATIVE	NA	NA	NA	10	1
C0221-05	NEGATIVE	NA	NA	NA	10	1
C0221-06	NEGATIVE	NA	NA	NA	10	1
C0221-07	NEGATIVE	NA	NA	NA	10	1
C0221-08	NEGATIVE	NA	NA	NA	10	1
C0221-09	NEGATIVE	NA	NA	NA	10	1
C0221-10	NEGATIVE	NA	NA	NA	10	1
C0221-11	NEGATIVE	NA	NA	NA	10	1
C0221-12	NEGATIVE	NA	NA	NA	10	1

✓ Correlation

✓

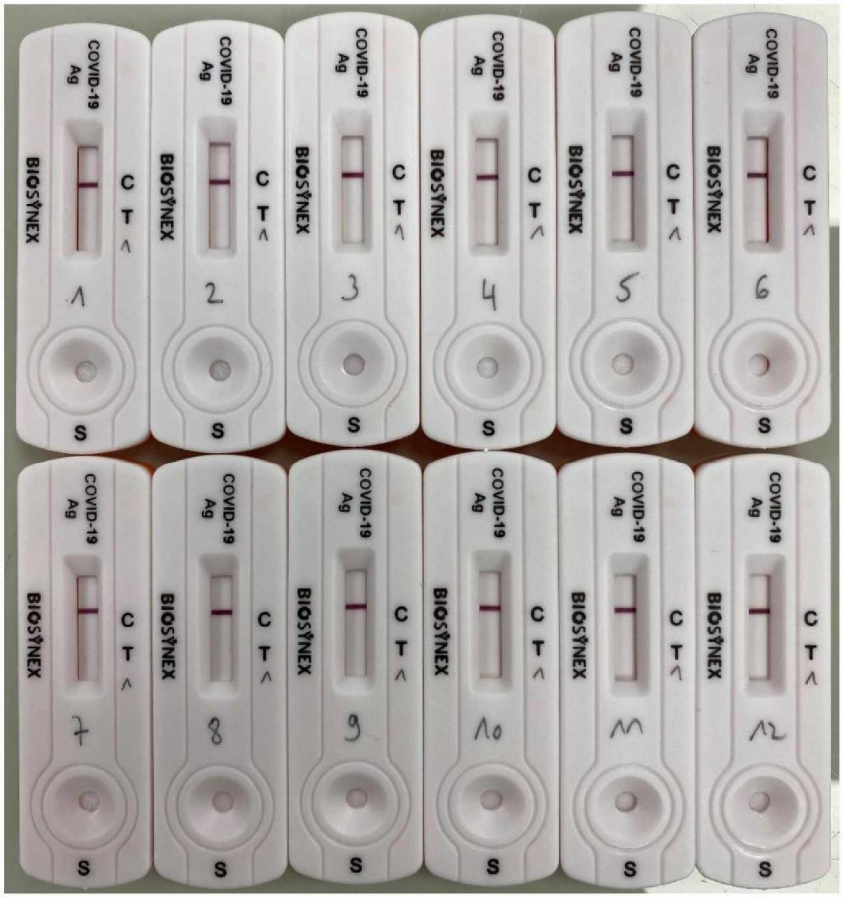
		Biosynex COVID-19 Ag BSS		
		Positive	Negative	
Life River (RT-PCR)	Positive	0	0	**0**
	Négative	0	12	**12**
		0	**12**	**12**

Relative Specificity: 12/(12+0)*100 = 100%

➢ Conclusion

According to the results we obtained, we can conclude that the Biosynex COVID-19 Ag BSS test gives 100% of correlation with the RT-PCR (Life River®) test.

➢ Annexes



VIII. Claimed performances for nasal swabs

Biosynex calculated test performances for nasal swabs (sensitivity, specificity, reliability) based on the compilation of the data from both studies.

Results from both studies were compiled to generate the following data:

Sensitivity, Specificity, Accuracy

		PCR		
		Positive	Negative	
BIOSYNEX COVID-19 Ag BSS	Positive	106	0	**106**
	Negative	3	140	**143**
		109	**140**	**249**

Based on this data: the sensitivity, specificity, accuracy were calculated:

Sensitivity : 97,2% (95%CI*: 92,1-99,4%) *Confidence interval
Specificity: 100% (95%CI*: 100%-100%)
Accuracy: 98,8% (95%CI*: 96,5-99,8%)

➢ Conclusion

Based on data from studies documented in §VII and VIII, the sensitivity of the test is 97,2%, the specificity is 100%, and the accuracy is 98,8%.

IX. History (changes)

Revision	Date	Part	Reason/Changes
01	2020-09-11	NA	Creation of the document
02	2020-09-15	II	Addition of data on table 3
03	2020-10-16	III IV.	Update of the study data Modification of the presentation Addition of § IV. 2., calculation of BIOSYNEX COVID-19 Ag BSS sensitivity according to Ct obtained by RT-PCR testing
04	2020-10-22	I. III. 2.	Precision of the reference of the commercial RT-PCR: indication of complete manufacturer name and product name §raw data : Correction of Ct data for patient n°40 §interpretation : Correction of results table *' Number of positive / negative BIOSYNEX COVID-19 Ag BSS test by category of Ct'* : number of RT-PCR positive (31 ≤ Ct ≤ 35) and BIOSYNEX COVID-19 Ag BSS positive = **30**
05	2020-11-04	Heading	Addition of the new variant BIOSYNEX® COVID-19 Ag BSX REF. SW40006_BSX
06	2021-01-06	§II. §IV. §V.	Addition of following information in the study design : "Note: "the tests were performed using fresh samples. Addition of §IV. performances according to HAS criteria in France Addition of the Technical Validation report Covid-19 Ag BSS - Federal Office of Public Health (Switzerland)
07	2021-02-18	§VI.; §VII.; §VIII.	Addition of studies on nasal performances: - Clinical study 3 including nasal samples (see §VI) - Clinical study 4 on nasal samples (see §VII) Justification of claimed performances on nasal samples (see § VIII)