VivaChek™

Usability Study Report
for
VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test

Document No.: TF075-001

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Ver2.0

1. **Scope**

   This document provides a usability evaluation for VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test for self-testing.

2. **Intended Use**

   a. Description

      The qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab. It is for self-testing.

   b. Medical Purpose

      The device is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 as an initial screening test result.

   c. Condition or disease to be tested

      SARS-CoV-2

3. **Patient Profile**

   a. Age: 2 years of age and older.
   b. Weight: Not relevant
   c. Health: Without facial or head injury/ surgery in the last 6 months.
   d. Nationality: Multiple
   e. Patient state:
      i. Patient is 16 years and older and is the user: alert, mentally competent
      ii. Patient is 70 years and older and is assisted by an adult (18-69 years old): alert, mentally competent
      iii. Patient is 2-15 years and tested by an adult (18-69 years old), patient state is not relevant
      iv. The user should fully understand how to use the test device and have ability to perform the test. The user are without color- impaired vision.

4. **Part of the body or type of tissue applied to or interacted with**

   a. Measurement site
      i. Nostril

5. **Intended User**

   a. Education:
      i. No special education needed, but at least can read and understand how to use the test device
      ii. No maximum
   b. Knowledge
      i. Minimum:
         a. Read and understand the package insert
         b. Can locate appropriate sample collection site
         c. Understands hygiene

d. Understand how to use the test device

ii. No maximum

c. Language understanding:

i. languages used the intended USER' official language for the device.

d. Experience:

i. minimum:

1. no special experience needed

ii. No maximum

e. Permissible impairments:

i. Corrected vision (far/near-sighted or wear bifocals)

ii. Average degree of aging-related short term memory impairment

iii. Significant hearing loss up to 100%

6. Application

a. Environment

i. General:

1. home use, personal monitoring
2. professional use point of care office or laboratory

ii. Working conditions:

1. Ambient temperature range: 15°C to 30°C
2. Relative humidity range: 10%~90%

iii. Transportation and storage conditions:

1. Ambient temperature range: 2°C to 30°C
2. relative humidity range: 10% to 90%

7. Primary Operating Functions

a. Frequently Used Functions

i. Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

ii. Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube.

iii. Collect specimen: Open swab package at stick end and take swab out. Do not touch the swab head. Insert the sterile swab into one nostril. The swab tip should be inserted up to 1-1.5 cm from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

iv. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction

tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.

v. Put on the tube tip.

vi. Take out a test device from sealed foil pouch and put it on a clean and level surface.

vii. Apply 3 drops of the extracted specimen into the specimen well.

viii. Read the test result at 15 minutes. Don't read the result after 20 minutes.

b. Functions related to safety

i. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube

ii. Collect specimen

iii. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

iv. Put on the tube tip.

v. Take out a test device from sealed foil pouch and put it on a clean and level surface

vi. Apply 3 drops of the extracted specimen into the specimen well

vii. Read the test result

8. Risk Analysis

a. Intended Use

i. See Section 2 above

b. User Profile

i. See Section 3 above

c. Things that could go wrong

i. Sources: literature, complaint file, sales force, risk analysis, user study

1. Different lots of test device and extraction solution are mixed for use
2. Use old used test devices, extraction solution, extraction tubes, extraction tube tips, sterile swabs
3. Use test kit beyond the expiration date
4. The specimen is too viscous, slow down chromatography speed
5. Use damaged test device or material
6. Unsuitable storage temperature and/or relatively humidity
7. Use the test device when it has been exposed to household cleaning products (especially bleach)

ii. Environment:

1. Out of range of temperature
2. Out of range of humidity
3. Perform the test in direct sunlight

iii. Patient/user:
   1. User does not read the test result within 15-20 minutes, or invalid test result first and then test again
   2. Wrong site is used to collect specimen
   3. The sterile swab is inserted into only one nostril
   4. Failure to interpretation of test results
   5. Open the foil pouch of the test device exposing it to the ambient environment before the test device is ready for use
   6. User has color-impaired vision
   7. Open swab package at stick head and touch the swab head.

iv. Reading
   1. Misreading result from Control Line instead of Test Line
   2. Incorrect reading time (reading time: 15-20 minutes)

v. Application:
   1. Used for measuring anyone under 2 years of age

9. Task Requirements

a. See primary Operating Functions above, section 7

10. The context of use

a. See Section 6 above.

11. Information on hazardous situations known for existing similar device

a. Included in risk analysis

12. Resulting Hazardous situations and harms

a. False positive = cause that additional molecular test performed and wasted.
b. False negative = delayed treatment
c. Invalid test result = test time is extended

13. Review and summary of the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test user interface concept based on Frequently Used Functions

a. Allow the Test Devices and Extraction Solution to equilibrate to 59-86°F (15-30°C) prior to testing.
   i. All components are stored in the test kit, and easily equilibrated to 59-86°F (15-30°C)
   ii. Conclusion: No issues
b. Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube.
   i. Instructions with pictures are provided in the package insert for sites of breaking and squeezing

ii. Sealed pouch can be hold vertically to let all extraction solution flow into the bulb with one hand
iii. Tip is easily break in one hand and squeeze the bulb with the other
iv. Package insert describes with pictures how to let extraction solution into the extraction tube
v. Conclusion: No issues

c. Collect specimen: Insert the sterile swab into one nostril. Open swab package at stick end and take swab out. Do not touch the swab head. The swab tip should be inserted up to 1-1.5 cm from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).
    i. The opening position of the swab package is marked
    ii. Instructions with pictures are provided in the package insert for collecting anterior nasal swab specimen
    iii. Conclusion: No issues
d. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.
    i. Instructions with pictures are provided in the package insert for squeezing site.
    ii. Conclusion: No issues
e. Put on the tube tip.
    i. Package insert describes with pictures how to put on the tip
    ii. The tube tip is designed to be used with the tube and easily to put on
    iii. Required force is very light
    iv. Conclusion: No issues
f. Take out a test device from sealed foil pouch and put it on a clean and level surface.
    i. Sealed foil pouch is designed with notches and easily to open
    ii. Required force is very light
    iii. Clean and level surface is common and easily to obtain
    iv. Conclusion: No issues
g. Apply 3 drops of the extracted specimen into the specimen well.
    i. Instructions with pictures are provided in the package insert for applying extraction specimen
    ii. Required force is very light
    iii. Conclusion: No issues
h. Read the test result at 15 minutes. Don't read the result after 20 minutes
    i. Timer is required to perform test and users are easily to read the test result within 15-20 minutes

ii. Instructions with pictures are provided in the package insert for reading test result

iii. Interpretation of test results is described in the package insert

iv. Conclusion: No issues

14. Review and summary of the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test user interface concept based on Risk Analysis/Things that could go wrong

i. Sources: risk analysis, user study:

Risk analysis items are listed here for reference only, please see completed Risk Analysis for complete list of risks and mitigation activities. Items with detail below are not covered in risk analysis due to inherent low level of the residual risk or risks apply only to usability. These items are listed here for usability evaluation purposes.

1. Different lots of test device and extraction solution are mixed for use
    a. Lot number is printed on the foil pouch and the label affixed in the self-styled bag, the self-styled bag contains sealed pouches (prefilled with extraction solution)
    b. Conclusion: No issues
2. Use old used test devices, extraction solution, extraction tubes, extraction tube tips, sterile swabs
3. Use test kit beyond the expiration date
    a. Expiration date is printed on the foil pouch and the label affixed in the self-styled bag, the self-styled bag contains sealed pouches (prefilled with extraction solution)
    b. Conclusion: No issues
4. Use damaged test device or material
5. Unsuitable storage temperature and/or relatively humidity
6. Use the test device when it has been exposed to household cleaning products (especially bleach)

ii. Environment:

Items below without detail are listed here for reference only and are included in Risk Management. Please see Risk Management for complete list of risks and mitigation activities. These items are listed here for usability evaluation purposes.

1. Ambient temperature too high or too low
2. Exposure to water, humidity too high or too low humidity
3. Perform the test in direct sunlight

ii. Patient/user:

Items below without detail are listed here for reference only and are included in Risk Management. Please see Risk Management for complete list of risks and mitigation activities. These items are listed here for usability evaluation purposes.

1. User does not read the test result within 15-20 minutes, or invalid test result first and then test again
2. Wrong site is used to collect specimen
    a. Instructions with pictures are provided in the package insert for collecting anterior nasal swab specimen.
    b. Conclusion: No issues

3. The sterile swab is inserted into only one nostril.
    a. Instructions with pictures are provided in the package insert for collecting anterior nasal swab specimen.
    b. Conclusion: No issues
4. Failure to interpretation of test results
    a. Interpretation of test results is described in the package insert
    b. Conclusion: No issues
5. Open the foil pouch of the test device exposing it to the ambient environment before the test device is ready for use
6. User has color-impaired vision
7. Open swab package at stick head and touch the swab head.
    a. The opening position of the swab package is marked
    b. Conclusion: No issues

iii. Reading

1. Misreading result from Control Line instead of Test Line
    a. Interpretation of test results is described in the package insert
    b. Conclusion: No issues
2. Incorrect reading time (reading time: 15-20 minutes)
    a. Timer is required to perform test
    b. Conclusion: No issues

iv. Application:

1. Used for measuring anyone under 2 years of age
    a. Package inserts for test device indicate not to be used for anyone under 2 years of age
    b. Conclusion: Non-reducable minimum risk of user misuse. Acceptable

15. Usability Goals

Since clinical user studies have already been undertaken, Usability Goals have not been developed because actual results are available. Please refer to the report included in the User Study Report which includes surveys regarding usability questions from various users fitting the user profile above.

16. Usability Verification/Validation

All items requiring validation for Usability have been added to the Risk Management report, and are tracked as part of Risk Management. Please refer to Risk Management for further information.

17. Usability Validation Traceability

Since Usability specific items have been added to Risk Management, Traceability is provided within the Risk Management traceability matrix.

18. Reference

EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices

19. Application of usability engineering to medical devices

1	GENERAL REQUIREMENTS		
1.1	General Requirements		
1.1.1	Usability Engineering Process		
	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?	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert; Quality manual: QM0l,	Compliance
	Does the Process address user interactions with the medical device according to the accompanying document including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal?	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
1.1.2			
	Are Residual Risks associated with Usability of the medical Device presumed to be acceptable, unless there is objective evidence to the contrary and documented?	TF075-004 Risk Management Report;	Compliance
1.1.3			
	Manufacturer shall 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.).	TF075-004 Risk Management Report; Instruction For Use: VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	Disregarding such information for safety is considered beyond any further reasonable means of risk control	TF075-004 Risk Management Report;	Compliance
1.2			
	The results of the usability engineering process are recorded in the usability engineering file	Quality manual: QM0l;	Compliance
	The records and other documents that make up the usability engineering file may form part of other documents and files (e.g., a manufacturer's product design file or risk management file)	Quality manual: QM0l;	Compliance
1.3	Scaling of the Usability Engineering effort		

	The usability engineering process is scaled based on the significance of any modifications depending on the results of the risk analysis and documented	TF075-004 Risk Management Report;	Compliance
2	USABILTY ENGINEERING PROCESS		
2.1	Application specification		
	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, diagnostrild, or prevented);	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– intended patient population (e.g., age, weight, health, condition);	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– intended part of the body or type of tissue applied to or interacted with;	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– intended conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); and	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– operating principle(s)	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
2.2	Identification of hazards and hazardous situations related to usability		
2.2.1	Identification of characteristics to safety		
	Identification of characteristics related to safety (part of a risk analysis) that focuses on usability performed according to ISO 14971:2012, 4.2.	TF075-004 Risk Management Report;	Compliance

	During the identification characteristics related to safety, the following are considered: – application specification, including user profile(s); and –frequently used functions.	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	Results of this identification characteristics related to safety recorded in the usability engineering file	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
2.2.2	Identification of known or foreseeable hazards and hazardous situations		
	Manufacturer has identified known or foreseeable hazards (part of a risk analysis) related to usability according to ISO 14971:2012, 4.3.	TF075-004 Risk Management Report;	Compliance
	Identification of hazards considered hazards to patients, users and other persons	TF075-004 Risk Management Report;	Compliance
	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.	TF075-004 Risk Management Report;	Compliance

	During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered: – application specification, including user rofile(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	TF075-004 Risk Management Report; Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY are recorded in the USABILITY ENGINEERING FILE.	TF075-004 Risk Management Report;	Compliance
2.3	Primary operating functions		
	The manufacturer has determined the primary operating functions and recorded in the usability engineering file	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The inputs to the primary operating functions include frequently used functions and functions related to Safety of the Medical Device	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
2.4	Usability Specification		
	manufacturer developed a usability specification recorded in the usability engineering file as part of the usability engineering process	Quality manual: QM0I;	Compliance

	The usability specification recorded in usability engineering file. The usability specification may be integrated into other specifications	Quality manual: QM0l;	Compliance
	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	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert; TF075-004 Risk Management Report;	Compliance
	The usability specification describes at least:		
	– use scenarios related to the primary operating functions, including – frequent Use Scenarios, and – reasonably foreseeable worst case Use Scenarios;	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert; TF075-004 Risk Management Report;	Compliance
	– User Interface requirements for the primary operating functions, including those to mitigate Risk;	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– Requirements for determining whether primary operating functions are easily recognizable by the User.	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
2.5	Usability validation plan		
	The manufacturer has developed and maintains a usability validation plan specifying:	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– any method used for validation of the usability of the primary operating functions;	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance

	– the criteria for determining successful validation of the usability of the primary operating functions based on the usability specification; and	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– the involvement of representative intended users	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The usability validation plan addresses: – frequent Use Scenarios, and – reasonably foreseeable worst case use scenarios that are identified in the usability specification	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The usability validation plan recorded in the usability engineering file	TF075-001 Usability Analysis report	Compliance
2.6	User interface design and implementation		
	Manufacturer designed and implemented the user interface as described in the usability Specification utilizing, as appropriate, usability engineering methods and techniques	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
2.7	Usability verification		
	Manufacturer verified the implementation of the Medical Device User interface design according to the usability specification	Design input	Compliance
	The results of the verification are recorded in usability engineering file	TF075-001 Usability Analysis report	Compliance
2.8	Usability Validation		
	The manufacturer has validated the Usability of the Medical Device according to the usability validation plan	Design input	Compliance
	The results are recorded in the usability engineering file	TF075-001 Usability Analysis report	Compliance

	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.	Design input; TF075-004 Risk Management Report;	Compliance
3	Accompanying documents		
	The Accompanying document includes a summary of the Medical Device application specification	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	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	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The Accompanying document is written at a level consistent with the intended operator profile	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	The Accompanying document for equipment are, optionally, provided electronically	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	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	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
4	training and materials for training		
	The required training on the medical device for safe and effective use of primary operating functions by the intended User is given by:	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance

	– necessary training materials provided by the manufacturer;	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	– necessary training materials are available; or	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance
	Intended use and user profile(s) are the basis for training and training material	Instruction For Use：VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test Package Insert;	Compliance

Usability Validation Plan

1. **General**
   - **Device**

     VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test
   - **Description**

     VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab. The test is for in vitro diagnostic use only. It provides only an initial screening test result. More specific alternative diagnosis methods (molecular diagnostic and / or CT) should be performed in order to obtain the confirmation of SARS-CoV-2 infection. For self-testing use.

     VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is based on immunoassay technology. Each test device has one line of anti-SARS-CoV-2 monoclonal antibody on the detection line (T line) and one line of anti-mouse IgG polyclonal antibody on the quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-SARS-CoV-2 monoclonal antibody on the detection line. If the specimen contains SARS-CoV-2 antigen, the detection line will appear purplish-red indicating the SARS-CoV-2 antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear purplish-red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

2. **Intended User**
   - **Education:**
     - No special education needed, but at least can read and understand how to use the test device.
     - No maximum
   - **Knowledge:**
     - Minimum:

       Can read and understand the package insert;

       Can locate appropriate sample collection site;

       Understands hygiene;

       Understand how to use the test device;
     - No maximum
   - **Language understanding:**
     - languages used the intended USER' official language for the device;
   - **Experience:**
     - minimum: no special experience needed
     - no maximum
3. **Patient Population**
   - **The patient is/isn't the user**

- **Age:** recommended for patient over 2 years old;
- **Weight:** Not relevant;
- **Health:** Without facial or head injury/ surgery in the last 6 months.
- **Nationality:** multiple
- **PATIENT state:**
  - Patient is 16-69 years and is the user: alert, mentally competent
  - Patient is 70 years and older and is assisted by an adult (18-69 years old): alert, mentally competent
  - Patient is 2-15 years and tested by an adult (18-69 years old), patient state is not relevant
  - The user should fully understand how to use the test device and have ability to perform the test. The user are without color- impaired vision.

4. Application Environment

- **General:**
  - home use, personal monitoring
  - professional use point of care office or laboratory
- **Working conditions:**
  - Ambient temperature range: 15°C to 30°C
  - Relative humidity range: 10%~90%
- **Transportation and storage conditions:**
  - Ambient temperature range: 2°C to 30°C
  - Relative humidity range: 10%~90%

5. Primary Operating Functions for Validation

Sample collection:

- Wash hands with soap and water or use hand sanitizer;
- Open swab package at stick end. Do not touch the swab head or remove the swab until ready for sample collection
- Collect specimen: Open swab package at stick end and take swab out. Do not touch the swab head. Insert the sterile swab into one nostril. The swab tip should be inserted up to 1-1.5 cm from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

Use the test device:

- Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing;
- Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube.
- Collect specimen;
- Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.
- Put on the tube tip.
- Take out a test device from sealed foil pouch and put it on a clean and level surface
- Apply 3 drops of the extracted specimen into the specimen well.

Result reading:

- Read the test result at 15 minutes. Don't read the result after 20 minutes.

Result interpretation:

- Positive result
  - There is currently a suspicion of a COVID-19 infection
  - Immediately contact your doctor/family doctor or the local health department
  - Follow local guidelines for self-isolation
  - Have a confirmatory PCR test performed
- Negative result
  - Continue to follow all applicable rules regarding contact with others and protective measures.
  - An infection can also be present if the test is negative
  - In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection.
- Invalid result
  - Possibly caused by incorrect testing.
  - Repeat the test
  - If the test results are still invalid, contact a doctor or a COVID-19 test center

6. Method for Validation of the Usability of the Primary Operating Functions

- User

  The users are laymen and 16 years and older. They are with either good or corrected vision (far/near-sighted or wear bifocals) and without color-impaired vision. They fully understand how to use the test device and have ability to perform the test.

  Numbers: 100
- Patient

  The patients are divided into two groups: 1) patients are 16-69 years and older and are the user; 2) patients are 2-15 years and tested by an adult (18-69 years old); 3) patients are 70 years and older and assisted by an adult (18-69 years old)

  Numbers (2-15 years): 21

  Numbers (16-69 years): 100

  Numbers (16-69 years): 9
- Environment

  In the R&D laboratory of VivaChek Biotech (Hangzhou) Co., Ltd. and according with test device's requirements for temperature, humidity.
- Method

  Choose 130 patients, and 21 are aged 2-15 years, 100 are aged 16-69 years, 9 are aged 16-69 years and older. 21 patients aged 2-15 years are tested by their guardians, 9 patients aged 70 years and older are assisted by their guardians and the other 100 patients are self-tested. The 130 users are laymen,

every user will read the package insert and perform the test procedures for the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test, including anterior nasal swab specimen collection, test operation, result reading and interpreting. A timer will be provided. The procedures will be observed by a study observer, without answering questions or providing corrections except in the case of a medical emergency.

After completing the tests, the users will be asked to read and interpret a panel of 9 different VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test results, including high positive, mild positive, low positive, negative and invalid results.

Then the users will be provided with a questionnaire regarding their experience using the VivaDiag™ ProSARS-CoV-2 Ag Rapid Test and asked to fill it out completely.

The study observer, with knowledge of the test procedure, observe the whole testing procedure and answer the questions on the observe check list to assess whether the user complete the test correctly.

- Evaluating method:

  There are 5 ranges for every index.

  5: the performance is excellent.

  4: the performance is good.

  3: the performance is ordinary.

  2: the performance is bad.

  1: the performance is unacceptable

- Criteria for determining successful validation of the USABILITY of the PRIMARY

  Calculation of results: Each answer got 1- 5 points (5 = excellent; 1 = unacceptable). Total points per question have been added and total performance was calculated in %. Each section required an 80% pass rate to be considered acceptable (refer to <Usability Engineering Plan> for details).

7. Usability Validation Record table template

- Observer Check List and Questionnair

If the patient is the user? ☐ **Yes** ☐ **No**

Patient Number:_____ **Users Number:** _____

Item	Test steps	Yes/No	Observer Notes
Sample collection	Wash hands with soap and water or use hand sanitizer		
	Open swab package at stick end. Do not touch the swab head or remove the swab until ready for sample collection		
	Collect specimen: Open swab package at stick end and take swab out. Do not touch the swab head. Insert the sterile swab into one nostril. The swab tip should be inserted up to 1-1.5 cm from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).		
	Did the user secure and prepare a timing device?		
Use the test device	Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing		
	Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube		

	Collect specimen		
	Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.		
	Put on the tube tip		
	Take out a test device from sealed foil pouch and put it on a clean and level surface		
	Apply 3 drops of the extracted specimen into the specimen well.		
Result reading	Read the test result at 15 minutes. Don't read the result after 20 minutes.		

- Results Reading and Interpretation Questionnair

Users Number: _____

1 Record of the Panel of 9 Different Test Results

Read the Panel of 9 Different Test Results in the pictures put on desk. Write your results in the table below.

Picture Number	Reading result (P=positive, N=negative, I=invalid)
1	
2	
3	
4	
5	
6	
7	
8	
9	

2 Result interpretation (multiple choice):

Positive :_____ Negative: _____ Invalid: _____

A. Possibly caused by incorrect testing

B. If the test results are still invalid, contact a doctor or a COVID-19 test center

C. Continue to follow all applicable rules regarding contact with others and protective measures

D. Repeat the test

E. Immediately contact your doctor/family doctor or the local health department

F. There is currently a suspicion of a COVID-19 infection

G. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection

H. Follow local guidelines for self-isolation

I. Have a confirmatory PCR test performed

J. An infection can also be present if the test is negative

- User Questionnair

If the patient is the user? ☐ Yes ☐ No							
Patient Number		**Patient Gender**		**Patient Age**		**Patient Education**	
User Number		**User Gender**		**User Age**		**User Education**	
Item			5	4	3	2	1
			Excellent	**Good**	**Ordinary**	**Bad**	**Unacceptable**
Instructions of use – Package insert							
Text: Comprehensibility & Simplicity& Sufficient							
Graphic instructions, picture guide: Comprehensibility & Simplicity& Sufficient							
Sample collection							
Swab is easy to obtain and use							
Collect Operation: Simple & Rapid							
After sampling, pain at the collection site is acceptable							
Use the test device							
Except timer, all components required for the test are provided							
User can easily perform the test per test procedures in package insert							
Expiration date and lot are printed on the foil pouch and box clearly							
All components in the test kit can be used conveniently							
All components have no burr or breakage, no injury to patient							
Result reading							
Know which is test line or control line							
The control line can be seen clearly							
Easy to read the result at 15-20 minutes							
Result interpretation							
Know clearly what should be done after negative, positive, invalid test result appear							

8. Results

130 lay users, including self-testing users (n=100), guardian users (n=21) and assisted users (n=9), participated in the study. The test results are valid and negative.

The self-testing user group completed 98.8% (1186/1200) of the total tasks/steps correctly. The guardian user group completed 98.0% (247/252) of the total tasks/steps correctly. The assisted user group completed 95.4% (103/108) of the total tasks/steps correctly. The most common use errors observed during tasks included contacting the test device or swab with the hands or with the surface.

The self-testing user group read 99.0% (891/900) of the test results correctly. The guardian user group read 98.9% (187/189) of the test results correctly. The assisted user group read 96.2% (77/81) of the test results correctly. The most common error appears in the low positive test result. 2 users made the wrong choice in the part of Result interpretation.

The usability validation questionnaire results are shown below.

Item No	5	4	3	2	1	Pass Rate
	Number					
(1)	128	2	0	0	0	648/650=99.7%
(2)	130	0	0	0	0	650/650=100%
(3)	120	7	3	0	0	637/650=98%
(4)	125	5	0	0	0	645/650=99.2%
(5)	115	9	6	0	0	629/650=96.8%
(6)	130	0	0	0	0	650/650=100%
(7)	127	3	0	0	0	647/650=99.5%
(8)	130	0	0	0	0	650/650=100%
(9)	129	1	0	0	0	649/650=99.8%
(10)	130	0	0	0	0	650/650=100%
(11)	130	0	0	0	0	650/650=100%
(12)	130	0	0	0	0	650/650=100%
(13)	130	0	0	0	0	650/650=100%
(14)	126	4	0	0	0	646/650=99.4%

9. Conclusion

98.5% users have the ability to collect sample and perform the test correctly. 100% users have the ability to deliver a valid result and obtain the correct result.

97.7% users have the ability to read the panel of 9 different VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test results correctly. False reading results appeared in low positive test result and the subjects are 70 years and older. 98.5% users know what actions should be taken for results interpretation.

Pass rate for each item on the questionnaire about ease of ease of device and instructions is all above 80%.

From the results above, the usability validation analysis and evaluation of the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test for self-testing purpose has passed.

In conclusion, the instructions given in the package insert are complete and have high simplicity; additionally, graphic instructions are given which enable a very fast and easy learning and test performance.

It is concluded that lay persons are able to perform the test without any issues.