Evaluation of clinical performance

PCL COVID19 Ag Gold Saliva (COV 04S) for the in vitro qualitative detection of SARS-CoV-2 antigen in fresh human nasopharyngeal and saliva specimens

1 Purpose

This study is intended to evaluate the clinical performance of PCL COVID19 Ag Gold Saliva (COV04S).

2 References

- MFDS guideline for IVD medical devices for high-risk infectious virus (No. 0629-02)
- CLSI EP12-A2_User Protocol for Evaluation of Qualitative Test Performance
- CLSI ILA21-A2_Clinical Evaluation of Immunoassays

3 Terms and definitions

- **Analyte**: Component represented in the name of a measurable quantity, the analyte is the particular component of interest to the patient
- **Limit of detection (LoD)**: lowest amount of analyte in a sample that can be detected with (stated) probability, although perhaps not quantified as an exact value (revised from WHOBS/95.1793).
- Sensitivity: The probability that the device gives a positive result in the presence of the target marker.
- **True positive**: A specimen known to be positive for the target marker and correctly classified by the device
- **False negative**: A specimen known to be positive for the target marker and misclassified by the device
- **Specificity**: The probability that the device gives a negative result in the absence of the target marker
- **False positive**: A specimen known to be negative for the target marker and misclassified by the device
- **True negative**: A specimen known to be negative for the target marker and correctly classified by the device.

4 Product descriptions

4.1 Product name (model name)

PCL COVID19 Ag Gold Saliva (COV04S)

4.2 Classification

- IVDD Classification: General IVDs (Neither listed in the Annex II of the IVDD, nor self-testing device)
- MFDS Classification: Class 3 IVD (Reagents for infectious disease marker, K05030.1)

4.3 Intended use

This product (PCL COVID19 Ag Gold Saliva) is an in vitro diagnostic medical device applying dual antibody sandwich reaction and immunochromatographic analysis to qualitatively detect COVID19 antigen in human saliva and nasopharyngeal specimens.

4.4 Intended user

Special conditions for use

- For the patients with symptom (high fever, running nose, cough)
- For POCT or at home-testing with saliva specimen only
- For professional use only with swab specimen
- For in vitro diagnostic use only

4.5 Principles of procedure

The COVID19 antibody of this product is immobilized in the test region of the nitrocellulose membrane. When the sample contains a SARS-CoV-2 antigen, it binds to the conjugate (COVID19 antibody-gold conjugate) to form a complex, moved along the nitrocellulose membrane by capillary principle and is immobilized with the COVID19 antibody immobilized in the test line region. Antigen-antibody immune responses form double complexes that appear color band. If the sample does not contain the SARS-CoV-2 antigen, it does not make a double complex in the test region, so the color band does not appear. The color band will appear in the control region of the product regardless of the presence/absence of the SARS-CoV-2 antigen in the sample.

5 Test descriptions

5.1 Test schedule and responsibilities

Protocol reviewed by	Chuntaek Oh	DRM	2020.05.20
Kit manufactured by	Dosun Park	MFTL	2020.05.04
Kit inspected by	Jihwan Hyun	Researcher	2020.05.09
Test performed by (5 operators)	Youmi Lee Seongyeon Hwang Nara Yoon Junhyeong Lee Chunmi Kim	Researcher (CHU)	2020.06.27 ~ 09.10
Test site	Chosun university hospital: 365 Pilmun-daero, Seonam-dong, Dong-gu, Gwangju, Korea		

5.2 Test materials

1) Test kit

Investigational kit			
Product name	PCL COVID19 Ag Gold Saliva		
REF	COV04S		
Manufacturer	PCL, Inc.		
Lot No.	2005K401		
Expiration date	2022.05.03		

Comparative kit	
Product Name	PowerChek™ 2019-nCoV Real-time PCR Kit
REF	R6900T
Manufacturer	Kogene

2) Specimens(samples)

Collection site	**Test site**	**Positive specimen tested by RT-PCR**			**Negative specimen tested by RT-PCR**		
		Saliva	**NP**	**total**	**Saliva**	**NP**	**total**
CUH	CUH	35	10	45	70	35	105

- Saliva: Saliva specimens, NP: Nasopharyngeal swab specimens
- CUH: Chosun university hospital
- RT-PCR: PowerChek™ 2019-nCoV Real-time PCR kit (Kogenebiotech)
- NP specimens were collected from those who agreed to collect NP specimens among patients who provided saliva specimen.

5.3 Test methods

1) Sample collection

Saliva specimen

- The patient collects saliva from the tip of the tongue for 30 seconds (does not include sputum, etc.).
- Spit the collected saliva into the extraction buffer tube directly for immediate use.
- Otherwise, after collecting saliva in patient's mouth for 30 seconds, use a sterile swap to collect saliva in the extraction buffer tube and store it at 2°C to 8°C for no more than 72 hours or at -70°C for the longer term. Long-term storage may result in a signal decrease.
- Do not re-freeze the sample after thawing. Multiple freeze/ thaw cycles may result in a signal decrease.

Nasopharyngeal swab specimen

- Nasopharyngeal swabs have been validated with the PCL COVID19 Ag Rapid Gold.
- Insert the sampling swab through the nostril/mouth and gently push the swab into the posterior oropharynx/nasopharynx.
- Rotate the sampling swab three times while avoiding touching the tongue and then remove the swab.
- Put the swab into the extraction buffer tube for immediate use.
- Otherwise, they should be stored in closed containers containing 1 ml or less of viral transport media at 2 to 8°C for no more than 72 hours or at -70°C for the longer term. Long-term storage may result in a signal decrease.
- Do not re-freeze the sample after thawing. Multiple freeze/ thaw cycles may result in a signal decrease.

2) Kit preparation

- Reagents are allowed to stand at room temperature for 20-30 minutes before testing.

3) Sample preparation

① Collect the sample as directed in the "Sample collection and storage" section.

② Put the patient swab or saliva into the extraction buffer tube.

③ Swirl the swab 10 times then remove it while squeezing the liquid from the swab in case of swab samples. For saliva samples, directly go to step 4.

④ Cover the tube with a filter cap and tighten the lid.

4) Assay procedure

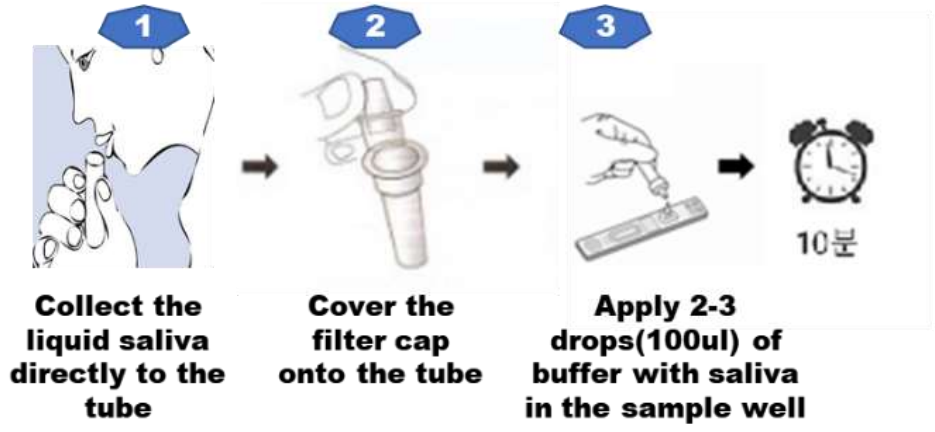
① Open the inspection pouch and place test card on a flat surface.

※ Open the test card pouch just before use. If the pouch is left unused after opening, it may cause inaccurate results.

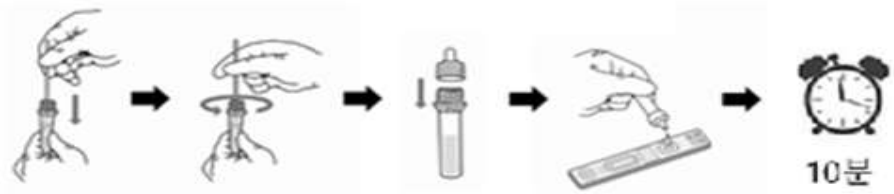
② Drop 2-3 drops (110 μl) of sample extraction buffer into the sample hole of the sample device after the sample has been loaded.

③ Read the results after 10minutes. Time of result reading should not be longer than 20 minutes after applying the sample diluent.

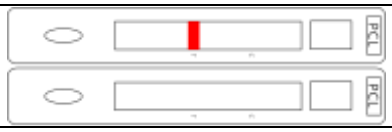
Saliva specimen



Nasopharyngeal swab specimen



5) Interpretation of results

COVID-19 Ag Negative	
COVID-19 Ag Positive	
Invalid	

6) Data analysis

Percent agreement: Test results will be expressed in 2X2 table and analyzed as percent agreement with comparator RT-PCR testing results, retrospectively.

		RT-PCR assay	
		Positive	Negative
PCL COVID19 Ag Gold Saliva	Positive	A	B
	Negative	C	D

- Positive Percent Agreement (PPA) = A / (A + C)
- Negative Percent Agreement (NPA) = D / (B + D)

Internal Controls

- The PCL COVID19 Ag Gold Saliva contains a built-in internal control in the test card. A red line appearing in the control region (C) is designed as an internal control. The appearance of the control line confirms that sufficient flow has occurred, and that the test card is working normally. If the control line does not appear within 10 minutes, it is considered an error in the test result and it is recommended to test again with a new device. If there is still no red line on the internal control line on the retest, contact the manufacturer or distributor.

External Controls

- External Positive and Negative controls may be used with the test kit. These controls provide additional quality control material to assess that the test reagents as expected.
- Controls are recommended to be run once for each new kit lot and each new operator
- For external positive control material, it is recommended to use "SARS-Related Coronavirus 2 (SARS-CoV-2) Culture Fluid (Heat Inactivated)" (Cat. No. 0810581CHI) of "ZeptoMetrix" (USA).

- It is advised to divide "SARS-Related Coronavirus 2(SARS-CoV-2) Culture Fluid (Heat Inactivated)" (Cat. No. 0810581CHI) into separate units each containing 15ul and stored at -70℃ until use. Prior to use, allow the control material to stand at room temperature for at least 30 minutes and thaw completely.
- Prepare solutions for positive controls following the instructions provided with the control material.
- For external negative controls it is recommended to use the Extraction buffer included in the kit.
- Perform controls using the same procedure as used for patient specimens.
- If the kit controls do not perform as expected, do not report patient results. Contact the place of purchase or the manufacturer.

7) Acceptance criteria

Clinical test results should have a sensitivity of at least 80% and a specificity of at least 90% compared to the confirmatory test device

6 Test results

Saliva

PCL COVID19 Ag Gold Saliva		RT-PCR*		PPA (%)	NPA (%)
		Pos	Neg		
CUH	Pos	33	0	94.29	100.0
	Neg	2	70		
	Total	35	70		

*RT-PCR: PowerChek™ 2019-nCoV Real-time PCR kit (Kogenebiotech)

Nasopharyngeal swab

PCL COVID19 Ag Gold Saliva		RT-PCR*		PPA (%)	NPA (%)
		Pos	Neg		
CUH	Pos	9	0	90.0	100.0
	Neg	1	35		
	Total	10	35		

Matrix comparison between saliva and nasopharyngeal swab

PCL COVID19 Ag Gold Saliva		Nasopharyngeal swab specimen		PPA (%)	NPA (%)
		Pos	Neg		
Saliva specimens	Pos	9	0	100.0	100.0
	Neg	0	36		
	Total	9	36		

7 Conclusion

- Fresh saliva specimens were used for the performance evaluation of the PCL COVID19 Ag Gold Saliva under Chosun university hospital's IRB (IRB 2020-02-011-002). Two separate fresh saliva swab specimens were obtained from each patient in parallel for Ag test (extraction buffer) and RT-PCR confirmation test according to the kit IFU.

- A total of 105 saliva specimens including 35 positive and 70 negative samples for COVID19 were evaluated prospectively by comparing the results obtained with PCL COVID19 Ag Gold Saliva (COV04S) and the results obtained with RT-PCR COVID-19 (PowerChekTM2019-nCoV Real-time PCR Kit: FDA-EUA,

MFDS-EUA authorized and CE marked test (Kogenebiotech). The performance was evaluated retrospectively in comparison with the test results of the confirmatory test device and the positive percent agreement (PPA) is 94.29% (95% CI: 80.84% - 99.30%), negative percent agreement (NPA) is 100% (95% CI: 94.87% - 100.00%).

- Fresh nasopharyngeal swab specimens were used for the performance evaluation of the PCL COVID19 Ag Gold Saliva under Chosun university hospital's IRB (IRB 2020-02-011-002). Two separate fresh nasopharyngeal swab specimens were obtained from each patient in parallel for Ag test (extraction buffer) and RT-PCR confirmation test according to the kit IFU.

- A total of 45 nasopharyngeal swab specimens including 10 positive and 35 negative samples for COVID19 were evaluated prospectively by comparing the results obtained with PCL COVID19 Ag Gold Saliva (COV04S) and the results obtained with RT-PCR COVID-19 (PowerChekTM2019-nCoV Real-time PCR Kit: FDA-EUA, MFDS-EUA authorized and CE marked test (Kogenebiotech). The performance was evaluated retrospectively in comparison with the test results of the confirmatory test device and the positive percent agreement (PPA) is 90.0% (95% CI: 85.00% - 99.30%), negative percent agreement (NPA) is 100% (95% CI: 94.87% - 100.00%).

- The total 90 samples including 70 negative samples (35 nasopharyngeal swabs and 35 saliva specimens) and 20 positive samples (10 nasopharyngeal swabs and 10 saliva specimens) showed high PPA (9/9=100%) and NPA (36/36=100%). The difference of matrix (nasopharyngeal swab and saliva specimen) did not affect the result.

- 연구책임자

김동민		2020 10 20
Name	*Signature*	*Date (YYYY/MM/DD)*

8 Appendix

- Appendix 1. Raw data

/. Site1: CUH (Chosun university hospital, Gwangju, Rep. of Korea), 5 Operators, According to IFU

No.	Sample ID	PCL COVID19 Ag Gold saliva (COV04S)						RT-PCR (Cut off: 38)							
		Specimen type	Specimen collection date	Specimen testing date	Days post symptom onset	Buffer	Result	Product name	Gene/Marker	Ct value	Gene/Marker	Ct value	Specimen type	Specimen collection date	Specimen testing date	Result
1	CS_S_P201	Saliva	2020-06-27	2020-06-27	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	26.04	E gene	26.15	Saliva	2020-06-27	2020-06-27	POS
2	CS_S_P202	Saliva	2020-06-27	2020-06-27	9	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	25.30	E gene	25.19	Saliva	2020-06-27	2020-06-27	POS
3	CS_S_P202NP	Nasopharyngeal	2020-06-27	2020-06-27	9	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	25.20	E gene	25.06	Nasopharyngeal	2020-06-27	2020-06-27	POS
4	CS_S_P203	Saliva	2020-06-27	2020-06-27	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.40	E gene	12.37	Saliva	2020-06-27	2020-06-27	POS
5	CS_S_P204	Saliva	2020-06-27	2020-06-27	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	21.70	E gene	21.77	Saliva	2020-06-27	2020-06-27	POS
6	CS_S_P205	Saliva	2020-07-01	2020-07-01	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	15.50	E gene	15.41	Saliva	2020-07-01	2020-07-01	POS
7	CS_S_P206	Saliva	2020-07-03	2020-07-03	0	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	28.14	E gene	27.89	Saliva	2020-07-03	2020-07-03	POS
8	CS_S_P206NP	Nasopharyngeal	2020-07-03	2020-07-03	0	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	28.24	E gene	28.08	Nasopharyngeal	2020-07-03	2020-07-03	POS
9	CS_S_P207	Saliva	2020-07-03	2020-07-03	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	27.26	E gene	26.70	Saliva	2020-07-03	2020-07-03	POS
10	CS_S_P208	Saliva	2020-07-03	2020-07-03	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	20.67	E gene	20.31	Saliva	2020-07-03	2020-07-03	POS
11	CS_S_P209	Saliva	2020-07-05	2020-07-05	10	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	21.24	E gene	21.21	Saliva	2020-07-05	2020-07-05	POS
12	CS_S_P209NP	Nasopharyngeal	2020-07-05	2020-07-05	10	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	20.57	E gene	20.58	Nasopharyngeal	2020-07-05	2020-07-05	POS
13	CS_S_P210	Saliva	2020-07-05	2020-07-05	8	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	24.76	E gene	24.51	Saliva	2020-07-05	2020-07-05	POS
14	CS_S_P211	Saliva	2020-07-08	2020-07-08	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	18.98	E gene	18.80	Saliva	2020-07-08	2020-07-08	POS
15	CS_S_P212	Saliva	2020-07-10	2020-07-10	6	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	18.65	E gene	18.50	Saliva	2020-07-10	2020-07-10	POS
16	CS_S_P213	Saliva	2020-07-13	2020-07-13	5	Extraction buffer (COV04S)	NEG	PowerChek™	RdRp	28.60	E gene	28.17	Saliva	2020-07-13	2020-07-13	POS
17	CS_S_P214	Saliva	2020-07-18	2020-07-18	12	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.66	E gene	11.84	Saliva	2020-07-18	2020-07-18	POS
18	CS_S_P214NP	Nasopharyngeal	2020-07-18	2020-07-18	12	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.46	E gene	12.40	Nasopharyngeal	2020-07-18	2020-07-18	POS
19	CS_S_P215	Saliva	2020-07-20	2020-07-20	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	23.08	E gene	22.52	Saliva	2020-07-20	2020-07-20	POS
20	CS_S_P216	Saliva	2020-07-20	2020-07-20	12	Extraction buffer (COV04S)	NEG	PowerChek™	RdRp	30.67	E gene	30.31	Saliva	2020-07-20	2020-07-20	POS
21	CS_S_P216NP	Nasopharyngeal	2020-07-20	2020-07-20	12	Extraction buffer (COV04S)	NEG	PowerChek™	RdRp	30.86	E gene	30.83	Nasopharyngeal	2020-07-20	2020-07-20	POS
22	CS_S_P217	Saliva	2020-08-08	2020-08-08	0	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	10.97	E gene	10.99	Saliva	2020-08-08	2020-08-08	POS
23	CS_S_P218	Saliva	2020-08-08	2020-08-08	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.20	E gene	12.15	Saliva	2020-08-08	2020-08-08	POS
24	CS_S_P219	Saliva	2020-08-11	2020-08-11	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	21.57	E gene	20.51	Saliva	2020-08-11	2020-08-11	POS
25	CS_S_P219NP	Nasopharyngeal	2020-08-11	2020-08-11	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	20.47	E gene	20.29	Nasopharyngeal	2020-08-11	2020-08-11	POS
26	CS_S_P220	Saliva	2020-08-22	2020-08-22	1	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	11.73	E gene	11.64	Saliva	2020-08-22	2020-08-22	POS
27	CS_S_P221	Saliva	2020-08-22	2020-08-22	6	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	25.06	E gene	24.45	Saliva	2020-08-22	2020-08-22	POS
28	CS_S_P222	Saliva	2020-08-22	2020-08-22	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	19.29	E gene	19.08	Saliva	2020-08-22	2020-08-22	POS
29	CS_S_P222NP	Nasopharyngeal	2020-08-22	2020-08-22	5	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	19.07	E gene	18.79	Nasopharyngeal	2020-08-22	2020-08-22	POS
30	CS_S_P223	Saliva	2020-08-23	2020-08-23	6	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	16.26	E gene	16.37	Saliva	2020-08-23	2020-08-23	POS
31	CS_S_P224	Saliva	2020-08-25	2020-08-25	3	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	9.50	E gene	9.27	Saliva	2020-08-25	2020-08-25	POS
32	CS_S_P225	Saliva	2020-08-27	2020-08-27	4	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	18.55	E gene	18.49	Saliva	2020-08-27	2020-08-27	POS
33	CS_S_P225NP	Nasopharyngeal	2020-08-27	2020-08-27	4	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	17.99	E gene	17.88	Nasopharyngeal	2020-08-27	2020-08-27	POS
34	CS_S_P226	Saliva	2020-08-28	2020-08-28	1	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	20.18	E gene	20.33	Saliva	2020-08-28	2020-08-28	POS
35	CS_S_P227	Saliva	2020-08-28	2020-08-28	4	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	20.80	E gene	20.92	Saliva	2020-08-28	2020-08-28	POS
36	CS_S_P228	Saliva	2020-08-28	2020-08-28	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.20	E gene	11.59	Saliva	2020-08-28	2020-08-28	POS
37	CS_S_P228NP	Nasopharyngeal	2020-08-28	2020-08-28	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.56	E gene	12.97	Nasopharyngeal	2020-08-28	2020-08-28	POS
38	CS_S_P229	Saliva	2020-08-29	2020-08-29	0	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	7.80	E gene	7.39	Saliva	2020-08-29	2020-08-29	POS
39	CS_S_P230	Saliva	2020-08-29	2020-08-29	1	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	13.63	E gene	13.66	Saliva	2020-08-29	2020-08-29	POS
40	CS_S_P231	Saliva	2020-08-30	2020-08-30	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	15.57	E gene	14.91	Saliva	2020-08-30	2020-08-30	POS
41	CS_S_P232	Saliva	2020-09-01	2020-09-01	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	7.03	E gene	6.78	Saliva	2020-09-01	2020-09-01	POS
42	CS_S_P232NP	Nasopharyngeal	2020-09-01	2020-09-01	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	7.03	E gene	6.79	Nasopharyngeal	2020-09-01	2020-09-01	POS
43	CS_S_P233	Saliva	2020-09-02	2020-09-02	6	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	14.28	E gene	13.81	Saliva	2020-09-02	2020-09-02	POS
44	CS_S_P234	Saliva	2020-09-05	2020-09-05	2	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	17.81	E gene	16.64	Saliva	2020-09-05	2020-09-05	POS
45	CS_S_P235	Saliva	2020-09-10	2020-09-10	4	Extraction buffer (COV04S)	POS	PowerChek™	RdRp	12.74	E gene	12.44	Saliva	2020-09-10	2020-09-10	POS
46	CS_S_N201	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
47	CS_S_N202	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
48	CS_S_N202NP	Nasopharyngeal	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-06-27	2020-06-27	NEG
49	CS_S_N203	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
50	CS_S_N203NP	Nasopharyngeal	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-06-27	2020-06-27	NEG
51	CS_S_N204	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
52	CS_S_N205	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
53	CS_S_N205NP	Nasopharyngeal	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-06-27	2020-06-27	NEG
54	CS_S_N206	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
55	CS_S_N206NP	Nasopharyngeal	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-06-27	2020-06-27	NEG
56	CS_S_N207	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
57	CS_S_N208	Saliva	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-06-27	2020-06-27	NEG
58	CS_S_N208NP	Nasopharyngeal	2020-06-27	2020-06-27		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-06-27	2020-06-27	NEG
59	CS_S_N209	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
60	CS_S_N209NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG

61	CS_S_N210	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
62	CS_S_N210NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
63	CS_S_N211	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
64	CS_S_N211NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
65	CS_S_N212	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
66	CS_S_N212NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
67	CS_S_N213	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
68	CS_S_N213NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
69	CS_S_N214	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
70	CS_S_N215	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
71	CS_S_N215NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
72	CS_S_N216	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
73	CS_S_N217	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
74	CS_S_N217NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
75	CS_S_N218	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
76	CS_S_N219	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
77	CS_S_N219NP	Nasopharyngeal	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-03	2020-07-03	NEG
78	CS_S_N220	Saliva	2020-07-03	2020-07-03		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-03	2020-07-03	NEG
79	CS_S_N221	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
80	CS_S_N222	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
81	CS_S_N223	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
82	CS_S_N223NP	Nasopharyngeal	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-20	2020-07-20	NEG
83	CS_S_N224	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
84	CS_S_N225	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
85	CS_S_N226	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
86	CS_S_N227	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
87	CS_S_N227NP	Nasopharyngeal	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-20	2020-07-20	NEG
88	CS_S_N228	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
89	CS_S_N229	Saliva	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-07-20	2020-07-20	NEG
90	CS_S_N229NP	Nasopharyngeal	2020-07-20	2020-07-20		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-07-20	2020-07-20	NEG
91	CS_S_N230	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
92	CS_S_N231	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
93	CS_S_N231NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
94	CS_S_N232	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
95	CS_S_N233	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
96	CS_S_N233NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
97	CS_S_N234	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
98	CS_S_N235	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
99	CS_S_N235NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
100	CS_S_N236	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
101	CS_S_N237	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
102	CS_S_N237NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
103	CS_S_N238	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
104	CS_S_N238NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
105	CS_S_N239	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
106	CS_S_N240	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
107	CS_S_N240NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
108	CS_S_N241	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
109	CS_S_N242	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
110	CS_S_N242NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
111	CS_S_N243	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
112	CS_S_N243NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
113	CS_S_N244	Saliva	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-22	2020-08-22	NEG
114	CS_S_N244NP	Nasopharyngeal	2020-08-22	2020-08-22		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-22	2020-08-22	NEG
115	CS_S_N245	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
116	CS_S_N246	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
117	CS_S_N246NP	Nasopharyngeal	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-28	2020-08-28	NEG
118	CS_S_N247	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
119	CS_S_N248	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
120	CS_S_N248NP	Nasopharyngeal	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-28	2020-08-28	NEG

121	CS_S_N249	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
122	CS_S_N250	Saliva	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-28	2020-08-28	NEG
123	CS_S_N250	Nasopharyngeal	2020-08-28	2020-08-28		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-28	2020-08-28	NEG
124	CS_S_N251	Saliva	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-29	2020-08-29	NEG
125	CS_S_N252	Saliva	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-29	2020-08-29	NEG
126	CS_S_N252NP	Nasopharyngeal	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-29	2020-08-29	NEG
127	CS_S_N253	Saliva	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-29	2020-08-29	NEG
128	CS_S_N254	Saliva	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-08-29	2020-08-29	NEG
129	CS_S_N254NP	Nasopharyngeal	2020-08-29	2020-08-29		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-08-29	2020-08-29	NEG
130	CS_S_N255	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
131	CS_S_N255NP	Nasopharyngeal	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-09-01	2020-09-01	NEG
132	CS_S_N256	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
133	CS_S_N257	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
134	CS_S_N257NP	Nasopharyngeal	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-09-01	2020-09-01	NEG
135	CS_S_N258	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
136	CS_S_N259	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
137	CS_S_N260	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
138	CS_S_N261	Saliva	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-01	2020-09-01	NEG
139	CS_S_N261NP	Nasopharyngeal	2020-09-01	2020-09-01		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-09-01	2020-09-01	NEG
140	CS_S_N262	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
141	CS_S_N263	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
142	CS_S_N264	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
143	CS_S_N265	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
144	CS_S_N265NP	Nasopharyngeal	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-09-05	2020-09-05	NEG
145	CS_S_N266	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
146	CS_S_N267	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
147	CS_S_N268	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
148	CS_S_N269	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG
149	CS_S_N269NP	Nasopharyngeal	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Nasopharyngeal	2020-09-05	2020-09-05	NEG
150	CS_S_N270	Saliva	2020-09-05	2020-09-05		Extraction buffer (COV04S)	NEG	PowerChek™	-	-	-	-	Saliva	2020-09-05	2020-09-05	NEG