Company Name	Shenzhen Homed Medical Device Co., Ltd.	Document No.: HOMED2101-CE-003A-01 Version: 1.0 Page: Total 6 Page 1

Project Name:

COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold)

Document Name:

Self-testing Usability Test Protocol

Drafted by: 5.1.2e Date: 202104	Checked by: 5.1.2e Date: 202104	Approved by: 5.1.2e Date: 202104

Summarized review comments:(another page could be attached if not enough)

Revision Records

Version	Summarized Revisions	Written by	Revised Date
V1.0	Initialization Version	5.1.2e	202104

1. Objective

This self-testing usability and label comprehension of the COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) is to ensure that the users can correctly operate the product.

2. Product Description

2.1 Intended use

The COVID-19 Nucleocapsid Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from COVID-19 in saliva swab. This product is for self-testing only.

2.2 Intended user

Lay person.

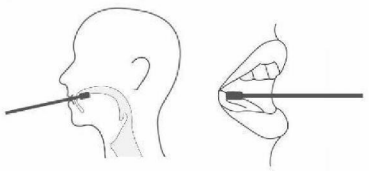
a) Age: not relevant
b) Gender: not relevant
c) Health: not relevant
d) Nationality: multiple
e) Education: not relevant
f) Knowledge: able to read instruction of use
g) Experience: no special experience needed

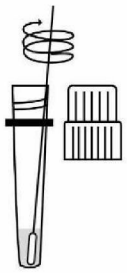
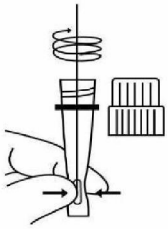
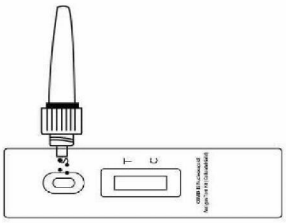
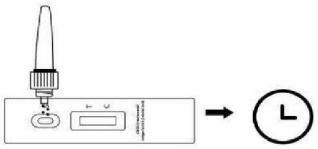
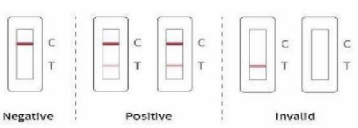
2.3 Intended use environment

Home setting.

2.4 User Interface

2.4.1 For nasal/nasopharyngeal sample:

No.	Step	Illustration
1	Use saliva swabs to collect sample from mouth	

2	Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.	
3	Press the sample tube to release the antigen in the swab and take out the swab.	
4	Screw off the dropper cap of the sample tube.	
5	Add two drops of the extraction sample into the sample well.	
6	Read the result within 15 minutes.	
7	Interpret test result.	

3. Study Design

3.1 Participate Selection

3.1.1 Inclusion Criteria

a) Age: not limited
b) Gender: not limited
c) Education: not limited
d) Health: not limited

3.1.2 Exclusion Criteria

People who is unable to read the instruction of use.

3.1.3 Quantity

33 children and adolescents ages from 2-17;
34 adults ages from 18-60;
33 elder person ages over 60
The age groups were determined to meet the normal user population that currently utilizes at home use this antigen test kit.
Children and adolescents will use this product with their parent's assistance.
Each participant shall perform all 3 sample type tests.

3.2 Study Procedure

3.2.1 Test Environment

Study will take place in the home setting with the normal environmental setting. The use of this product in the test environment will be under the normal conditions found in that environment such as noise, lighting, and distractions typically found in the home setting.

3.2.2 Enrollment Log

Participant must sign the enrollment log and will receive an ID.

3.2.3 Study Staff

The study staff will monitor each study participant using the product and will direct study participant to perform the tasks. The study staff will do no training in use and cannot interfere with the user as they perform the mandatory tasks for the proper use of COVID-19 Nucleocapsid Antigen Test Kit. The study staff will record the successful completion of the various tasks. If the participant fails to perform the task correctly it must be reported that the participant failed in performing the required task. The participant will complete the Participant Usability and Label Comprehension Form at the end of the session.

3.2.4 Use of Product

Step 1: The study participants will receive the instruction of use, test procedure quick guide card and COVID-19 Nucleocapsid Antigen Test Kit before study start. Participant shall read the instruction of use and test procedure quick guide card before using the product.
Step 2: The participant will then be directed by the study staff to perform the following mandatory use steps for evaluation. Mandatory tasks are essential task required for successful use of the product.

Mandatory Task	Rationale
1. Identified the following product components: -Test cassette; -Sample tube with extraction reagent;	For understanding all required components of the product. If misunderstanding components, which

-Saliva Swab;	may lead to misuse and incorrect or invalid test result.
2. Able to correctly collect samples by saliva swab.	If sample collect incorrectly, test result may be inaccurate or invalid.
3. Able to correctly prepare sample in sample tube with extraction reagent.	If sample prepared incorrectly, test result may be inaccurate or invalid.
4. Able to correctly add extraction samples into test cassette sample well.	If extraction samples being add incorrectly, test result may be inaccurate or invalid.
5. Able to observe and interpret test results.	If unable to interpret test result, user may misunderstand the health state of himself/herself.

Step 3: Success/failure of use this product will be documented by the study staff who will observe and record the subjects on their success at performing the mandatory tasks using a yes/no evaluation, which will be explained as:

Yes: Success in performing tasks correctly without assistance

No: Subject did not perform task correctly and study staff intervention was required.

The Study Staff Observation Form please refer to attachment 1.

Step 4 : The Study Participant will complete the Usability Questionnaire and a Label Comprehension Questionnaire. Rating sale includes: Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree. These will be collated and data analyzed as per statistical analysis.

The Usability Questionnaire and a Label Comprehension Questionnaire please refer to attachment 2.

Step 5: The study participant is encouraged to write any comments on the forms either at the question or in the Comments section at the end of the questionnaire.

Once the participant has completed the usability and label comprehension forms the study staff will ask the following questions:

1. Did you have any difficulty using the product? If the answer is yes have participant explain the difficulties.

2. Did you have any difficulty understanding the instruction of use? If the answer is yes have participant explain the difficulties.

Study participant's comments will be recorded on the Study staff Observation Form.

4. Data Analysis

a) Calculate percent of successfully completion of each mandatory tasks by each age group as observed by the Study Staff.

b) Calculate percent of Strongly Agree/Agree of each task by each age group by Usability Questionnaire

c) Calculate percent of Strongly Agree/Agree of each task by each age group by Label Comprehension Questionnaire

5. Acceptance Criteria

a) At least 90% successfully completion of each mandatory tasks by each age group as observed by the Study Staff.

b) At least 90% Strongly Agree/Agree of each task by each age group by Usability Questionnaire
c) At least 90% Strongly Agree/Agree of each task by each age group by Label Comprehension Questionnaire

6. Attachment

Attachment 1 - Study Staff Observation Form.
Attachment 2 - Usability Questionnaire and Label Comprehension Questionnaire.
Attachment 3 - Enrollment Log.

Company Name	Shenzhen Homed Medical Device Co., Ltd.	Document No.: HOMED2101-CE-003A-02
		Version: 1.0
		Page: Total 16 Page 1

Project Name:

COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold)

Document Name:

Usability Engineering File

According to EN 62366-1:2015

Drafted by: 5.1.2e	Checked by: 5.1.2e	Approved by: 5.1.2e
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1. Objective

This self-testing usability and label comprehension of the COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) is to ensure that the users can correctly operate the product. The evaluated product COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold), which is an *in vitro* diagnostic device. Product specification and package information are listed in below table.

Table 1. Product specification and package information

Specification / Component	1 test/kit	5 tests/kit	25 tests/kit
Test Cassette	1	5	25
sample tube with extraction reagent	1×0.5 mL	6×0.5 mL	25×0.5 mL
Saliva Swab	1	5	25
Instruction for use	1	1	1

2. Product description

2.1 General information

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

The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection. The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.

2.2 Principle of the test

The COVID-19 Nucleocapsid Antigen Test Kit is a rapid lateral flow immuno-chromatographic sandwich assay to directly detect nucleocapsid protein of COVID-19 Nucleocapsid in saliva swab and diagnosis of COVID-19 Nucleocapsid infection.

The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is added into the Test Cassette sample well. And the sample migrates through a test strip, if the COVID-19 Nucleocapsid virus antigen is present, a red color line will be showed on the T line. If COVID-19 Nucleocapsid viral antigen is absent, there is not a red line will be showed on the T line, however, a red line will be always showed on the C line indicating that the reaction system is properly happened.

2.3 Product specifications and packages

See Table 1.

3. Device USE SPECIFICATION

3.1 Purpose

3.1.1 Intended use

The COVID-19 Nucleocapsid Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from COVID-19 Nucleocapsid in saliva swab. This product is for self-testing only.

4. Precautions

1) For *in vitro* diagnostic use only.
2) Please read this manual carefully prior to using this test kit. And follow the testing procedures strictly described in the manual, otherwise it will lead to incorrect results.
3) Do not use expired reagents.
4) Do not re-use the test kit.
5) All samples, used reagents, test cards, and other materials used during testing are considered to be infectious, and personal protection should be done during the experiment.
6) Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wear suitable protective clothing and eye/face protection when handling the contents of this kit.
7) Sample handling and waste disposal must comply with relevant regulations. Wash hands thoroughly after handling.
8) Avoid using visually bloody or overly viscous samples for testing.
9) Do not use components from different batch lots.
10) The sample tube contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.

5. Storage and stability

1) The test device is sensitive to humidity as well as to heat.
2) Store kit components at 2-30°C, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.
3) After unsealing the aluminum foil bag, the test cassette should be used as soon as possible within Two hours.
4) Do not freeze.

6. Limitations

1) This test is for *in vitro* diagnostic use only.
2) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
3) Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4) Test results must be evaluated in conjunction with other clinical data available to the physician.
5) This test cannot distinguish between asymptomatic carriers and infected persons of the

COVID-19 Nucleocapsid.

6) A false negative result may be obtained if the concentration of the viral antigen in the saliva swab is below the sensitivity.
7) Negative results should be treated as presumptive and confirmed with an approved molecular assay.
8) Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.

3.2 Patient Population

a) Age: not relevant
b) Gender: not relevant
c) Weight: not relevant
d) Health: not relevant
e) Nationality: multiple
f) Patient state:
   - Patient is the Operator: able to read instruction of use; People without visual impairment;
   - Patient is not the Operator: unable to read instruction of use; with visual impairment;

3.3 Part of the body or the type of tissue applied to or interacted with

The saliva swab will be contacted with people's inner oral wall and sublingual area.

3.4 Intended User (User profile)

Laypersons.

a) Education: not relevant
b) Knowledge:
   - Able to read and understand instruction of use
   - No maximum
c) Language understanding:
   - Understand the language provided in the IFU
d) Experience: no special experience needed

3.5 Application

a) Environment:
   - Home use, not intended for professional use
b) Conditions of visibility:
   - Viewing distance: 20cm to 40cm
c) Physical:
   - Room temperature
   - Relative humidity range: not relevant
d) Frequency of use:
   - Single use.
e) Mobility:
   - Portable. After use, the device should be discarded.
f) Use place:
   - Home setting.

4. Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

4.1 Primary operating function

a) Use saliva swabs to collect sample from inner oral wall and sublingual area.

b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.

c) Press the sample tube to release the antigen in the swab and take out the swab.

d) Unscrew the dropper cap of the sample tube.

e) Add two drops of the extraction sample into the sample well

f) Read the result within 15 minutes.

g) Interpret test result.

4.2 User interface related to the device

No.	User interface		Related to SAFETY or not?	Potential USE ERRORs
1.	Accompanying documentation	Label	Yes	Misreading, wrong reading,
2.		IFU	Yes	Misreading, wrong reading, incorrect operation methods/wrong operation
3.	Test cassette		Yes	Misreading test line;
4.	Sample tube with extraction reagent		Yes	Incorrectly prepare sample
5.	Saliva Swab		Yes	Incorrectly collect samples

4.3 Possible Use errors

Sources: Literature, Complaint file, Adverse Event of similar devices, Risk Analysis, etc.

a) During normal use:
- Breaking of the device;
- Solution leakage;
- Head of Swab fall off

b) Use errors:
- Reuse the device which had been used;
- Cross use the device;
- Use the device with damaged package;
- Process the device not according to the Step-by-Step instructions;
- Improper operation methods;
- Wrong sampling of Swab;
- Wrong storage environment;
- Solution contacts the skin or eye;

c) Environment:
- Used in the outdoor;
- Incorrect storage environment;

d) Patient
- Operated the device by patient with unable read the IFU or with visual impairment

e) Reading:
- Misread the product label & IFU;
- Misread the test line;
- Misread the saliva volume;

f) Hygiene:
- Cross-contamination;
- Infection;

4.4 Hazardous situations and harms

No.	Hazardous situations	Harms
1.	Patients exposed to polluted products	Infection
2.	Breaking of the swab	Solution leakage, injury the patient
3.	Patients are inserted with reused products	infection
4.	Use confuse of models	failure of sampling, delay the diagnosis
5.	Improper invert times	invalid lysis
6.	Use the expired Tube reagent Solution	sampling failure; delay the diagnosis
7.	Use the expired Swab	Maybe result in contamination or infection
8.	Incorrect storage (low temperature)	Result in frozen, delay the sampling, diagnosis
9.	Incorrect disposal the used device	Contaminate the environment
10.	Reuse the Swab	Contamination or infection
11.	Reuse the tube	delay the sampling, diagnosis
12.	Wrong symbol in the label	Result in use error; delay the sampling
13.	Wrong operating steps	Result in use error; delay the sampling
14.	Incorrect dropping	Incorrect test results
15.	Fail to close the cap	Leakage, delay the diagnosis

4.5 User interface specification

a) Select materials for the swabs, tubes according to standards;
b) Correct labels and information of the devices;
c) Provide "Instruction for use" to the Users;
d) Clear and correct symbol on the label;
e) Provide the detailed Step-by-Step instructions for operation;
f) Sampling diagram of the devices should be clearly shown in IFU;
g) Demonstrate the important information about application of the devices in IFU such as "Warnings, Precautions" and so on;
h) No leakage design;
i) Readable/legible mark;

4.6 Preliminary User interface evaluation

Note: This review could be conducted utilizing a combination of cognitive walkthroughs, mock-up testing and early prototype testing.

a) Use saliva swabs to collect sample from inner oral wall and sublingual area.
- Follow the procedures according to related IFU;
- Easy to sample;
- The head of swab will not drop off;

Conclusion: No problem.

b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to insert the swab into the tube;

Conclusion: No problem.

c) Press the sample tube to release the antigen in the swab and take out the swab.
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to operation;

Conclusion: No problem.

d) Unscrew the dropper cap of the sample tube.
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to operation;

Conclusion: No problem.

e) Add two drops of the extraction sample into the sample well
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to operate the dropper;

Conclusion: No problem.

f) Read the result within 15 minutes.
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to follow.

Conclusion: No problem.

g) Interpret test result.
- Follow the procedures according to related IFU;
- The detailed operation steps described in the IFU;
- Easy to identify the test line;
- The mark is showed very clearly;

Conclusion: No problem.

5 Usability specification

5.1 General

a) **Device**

COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold).

b) **Basis:**

- Intended use, see 3.1.1
- Possible use error, see 4.2.2, 4.2.3
- Hazardous situation or harms related to use, see 4.2.5
- Context of use
  - Background noise from the outdoor
  - At home, room temperature
- Preliminary use scenarios
  - Open the bag, take out the swab
  - Open the aluminum foil bag, put the test cassette on the bench
  - Place the swab into the mouth, gently rotate the swab several times when remove it on the surface of inner oral wall and sublingual area.
  - Place the swab into the sample tube, rotate the swab for about 10s
  - Press the sample tube to release the antigen in the swab and take out the swab.
  - Unscrew the dropper cap of the sample tube, add two drops of the extraction sample into the sample well and start the timer
  - Read the results within 15minutes.

5.2 Use scenarios

The COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold) is an *in vitro* diagnostic device. The device is used in the home setting, not intended for professional use.

The user must can read the instructions for use, and understand how to operate it, user with visual impairment need to use it with the help of others.

Worst case use scenarios to provide a basis for validation with users:

5.2.1 Scenarios 1:

At home, room temperature

Procedure:

a) Use swabs to collect saliva sample from inner oral wall and sublingual area.
b) Place the swab into the sample tube that has been pre-filled with 0.5 mL sample buffer, rotate the swab for about 10 seconds.
c) Press the sample tube to release the antigen in the swab and take out the swab.
d) Install the dropper cap onto the sample tube.
e) Add two drops of the extraction sample into the sample well
f) Read the result within 15 minutes.
g) Interpret test result.

Before clinical use, the user should thoroughly understand all aspects of the sampling procedure and limitations of the device. Knowledge of sampling techniques and *in vitro* diagnosis management are other considerations essential to a successful diagnosis outcome. Consult the device literature for information regarding proper sampling and diagnosis techniques, precautions, and potential adverse effects associated with the sampling.

5.3 User interface requirements for the primary operating functions

The labels and markings of the devices such as Type, Specification are provided to the users.

a) Swabs

- Easy to hold
- Comfortable head of swab

- Appropriate length for sampling swab

b) Sample tube
   - Easy to hold
   - Easy to cover the cap, and tighten it
   - Extraction sample well drop out of tube

c) Test cassette
   - Clear mark to identify

d) IFU
   - Easy to understand
   - Appropriate font size
   - Clear and comprehensive schematic diagram

e) Label
   - Correct icon
   - Adequate label information

5.4 User interface requirements for those Use scenarios that are frequent or related to safety

a) The whole procedure shall be easy to do after reading the IFU. Product Name, Performance structure, Indications, Precautions, Potential adverse reaction, Contraindications, Operation methods, Storage and transportation, Explanation of symbols

b) Text: The expected user's language font size is 9-20pt.

c) Symbols proven to be intuitive for intended USERS.

d) Readable/legible mark in the label.

e) Clear Sampling diagram showed in the Procedure card.

5.5 Requirements for determining whether primary operating functions are easily recognizable by User

a) Labels and markings of the devices:
   - The correct type and specification of the device;

b) IFU of the devices:
   - Principles, Precautions, Operations, Storage, Samplings, etc.

6. Usability Formative Evaluation

6.1 Formative evaluation protocol

To conduct the usability formative evaluation, we conducted the usability tests, which is the most commonly used methods. The usability test involves observing representative users while they perform specific tasks with medical device. We also released the usability questionnaire and label comprehension questionnaire to ask the representative users to finish the questionnaire investigation.

We used a small sample of test participants representing the entire User population. Many usability specialists recommend small sample sizes (e.g., 5-8) when conducting Formative Evaluations because it is usually sufficient to uncover major User Interface design issues. So, we enrolled at least five participants of each representative user group for the usability test for three user group.

A separate usability formative evaluation protocol was established, for the detailed formative evaluation protocol, please refer to:

Folder: Formative evaluation\formative evaluation protocol

HOMED2101-CE-003A v1.0 Usability formative evaluation protocol.

1) HOMED2101-CE-003A-01 attachment 1 - study staff observation form
2) HOMED2101-CE-003A-01 attachment 2 - usability questionnaire and label comprehension questionnaire
3) HOMED2101-CE-003A-01 attachment 3 - Enrollment Log

6.2 Formative evaluation report

6.2.1 Formative usability test and questionnaire investigation results

The formative usability test and questionnaire investigation have been conducted according to the usability formative evaluation protocol.

For the enrollment logs, Formative usability test records and questionnaire investigation results are listed below:

1) 1.attachment 1 - study staff observation form---Children and Adolescent
2) 1.Usability Questionnaire and Enrollment Log---Children and Adolescent
3) 2.attachment 1 - study staff observation form---Adult ages from 18-60
4) 2.Usability Questionnaire and Enrollment Log---Adult ages from 18-60
5) 3.attachment 1 - study staff observation form---over 60
6) 3.Usability Questionnaire and Enrollment Log---over 60

The detailed records are located in the **Folder: Formative evaluation\formative evaluation record**

6.2.2 Data analysis

a) Study staff observation-Successfully completion of each mandatory tasks

User Group	Number of participants	Successfully completion	Completion rate	Acceptance criteria	Verdict
Children and Adolescent	5	5	100%	≥90%	Pass
Adult ages from 18-60	8	8	100%	≥90%	Pass
Adult ages over 60	6	6	100%	≥90%	Pass

Total 19 participants performed the usability test, among them, sixteen participants finished successfully the test by himself, and another 3 participants listed below:

1) In the children and adolescent user group, one participant need help from his parent to use the swab, because he is too young, had difficulty in reading the instructions. Children and adolescents will use this product with their parent's assistance.
2) In the over 60 user group, one participant had little difficulty in dropping sample into loading hole because of some brain disease, but she finished the test correctly.
3) In the over 60 user group, one participant had a little bit of visual impairment, so he needs to wear glasses to recognize lines for use. He finished the test successfully.

No use error observed.

b) Usability questionnaire

User Group	Number of participants	Strongly agree/agree (Total)	Strongly agree/agree (result)		Rate	Acceptance criteria	Verdict
Children and Adolescent	6	5*5=25	23	7	100%	≥90%	Pass
Adult ages from 18-60	7	8*5=40	28	7	100%	≥90%	Pass
Adult ages over 60	8	6*5=30	23	17	100%	≥90%	Pass

The rate of total Strongly agree/agree of each age group are 100%, according to acceptance criteria in the formative evaluation protocol: *At least 90% Strongly Agree/Agree of each task by each age group by Usability Questionnaire.* The usability questionnaire investigation results are positive.

c) Label comprehension questionnaire

User Group	Number of participants	Strongly agree/agree (Total)	Strongly agree/agree (result)		Rate	Acceptance criteria	Verdict
Children and Adolescent	6	5*5=25	28	8	100%	≥90%	Pass
Adult ages from 18-60	7	8*5=40	38	4	100%	≥90%	Pass
Adult ages over 60	8	6*5=30	33	15	100%	≥90%	Pass

The label comprehension questionnaire investigation has been performed, total 21 participants attend the investigation, the rate of total Strongly agree/agree of each age group are 100%, according to acceptance criteria in the formative evaluation protocol: *At least 90% Strongly Agree/Agree of each task by each age group by Label Comprehension Questionnaire*, The Label Comprehension Questionnaire investigation results are positive.

6.2.3 Conclusion of Formative evaluation

Through the usability formative test and questionnaire investigation, according to above data analysis, all the usability goals have arrived and all use-related risks have been adequately controlled, the user interface and Primary operating function can meet the user requirements. The medical device can be ready to proceed to Summative evaluation.

7. Usability Summative Evaluation

The purpose of Summative Evaluation is to evaluate the usability of the user interface as it relates to the successful completion of the tasks associated with the hazard-related use scenarios.

7.1 Summative evaluation protocol

To conduct the usability summative evaluation, we conducted the usability tests, which is the most commonly used methods. The usability test involves observing representative users while

they perform specific tasks with medical device. We also released the usability questionnaire and label comprehension questionnaire to ask the representative users to finish the questionnaire investigation.

We used a large sample of test participants representing the entire User population. According to the methodology of Annex K of IEC 62366-2:2016, assuming for a USER GROUP that a USE ERROR occurs with a probability of 15 % for a single test participant, this USE ERROR would be observed with a probability of 98 % when the sample size is 25 test participants. So, we determined to enroll at least thirty participants of each representative user group for the usability test, total 105 participants for three user group.

A separate usability Summative evaluation protocol was established, for the detailed Summative evaluation protocol, please refer to:

Folder: Summative evaluation\Summative evaluation protocol

HOMED2101-CE-003A v1.0 Usability Summative evaluation protocol.

1) HOMED2101-CE-003A-01 attachment 1 - study staff observation form
2) HOMED2101-CE-003A-01 attachment 2 - usability questionnaire and label comprehension questionnaire
3) HOMED2101-CE-003A-01 attachment 3 - Enrollment Log

7.2 Summative evaluation report

7.2.1 Summative usability test and questionnaire investigation results

The Summative usability test and questionnaire investigation have been conducted according to the usability Summative evaluation protocol.

For the enrollment logs, Summative usability test records and questionnaire investigation results are listed below:

1) 1.attachment 1 - study staff observation form---Children and Adolescent
2) 1.Usability Questionnaire and Enrollment Log---Children and Adolescent
3) 2.attachment 1 - study staff observation form---Adult ages from 18-60
4) 2.Usability Questionnaire and Enrollment Log---Adult ages from 18-60
5) 3.attachment 1 - study staff observation form---over 60
6) 3.Usability Questionnaire and Enrollment Log---over 60

The detailed records are located in the **Folder: Summative evaluation\Summative evaluation record**

7.2.2 Data analysis:

a) Study staff observation-Successfully completion of each mandatory tasks

User Group	Number of participants	Successfully completion	Completion rate	Acceptance criteria	Verdict
Children and Adolescent	33	33	100%	≥90%	Pass
Adult ages from 18-60	36	36	100%	≥90%	Pass
Adult ages over 60	36	36	100%	≥90%	Pass

All user groups, total 105 participants correctly performed the tasks successfully without assistance.

No use error observed.

According to acceptance criteria in the summative evaluation protocol: *At least 90% successfully completion of each mandatory task by each age group as observed by the Study Staff*, the usability test results are positive.

b) Usability questionnaire

The usability questionnaire investigation had been conducted; the investigation results are showed below table:

User Group	Number of participants	Strongly agree/agree (Total)	Strongly agree/agree (result)		Rate	Acceptance criteria	Verdict
Children and Adolescent	33	33*5=165	148	17	100%	≥90%	Pass
Adult ages from 18-60	36	36*5=180	149	31	100%	≥90%	Pass
Adult ages over 60	36	36*5=180	123	57	100%	≥90%	Pass

The rate of total Strongly agree/agree of each age group are 100%, according to acceptance criteria in the summative evaluation protocol: *At least 90% Strongly Agree/Agree of each task by each age group by Usability Questionnaire.* The usability questionnaire investigation results are positive.

c) Label comprehension questionnaire

User Group	Number of participants	Strongly agree/agree (Total)	Strongly agree/agree (result)		Rate	Acceptance criteria	Verdict
Children and Adolescent	33	33*5=165	152	46	100%	≥90%	Pass
Adult ages from 18-60	34	36*5=180	197	19	100%	≥90%	Pass
Adult ages over 60	33	36*5=180	158	58	100%	≥90%	Pass

The label comprehension questionnaire investigation has been performed, total 105 participants attend the investigation, the rate of total Strongly agree/agree of each age group are 100%, according to acceptance criteria in the summative evaluation protocol: At least 90% Strongly Agree/Agree of each task by each age group by Label Comprehension Questionnaire, The Label Comprehension Questionnaire investigation results are positive.

7.2.3 Summative evaluation conclusion:

Through the usability summative test, usability questionnaire investigation and label comprehension questionnaire investigation according to above data analysis, all the usability goals have arrived, and all use-related risks have been adequately controlled, the user interface and Primary operating function can meet the intended use of the medical device.

8. Usability Engineering Conclusion

This product follows EN 62366 above and has satisfied the acceptance criteria in the usability validation protocol, therefore, the usability related residue risks of this product are acceptable according to EN ISO 14971. The user interface design meets the requirements of operating specifications, meets the intended use and application.

9. Reference

1) EN 62366:2008 Medical devices -Application of usability engineering to medical devices
2) EN 62366-1:2015 Medical devices –Part 1: Application of usability engineering to medical devices
3) IEC TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
4) EN ISO 14971:2012 Medical devices — Application of risk management to medical devices
5) EN ISO 14971:2019 Medical devices — Application of risk management to medical devices
6) HOMED2101-CE-001A Instructions for Use

Company Name	Shenzhen Homed Medical Device Co., Ltd.	Document No.: HOMED2101-CE-003A-03 Version: Page: Total 20 Page 1

Project Name:

COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold)

Document Name:

Self-testing Usability Checklist

(according to IEC 62366)

Drafted by: 5.1.2e Date: 20200430	Checked by: 5.1.2e Date: 20200430	Approved by: 5.1.2e Date: 20200430

Summarized review comments:(another page could be attached if not enough)

Revision Records

Version	Summarized Revisions	Written by	Revised Date
V1.0	Initialization Version	5.1.2e	20210430

IEC 62366 Medical devices Application of usability engineering to medical devices	
Report Reference No. ..... :	Usability report
Date of issue…….. ……:	20210430
Total number of pages	20
CB Testing Laboratory ..... :	N/A
Address ..... :	N/A
Applicant's name ..... :	5.1.2e
Address ..... :	3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China
Test specification:	
Standard..... :	IEC 62366-1:2015
Test procedure ..... :	CB
Non-standard test method……..:	N/A

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description..... :	**COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold)**
Trade Mark ..... :	
Manufacturer ..... :	Shenzhen Homed Medical Device Co., Ltd.
Model/Type reference..... :	2019N1
Ratings..... :	

Testing procedure and testing location:	
☐ **CB Testing Laboratory:** Testing location/ address.....:	N/A
☐ **Associated CB Test Laboratory:** Testing location/ address.....: Tested by (name + signature).....: Approved by (+ signature).....:	
☐ Testing procedure: TMP Tested by (name + signature).....: Approved by (+ signature).....: Testing location/ address.....:	N/A
☐ Testing procedure: WMT Tested by (name + signature).....: Witnessed by (+ signature) .....: Approved by (+ signature).....: Testing location/ address.....:	N/A
☐ Testing procedure: SMT Tested by (name + signature).....: Approved by (+ signature).....: Supervised by (+ signature) .....: Testing location/ address.....:	N/A
☐ Testing procedure: RMT Tested by (name + signature).....: Approved by (+ signature).....: Supervised by (+ signature) .....: Testing location/ address.....:	N/A

Summary of testing:	
Tests performed (name of test and test clause): All clause of standard.	**Testing location:** **Location 1: No. 23 Xinning Road, Xining, China** **Location 2: 3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China**
Summary of compliance with National Differences: List of countries addressed: N/A ☒ The product fulfils the requirements of IEC 62366-1:2015	
Copy of marking plate The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.	

Test item particulars ..... :			
Classification of installation and use……:	N/A		
Supply connection ……:			
Context of Use ……:			
Abbreviations used in the report:			
- Usability Engineering:	UE	- Risk analysis:	RA
- User interface:	UI	- Risk management:	RM
- Primary operating function:	POF		
Possible test case verdicts:			
- test case does not apply to the test object .....:	N/A		
- test object does meet the requirement.....:	Pass (P)		
- test object does not meet the requirement.....:	Fail (F)		
Testing:			
Date of receipt of test items……:	20210401		
Date(s) of performance of tests .....:	20210415		

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report, a point (coma) is used as the decimal separator.
List of test equipment must be kept on file and available for review.

This Test Report contains the general safety requirements as related to the usability of Medical Equipment.

Name and address of factory (ies) .....:

Manufacturer:

Shenzhen Homed Medical Device Co., Ltd.

3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China

General product information:

The COVID-19 Nucleocapsid Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from COVID-19 Nucleocapsid in nasopharyngeal (NP) swab, nasal (NS) swab, and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.
Results are for the identification of COVID-19 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical

signs and symptoms consistent with COVID-19.
This product is suitable for self-use only. People with visual impairment need to use it with the help of others. Sampling of persons under 15-year-old should be carried out under adult supervision. People over seventy years should be supported in the recruitment process.

4	**GENERAL REQUIREMENTS**		
4.1	General Requirements		P
4.1.1	USABILITY ENGINEERING PROCESS		P
	Has the MANUFACTURER established, documented and maintained a usability engineering process to provide Safety for the patient, user and others related to usability for the product?	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report HOMED2101-CE-004A V1.0 Performance Characteristics HOMED2101-CE-005A V1.0 Clinical Evaluation	P
	Does the process addressed user interactions with the medical device according to the accompanying document including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	HOMED2101-CE-001A V1.0 Instruction for Use	P
4.1.2	Residual risk		P
	Are residual risks associated with usability of the medical device presumed to be acceptable, unless there is objective evidence to the contrary and documented?	HOMED2101-CE-002A V1.0 Risk Management report	P
4.1.3	Information for Safety		P
	Manufacturer subject the information for safety used as a risk control to the usability engineering process (e.g., warnings or limitation of use in the accompanying documents, marking, etc.) in the use file and accompanying documents.	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report HOMED2101-CE-007A V1.0 Label Introduce for use	P
	Disregarding such information for safety is considered beyond any further reasonable means of risk control	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
4.2	Usability Engineering File		P
	The results of the usability engineering process are recorded in the usability engineering file	HOMED2101-CE-002A V1.0 Risk Management report	P

	The records and other documents that make up the usability engineering file form part of other documents and files (e.g., a manufacturer's product design file or risk management file), (see List of documents make up the UE file)	SEE list of documents make up the UE file.	P
4.3	Tailoring of the USABILITY ENGINEERING effort		P
	The usability engineering process is scaled based on the significance of any modifications depending on the results of the risk analysis and documented	HOMED2101-CE-002A V1.0 Risk Management report	P

5	**USABILTY ENGINEERING PROCESS**		P
5.1	Application specification		P
	Application of medical device in the usability engineering file is specified by the manufacturer and includes	/	/
	– intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented);	HOMED2101-CE-001A V1.0 Instruction for Use: Intended Use	P
	– intended patient population (e.g., age, weight, health, condition);	HOMED2101-CE-001A V1.0 Instruction for Use: Intended Use	P
	– intended part of the body or type of tissue applied to or interacted with;	HOMED2101-CE-001A V1.0 Instruction for Use : Intended Use	P
	– intended conditions of use (e. g. environment including hygienic requirements, frequency of use, location, mobility); and	HOMED2101-CE-001A V1.0 Instruction for Use : Storage and Stability Limitaions	P
	– operating principle(s)	HOMED2101-CE-001A V1.0 Instruction for Use	P
5.2	Frequently used functions		P

	Are frequently used functions that involve user interaction with the medical device are determined and recorded in the usability engineering file?	HOMED2101-CE-001A V1.0 Instruction for Use: HOMED2101-CE-007A V1.0 Label Introduce for use	P
5.3	Identification of hazards and hazardous situations related to usability		P
5.3.1	Identification of characteristics to safety		P
	Identification of characteristics related to safety (part of a risk analysis) that focuses on usability performed according to ISO 14971:2012, 4.2.	HOMED2101-CE-002A V1.0 Risk Management report	P
	– application specification, including user profile(s); and –frequently used functions.	HOMED2101-CE-002A V1.0 Risk Management report	P
	Results of this identification characteristics related to safety recorded in the usability engineering file	HOMED2101-CE-002A V1.0 Risk Management report	P
5.3.2	Identification of known or foreseeable hazards and hazardous situations		P
	Manufacturer has identified known or foreseeable hazards (part of a risk analysis) related to usability according to ISO 14971:2009, 4.3.	HOMED2101-CE-002A V1.0 Risk Management report	P
	Identification of hazards considered hazards to patients, users and other persons	HOMED2101-CE-002A V1.0 Risk Management report	P
	Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a hazardous situation associated with the medical device were identified. the severity of the resulting possible harm is determined.	HOMED2101-CE-002A V1.0 Risk Management report	P

	During the identification of hazards and hazardous situations, the following was considered: – application specification, including user profile(s); – task related requirements; – context of use; – information on hazards and hazardous situations known for existing user interfaces of medical devices of a similar type, if available; – preliminary use scenarios; – possible use errors; – if an incorrect mental model of the operation of the medical device can cause a use error resulting in a hazardous situation;and – results of the review of the user interface The results of this identification of hazards, hazardous situations and severity are recorded in the usability engineering file.	HOMED2101-CE-002A V1.0 Risk Management report	P
5.4	Primary operating functions		P
	The manufacturer has determined the primary operating functions and recorded in the usability engineering file	HOMED2101-CE-001A V1.0 Instruction for Use ; Test Procedure	P
	The inputs to the primary operating functions include frequently used functions and functions related to safety of the medical device	HOMED2101-CE-001A V1.0 Instruction for Use ; Test Procedure HOMED2101-CE-002A V1.0 Risk Management report	P
5.5	Usability specification		P
	Manufacturer developed a usability specification recorded in the usability engineering file as part of the usability engineering process	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
	The usability specification recorded in usability engineering file. The usability specification may be integrated into other specifications	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P

	The usability specification includes: – application specification; – primary operating functions – hazards and hazardous situations related to the usability; and – known or foreseeable use errors associated with the medical device	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
	The usability specification describes at least:	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
	– use scenarios related to the primary operating functions equipment, including – frequent use scenarios, and – reasonably foreseeable worst case use scenarios;	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
	– user interface requirements for the primary operating functions equipment including those to mitigate risk;	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
	– requirements for determining whether primary operating functions are easily recognizable by the user.	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report	P
5.6	Usability validation plan		

	The manufacturer has developed and maintains a usability validation plan specifying:	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P
	– any method used for validation of the usability of the primary operating functions;	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P

	– the criteria for determining successful validation of the usability of the primary operating functions based on the usability specification; and	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P
	– the involvement of representative intended users	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P

	Usability validation performed in a laboratory setting	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P
	Usability validation performed in a simulated use environment	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist HOMED2101-CE-004A V1.0 Performance Characteristics	P

	Usability validation performed in the actual use environment	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist HOMED2101-CE-004A V1.0 Performance Characteristics HOMED2101-CE-005A V1.0 Clinical Evaluation	P

	The usability validation plan addresses: – frequent use scenarios, and – reasonably foreseeable worst case use scenarios That are identified in the usability specification	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist HOMED2101-CE-004A V1.0 Performance Characteristics HOMED2101-CE-005A V1.0 Clinical Evaluation	P
	The usability validation plan recorded in the usability engineering file	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol	P
5.7	User interface design and implementation		P
	Manufacturer designed and implemented the user interface as described in the usability specification utilizing, as appropriate, usability engineering methods and techniques	HOMED2101-CE-001A V1.0 Instruction for Use	P
5.8	Usability verification		P
	Manufacturer verified the implementation of the medical device user interface design according to the usability specification	HOMED2101-CE-004A V1.0 Performance Characteristics	
	The results of the verification are recorded in usability engineering file	HOMED2101-CE-004A V1.0 Performance Characteristics	P
5.9	Usability validation		P

	The manufacturer has validated the usability of the medical device according to the usability validation plan	HOMED2101-CE-005A V1.0 Clinical Evaluation	P
	The results are recorded in the usability engineering file	HOMED2101-CE-005A V1.0 Clinical Evaluation	P
	For the acceptance criteria documented in the usability validation plan that are not met: - further user interface design and implementation activities are performed; or - if further improvement is not practicable, the manufacturer may gather and review data And literature to determine if the medical benefits of the intended use outweigh the risk Arising from usability problems To perform this step, the manufacturer needs to estimate the risk arising from usability problems.	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-002A V1.0 Risk Management report HOMED2101-CE-005A V1.0 Clinical Evaluation	P
5.10	Questionnaire survey		P
	The manufacturer evaluates the usability of the product by obtaining feedback information from users after using the product through questionnaire survey.	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P

	The questionnaire includes age, gender, occupation, feedback in the process of product use and so on.	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P
	The manufacturer has collected the information obtained from the questionnaire survey and concluded that the product is suitable for people of different age（age 7-15, age 15-25, age 25-40, age 40-60, age 60-70 and elder than 70 years),education（primary school, high school, bachelor and master）, gender (female and male), occupation (driver, teacher, student, lawyer, accountant, officer, police, worker and so on),meets the needs of the product for self-use.	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist	P
6	Accompanying documents		P
	The accompanying document includes a summary of the medical device application specification	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-007A V1.0 Label Introduce for use	P
	A concise description of the medical device, its operating principles, significant physical and performance characteristics and intended user profile are included in the accompanying document	HOMED2101-CE-001A V1.0 Instruction for Use HOMED2101-CE-007A V1.0 Label Introduce for use	P

	The accompanying document is written at a level consistent with the intended operator profile	HOMED2101-CE-007A V1.0 Label Introduce for use	P
	The accompanying document is written at a level consistent with the intended operator profile	HOMED2101-CE-001A V1.0 Instruction for Use	P
	The accompanying document for equipment is, optionally, provided electronically	N/A, the accompanying documents for equipment aren't provided electronically.	N/A
	Usability engineering process includes the information that will need to be provided as a hard copy or as markings on medical device when accompanying documents are provided electronically	N/A, the accompanying documents for equipment aren't provided electronically	N/A
7	Training and materials for training		N/A
	The required training on the medical device for safe and effective use of primary operating functions by the intended user is given by:	N/A, the manufacturer does not provide training.	
	– necessary training materials provided by the manufacturer;	N/A, the manufacturer does not provide training.	
	– necessary training materials are available; or	N/A, the manufacturer does not provide training.	
	– the manufacturer provides training	N/A, the manufacturer does not provide training.	
	The accompanying document describes the available training options (recommendation: accompanying document include the suggested duration and frequency of such training)	N/A, the manufacturer does not provide training.	

List of documents make up the UE file

No.	Document title
1	HOMED2101-CE-001A V1.0 Instruction for Use
2	HOMED2101-CE-002A V1.0 Risk Management report
3	HOMED2101-CE-004A V1.0 Performance Characteristics
4	HOMED2101-CE-005A V1.0 Clinical Evaluation
5	HOMED2101-CE-007A V1.0 Label Introduce for use
6	HOMED2101-CE-003A-01 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability protocol
7	HOMED2101-CE-003A-02 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing Usability engineering file
8	HOMED2101-CE-003A-03 V1.0 COVID-19 Nucleocapsid antigen test kit self-testing usability checklist
supplementary information: N/A	