Title : **Usability Engineering Report**

Product : PCL COVID19 Ag Gold

Date : 2021-02-15

Revision History		
Rev.0	2021-02-15	First study after design

Prepared by/ date	Reviewed by/ date	Approved by/ date
[redacted]	5.1.2e	

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1. Scope

This usability engineering file specifies a process for a manufacturer to analyse, specify, design, verify and validate usability as it relates to safety of a medical device manufactured by our company. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors with normal use.

The usability engineering is performed in parrelel with, or together with risk management and performance evaluation within design process. For the relationship between risk management, design process and usability engineering process and requirements, please see the Appendix #1.

This report summariese the concept and process of the usability engineering, also refering risk management and performance evaluation, in accordance with EN 62366:2008.

2. Normative references

The standards used in the usability engineering file are followings:

- European *In vitro* diagnostic directive 98/79/EC
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- EN 62366:2008 Medical devices – Application of usability engineering to medical devices
- PCL-P-730 Development Process
- PCL-P-731 Risk Management Process
- PCL-P-734 Usability Engineering Process

3. Terms and definitions

The terms and definitions used in this usability engineering file refer to the ISO 14971 standard basically and in the following:

- Abnormal use: intentional act or intentional omission of an act by the responsible organization or user of a medical device as a result of conduct that is beyond any further reasonable means of risk control by the manufacturer
- Accompanying document: document accompanying a medical device and containing information for those accountable for the installation, use and maintenance of the medical device or the user, particularly regarding safety
- Alarm limit: threshold used by an alarm system to determine an alarm condition
- Alarm off: state of indefinite duration in which an alarm system or part of an alarm system does not generate alarm signals
- Alarm signal: type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition
- Alarm system: parts of the medical device that detect alarm conditions and, as appropriate, generate alarm signals
- Correct use: normal use without use error
- Effectiveness: measure of accuracy and completeness with which users achieve specified goals
- Efficiency: effectiveness in relation to the resources expended
- Information signal: any signal that is not an alarm signal or a reminder signal
- Medical device: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or

calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- Diagnosis, prevention, monitoring, treatment of alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

- Normal use: Operation, including routine inspection and adjustments by user, and standard-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use
- Patient: living being (person) undergoing a medical, surgical or dental procedure
- Primary operating function: function that involves user interaction that is either frequently used or related to the safety of the medical device
- Reminder signal: periodic signal that reminds the user that the alarm system is in an alarm signal-inactivation state
- Responsible organization: entity accountable for the use and maintenance of a medical device of combination of medical devices
- Usability: characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction
- Usability engineering: application of knowledge about human behavior, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability
- Usability engineering file: set of records and other documents that are produced by the usability engineering process
- Usability specification: documentation defining the user interface requirements related to usability
- User error: Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user
- Use scenario: specified sequence of events and tasks as performed by a specified user in a specified environment
- User: person using, i.e. operating or handling, the medical device
- User interface: means by which the user and the medical device interact
- User profile: summary of the mental, physical and demographic traits of an intended user population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements
- Validation: confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

4. Device description and Intended use

1) Product Name (Model Name)
PCL COVID19 Ag Gold (COV04S)

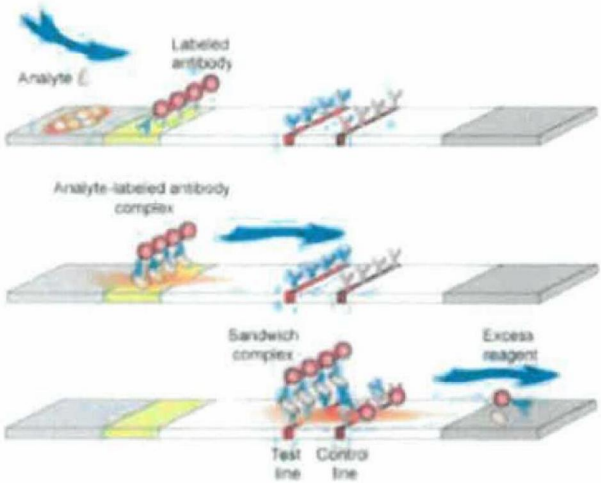
2) Device description

No.	Component	Description	Unit
①	Test card	Test card with antibody coating and built-in strip (pouch sealed with desiccant)	1ea
②	Extraction buffer tube	Liquid reagent for sample extraction and development	1 buffer tube with 500 µL
③	Filter cap	Disposable lid for depositing a certain amount of sample on the test card	1ea
④	Paper funnel	Optional aid for saliva collection	1ea
⑤	IFU	Instructions for use	1ea

3) Intended Use
PCL COVID19 Ag Gold is an in vitro diagnostic medical device based on immunochromatographic assay (ICA) principle for the qualitative detection of SARS-CoV-2 antigen in human saliva or nasopharyngeal specimens. This test is used to detect antigens of the SARS-CoV-2 virus in people suspected of COVID-19. This product is intended exclusively for professional use in the laboratory or at the point-of-care.

4) Intended User
Lay person

5) Principle of procedure
PCL COVID19 Ag Gold uses COVID19 antibodies, which are labeled with small gold particles and are attached to a nitrocellulose membrane near the sample hole of the test card (see also illustration below). After its application, capillary forces are pulling the sample from the sample hole to the test region of the device. When the liquid of the sample reaches the COVID19 antibodies, they detach from the membrane and are moved along the test card.



If the sample contains SARS-CoV-2 antigens ("analyte"), these bind to the labelled antibodies to form analytelabeled antibody complexes. When these complexes reach the test line of the test card, they are retained on the test line by another set of COVID19 antibodies, which are immobilized on the nitrocellulose membrane. These so-called sandwich complexes appear as a color band on the test line. If the sample does not contain SARS-CoV-2 antigens, no sandwich complexes are formed and no color band appears on the test line.
Regardless of the presence or absence of SARS-CoV-2 antigens in the sample, a color band will appear on the control line of the test card. If no color band appears on the control line, the test card has not worked as intended.

5. Evaluation

1) Participants Information

No.	Participant	Sex	Age	Education	Occupation
1	P01	F	29	Bachelor's	Researcher
2	P02	M	27	Highschool	Employee
3	P03	F	31	Master's	Researcher
4	P04	M	60	Highschool	Employee
5	P05	F	56	Highschool	Housewife
6	P06	F	81	Primaryschool	Unemployed
7	P07	F	57	Bachelor's	Employee
8	P08	M	55	Bachelor's	Employee
9	P09	F	29	Bachelor's	Researcher
10	P10	F	27	Bachelor's	Unemployed
11	P11	M	22	Highschool	Soldier
12	P12	M	68	Bachelor's	Employee
13	P13	F	64	Bachelor's	Employee
14	P14	M	37	Master's	Researcher
15	P15	M	33	Master's	Employee
16	P16	F	34	Doctorate	Researcher
17	P17	M	60	Bachelor's	Employee
18	P18	F	57	Associate	Housewife
19	P19	M	29	Bachelor's	Researcher
20	P20	M	53	Bachelor's	Police
21	P21	F	52	Highschool	Housewife
22	P22	F	26	Associate	Secretary
23	P23	M	34	Bachelor's	Employee
24	P24	F	31	Bachelor's	Bank clerk
25	P25	F	37	Doctorate	Researcher
26	P26	M	32	Master's	Student
27	P27	F	60	Bachelor's	Housewife
28	P28	M	75	Bachelor's	Unemployed
29	P29	F	60	Highschool	Unemployed
30	P30	F	44	Bachelor's	Employee
31	P31	F	10	N/A	Student
32	P32	M	6	N/A	N/A
33	P33	F	6	N/A	N/A
34	P34	M	47	Bachelor's	Employee
35	P35	M	57	Highschool	Employee
36	P36	F	58	Highschool	Housewife
37	P37	F	32	Bachelor's	Employee
38	P38	F	30	Master's	Researcher
39	P39	F	29	Master's	Employee
40	P40	F	46	Bachelor's	Employee
41	P41	F	17	Middleschool	Student
42	P42	M	14	Primaryschool	Student
43	P43	M	46	Bachelor's	Employee
44	P44	F	74	Primaryschool	Unemployed
45	P45	F	46	Bachelor's	Employee
46	P46	F	74	Primaryschool	Unemployed
47	P47	F	22	Highschool	Student

48	P48	F	42	Bachelor's	Housewife
49	P49	M	31	Master's	Employee
50	P50	F	32	Bachelor's	Employee
51	P51	M	38	Bachelor's	Employee
52	P52	F	33	Master's	Researcher
53	P53	M	28	Highschool	Unemployed
54	P54	F	57	Highschool	Employee
55	P55	M	59	Bachelor's	Employee
56	P56	M	27	Master's	Researcher
57	P57	M	63	Doctorate	Doctor
58	P58	F	60	Bachelor's	Pianist
59	P59	F	25	Bachelor's	Accountant
60	P60	M	27	Bachelor's	Soldier
61	P61	F	27	Bachelor's	Employee
62	P62	F	28	Bachelor's	Employee
63	P63	F	40	Bachelor's	Employee
64	P64	M	27	Bachelor's	Employee
65	P65	M	70	Bachelor's	Employee
66	P66	M	45	Bachelor's	Employee
67	P67	M	10	N/A	Student
68	P68	F	65	Highschool	Housewife
69	P69	F	42	Bachelor's	Housewife
70	P70	F	12	N/A	Student
71	P71	F	34	Bachelor's	Employee
72	P72	F	23	Bachelor's	Student
73	P73	F	53	Bachelor's	Housewife
74	P74	M	57	Bachelor's	Employee
75	P75	F	24	Bachelor's	Unemployed
76	P76	F	55	Bachelor's	Employee
77	P77	M	30	Bachelor's	Unemployed
78	P78	M	27	Bachelor's	Employee
79	P79	M	30	Bachelor's	Employee
80	P80	M	31	Bachelor's	Employee

2) Evaluation Methods

- The evaluation was conducted pursuant to 'EN 62366:2008 Medical devices - Application of usability engineering to medical devices.
- The evaluation was conducted in the form of the layperson review, where 80 voluntary participants (intended users of the given device) reviewed the device in the simulated use environment in the presence of one tester and one record analyst, for an average duration of 35 minutes.
- The test operator led the test according in the test room that is being moitored. The tester followed the test protocol in confirming the presence of participants and explaining the purpose of the test, confidentiality requirement, and risks/protections related to the test, post-interviewing, and etc.
- The recording analyst monitored all the process of test and recorded the use errors, and their opinions received during the test. The analyst also observed and recorded opinions of participants through the questionnaire and the post-interview.
- The evaluation was conducted in accordance with the test scenario and participants addressed their opinions regarding the given medical device and filled in the questionnaire afterwards.

Tasks	Desciption	Duration
Orientation	• Introducing overview of the usability test for those who are not familiar with usability tests. • Explaining the purpose of the subject medical device and methods of the usability test using power point presentation.	5 mins
Introducing the medical device	• Product introduction	5 mins
Signing the agreement	• Before conducting the usability test, the user confirms that the participants understand the content of the test and their will to participate. • Signing the agreement	5 mins
Conduct usability test	• Participants use the given products according to the steps described in the questionnaire and give feedbacks simultaneously. • The record analyst observes each participant during each test	10 mins
Fill in the questionnaire	• Fill out the survey • If necessary, the test operator asks each participant about what has been observed.	10 mins

3) Evaluation Results

- The same scenario was applied for a total of 80 participants. Pre-test survey, evaluation survey, and participants' feedback were collected and analyzed for each participant.
- Results are shown below and some of data are provided in a brief summary.

A. Pre-evaluation Survey Results

No.	Question	Answer	
1	Did you attempt the antigen test (either on your own or with help?)	a.	80
		b.	0
2	If not, why did you not attempt to complete the antigen test?	a.	0
		b.	0
		c.	0
		d.	0
		e.	0
		f.	0
		g.	0
		h.	0
		i.	0
3	Did you seek for help in order to perform the test?	a.	72
		b.	8
4	Did you manage to successfully complete the test?	a.	78
		b.	2
5	If no, why did you not successfully complete the test?	a.	1
		b.	0
		c.	0
		d.	1
		e.	0
		f.	0
		g.	0
		h.	0
		i.	0

B. Summary of Survey Results

- The questionnaire on a scale 1 to 5 was used for the survey given to each participant.
- 5 point represents 'Strongly Agree' while 1 point indicates 'Strongly Disagree', showing that the result score close to 5 implies that participants agree more with the questionnaire.

The average values for each question are presented as the results of the survey.

No.	Question	Average	
	Preparation		
6	How easy was it to open the packaging?	4.8	
7	How easy was it to look for necessary kit components included in the package?	4.7	
8	How clear was it to read the indicated labels/warnings on the box/test card packaging?	4.2	
	Test Procedure		
9	How easy was it to follow the instructions for use?		
a.	collecting saliva with the tip of the tongue	4.0	
b.	peeling off the sealing of the extraction buffer tube	4.1	
c.	spitting the saliva specimen into the extraction buffer tube with paper funnel	4.0	
d.	getting the total volume of the sample up to the indicated line of the tube	3.8	
e.	inserting the filter cap accurately to the tube	4.5	
f.	inverting the capped tube up and down for mixing the sample	4.8	
g.	finding the sample loading well of the test card	4.6	
h.	adding 2 to 3 drops the mixture to the sample loading well of the test card	4.3	
i.	waiting for 10 - 15 minutes to get the test result	4.2	
	Result Interpretation		
10	How easy/difficult did you find it to understand the result interpretation in the Instructions for Use (Positive/Negative/Invalid).	4.0	
11	How easy/difficult was it to match the possible results (positive/negative/invalid) to the actual test result?	4.6	
12	How clear/visible were the lines shown on the test card?	4.2	
	Additional information		
13	Do you think it would be easy/difficult to perform the same antigen test?	4.5	
14	Would you be willing to do another PCL COVID-19 Ag Gold test in the future when needed?	a.	70
		b.	0
		c.	10
15	If you had a choice, where would you prefer to perform the same saliva antigen test?	a.	60
		b.	7
		c.	10
		d.	1
		e.	2
16	Would you recommend this product to others for COVID-19 rapid diagnostics?	4.7	
	For children		
17	Please provide the information if you have a child of age between 5 to 17	a.	0
		b.	4
		c.	1
		d.	1
18	Please provide the acceptable age range to perform this type of saliva antigen test	a.	0
		b.	6
		c.	0
		d.	0

C. Participants' Feedback Data

- There was no common opinion from participants that is related to the critical use error.

4) Summary of Results

- The usability engineering test of PCL COVID-19 Ag Gold was conducted with a total of 80 lay person, in order to assess possible risks, use errors and use-related hazardous situations.
- The evaluation was conducted in the form of the lay person review, where 80 voluntary participants (intended users of the given device) reviewed how to use the device in the use-scenarios, used it on their own and gave their opinions on the usability of the device. They also filled up the survey on the use of the device.
- The same scenario was applied for a total of 5 participants. Pre-test survey, evaluation survey, and participants' feedback were collected and analyzed for each participant.
- The questions on ‚How easy was it to open the packaging?' and ‚inverting the capped tube up and down for mixing the sample' showed the highest score of 4.80, while question on 'getting the total volume of the sample up to the indicated line of the tube' showed the lowest score of 3.8.
- Most of the survey question had a score range between 4 and 5, showing a very positive feedback on the usability of the PCL COVID-19 Ag Gold.
- There was no common opinion from participants that is related to the critical use error.

5) Conclusion

- As a result of the Usability engineering test of PCL COVID-19 Ag Gold with 80 lay persons, there were no critical use errors observed that can potentially induce any harms to users.

6. Frequently Used Function

ID	Process description
U1	Preparation
U2	Sample Collection (Saliva Specimen)
U3	Specimen analysis
U4	Test result interpretation

7. Hazard analysis for Frequently Used Function

ID	Frequently Used Function	Hazard ID	Failure Mode	Effect of failure (Hazard/Hazardous situation)	Potential Cause	Action taken
U1	Preparation	H2	The extraction tube is reused or polluted.	Incorrect medical diagnosis	Incorrect or belated medical treatment; overtreatment.	Clarify the operations in the instructions and point out that the droppers cannot be mixed for different samples.
		H7	Improper storage of reagent	Incorrect or belated medical diagnosis	Incorrect or belated treatment; transmission to others	Clarify the production date and expiration date in the packaging and main components, storage condition.
		H8	Discard of used product Product discarded contains biological pollution	Not handled as medical waste	Caused environmental pollution	Clarify the waste handling requirements in the instruction
U2	Sample Collection (Saliva Specimen)	H2	Testing samples are polluted by positive samples	Incorrect medical diagnosis	Incorrect or belated medical treatment; overtreatment	Clarify the operations in the instructions and point out that the droppers cannot be mixed for different samples
U3	Specimen analysis	H16	Reagent is used incorrectly	Incorrect medical diagnosis	Incorrect or belated medical diagnosis, overtreatment or transmission to others	Clarify the test procedure (operation steps) in the instruction
U4	Test result interpretation	H16	Test result invalid	Incorrect medical diagnosis	Incorrect or belated medical diagnosis, overtreatment or transmission to others	Clarify the test procedure (operation steps) in the instruction

* Reference: Risk Summary Table (Appendix 3) included in Risk Management Report # COV04S-RMR-001S R0 (2021.02.19)

8. Accompanying document

Instruction for use (IFU), COV04S-IFU-001 [Appendix 2]

Appendix 1. [Relationship between Risk Management, Design, and Usability Engineering Process]