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## INTRODUCTION

CHIL Tıbbi Mal. San. ve Tic. Ltd Şti. conducted Usability Study to evaluate CHIL COVID-19 Antigen Rapid Test usability performance for participants at the observation of the independent laboratory.

Rapid Tests are supplied with Instructions for Use, box which provided Quick Reference Instructions and QR code for the Operation Video on it, nasal swab and extraction tube by the manufacturer CHIL Tıbbi Mal. San. ve Tic. Ltd Şti.

A usability Study is intended to determine the extent to an interface facilitates a user's ability to complete routine tasks. Typically the test is conducted with a group of potential users on-site with portable Rapid Test Kits. Users are asked to complete a series of routine tasks. Results are recorded and analyzed whether needed improve on the test design or not.

The 100 participants applied the CHIL COVID-19 Antigen Rapid Test by using given Instructions for Use and Quick Reference Instructions, QR Code for Operation Video on the box with the given tasks by the independent Laboratory Staff. According to this procedure, participant's task completion rates, comments, overall satisfaction ratings, questions, and feedback were recorded in Annex I.


## EXECUTIVE SUMMARY

The CHIL Tıbbi Mal. San. ve Tic. Ltd. Şti. conducted with Ege Laboratory an onsite usability study in Turkey on Feb 9th and Feb 10th, 2021.

100 participants, including individuals (n=50), caregivers (n=30) and age of 2-11 years individuals(n=20) participated in the study. Each individual or caregiver pair participated in a 30-minute session with a single proctor.

Participants were separated into positive and negative cases in accordance with clinical diagnosis and PCR results approved by medical doctors before the usability study was conducted. 32 participants were confirmed clinically as positive and 68 participants were confirmed as negative. Participants have conducted the usability study in different rooms according to positive and negative PCR test results.

The usability evaluation session included one simulated use of the CHIL Tıbbi Mal. San. ve Tic. Ltd. Şti. in which a user was already connected with a laboratory staff, knowledge tasks, and opportunities to provide feedback.

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The purpose of this study was to assess the usability of the CHIL COVID-19 Antigen Rapid Test, the comprehensibility and applicability of the provided instructions.

In general, all participants found the given Instructions for Use and Quick Reference Instructions on the box to be clear, straightforward. 97% (97 out of 100) participants thought that the CHIL COVID-19 Antigen Rapid Test was easy to use. All of the participants (100) used Instructions for Use and thought that the instructions were comprehensible.

This Usability Study identified only a few minor problems including:

- Insufficient amount of specimen due to not tightening the Extraction Tube sufficiently.
- Insufficient sampling because the swab is not rotated enough in the nose.
- Problem with breaking the top of the extraction tube.
- Reading the test results early or late than advised in Instructions for Use because the timer is not started on time. Late or early start of timer was not a level that would affect the test result.

This document contains the participants' feedback, satisfaction ratings, task completion rates, ease or difficulty of completion ratings, errors, and recommendations for improvements. The scenarios and questionnaires is included in the Annex I and II section.

## **METHODOLOGY**

The staff from Ege Laboratory have contacted participants, necessary information regarding the usability study was provided, and appropriate dates and times were determined to start usability study.


Each individual and caregiver session lasted approximately 30 minutes. During the session, the laboratory staff explained the test session and asked the participant to fill out a brief questionnaire (see Annex I). Participants read the task scenarios and tried to perform the CHIL COVID-19 Antigen Rapid Test according to the given Instructions for Use, and Quick Reference Instructions on the box.

- 20 Caregivers also applied the test to people aged 2-11 years and evaluated the questionnaire accordingly.

After the tasks, the laboratory staff asked the participant to rate the test kit on a 5-point Likert Scale with measures ranging from Strongly Disagree to Strongly Agree (see Annex I):

Questionnaire was prepared for answers that assess below example questions,

- Were the Quick Reference Instructions on the box and Instructions for Use clear enough?

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- How easy it was to find the information from the Instructions for Use and Quick Reference Instructions on the box?
- Were the visual instructions clear or enough when performing the test?
- Have you had difficulty using the QR code on the box for the Operation Video?

After the tasks were completed, the laboratory staff asked the participant to rate the CHIL COVID-19 Antigen Rapid Test overall for below subjective measures including:

- Ease of use
- Ergonomic design of the CHIL COVID-19 Antigen Rapid Test
- Frequency of use
- Difficulty to following test procedure in Instructions for Use
- Learn ability- how easy it would be for most users to learn to use the CHIL COVID-19 Antigen Rapid Test
- Information facilitation – how quickly participant could find information
- Look & feel appeal – Box design makes me want to use the test further


In addition, the test laboratory staff asked the participants the following overall test questions:

- What the participant liked most?
- What the participant liked least?
- Recommendations for improvement.

See Annex I for the overall questionnaires.

## **PARTICIPANTS**

100 participants, including individuals (n=50), caregivers (n=30), and age of 2-11 years individuals(n=20) completed the usability study in the two testing dates. 50 participants were involved in testing on Feb 9th and 50 on Feb 10th. Of the 100 participants, 50 were male and 50 were female. 97 of the 100 participants performed the CHIL COVID-19 Antigen Rapid Test correctly. 32 of the 97 participants who completed the test correctly had positive PCR results others had a negative PCR test results. Usability Study Focus groups prepared according to IEC 62366-1 and 'Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use' Usability Study Recommendations are shown in the table 1.

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*Table 1. Focus Grups*

	Caregivers 1*	Caregivers 2**	Individuals
Sex n (%)			
Male	10	8	32
Female	10	2	38
Age	21-64	21-64	2-73*
Education n (%)			
≤High School	2	6	23
Bachelors' degree	7	5	25
Post-graduate/Specialty	3	4	12
PhD degree	1	2	10

\*Caregivers 1 applied the tests to the individuals at the age of 2-11 years old.

\*\* Caregivers 2 applied the tests only for themselves.


### EVALUATION TASKS/SCENARIOS

Test participants attempted completion of the following tasks (see Table 2. for complete test scenarios/tasks)

- Obtain information about the performing of the CHIL COVID-19 Antigen Rapid Test by examining the box.
- Check the contents of the box according to the information on the box.

*Table 2. Tasks*


User Task	Task Requirements	Potential Use Errors
1.Clean your hands before starting the test.	Wash or disinfect your hands before you start testing and make sure your hands are dry.	Failure to clean and dry the hands may result in contamination that can affect the test result.
2.Check the expiration date on the box	Compare today's date with expiry date on the box	Failure to notice expired product
3.Check the box content	Compare the instructions for use and the contents of the box	Failure to notice the damaged or missing materials
4.Remove the swab from the pouch.	Remove without touching the head of the swab that advised in Instructions for Use	Failure to notice the warning

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<b>5.</b> Collect the nasal specimen by using swab	Insert the swab 1,5-2,5 cm (0,6-1 inch) into the patient's nostrils and rotate the swab around the inside wall of the nostril 5-6 times.	Failure to sufficient sampling because the swab is not rotated enough in the nose
<b>6.</b> Place swab in the extraction tube	Put the swab into the extraction tube, rotate the swab for about 10 seconds.	Failure to keep and rotate the swab sufficiently in the tube.
<b>7.</b> Take swab out from the extraction buffer tube.	Squeeze the bottle when taking the swab out to remove as much liquid as possible from the swab.	Failure to squeeze the extraction buffer tube sufficiently.
<b>8.</b> Break the top part of the extraction tube	Keep the extraction tube vertical as the breaking part will be upward to avoid specimen solution spills and break the top part of the extraction tube.	Failure to break the top part of the extraction tube correctly.
<b>9.</b> Add 4 drops of the specimen from the extraction buffer tube to the sample well of the test cassette.	Carefully add 4 drops of sample from the extraction buffer tube to the sample well of the test cassette without spilling around.	Failure to add insufficient drops to the sample well can affect the test result.
<b>10.</b> Start the timer and read the test result in 15 minutes.	Do not read the test results before 15 minutes or after 30 minutes.	Reading the test results early or late than advised in Instructions for Use.

## RESULTS

Laboratory staff observed and recorded whether the participant used the test correctly or not. Most of the participants completed all tasks correctly. According to this observation, 99 of the 100 (99%) completed Task 5 (Collect the nasal specimen by using swab), 99 of the 100 (99%) completed Task 7 (Take swab out from the extraction buffer tube) and 99 of the 100 (99%) completed Task 8 (Break the top part of the extraction tube). The user who had problems with Task 5 was a 25-year-old female from the Individual group with bachelor degree. The user who had problems with Task 7 was the caregiver who tested his 8-year-old individual. The caregiver was a 43-year-old male with post graduate/specialty.

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The user who had problems with Task 8 is a 67-year-old male retired from the Individual group.

32 participants who were confirmed clinically as positive PCR, performed their tasks correctly and each participant obtained positive test results after performing the CHIL COVID-19 Antigen Rapid Test.

68 participants who were confirmed clinically as negative, performed their tasks. Laboratory staff observed that 3 of the 68 participants had problems with tasks 5, and 8 however that can be tenable. After performing the CHIL COVID-19 Antigen Rapid Test each participant obtained negative test results.

*Table 3. Summary of the Results*

	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9	Task 10
<b>Number of participant who completed the task correctly</b>	100	100	100	100	99	100	99	99	100	100
<b>Completion Rates</b>	100%	100%	100%	100%	99%	100%	99%	99%	100%	100%

According to IEC 62366, questions were prepared for the Usability Study and a questionnaire was created. Refer to Annex I.


### **LIKES, DISLIKES, PARTICIPANT RECOMMENDATIONS**

Upon completion of the tasks, participants provided feedback for what they liked most and least about the CHIL COVID-19 Antigen Rapid Test, and recommendations for improving the instructions.

#### **LIKED MOST**

The following comments capture what the participants liked most:

- Easy to use
- Reading results in a short time
- Easy to interpret the the test result
- Portable device
- Visual instructions to be effective and helpful
- Clear demonstration of the performing the test with the Operation Video

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### LIKED LEAST

Most of the participants found CHIL COVID-19 Antigen Rapid Test to be very useful and easy to use but the following comment capture what the some of participants liked the least:

- Collection of the specimen from the nostril with a nasal swab


### RECOMMENDATIONS FOR IMPROVEMENT

Participants were generally satisfied with the use of the CHIL COVID-19 Antigen Rapid Test and the instructions but the following comments capture what the some of participants recommended for improvement:

- Mobile application can be developed.
- Customer services hotline can be provided on the box.

### CONCLUSION

Most of the participants found CHIL COVID-19 Antigen Rapid Test to be well-organized, very useful, and easy to use. Having a more than one instructions like Instruction for Use and Operation Video to find information is key to many of the participants. All participants thought the instructions were straightforward and easy to understand and follow. Caregivers did not have any problems while testing individuals aged 2-11 years.

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## ANNEX I

**Sex:**

**Date:**

**Age:**


**Nationality:**

**Educational Status:**


Please fill in the following questionnaire related to CHIL COVID-19 Antigen Rapid Test based on your experience while performing the CHIL COVID-19 Antigen Rapid Test.

	<b>Strongly Disagree</b>	<b>Disagree</b>	<b>Neutral</b>	<b>Agree</b>	<b>Strongly Agree</b>
CHIL COVID-19 Antigen Rapid Test is easy to use.					
CHIL COVID-19 Antigen Rapid Test can be preferred to use frequently					
Instructions for Use is straightforward, easy to understand and follow.					
Quick Reference Instructions and shown on the box is straightforward, easy to understand and follow.					
Operation Video QR Code is easy to scan.					
Operation Video is descriptive and helpful to perform the test.					
Most people would learn to use CHIL COVID-19 Antigen Rapid Test easily.					
CHIL COVID-19 Antigen Rapid Test can be performed correctly just by reading the Instructions for Use.					
The test result is easy to interpret.					
The warnings and precautions prevent mistakes that could be made while performing the test.					
It is easy as shown in the instructions to use the swab and collect nasal specimen from the nostril.					
It is easy to remove the swab from the extraction buffer tube.					
The top part of the extraction tube can be broken easily.					
It is easy to add 4 drops of specimen to the sample well of the test cassette.					



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The test result is clear within 15 minutes.					
It is clearly visible to see line conditions when interpreting the test results.					
The labels and symbols on the box is understandable.					
CHIL COVID-19 Antigen Rapid Test has ergonomic design.					
Box design is appeal to the eye.					
Please answer the following questions related to CHIL COVID-19 Antigen Rapid Test based on your experience while performing the CHIL COVID-19 Antigen Rapid Test.					
What did you like most when performing the test?					
What did you like least when performing the test?					
What do you recommend to improve CHIL COVID-19 Antigen Rapid Test?					

	<b>USABILITY STUDY TASKS AND SCENARIOS</b>	Doküman Kodu/ Document Code:	US-A2
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## Annex II

Please read the tasks and scenarios carefully and perform the test accordingly.

User Tasks and Scenarios
1.Clean your hands before starting the test and read the instructions for use.
2.Check the expiration date on the box.
3.Check the box content.
4.Remove the swab from the pouch.
5.Collect the nasal specimen by using swab.
6.Place swab in the extraction tube.
7.Take swab out from the extraction buffer tube.
8.Break the top part of the extraction tube.
9. Add 4 drops of the specimen from the extraction buffer tube to the sample well of the test cassette.
10. Start the timer and read the test result in 15 minutes.

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