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Assessment usability study

Dear 5.1.2e

We hereby confirm that we have assisted you in the preparation, execution and writing of the final report and that the evaluation complies with the IEC 62366-1:2015+AMD1:2020 CSV Application of Usability Engineering to Medical Devices standard.

With my best regards

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Summative Usability Evaluation Report

ZandCell COVID-19 Saliva Antigen Test

March 4th, 2021

1 Release

Document	ZandCell_Summative-Usability-Evaluation_report_v01	Version	1.0
Author(s)	5.1.2e	Date	4.3.2021

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2 Meta information

2.1 Product

Product name	Product version
ZandCell COVID-19 Saliva Antigen Test	/

2.2 Document version history

Version	Date	Author(s)	Changes
1.0	3.3.2021	5.1.2e	First draft

2.3 Purpose of the document

This document summarizes the results of the usability evaluation.

2.4 Relevant documents

No.	Document	Description
1	ZandCell_Usability Evaluation Plan	Usability Evaluation Plan
2	ZandCell_Usability-Evaluation-Protocol-UEP	Usability evaluation protocol
3	Risk management report-Antigen Rapid Test Kit	Risk analysis of the manufacturer
4	IFU-German-2021-V5	Instruction manual

2.5 Definitions

Abbreviation	Term
Abnormal use	Deliberate, intentional act or deliberate failure to act in a manner that conflicts with or violates the intended use and is also beyond any other reasonable means of user interface - related risk control by the manufacturer.
Usage error	Performance or omission of a user action that leads to a different result than intended by the manufacturer (acceptance criterion is not met) or expected by the user.
Difficulty of use	The task is performed correctly (or the acceptance criterion is met), but the user has

	initial problems with the action, is visibly confused or irritated, or initially makes a mistake, which he corrects in time (close call).
Correct use	Intended use without usage errors or usage difficulties (the acceptance criterion is met).

2.6 List of abbreviations

Abbreviation	Term
F#	Usage error
GA	Instruction manual
IVD	*In Vitro* Diagnostic
SB#	Other observation
S#	Difficulty of use
Tn	Test participant

3 Summary

3.1 Targets

This usability evaluation report contains the results of a summative usability test conducted for the IVD "ZandCell COVID-19 Saliva Antigen Test". The purpose of the usability test is to determine whether the product can be used effectively and safely by the intended user groups in the intended use environment.

3.2 Material and methods

In the usability test, participants were observed individually using the product as intended. A test moderator conducted the usability test using a test protocol [2]. He introduced the test setting to the participants, handed them their tasks, and asked questions about important safety information. The moderator observed the participants and noted any usage errors, usage difficulties, and other relevant observations, as well as comments from the participants, based on 20 pre-established acceptance criteria. In the case of usage errors and difficulties, participants were subsequently asked about the cause. The participants did not receive any help or other support during the test but had to solve the task alone with the help of the product including the enclosed instructions for use.

A total of 130 lay users took part in the usability test, two participants were excluded from the analysis due to background knowledge (health professionals). The lay users were untrained persons. This means that there were no health professionals among the participants, nor had they previously been trained in the use of the product. None of the participants reported performing rapid tests on a regular basis. 10% of the participants were from the 10-14 age group, 28,5% from the 18-30 age group, 28,5% were from the 31-50 group, and 33,1% were between 51-70 years old. 48,8% of the participants were male and 51,2% were female. Participants provided the following information regarding their highest level of education: Hauptschulabschluss (3,1 %), Vocational Training (1,6%), Magister (1,6%), Staatsexamen (5,4%), Master (12,4%), Diploma (13,2%), Bachelor (2,3%), Realschulabschluss/Mittlere Reife (12,4%), Fachhochschul - or Hochschulreife/Abitur) (31%).

The participants were given the product in its original packaging and asked to use the product to find out whether they were infected with the coronavirus. They were asked to perform all the steps exactly as they would normally do in a realistic situation.

3.3 Results

With 20 acceptance criteria and 130 participants, this resulted in 2600 observed and documented participant actions. Of the 2600 actions, 97,7% (2461) were correct uses, 1,5% (41) were use errors, and 3,8% (98) were use difficulties.

46% of the participants met all 20 acceptance criteria and thus had no usage errors or usage difficulties. For the remaining 54%, 1 to a maximum of 7 usage errors or usage difficulties were observed.

Since the different acceptance criteria as well as the different usage errors or usage difficulties can be associated with quite different consequences, this static evaluation of the observations has only a subordinate significance about the safety of the product. For example, no critical harm to users is expected unless you know that the test kit should be stored away from dryness (dry storage is inherent

by design due to the sealed primary packaging). On the other hand, misinterpretation of the displayed test results could have critical consequences. Therefore, each observed usage error and difficulty was qualitatively examined for the possible causes and consequences. The errors and difficulties were grouped by type and cause. This resulted in 11 error types as well as 14 difficulty types. The following is a brief summary of only those observations that the authors of this report believe could potentially have the most critical consequences. A detailed analysis of all observations can be found in chapter 6.2"Qualitative analysis of the usage errors and usage difficulties", and 6.3"Qualitative Qualitative analysis of other relevant observations and comments of the participants ".

- The misinterpretation of a faulty test or test execution has been defined as a critical usage error. After applying the solution with saliva to the test kit, only one line in the area of the "T" appears, meaning that the line of the control area is missing. 13.2% of the Tn interpreted this result as positive, so that a false positive result could be concluded (Tn incorrectly assumes that it is positive). However, this invalid and incorrect result has a very low probability of occurrence and thus has little clinical relevance. In addition, in the event of a misinterpretation, there would be no spread of germs and a subsequent medical clarification and testing would provide clarity. In addition, the Tn tended to make a hasty decision in the artificial test situation. In a real situation, the Tn would probably look more closely and again into the GA with a supposedly positive result and compare the result with the images in the GA and thus counteract a misinterpretation.
- A critical difficulty of use is that 16.8% of the Tn had difficulty assessing whether sufficient saliva was spat into the tube. This was due to the lack of a clear marking on the tube. A mark was described in the GA, but it was hardly visible on the tube. According to the manufacturer, an amount of saliva of at least 0.5ml is required for the test to be performed correctly. Regardless of the test result, the discrepancy between the GA and the lack of marking on the tube led to uncertainty in some Tn. The reduced saliva output by the Tn must, however, also be seen in the context of the test situation. For some Tn it was visibly uncomfortable to take off the protective masks in the test setting in order to spit into the saliva funnel. It is likely that this uncomfortable situation and the tendency to complete this sub-task quickly led to the production of too little saliva into the tube. Spitting without being under observation (e.g. at home) would take this pressure off and offer more time and space for sufficient saliva to be released.
- Another critical difficulty of use was that 18% of the Tn did not discover the back of the GA until the test was carried out or not at all. Concrete errors could not be observed from this, as all information required for correct implementation could be read on the front page. However, in over 70% of the participants who did not see the back or only saw it later, at least one difficulty of use and / or usage error were observed. As mentioned in the previous difficulty of use, the test setting could have influenced the performance of the Tn as well. Even though the Tn had been told that they have as much time as necessary to complete the task, a feeling of time pressure under observation and thus an influence on the oversight of the back of the GA is quite possible. Using the test in a familiar environment would remove the time pressure appearing under observation. The manufacturer has already confirmed that the upcoming tests will have a GA printed on one side. This should lead to a significantly improved link between the written and illustrated implementation of the test.

The causes of the above-mentioned errors in use are either due to the fact that the participants overread or misunderstand the relevant instructions and notes in the instructions for use or on the test card, or deliberately decide to act contrary to the manufacturer's specifications. It must be checked whether these errors would cause false-positive, false-negative or invalid results to be displayed.

3.4 Conclusion

Almost all acceptance criteria (94.7%) were correctly met by the participants. Some difficulties and errors in use were observed. However, the sources of error mentioned such as the misinterpretation of the incorrect test result, are to be interpreted with a low risk for the consumer due to the very low probability of occurrence and the low clinical relevance. The reduced release of saliva into the tube was partly due to a poorly visible marking. The manufacturer has already confirmed that they will replace the previous marking with a clear, red line and thus optimize future use of the test. The red line has been already mentioned in the instruction for use due to a translation error which has been already corrected. It should also be mentioned that a reduced saliva output was very likely influenced by the observation in the test setting. This negative influence would not exist if the test were used in a familiar environment. The study showed that errors were associated with double-sided printing of the instructions for use. Some of the test persons overlooked the illustrated instructions on the back of the GA. The producer has already confirmed that its product will be adapted to improve user-friendliness, so that the instructions for use will be printed on one side prospectively. With these adjustments taken the test "ZandCell COVID-19 Saliva Antigen Test" is safe and easy to use for a lay person.

4 Introduction

4.1 Product type and name

Type: SARS-CoV-2 Rapid Antigen Test

Name: ZandCell COVID-19 Saliva Antigen Test

Variants: There is a variant for professional use

4.2 Aim of the usability test

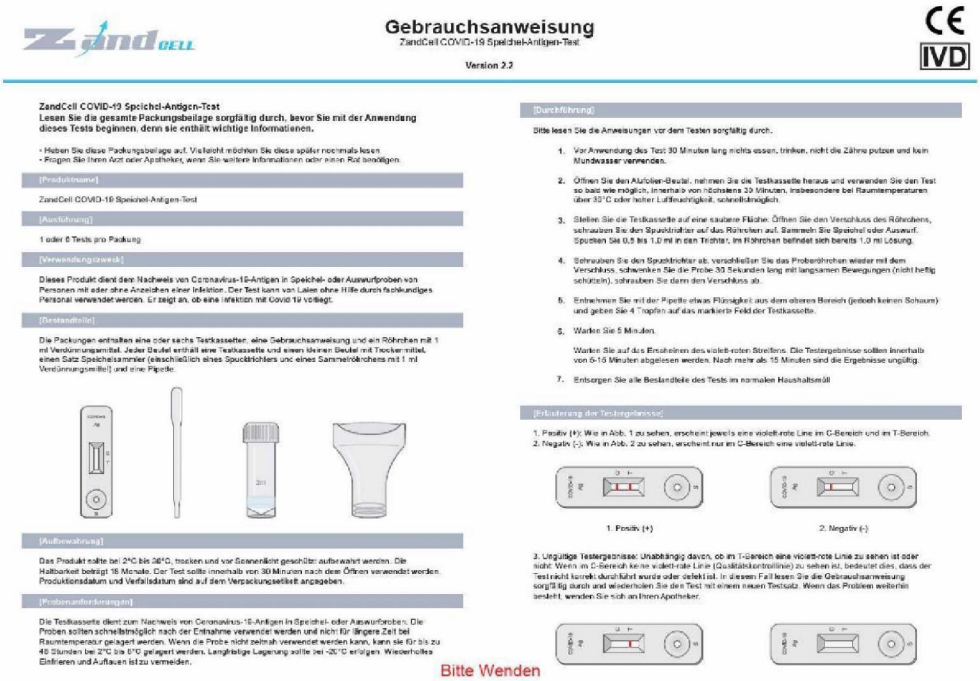
The purpose of the usability test is to determine that the ZandCell COVID-19 Saliva Antigen Test can be used effectively and safely by the intended user groups in the intended application environment.

4.3 Parts of the user interface in the focus of the usability test

ZandCell COVID-19 Saliva Antigen Test consists of the following elements of the user product interface. All of the above elements were the focus of the usability test.

- Packing (See Figure 1)
- Instructions for use (See Figure 2 & 3)

Figure 1: opened packing with content



Gebrauchsanweisung

ZandCell COVID-19 Speichel-Antigen-Test

Version 2.2

CE IVD

ZandCell COVID-19 Speichel-Antigen-Test
Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Anwendung dieses Tests beginnen, denn sie enthält wichtige Informationen.

- Heben Sie diese Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Fragen Sie Ihren Arzt oder Apotheker, wenn Sie weitere Informationen oder einen Rat benötigen.

[Produktname]

ZandCell COVID-19 Speichel-Antigen-Test

[Ausführung]

1 oder 6 Tests pro Packung

[Verwendungszweck]

Dieses Produkt dient dem Nachweis von Coronavirus-19-Antigen in Speichel- oder Auswurfproben von Personen mit oder ohne Anzeichen einer Infektion. Der Test kann von Laien ohne Hilfe durch fachkundiges Personal verwendet werden. Er zeigt an, ob eine Infektion mit Covid 19 vorliegt.

[Bestandteile]

Die Packungen enthalten eine oder sechs Testkassetten, eine Gebrauchsanweisung und ein Röhrchen mit 1 ml Verdünnungsmittel. Jeder Beutel enthält eine Testkassette und einen kleinen Beutel mit Trockenmittel, einen Satz Speichelsammler (einschließlich eines Spucktrichters und eines Sammelröhrchens mit 1 ml Verdünnungsmittel) und eine Pipette.

[Aufbewahrung]

Das Produkt sollte bei 2°C bis 30°C, trocken und vor Sonnenlicht geschützt aufbewahrt werden. Die Haltbarkeit beträgt 18 Monate. Der Test sollte innerhalb von 30 Minuten nach dem Öffnen verwendet werden. Produktionsdatum und Verfalldatum sind auf dem Verpackungsetikett angegeben.

[Probenanforderungen]

Die Testkassette dient zum Nachweis von Coronavirus-19-Antigen in Speichel- oder Auswurfproben. Die Proben sollten schnellstmöglich nach der Entnahme verwendet werden und nicht für längere Zeit bei Raumtemperatur gelagert werden. Wenn die Probe nicht zeitnah verwendet werden kann, kann sie für bis zu 48 Stunden bei 2°C bis 8°C gelagert werden. Langfristige Lagerung sollte bei -20°C erfolgen. Wiederholtes Einfrieren und Auftauen ist zu vermeiden.

[Durchführung]

Bitte lesen Sie die Anweisungen vor dem Testen sorgfältig durch.

1. Vor Anwendung des Test 30 Minuten lang nichts essen, trinken, nicht die Zähne putzen und kein Mundwasser verwenden.
2. Öffnen Sie den Alufolien-Beutel, nehmen Sie die Testkassette heraus und verwenden Sie den Test so bald wie möglich, innerhalb von höchstens 30 Minuten, insbesondere bei Raumtemperaturen über 30°C oder hoher Luftfeuchtigkeit, schnellmöglich.
3. Stellen Sie die Testkassette auf eine saubere Fläche. Öffnen Sie den Verschluss des Röhrchens, schrauben Sie den Spucktrichter auf das Röhrchen auf. Sammeln Sie Speichel oder Auswurf. Spucken Sie 0,5 bis 1,0 ml in den Trichter, im Röhrchen befindet sich bereits 1,0 ml Lösung.
4. Schrauben Sie den Spucktrichter ab, verschließen Sie das Probenröhrchen wieder mit dem Verschluss, schwenken Sie die Probe 30 Sekunden lang mit langsamen Bewegungen (nicht heftig schütteln), schrauben Sie dann den Verschluss ab.
5. Entnehmen Sie mit der Pipette etwas Flüssigkeit aus dem oberen Bereich (jedoch keinen Schaum) und geben Sie 4 Tropfen auf das markierte Feld der Testkassette.
6. Warten Sie 5 Minuten.

   Warten Sie auf das Erscheinen des violett-roten Streifens. Die Testergebnisse sollten innerhalb von 6-15 Minuten abgelesen werden. Nach mehr als 15 Minuten sind die Ergebnisse ungültig.
7. Entsorgen Sie alle Bestandteile des Tests im normalen Haushaltsmüll

[Erläuterung der Testergebnisse]

1. Positiv (+): Wie in Abb. 1 zu sehen, erscheint jeweils eine violett-rote Linie im C-Bereich und im T-Bereich.
2. Negativ (-): Wie in Abb. 2 zu sehen, erscheint nur im C-Bereich eine violett-rote Linie.

1. Positiv (+) 2. Negativ (-)

3. Ungültige Testergebnisse: Unabhängig davon, ob im T-Bereich eine violett-rote Linie zu sehen ist oder nicht: Wenn im C-Bereich keine violett-rote Linie (Qualitätskontrolllinie) zu sehen ist, bedeutet dies, dass der Test nicht korrekt durchgeführt wurde oder defekt ist. In diesem Fall lesen Sie die Gebrauchsanweisung sorgfältig durch und wiederholen Sie den Test mit einem neuen Testsatz. Wenn das Problem weiterhin besteht, wenden Sie sich an Ihren Apotheker.

Bitte Wenden

Figure 2: instruction for use (frontpage)

Figure 3: instruction for use (rear page)

5 Mate rial and methods

5.1 General procedure

Upon arrival at the usability lab, participants were greeted and informed about the general procedure of the usability study. The sessions started with an interview in which demographic data of the participants were collected. After the interview, participants were introduced to the test setting. Participants were asked to perform the test tasks and to treat the simulated situation as if it were a realistic situation from their daily lives. They were also instructed to solve any problems or difficulties that might arise on their own. After the test scenario, the moderator asked the participants about observed usage errors or difficulties in determining the cause.

5.2 Facilities

5.2.1 Test location and test environment

The summative usability evaluation was conducted in the usability lab of the RapidCare GmbH. The labs were equipped as described in Chapter 5.2.2"Test equipment " to sufficiently represent the intended usage environment (See Figure 4 - 7).

Figures 4 – 7: Usability lab

5.2.2 Test equipment

The following test materials were available during the test sessions:

- Test kits in original packaging for at least 135 tests
- Waste garbage can (residual waste)
- Chairs
- Tables
- Digital clock
- Tissues
- Pen
- Disinfectant

5.2.3 Test moderation

The sessions were conducted by two facilitators, who also took minutes, from RapidCare GmbH.

5.3 Test participant

5.3.1 Participant profiles

130 representative users were recruited from the user group "lay users" according to the usability engineering plan [1]. Each session was conducted with only one participant. The demographic data of the participants are listed below as well as in the appendix (see Appendix A).

The lay users were untrained persons. That is, there were no health professionals among the participants, nor were they previously trained in the use of the product. None of the participants reported taking regular nasal swabs.

10% of the participants were from the 10-14 age group, 28,5% from the 18-30 age group, 28,5% were from the 31-50 group, and 33,1% were between 51-70 years old (figure 8).

48,8% of the participants were male and 51,2% were female (figure 9).

Participants provided the following information regarding their highest level of education: Hauptschulabschluss (3,1%), Vocational Training (1,6%), Magister (1,6%), Staatsexamen (5,4%), Master (XX%), Diploma (13,2%), Bachelor (2,3%), Realschulabschluss/Mittlere Reife (12,4%), Fachhochschul - or Hochschulreife/Abitur) (31%). (Figure 1).

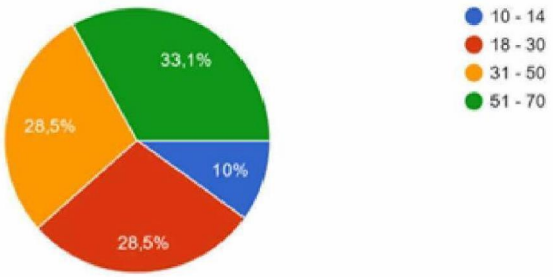


Figure 1: distribution of the participants in age groups in percentages. 10-14: 13 participants, 18-30: 37 participants, 31-50: 37 participants, 51-70: 43 participants.

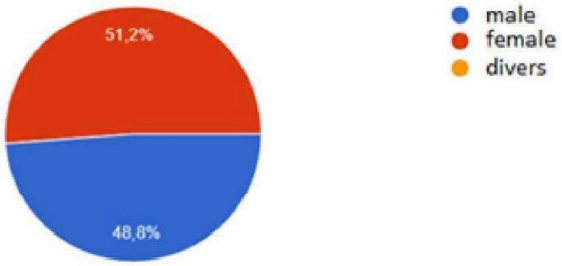


Figure 2: distribution of gender in percentages, female participants: 66, male participants: 64

Figure 10: distribution of highest educational level in percentages

5.4 Training

No training was provided for the product.

5.5 Test scenarios

All hazard-related Use Scenarios (critical tasks) were covered in the test scenario. The user groups were asked to perform the following Use Scenarios, which were covered in the following test scenario. Twenty acceptance criteria were defined for the test scenario (see Chapter 6.1, Table 1).

Use Scenario	Test scenario
1. Unpacking the test kit	1. Complete test procedure with simulated sampling
2. Read instructions on how to perform the test	
3. Perform test	
4. Interpret the test results	
5. Disposal	
6. Knowledge Tasks	

5.6 Data analysis

All data collected in this summative usability assessment was analyzed, including the

- Facilitator observation notes including evaluation of acceptance criteria,
- Comments and interview responses from participants

Participants' performance on the acceptance criteria was evaluated according to the following categories:

- **Correct use:** Intended use without usage errors or usage difficulties (the acceptance criterion is met). The participant performs the task without usage errors and without help or support from the moderator.
- **Difficulty of use:** The participant had difficulties completing the task. The task is performed correctly (or the acceptance criterion is met), but the user has initial problems with the action, is visibly confused or irritated, or initially makes a mistake but corrects it in time (near miss (close call)).
- **Usage error:** Execution or omission of a user action that leads to a different result than intended by the manufacturer (acceptance criterion is not met) or expected by the user. The participant was unable to complete the task using the user-product interface.

Facilitators assessed all acceptance criteria during the session and reviewed their observation notes as needed. This report documents the results, including a description of any usage errors, usage difficulties, or relevant comments made by participants. Usage errors and usage difficulties were analyzed, and their causes identified. Participants' subjective feedback was also analyzed.

6 Results and analysis

6.1 Statistical analysis

In the test protocol [2], 20 acceptance criteria were defined for the correct and safe use of the product.

With 20 acceptance criteria and 130 participants, this resulted in 2600 observed and documented participant actions. Of the 2600 actions, 94,7% (2461) were correct uses, 1,5% (41) were use errors, and 3,8 % (98) were use difficulties.

46% of the participants met all 20 acceptance criteria and thus had no usage errors or usage difficulties. One usage error or difficulty was observed in 17,7% of the participants, two in 14,6%, three in 8,5%, four in 1,5%, five in 1,3%, six in 0% and seven usage error or usage difficulties were observed in 1,5% of the participants (Figure 3).

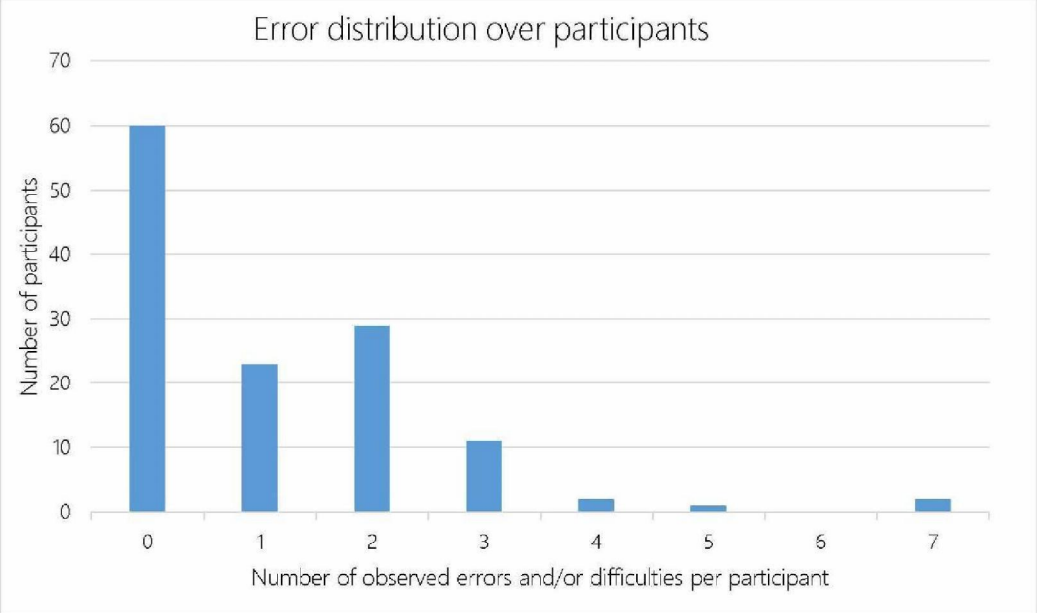


Figure 3: Error distribution across participants

Use Scenario	Tasks	Acceptance criteria	Correct use. [%]	User error [%]	User difficulty [%]
1. Unpacking the test kit	1.1 Unpack all components of the test kit	1.1 User unpacks all components of the test kit intact.	94,6 %	0 %	5,4 %
2. Read instructions on how to perform the test	2.1 Read instructions (user manual and/or test card)	2.1 User reads through the instructions (user manual and/or test card)	82 %	0 %	18 %
3. Perform test	3.1 User screws saliva funnels onto the tube	3.1 Saliva funnel is screwed tight without spilling liquid	100 %	0 %	0 %
	3.2 User spits saliva into the tube at least up to the mark	3.2 User spits saliva into the tube until it reaches the mark.	83,1 %	0 %	16,9 %
	3.3 User unscrews saliva funnel.	3.3 User unscrews saliva funnels from the tubes	99,2 %	0,8 %	0 %
	3.4 User screws down tube.	3.4 User screws the tube shut.	100 %	0 %	0 %
	3.5 Swivel reaction tube.	3.5 User swivels approx. 30 seconds.	90,2 %	3 %	6,7 %
	3.6 Remove sample from reaction tube.	3.6 User takes the sample from the tube using the pipette.	100 %	0 %	0 %
	3.7 Place the sample on the test cassette.	3.7 User puts 4 drops of the sample on the deepening of the test cassette.	93,2 %	0,8 %	6

Use Scenario	Tasks	Acceptance criteria	Correct use. [%]	User error [%]	User difficulty [%]
	3.8 Wait 5 minutes until the test result is available.	3.8 User waits 5 minutes until the test result is available.	96,8 %	0 %	3,2 %
4. Interpret the test results	4.1 Recognize positive test result (red lines in the quality control area (C) and in the test area (T)) and verbally reproduce test result.	4.1 User reports positive test result (red line in (C) and (T)).	97,6 %	1,6 %	0,8 %
	4.2 Recognize negative test result (red line in the quality control area (C)) and verbally reproduce test result.	4.2 User reports negative test result (red line (C)).	95,3 %	2,3 %	2,3 %
	4.3 Recognize invalid test result (red line in test area (T)) and verbally reproduce test result.	4.3 User reports invalid test result (red line in (T)).	78,3 %	13,2 %	8,5 %
	4.4 Recognize invalid test result (no line) and verbally reproduce test result.	4.4 User reports invalid test result (no line).	94,5 %	0 %	5,5 %
4 Disposal	5.1 Dispose of the test kit components as described in the IFU.	5.1 User disposes of test kit components in a separate bag, seals it and disposes of it in household waste.	100 %	0 %	0 %
5 Knowledge Tasks	6.1 User answers the question about the application temperature correctly.	6.1 User says room-temperature.	92,2 %	3,9 %	3,9 %
	6.2 User answered the question about storage correctly.	6.2 User says that the test must be stored dry and protected from the sun.	95,3 %	2,35 %	2,35 %
	6.3 User answers question about damaged test packaging correctly.	6.3 User says that the test should no longer be used.	97,7 %	0,8 %	1,5 %
	6.4 User answers the question about frequency of use correctly.	6.4 User says that the test is intended for one-time use only.	99,2 %	0,8 %	0 %
	6.5 User answers the question about using the test by expiration date correctly.	6.5. User says that the test can no longer be used after the expiration date.	99,2 %	0,8 %	0 %

Table 1: Error distribution over acceptance criteria

6.2 Qualitative analysis of the usage errors (F), usage difficulties (S)

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
F1	4.3 User reports invalid test result (red line in (T)).	003, 013, 015, 028, 044, 055, 056, 061, 066, 072, 095, 124, 140, 161, 175, 190, 231	Tn describes the result as positive, thus makes a false positive error.	Tn does not look the correct results up in the GA but decides spontaneously. Other subscribers state that they have not read the GA carefully. Exemplary commentary by the Tn: Tn072: "*I only took a glance at the GA*"	The subscriber would incorrectly assume that she/he has a positive result. According to the manufacturer, the probability of this event occurring is very low and has never occurred before. In addition, a false positive result would be of little clinical relevance and thus be assessed as a very low risk for the Tn.	Illustrations should be labeled more clearly, similar to the way in which "positive" or "negative" is written under the positive or negative images in the GA, therefore "invalid" should also be written under the invalid images. The back of the GA should also be supplemented with the invalid images (so far only images of positive or negative results can be seen here).
F2	3.1 User unscrews saliva funnels from the tube	194	Subject does not read the GA sufficiently, processing it incompletely.	Subject does not read the GA sufficiently, processing it insufficiently.	Adequate processing of the task not possible because of difficulties in administering the saliva into the tube.	/
F3	3.3 User unscrews saliva funnels from the tubes.	003	Saliva funnel is not unscrewed from the tube.	Tn takes too little time to read through the GA carefully.	The lid cannot be screwed onto the tube and therefore the saliva and carrier fluid cannot be mixed. Adequate processing of the task not possible.	/

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
F4	3.5 The user swings the tube for about 30 seconds.	003, 004, 066, 126	Tube is not shaken for approximately 30 seconds. Tn only shook the sample vigorously and briefly.	Tn showed themselves to be hasty in their processing. Tn shake only briefly and vigorously. Discrepancy between the front and the back of the GA. Tn only paid attention to the rear of the GA, where no time for swiveling the tube is noted. On the front it says "swivel", on the rear of the GA it says "shake".	Asking the manufacturer, he stated that it only takes a few seconds for the chemical reaction between saliva and carrier fluid.	Note also on the rear next to the illustrations that swiveling should be carried out for 30 seconds. Standardization of the information: "Swivel" or "Shake".
F5	3.7 The user puts 4 drops of the sample on the deepening of the test cassette.	161	Tn gives the mixture of carrier fluid and saliva in the wrong place.	Tn does not see the back of the GA, where the deepening is marked.	The test cannot be evaluated because the liquid cannot flow through the test kit.	Under the "Implementation" section of the GA supplement with reference to the illustrations on the reverse. The marked deepening can be seen there.
F6	4.1 User reports positive test result (red lines in (C) and (T)).	015, 135	The question is answered incorrectly. A true positive result not recognized.	Tn state that they have not read the GA sufficiently. Exemplary commentary by the Tn: Tn015: "*I did not read the GA correctly*"	A positive result would not be recognized.	/
F7	4.2 User reports negative test result (red line (C)).	002, 140, 211	The question is answered incorrectly. A true negative result has not been recognized.	Tn state that they have not read the GA sufficiently. Exemplary commentary by the Tn: Tn002: "*I have made a misreading.*"	A negative result would not be recognized.	/

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
F8	4.3 User reports invalid test result (red line in (T)).	014	Question is answered incorrectly. The invalid result was not recognized.	Tn state that they have not read up in the GA. Exemplary commentary by the Tn: Tn014: "*I haven't checked the manual again.*"	An invalid result would not be recognized.	/
F9	6.1 User says room-temperature.	066, 084, 126, 140, 161	Question cannot be answered correctly.	Tn do not take enough time to read the GA again.	Not using the test within the scope of application (at room temperature) would produce an invalid result.	A clearer reference in the GA that the test should be used at room temperature may be considered.
F10	6.2 User says that the test must be stored dry and protected from the sun.	014, 072, 140	Question cannot be answered correctly.	Tn state that they have not looked up in the GA. Exemplary commentary by the Tn: Tn072: "*I haven't checked the manual again.*"	No critical damage to users is to be expected if you do not know that the test kit should be stored away from dryness. Dry storage is inherent in the design thanks to the welded primary packaging.	/
F11	6.3 User answers question about damaged test packaging correctly.	015	Question cannot be answered.	Tn is only focused on the information given in the GA. At that moment, Tn does not think independently of the GA.	An invalid result when used despite damaged packaging is to be assumed.	A note in the GA stating that the test kit can no longer be used if the packaging is damaged can be considered.

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
S1	3.2 User spits saliva into the tube at least up to the mark	027, 013, 018, 028, 117, 120, 123, 136, 139, 143, 145, 153, 159, 171, 174, 191, 192, 195, 209, 213, 211	Tn expresses difficulty in finding the mark on the tube. As a result, it is not clear to the Tn whether sufficient saliva has been spat into the tube. Tn feels insecure, as the subjective assessment of 0.5 to 1 ml proves to be difficult.	There is no clear marking on the tube as a guide. An influence of the test situation and the unpleasant situation of spitting under observation appears to be very likely. Subjects who were nervous were inclined to process the subtask more quickly. Subjects tended to put the protective mask back on quickly.	According to the manufacturer, the lower limit of the required amount of saliva added is 0.5ml. This means that a saliva discharge of less than 0.5ml can lead to an incorrect or possibly a false negative result.	The manufacturer has already confirmed that future tubes will be marked with a clearly visible red line. A further relief would be achieved if a second marking / line - i.e., a range between 0.5 and 1 ml - were determined to where the saliva must be spat into the tube. This would make handling easier for the Tn in the event of difficulties in producing 1 ml of saliva.
S2	2.1 User reads through the instructions (user manual and/or test card)	011, 015, 027, 030, 031, 055, 058, 061, 065, 074, 077, 087, 120, 123, 124, 134, 144, 161, 177, 189, 191, 193, 209, 210	Tn does not read or see the back of the GA with the illustrations for the usage. As a result, uncertainties arise with some Tn (see S3) and the implementation is extended.	The reference "Please turn over" at the lower edge on the front is not sufficient to make it clear to the user that there is a rear with illustrations for application. Exemplary commentary by the Tn: Tn074: "*At first I didn't see the back of the GA.*"	No serious errors are to be expected, as the implementation is fully explained in writing on the front page.	The manufacturer has already confirmed that they will print the GA on one side in future test packages. In addition, an additional reference could be made in the "Implementation" section, e.g. "see figure".

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
S3	3.5 The user observes the time and swivels for 30 seconds.	123, 136, 190, 191, 194, 209, 210, 242	Von Tn shakes the tube and does not swivel and / or does not swivel for 30 seconds.	Tn do not read the GAs carefully, do not swivel for 30 seconds. Contradiction in the GA, on the front it says "swivel", on the rear it says "shake". On the rear, next to the illustration, it does not say that swiveling should be carried out for 30 seconds. Exemplary commentary by the Tn: Tn242: *"On the front it says that I should swivel the tube, next to the illustrations that I should shake it, what is correct now?"*	When asked, the manufacturer states that the required chemical reaction takes place after a few seconds, regardless of whether the device is swiveled or shaken. Thus, the deviations that occurred in the implementation of the GA can be seen without any impact on the result.	A standardization and addition of the GA can be considered. If necessary, "Shake" on the back should be changed to "swivel". The time specification of 30 seconds should be added to the illustrations on the rear of the GA.
S4	3.8 The user observes the time and waits 5 minutes until the test result is available.	029, 049, 074, 141, 144, 158, 175	The control line does not appear exactly next to the "C" but a little offset.	The cause lies in the production.	Uncertainty with Tn whether the test worked correctly.	Adjustment in production so that the control line appears at the height of the "C". Adjustment has already been implemented by the manufacturer.
S5	1.1 User unpacks all components of the test kit intact.	015, 026, 031, 072, 091, 124, 142	The packaging of the test cassette did not get open at first. Not all components of the test are found immediately. In particular, the pipette that is in the welded primary packaging with the test cassette is sought.	The GA does not indicate that the pipette is in the sealed primary packaging.	As a result, the Tn needs longer to carry out the test.	An additional mentioning in the GA that the pipette is in the sealed primary packaging should be considered.
S6	3.1 Saliva funnel is screwed tight without spilling liquid	191	Tn had difficulty assembling the parts properly.	The required fine motor skills of the Tn could be reduced.	As a result, the Tn takes longer to carry out and may not be able to carry out the test.	/

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
S7	3.7 The user puts 4 drops of the sample on the deepening of the test cassette.	054, 072 120, 145, 175, 191, 195, 211	The saliva pulls threads and is difficult to pipette. Accidentally, too much liquid has been pipetted.	Viscous saliva is likely responsible for causing the formation of threads. Too much pipetting is caused by a brief carelessness or is to be assessed as a learning effect of pipetting.	Difficult and prolonged execution of the test. Pipetting more than 4 drops may result in an invalid result.	An addition to the GA with reference to the handling of tough or highly viscous saliva can be considered.
S8	4.1 User reports positive test result.	091	The young Tn has difficulties and takes a lot of time to answer the questions. Needs help from the legal guardian present.	The young person is visibly insecure and cautious due to the test situation. Difficulties in understanding the question and / or the GA are possible.	Independent testing at home would certainly alleviate the nervousness and uncertainty. If there are difficulties in implementation, the parent or a present adult would probably also provide support in the home environment.	/
S9	4.2 User reports negative test result.	083, 091, 242	Tn is initially unsure about the interpretation of the result. However, she/he comes to the correct result.	At first Tn only takes a quick look at the GA. Understanding problems of the task.	A hasty decision is less likely in real situations and at home. If necessary, the GA would be checked more thoroughly. It is not associated with an increased risk for the TN.	/
S10	4.3 User reports invalid test result.	010, 032, 045, 091, 109, 143, 153, 159, 171, 174, 176	Tn is initially unsure about the interpretation of the result. However, she/he comes to the correct result.	Tn does not look closely enough into the GA. Exemplary commentary by the Tn: Tn045: *"I haven't read very carefully."*	According to the manufacturer, this is a very rare result, very low probability of occurrence. No increased risk for the Tn. A hasty decision is less likely in real situations and in the home environment. If necessary, the GA would read more thoroughly.	see recommendation "F1"

ID	Acceptance criterion	Participant ID	Description Usage error	Root cause analysis	Impact analysis	Recommendation
S11	4.4 User reports invalid test result.	021, 045, 091, 123, 142, 143, 174	Tn is initially unsure about the interpretation of the result. However, she/he comes to the correct result.	Tn does not look closely enough into the GA. Exemplary commentary by the Tn: Tn045: *"I haven't read very carefully."*	Tn were unsure about the result. A hasty decision is less likely in real situations and at home. If necessary, the GA would be checked more thoroughly.	see recommendation "F1"
S12	6.1 User says room-temperature.	030, 091, 117, 119, 191	At first Tn finds it difficult to answer the question. Finally, Tn can answer correctly.	Initially Tn do not take enough time to read the GA.	Using the test outside of the scope (at room temperature) would produce an invalid result.	see recommendation "F9"
S13	6.2 User says that the test must be stored dry and protected from the sun.	045, 091, 153	The GA is initially not read accurately enough, but the question is then answered correctly.	Initially Tn do not take enough time to read the GA. Tn045: *"I just scanned the front page."*	No critical damage to users is to be expected if you do not know that the test kit should be stored away from moisture. Dry storage is inherent in the design due to the welded primary packaging. In the home environment, a closer reading of the GA is likely.	/
S14	6.3 User says that the test should no longer be used.	014, 017	The GA is initially not read accurately enough, but the question is then answered correctly.	Tn is initially only oriented on information in the GA. But then comes to the right solution.	An invalid result when used despite damaged packaging can be assumed, but the participants gave the correct answer.	see recommendation "F11"

Table 2: Qualitative analysis of the difficulties of use

6.3 Qualitative analysis of other relevant observations and comments of the participants

ID	Participant ID	Description	Impact analysis	Recommendation
SB01	030, 032, 119, 144, 231	Tn are somewhat irritated that the mixture of saliva and carrier liquid turns purple after application to the test cassette.	There are no serious consequences to name, but the discoloration creates uncertainty about the correct implementation with the Tn.	A reference in GA that the purple discoloration is a normal reaction should be considered.
SB02	069	Tn indicates that there is no time specification for the validity of the test. Tn would like to read in the GA that this test is only a snapshot and is not valid for several days.	The observation of the Tn is legitimate. A false assumption by Tn that the result is valid for a longer period of time could lead to the infection of other people.	A brief note in GA that the test is only valid for a very limited period of time should be considered.
SB03	144	Tn would like to read more information about the occurrence and intensity of the line in the GA. In particular, she/he would like to read that the control line and the T-line do not necessarily have to be equally pronounced for a positive result to be available.	A misinterpretation of a weakly positive result as negative could infect other people.	Brief information in the GA that a weak T-line should also be interpreted as positive should be considered in the GA.
SB04	209	Tn would like information in the GA about what to do if the test is positive.	Missing information on how to deal with and behave with a positive result could infect other people. However, since the beginning of the pandemic there has been a lot of information about how to behave in the event of a positive test result.	Brief information on how to proceed in the event of a positive test result can be considered.
SB05	178	Tn would like a short definition of "C" or "T" on the test kit in the GA.	Tn is afraid that people could interpret a line at "C" as Corona.	A brief definition in the GA is conceivable, but the situations in which lines appear at "C" or "T" are described with and without images in the GA.

Table 3: Qualitative analysis of other relevant observations and comments of the participants

7 Conclusion

Almost all acceptance criteria (94.7%) were correctly met by the participants. Some difficulties and errors in use were observed. However, the sources of error mentioned such as the misinterpretation of the incorrect test result, are to be interpreted with a low risk for the consumer due to the very low probability of occurrence and the low clinical relevance. The reduced release of saliva into the tube was partly due to a poorly visible marking. The manufacturer has already confirmed that they will replace the previous marking with a clear, red line and thus optimize future use of the test. The red line has been already mentioned in the instruction for use due to a translation error which has been already corrected. It should also be mentioned that a reduced saliva output was very likely influenced by the observation in the test setting. This negative influence would not exist if the test were used in a familiar environment. The study showed that errors were associated with double-sided printing of the instructions for use. Some of the test persons overlooked the illustrated instructions on the back of the GA. The producer has already confirmed that its product will be adapted to improve user-friendliness, so that the instructions for use will be printed on one side prospectively. With these adjustments taken the test "ZandCell COVID-19 Saliva Antigen Test" is safe and easy to use for a lay person.

8 Appendix

A: Demography of Tn

Number of subjects	n	130
Distribution of gender		
- Male	n (%)	67 (51,5%)
- Female	n (%)	63 (48,5%)
Age range		10 – 70
Distribution of age		
- 10 – 14	n (%)	13 (10%)
- 18 – 30	n (%)	37 (28,5%)
- 31 – 50	n (%)	37 (28,5%)
- 51 – 70	n (%)	43 (33,1%)
Highest educational level		
- Fachhochschule- oder Hochschulreife (Abitur)	n (%)	40 (31%)
- Diploma	n (%)	18 (14%)
- Realschulabschluss / Mittlere Reife	n (%)	16 (12,4%)
- Master	n (%)	16 (12,4%)
- Still in schooling	n (%)	14 (10,9%)
- Staatsexamen	n (%)	7 (5,4%)
- Hauptschulabschluss	n (%)	4 (2,9%)
- Bachelor	n (%)	4 (2,9%)
- No school leaving qualification	n (%)	3 (2,3%)
- Doctors degree	n (%)	3 (2,3%)
- Magister	n (%)	2 (1,6%)
- Vocational Training	n (%)	2 (1,6%)

B: ZandCell Usability Evaluation Plan

Usability Evaluation Plan

ZandCell COVID-19 Saliva Antigen Test

February 22nd, 2021

1 Release

Document	ZandCell_Usability-Evaluation-Plan_2021-02-22	Version	1.0
Author(s)	5.1.2e	Date	24.02.2021

Name / Role Dr. Ines Schöning / Study Leader	Name / Role	Name / Role	Name / Role
Signature 5.1.2e Date 26.02.21	Signature Date	Signature Date	Signature Date

Content

2 Metainformation

2.1 Product / Software

Product name	Product version
ZandCell COVID-19 Saliva Antigen Test	/

Table 1: Product and software list

2.2 Document version history

Version	Date	Author(s)	Changes
1.0	2021-02-22	5.1.2e	First draft

Table 2: Document version history

2.3 Purpose of the document

This document describes the planning of the usability evaluation.

The objectives of this document are:

- Enable usability evaluation activities to be conducted in a planned and efficient manner.
- The definition of usability evaluation activities.
- The creation of a usability evaluation schedule.
- the identification of possible use errors.
- the identification of possible problems and confusions during the use of the product.
- The evaluation of the effectiveness, efficiency, and satisfaction with which the product's user interface can be used in the intended use environment by the intended users.
    - proof of conformity with IEC 62366-1 Technical Corrigendum 1:2016

3 Overview of Summative Evaluation Activities

3.1 Product type and name

Type: SARS-CoV-2 Rapid Antigen Test

Name: ZandCell COVID-19 Saliva Antigen Test

Variants: None

3.2 Schedule

	Method	*Date*
Summative evaluation	Usability test	25.02-28.02.2021

3.3 Details

Test Participants: Test participants will be recruited from the designated user group "Lay Users".

Number of test participants: 100

Test environment: The use of the product is not limited to a specific usage environment. Thus, a special simulation of the usage environment in the test environment is not necessary. The test environment will provide a chair, a table and normal room lighting.

Accompanying **documentation:** The product is provided to the participants in the designated packaging including instructions for use.

Training: No training is provided for the product and therefore no training is provided for the test.

4 Summative Usability Evaluation

4.1 Method, rationale and objectives

The method intended for summative usability evaluation is a usability test in which representative users use the product within predefined test scenarios without the help of a moderator or anyone else. A moderator hands over each of the test tasks to the participants and monitors task completion according to

- Use Errors,
- and usage difficulties (including close calls).

Each observed use error and use difficulty (including close calls) is analyzed for its impact in terms of:

- Has or could the observation lead to a hazardous situation?
- Could the hazardous situation have resulted in unacceptable harm according to the risk policy to users, patients, or other people in the vicinity of the product?

This method is considered appropriate to provide objective evidence that the user interface can be used safely with the intended users in the intended use environment for the intended purpose.

4.2 Description of the parts of the user interface in the focus of the evaluation

The entire user product interface is tested in the usability test. This includes the following components:

- Packing
- Instruction manual
- SARS-CoV-2 test card
- Ampoule vial with extraction buffer solution
- Pipette
- Saliva funnel

4.3 Selection of usage scenarios

All hazard-related usage scenarios must be included in the summative usability evaluation.

The entire application process, and thus including all hazard-related usage scenarios, is tested and/or interrogated. This includes:

- Unpacking the test kit
- Read instructions on how to perform the test
- Sampling
- Perform test
- Interpret the test results
- Disposal
- Read and understand important safety instructions

4.4 User Groups

The intended user group for the product is lay users. Accordingly, lay users are recruited for the usability test.

Recruitment will be from the 4 age groups 10 - 14, 18 - 30, 31 - 50, and 51- 70. Attention is paid to a balanced gender ratio.

4.5 Number of test participants

Nielsen 2000&2012, Faulkner 2003 have found that in usability tests with 5 users, a statistical average of 85.55% of usability problems can be identified in the relevant tasks of a user group. To identify an average of 97.05% of usability problems, 15 users are sufficient.

Therefore, the total number of 120 participants is considered sufficient to identify all potential use errors with a high probability.

4.6 Test session duration

A test session lasts a maximum of 45 minutes.

4.7 Moderator

The test sessions are moderated by usability experts from RapidCare GmbH.

4.8 Test protocols

A testing protocol will be developed that includes the following topics:

- Preparation of the test environment and other conditions of use
- List of questions about the test taker to verify and supplement information from the screening. The interview takes place before the test.
- Briefing given to each test taker before testing begins.
- Test scenarios including acceptance criteria, which the participant must fulfill.
- Post-session debriefing/list of interview questions.

4.9 Location

The usability test is conducted in RapidCare's usability lab in Aachen.

The usability lab ensures that the test environment simulates the intended usage environment sufficiently realistically (see Chapter 4.10).

4.10 Test environment

The use of the product is not limited to a specific usage environment. Thus, a special simulation of the usage environment in the test environment is not necessary. The test environment will provide a chair, a table and normal room lighting.

4.11 Acceptance criteria

A test task is considered to be fulfilled if it is completed by the participant without user error or difficulty. The acceptance criteria for each task are specified in more detail in the protocol.

4.12 Documentation and analysis

The moderator observes and takes critical notes. The observations include use errors use difficulties (including close calls). The moderator's notes consolidated and documented in the final report.

Each observed use error and use difficulty (including close calls) is analyzed for its impact in terms of:

- Could the use error or usage difficulty that occurred lead to a hazardous situation?
- Could the hazardous situation have resulted in unacceptable harm to users, patients, or others in the vicinity of the product?
- What was the cause of the Use Error?

The results of the summative assessment are analyzed qualitatively according to ISO 14971 to determine whether the product was found to be safe for the intended users, patients and third parties, or whether the design of the product needs to be modified to reduce the use-related risks to an acceptable level.

A final report will address at least the following topics:

- Summary of test conditions and methods
- Profiles of the test participants
- Summary of test results and conclusion
- Details of data collection and results including:
    - Answers to questions about the interview before and after the session

  - Results of the test items
  - Deviations from the pass/fail criteria
  - Use errors and use difficulties (including close calls)
  - Cause of possible Use Errors and Usage Difficulties (including Close Calls).
- Final conclusion on whether the user interface is secure.

Usability Evaluation Protocol (UEP)

ZandCell COVID-19 Saliva Antigen Test

February 24nd, 2021

1 Release

Document	ZandCell_Usability-Evaluation-Plan_2021-02-22	Version	1.0
Author(s)	5.1.2e	Date	22.02.2021

Name / Role Dr. Ines Schöning / Study Leader	Name / Role	Name / Role	Name / Role
Signature 5.1.2e	Signature Date	Signature Date7	Signature Date

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2 Meta information

2.1 Product / Software

Product name	Product version
ZandCell COVID-19 Saliva Antigen Test	/

Table 3: Product and software list

2.2 Document version history

Version	Date	Author(s)	Changes
1.0	2021-02-17	5.1.2e	First draft

Table 4: Document version history

2.3 Purpose of the document

This document contains a moderation guide and test scenarios as well as corresponding acceptance criteria for a usability test.

2.4 Relevant documents

No.	Document	Connection
1	ZandCell_Usability-Evaluation-Plan_2021-02-22	Usability Evaluation Plan

Table 5: List of relevant documents

3 Product type and name

Type: SARS-CoV-2 Rapid Antigen Test

Name: ZandCell COVID-19 Saliva Antigen Test

Variants: None

4 Moderation Guide

4.1 Test method

A detailed description of the test method used can be found in the Usability Evaluation Plan.

4.2 Training for each participant

No training is provided for the participants.

4.3 Preparations before the start of the meeting

Have the following materials available and accessible to the participants:

- Test kits in original packaging for at least 120 tests
- Latex gloves in three different sizes (S, M, L)
- Waste garbage can (residual waste)
- Household paper
- Tissues
- FFP2 masks
- Surface disinfection
- Hand disinfection
- Highlighter
- Ruler
- Instruction manual
- Declaration of consent
- Confidentiality agreement
- Corona contact form
- Expense allowance
- Receipt of the expense allowance

Prepare the following:

- Optimize lighting conditions
- Disinfection of the surfaces
- Provide test kit

4.4 Briefing / Introduction

The following briefing is given to each test taker before the test items are given to the test taker.

- Welcome and thank you for your participation in today's study.
- [Introduce test team and attendees.]
- Before we begin, I would like to go over a few points.
- Today's session will last approximately 30 minutes. The goal of the study is to find out to what extent the design of the product supports you in performing typical tasks with the product.
- The product you are testing today is a SARS-CoV-2 antigen rapid test. It is a self-test for individuals that can be performed at home.
- I will first ask you a few background questions and then ask you to perform some typical tasks using the quick test.
- You will receive the product in its original packaging with enclosed instructions for use. You are allowed to use it when you want and as often as you want.
- Do you have any questions at this point of time?

4.5 Selection of use scenarios for the usability test

List of Use Scenarios and the corresponding Test Scenarios in which they are addressed.

Use Scenario	Test scenario
1. Unpacking the test kit	1. Complete test procedure
2. Read instructions on how to perform the test	
3. Sampling	
4. Perform test	
5. Interpret the test results	
6. Disposal	
7. Knowledge Tasks	

Table 6: Selection of Use Scenarios

5 Interview before the meeting

I have a few questions about your personal background.

1. How old are you? (10 – 14, 18 - 30, 31 - 50, 51 - 70)
2. Gender? (m, w, d)
3. What is your highest educational qualification?
4. What is currently your exact job title?
5. Do you regularly perform nasal swabs as part of your job?

6 Briefing

- The rapid test is fully functional.
- In a moment I will give you a few typical tasks that are necessary to perform the test.
- You just do what you think is right. You cannot do anything wrong.
- It is important to us that you imagine that this is an absolutely realistic situation from your everyday life.
- That is why I stay in the background. Just pretend that I am not here, and you are at home alone applying this test.
- If you have questions, try to answer them yourself first. If you get stuck, I will of course help you.
- Remember that you can refer to the instruction manual at any time and as often as you want.

7 Detailed test scenarios for the usability test

7.1 Test scenario 1: Complete test procedure

7.1.1 Required preparation specifically for this scenario

- Provide test kits in original packaging.
- Provide prepared results (positive, negative and invalid) of the test card.

7.1.2 Instructions for the moderator

- You instruct the participant according to the next chapter.
- Change the order of the results presented so that no sequence effects occur (see AK 4.3).
- Start with invalid test result for every 10th participant in test result interpretation.

7.1.3 Instructions (tasks) for the participant (to print)

Imagine the following situation:

- You bought the rapid test in the supermarket and now you are at home with it.

- You suspect that you are infected with the SARS-CoV-2 coronavirus.
- With the help of the test kit, you want to find out if your suspicions are confirmed.

Please complete the following tasks:

- Do what you think is necessary to find out if you are infected with SARS-CoV-2 coronavirus using the test kit.
- Please let me know when you think you are done with the task.

7.1.4 Tasks and pass/fail criteria

Use Scenario	Tasks	Acceptance criteria	Pass/fail criteria	Comments
5. Unpacking the test kit	1. All components of the test kit are unpacked intact	1. User unpacks all components of the test kit intact	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
6. Read instructions on how to perform the test	1. The instructions (user manual) are read	1. User reads through the instructions	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
7. Perform test	1. Screw saliva funnel onto tube	1. User screws saliva funnel onto tube	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	2. Spit saliva into tube	2. User spits saliva at least up to the mark in the tube	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	3. Unscrew saliva funnel	3. User unscrews saliva funnel from tube	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	4. Screw down tube	4. User screws the tube shut	☐ Passed ☐ Failed ☐ Use Difficulty	

			☐ Not applicable	
	5. Swivel reaction tube	5. User swivels the tube for approx. 30 seconds.	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	6. Remove sample from reaction tube	6. User takes the sample from the reaction tube	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	7. Place the sample on the test cassette	7. User places 4 drops of the sample on the well of the test cassette	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	8. Wait 5 minutes until the test result is available	8. User waits 5 minutes until the test result is available	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
8. Interpret the test results	1. Recognize positive test result (red lines in the quality control area (C) and in the test area (T)) and verbally reproduce test result	1. User reports positive test result (red line in (C) and (T))	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	2. Recognize negative test result (red line in the quality control area (C)) and verbally reproduce test result	2. User reports negative test result (red line (C))	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	3. Recognize invalid test result (red line in test area (T)) and verbally reproduce test result	3. User reports invalid test result (red line in (T))	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	

	4. Recognize invalid test result (no lines) and verbally reproduce test result	4. User reports invalid test result (no lines)		
9. Disposal	1. Dispose of the test kit components as described in the IFU.	1. User disposes of test kit components in a separate bag, seals it and disposes of it in household waste	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
10. Knowledge Tasks	1. At what temperature should the test be used?	1. At room temperature	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	2. How should the test be stored?	2. Store dry and protected from sun	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	3. What do you do if you notice that the packaging is damaged?	3. Do not use the test anymore	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	4. How often can you use the test?	4. The test is intended for single use only	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	
	5. What do you do if you notice that the test has expired?	5. Do not use the test anymore and dispose of it	☐ Passed ☐ Failed ☐ Use Difficulty ☐ Not applicable	

Table 7: Test Scenario 1: Pass / Fail Criteria

7.1.5 Questions

After the test participant completes all test scenarios, the following post-session interview questions are asked to identify the subjective cause of each usage error.

1. *After the test card is closed:* How long would you wait to read the test result?
2. Have you read the instructions on how to perform the test?
    a. *Asking no:* Would you normally read them on a test like this? Did you leave out any parts?
3. If necessary: Ask for root cause.

D: IFU-German (front and rear page)

Gebrauchsanweisung

ZandCell COVID-19 Speichel-Antigen-Test

Version 2.2

CE IVD

ZandCell COVID-19 Speichel-Antigen-Test
Lesen Sie die gesamte Packungsbeilage sorgfältig durch, bevor Sie mit der Anwendung dieses Tests beginnen, denn sie enthält wichtige Informationen.

- Heben Sie diese Packungsbeilage auf. Vielleicht möchten Sie diese später nochmals lesen.
- Fragen Sie Ihren Arzt oder Apotheker, wenn Sie weitere Informationen oder einen Rat benötigen.

[Produktname]

ZandCell COVID-19 Speichel-Antigen-Test

[Ausführung]

1 oder 5 Tests pro Packung

[Verwendungszweck]

Dieses Produkt dient dem Nachweis von Coronavirus-19-Antigen in Speichel- oder Auswurfproben von Personen mit oder ohne Anzeichen einer Infektion. Der Test kann von Laien ohne Hilfe durch fachkundiges Personal verwendet werden. Er zeigt an, ob eine Infektion mit Covid 19 vorliegt.

[Bestandteile]

Die Packungen enthalten eine oder sechs Testkassetten, einen Gebrauchsanweisung und ein Röhrchen mit 1 ml Verdünnungsmittel. Jeder Beutel enthält eine Testkassette und einem kleinen Beutel mit Trockenmittel, einen Satz Speichelsammler (einschließlich eines Spudrichters und einem Sammelröhrchen mit 1 ml Verdünnungsmittel) und eine Pipette.

[Aufbewahrung]

Das Produkt sollte bei 2°C bis 30°C, trocken und vor Sonnenlicht geschützt aufbewahrt werden. Die Haltbarkeit beträgt 18 Monate. Der Test sollte innerhalb von 30 Minuten nach dem Öffnen verwendet werden. Produktionsdatum und Verfallsdatum sind auf dem Verpackungsetikett angegeben.

[Probenanforderungen]

Die Testkassette dient zum Nachweis von Coronavirus-19-Antigen in Speichel- oder Auswurfproben. Die Proben sollten schnellstmöglich nach der Entnahme verarbeitet werden und nicht für längere Zeit bei Raumtemperatur gelagert werden. Wenn die Probe nicht sofort verarbeitet werden kann, kann sie für bis zu 48 Stunden bei 2°C bis 8°C gelagert werden. Langfristige Lagerung sollte bei -20°C erfolgen. Wiederholtes Einfrieren und Auftauen ist zu vermeiden.

[Durchführung]

Bitte lesen Sie die Anweisungen vor dem Testen sorgfältig durch.

1. Vor Anwendung des Test 30 Minuten lang nichts essen, trinken, nicht die Zähne putzen und kein Mundwasser verwenden.
2. Öffnen Sie den Alufolie-Beutel, nehmen Sie die Testkassette heraus und verwenden Sie den Test so bald wie möglich, innerhalb von höchstens 30 Minuten, insbesondere bei Raumtemperaturen über 30°C oder hoher Luftfeuchtigkeit, schnellstmöglich.
3. Stellen Sie die Testkassette auf eine saubere Fläche. Öffnen Sie den Verschluss des Röhrchens, schrauben Sie den Spudrichter auf das Röhrchen auf. Sammeln Sie Speichel oder Auswurf. Spucken Sie 0,6 bis 1,0 ml in den Trichter, im Röhrchen befindet sich bereits 1,0 ml Lösung.
4. Schrauben Sie den Spudrichter ab, verschließen Sie das Proberöhrchen wieder mit dem Verschluss, schwenken Sie die Probe 30 Sekunden lang mit langsamen Bewegungen (nicht heftig schütteln), schrauben Sie dann den Verschluss ab.
5. Entnehmen Sie mit der Pipette etwas Flüssigkeit aus dem oberen Bereich (jedoch keinen Schaum) und geben Sie 4 Tropfen auf das markierte Feld der Testkassette.
6. Warten Sie 5 Minuten.

   Warten Sie auf das Erscheinen des violett-roten Streifens. Die Testergebnisse sollten innerhalb von 5-15 Minuten abgelesen werden. Nach mehr als 15 Minuten sind die Ergebnisse ungültig.
7. Entsorgen Sie alle Bestandteile des Tests im normalen Haushaltsmüll.

[Erläuterung der Testergebnisse]

1. Positiv (+): Wie in Abb. 1 zu sehen, erscheint jeweils eine violett-rote Linie im C-Bereich und im T-Bereich.
2. Negativ (-): Wie in Abb. 2 zu sehen, erscheint nur im C-Bereich eine violett-rote Linie.

1. Positiv (+) 2. Negativ (-)

3. Ungültige Testergebnisse: Unabhängig davon, ob im T-Bereich eine violett-rote Linie zu sehen ist oder nicht: Wenn im C-Bereich keine violett-rote Linie (Qualitätskontrolllinie) zu sehen ist, bedeutet dies, dass der Test nicht korrekt durchführt wurde oder defekt ist. In diesem Fall lesen Sie die Gebrauchsanweisung sorgfältig durch und wiederholen Sie den Test mit einem neuen Testsatz. Wenn das Problem weiterhin besteht, wenden Sie sich an Ihren Apotheker.

Bitte Wenden

Gebrauchsanweisung

ZandCell COVID-19 Speichel-Antigen-Test

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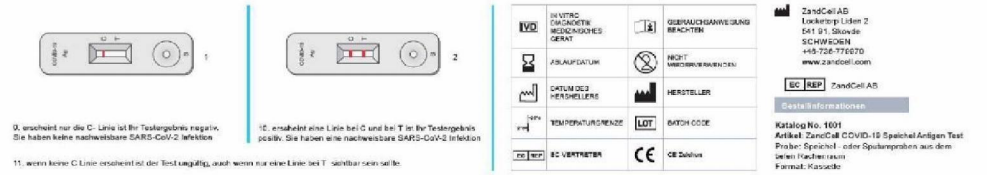
CE IVD

1. Schrauben Sie den Deckel des Röhrchens auf.
2. schrauben Sie den Spudrichter auf das Proberöhrchen.
3. bringen Sie durch ein tiefes „räuspern" Speichel aus dem tiefen Rachen nach vorne in den Mund
4. spucken Sie bis zur 2ml Marke des Proberöhrchens Ihren Speichel durch den Spudrichter ins Proberöhrchen.

5. entfernen Sie den Spudrichter
6. verschließen Sie das Proberöhrchen erneut mit dem Verschluss und schütteln Sie das Proberöhrchen mehrfach
7. öffnen Sie das Proberöhrchen und entnehmen Sie mit der beiliegenden Pipette etwas von Ihrem Probenmaterial.
8. geben Sie 4 Tropfen mit der Pipette in das dafür markierte Feld des Teststreifens



9. erscheint nur die C- Linie ist Ihr Testergebnis negativ. Sie haben keine nachweisbare SARS-CoV-2 Infektion
10. erscheint eine Linie bei C und bei T ist Ihr Testergebnis positiv. Sie haben eine nachweisbare SARS-CoV-2 Infektion

11. wenn keine C Linie erscheint ist der Test ungültig, auch wenn nur eine Linie bei T sichtbar sein sollte.

IVD	IN VITRO DIAGNOSTIK MEDIZINISCHES GERÄT		GEBRAUCHSANWEISUNG BEACHTEN
	ABLAUFDATUM		NICHT WIEDERVERWENDEN
	DATUM DES HERSTELLERS		HERSTELLER
	TEMPERATURGRENZE	LOT	BATCH CODE
REP	EC VERTRETER	CE	CE Zeichen

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Bestellinformationen

Katalog No. 1601
Artikel: ZandCell COVID-19 Speichel Antigen Test
Probe: Speichel - oder Sputumproben aus dem tiefen Rachenraum
Format: Kassette