VivaChek™

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

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Ver1.0

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: Not relevant
   d. Nationality: Multiple
   e. Patient state:
      i. Patient is 16 years and older and is the user: alert, mentally competent
      ii. Patient is 2-15 years and tested by an adult (18+ years old), patient state is not relevant

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. At least a secondary education, 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. No special requirements

d. Experience:

i. minimum:

1. no special experience needed

ii. No maximum

e. Permissible impairments:

i. Mild to moderate visual impairment

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
3. not for use in shower, bath tub or sink

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: Insert the sterile swab into one nostril. The swab tip should be inserted up to 1-1.5cm 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. Firmly squeeze the top bulb to empty the contents of pipette into the extraction tube with extraction solution. Extra liquid over in the overflow bulb should be left behind. Shake the tube 10 times.
    iv. Take out a test device from sealed foil pouch and put it on a clean and level surface
    v. Apply 3 drops of the extracted specimen into the specimen well
    vi. 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. 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
    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
    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 Section 9 above

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 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. The swab tip should be inserted up to 1-1.5cm 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. Instructions with pictures are provided in the package insert for collecting anterior nasal swab specimen
   ii. 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. The top bulb is easily squeezed to empty the contents of pipette
    iii. Extra liquid over in the overflow bulb is left behind to facilitate adding a suitable volume of specimen to the extraction solution.
    iv. User is easily to shake the tube slowly and gentle for 10 times.
    v. Required force is very light
    vi. 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. Instructions with pictures are provided in the package insert for read test result
    ii. Interpretation of test results is described in the package insert
    iii. Timer is required to perform test and users are easily to read the test result within 15-20 minutes
    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

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 Technical File titled The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test 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: QM0I;	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