CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number
CW250003

II. Parent Document Number
K251289

III. CLIA Waiver Type
Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant
Guangzhou Wondfo Biotech Co., Ltd.

V. Proprietary and Established Names
WELLlife COVID-19 Antigen Test Rx

VI. Measurand (analyte)
Nucleocapsid protein antigen from SARS-Coronavirus 2 (SARS-CoV-2)

VII. Sample Type(s)
Anterior nasal swab specimens

VIII. Type of Test
Qualitative lateral flow immunoassay

IX. Test System Description

A Overview

The WELLlife COVID-19 Antigen Test Rx is a lateral flow immunoassay intended for non-prescription home use for the qualitative detection of nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first five (5) days of symptom onset. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen.

Principle

A nasal swab sample is collected by the user and then inserted into the extraction buffer that disrupts the virus particles in the specimen to expose internal viral nucleocapsid antigens. The extracted specimen is then added into the sample well of the test cassette. When an adequate volume of the specimen is added to the sample well of the test cassette, the specimen migrates by capillary action from the sample well over the conjugated pad and across the nitrocellulose membrane test strip. During the migration, the reagents contained in the conjugated pad are solubilized. If SARS-CoV-2 nucleocapsid antigens are present in the sample, the antigens bind to the specific anti-SARS-CoV-2 antibody that is conjugated with dye particles. These antigen-

antibody complexes are captured by the anti-SARS-CoV-2 antibody immobilized at the test line region (T) to form sandwich complexes that generate a visible pink to purple test line. Unbound conjugate molecules continue to migrate across the nitrocellulose membrane and are captured at the control line region (C) to result in a visible colored control line that indicates adequate operations and sample flow during the test. If no SARS-CoV-2 nucleocapsid antigens are present in the sample, the conjugate will only be captured at the control line of the test.

Results are interpreted between 10 and 20 minutes after adding the extracted sample into the sample well. A false negative or false positive result may occur if the test result before 10 minutes or after 20 minutes.

External positive control and negative control swabs are sold separately from the WELLlife COVID-19 Antigen Test Rx and should be processed according to the external controls IFU at a frequency defined by that IFU. The control swabs are intended to be used as quality control samples representative of positive and negative test samples to demonstrate that the reagents are functional, and the assay procedure is performed correctly.

B Test System Components

The WELLlife COVID-19 Antigen Test Rx consists of components below:

- Test Cassette
- Tube (pre-filled extraction buffer)
- Swab (sterile)
- Tube Holder (located in kit box)
- Quick Reference Instructions (QRI)
- Instructions for Use (IFU)

X. Specific Contents for CLIA Waiver

A. Demonstrating "Simple":

The WELLlife COVID-19 Antigen Test Rx is designed to be simple and easy to use incorporating the following key features:

- The WELLlife COVID-19 Antigen Test Rx is a unitized, self-contained test and only requires sample incubation in the extraction buffer prior to sample application.
- The WELLlife COVID-19 Antigen Test Rx uses direct unprocessed anterior nasal swab specimens.
- An untrained operator can conduct the test by performing simple steps without sample manipulation:
    - Remove the swab from packaging and collect the anterior nasal sample
    - Insert the swab to the tube with extraction buffer, swirl the sample swab in the extraction buffer with 15 circles and incubate for 1 minute
    - Remove swab, screw the large blue cap onto the buffer tube, and then remove the small white cap
    - Use the buffer tube to apply 4 drops of the sample to the sample well of the cassette
    - Wait 10 minutes
    - Read the test results

No specialized equipment is needed for sample processing.

- The WELLlife COVID-19 Antigen Test Rx contains all pre-measured reagents in sealed, single-use vials. No measuring or processing of buffer is needed prior to combining the sample and the extraction buffer.
- The WELLlife COVID-19 Antigen Test Rx does not require any operator intervention during the analysis step. After application of 4 drops of the extracted sample to the test cassette, the test develops without user intervention for 10 minutes. Upon completion of the run time, the user interprets the test results by visual interpretation using the guidance provided in the Quick Reference Instructions (QRI) or Instruction for Use (IFU).
- The WELLlife COVID-19 Antigen Test Rx does not require any instrumentation or machinery, and therefore does not need any technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes.
- The WELLlife COVID-19 Antigen Test Rx does not require any electronic or mechanical maintenance.
- The WELLlife COVID-19 Antigen Test Rx does not require any operator calibration or calculation to interpret results. Operator visual interpretation of test results is required.
- The WELLlife COVID-19 Antigen Test Rx results are simple and, easy to determine results as positive, negative or invalid based on the presence or absence of pink to purple test lines and control lines. The QRI/IFU provided with the test kit include descriptions of how to interpret test results, including visual examples and next steps to take based on the results.
- Contains a quick reference instruction sheet that is written at a 7th grade comprehension level.

B. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-Safe Mechanisms

1. <u>Risk Analysis:</u>

The comprehensive risk analysis included the Design Failure Mode and Effects Analysis (DFMEA), Process Failure Mode and Effects Analysis (PFMEA) and User FMEA. The FMEAs included identification and addressing of potential risks or error sources, analyzing potential causes, effects and the existing measures or mitigation factors related to the WELLlife COVID-19 Antigen Test Rx. The elements considered included operator error, environmental factors, specimen and reagent handling and storage.

Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design verification and validation studies and then through additional precautions and warnings in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see Item 3 below).

2. Fail-Safe and Failure Alert Mechanisms:

The WELLlife COVID-19 Antigen Test Rx was designed to include numerous features and fail-safe mechanisms built into the system to prevent erroneous results. The summary of the Design Failure Mode and Effects Analysis (DFMEA), Process Failure Mode and Effects Analysis (PFMEA) and User FMEA is presented below.

Design Features

- Each test is packaged in a foil pouch with desiccant to maintain the integrity of the test device and reagents.
- Each kit is printed with the assay name/type, lot number, and expiration date to ensure clarity and appropriate use.
- The instructions for use/quick instructions for use clearly define the intended user, environment and indications for use for test device.
- The test device was also designed to include a window for internal procedural controls. The external controls (WELLlife COVID-19 Antigen Test Rx Control Kit) are provided separately and can also be tested with this test device.
- Each test cassette features distinct position marks to facilitate clear result interpretation for the test and control locations that are denoted by "T" and "C" respectively.

Process Features

The extreme conditions when testing and the variabilities in the testing procedures were assessed as part of their flex studies.

Fail-safe Features (Controls)

- *Internal Control:* The WELLlife COVID-19 Antigen Test Rx has a built-in internal procedural control. A pink to purple line should always appear in the control line region (C) indicating that proper volume of sample has been added and that membrane wicking has occurred. If the control line is not present, regardless of whether a sample line is present, the test is invalid. Testing with a new sample and new device is recommended.
- *External Controls (WELLlife COVID-19 Antigen Test Rx Control Kit):* – Two external control swabs (a positive swab and a negative swab) that are packaged and sold separately from the test kit, are available to ensure that the reagents and test cassette are functioning properly, and to demonstrate proper use and performance by the operator. External control swabs are treated the same way as the patient sample swab and processed according to the test instructions for use.

  The manufacturer recommends the external quality control requirements should be established as required by site quality control procedure and in accordance with local, state, and federal regulations or accreditation requirements. Minimally, Wondfo recommends that positive and negative external controls be run once for each new kit lot, each new shipment received, and each new operator.

3. **Flex Studies:**

To assess the robustness and risk for false results of the test when deviating from the IFU/QRI test steps, flex studies were conducted that assessed all major aspects of the test procedure (e.g., sample volume, reading time, swab extraction time, swab rotation, and tube squeezing) and variability of environmental test conditions that the test may be subjected to when in use (e.g., lighting, disturbance during use, temperature, and humidity stress conditions). Testing was performed with contrived positive nasal swabs prepared by diluting SARS-CoV-2 virus into negative negative clinical matrix (NCM) at 2x LoD. The flex studies support the CLIA Waiver Application for the WELLlife COVID-19 Antigen Test Rx. The result summaries are listed in the table below.

Table 1. Summary Results of Flex Studies

Condition		Sample	Positive results/total results
Varying extraction volume	50 µL	Negative	0/5[1]
		SARS-CoV-2 positive	5/5
	100 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	200 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	300 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	400 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	500 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	600 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	800 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	1000 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	1200 µL	Negative	0/5
		SARS-CoV-2 positive	5/5
	1500 µL	Negative	0/5

		SARS-CoV-2 positive	5/5
[1] – Extraction buffer volume of 50 µL yielded 1/5 invalid results for the negative sample.			
Varying times of swab rotation in extraction buffer	0 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	1 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	3 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	5 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	10 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	15 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	20 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
	30 swab rotations	Negative	0/5
		SARS-CoV-2 positive	5/5
Swab incubation time	0 minute	Negative	0/5
		SARS-CoV-2 positive	5/5
	0.5 minute	Negative	0/5
		SARS-CoV-2 positive	5/5
	1 minute	Negative	0/5
		SARS-CoV-2 positive	5/5
	5 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	10 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
Specimen volume	1 drop	Negative	Invalid results
		SARS-CoV-2 positive	
	2 drops	Negative	0/5
		SARS-CoV-2 positive	5/5

	3 drops	Negative	0/5
		SARS-CoV-2 positive	5/5
	4 drops	Negative	0/5
		SARS-CoV-2 positive	5/5
	6 drops	Negative	0/5
		SARS-CoV-2 positive	5/5
	8 drops	Negative	0/5
		SARS-CoV-2 positive	5/5
	10 drops	Negative	0/5
		SARS-CoV-2 positive	5/5
	Whole volume	Negative	0/5
		SARS-CoV-2 positive	5/5
Reading time	1 minute	Negative	Inconclusive[2]
		SARS-CoV-2 positive	Inconclusive[2]
	2 minutes	Negative	Inconclusive[2]
		SARS-CoV-2 positive	Inconclusive[2]
	5 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	8 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	10 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	15 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	20 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	30 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	45 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	60 minutes	Negative	0/5

		SARS-CoV-2 positive	5/5
[2] – Too much background color observed at 1 and 2 minutes.			
Delay in testing after sample extraction	**Time**	**Sample**	**Positive results/total results**
	No delay	Negative	0/5
		SARS-CoV-2 positive	5/5
	15 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	30 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	60 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	90 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
	120 minutes	Negative	0/5
		SARS-CoV-2 positive	5/5
Light condition	**Sample**		**Positive results/total results**
Fluorescent environment (~1750 Lux)	Negative		0/5
	SARS-CoV-2 positive		5/5
Incandescent environment (~630 Lux)	Negative		0/5
	SARS-CoV-2 positive		5/5
Natural day light (outside ~6pm PST)	Negative		0/5
	SARS-CoV-2 positive		5/5
Dim lighting environment (100 Lux)	Negative		0/5
	SARS-CoV-2 positive		5/5
Natural lighting environment (300 Lux)	Negative		0/5
	SARS-CoV-2 positive		5/5
Strong lighting environment (500 Lux)	Negative		0/5
	SARS-CoV-2 positive		5/5
Incandescent environment	Negative		0/5
	SARS-CoV-2 positive		5/5
Disturbance during testing	**Sample**		**Positive results/total results**
Drop the test cassette from the operation table to the floor, pick	Negative		0/5
	SARS-CoV-2 positive		5/5

up immediately and place back to the operation table		
Move the test cassette to another surface during sample flow	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test cassette vertically along the short side (sample well on the top)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test cassette vertically along the short side (sample well at the bottom)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test cassette vertically along the long side	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test cassette horizontally	Negative	0/5
	SARS-CoV-2 positive	5/5
Placement on non-level surface with an inclination angle of 20 degrees (∠20°) after 0 minutes of sample addition (execute immediately)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test obliquely along the long side (sample well at the top)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test obliquely along the long side (sample well at the bottom)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test obliquely along the short side (the long side of the test cassette is at the same height on the slope)	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test next to a centrifuge with vibration	Negative	0/5
	SARS-CoV-2 positive	5/5
Place the test on a non-levelled surface	Negative	0/5
	SARS-CoV-2 positive	5/5
Extreme environmental testing conditions	**Sample**	**Positive results/total results**
Room temperature (15° - 30°C) & 10 - 80% relative humidity (RH)	Negative	0/5
	SARS-CoV-2 positive	5/5
Low Temperature (5°C) & Low Humidity (5% RH)	Negative	0/5
	SARS-CoV-2 positive	5/5
Low Temperature (5°C) & High Humidity (95% RH)	Negative	0/5
	SARS-CoV-2 positive	5/5
High Temperature (45°C) & Low Humidity (5% RH)	Negative	0/5
	SARS-CoV-2 positive	5/5
	Negative	0/5

High Temperature (45°C) & High Humidity (95% RH)	SARS-CoV-2 positive	5/5
Freeze at -20°C for 24 hours	Negative	0/5
	SARS-CoV-2 positive	5/5
Refrigerate at 4°C for 24 hours	Negative	0/5
	SARS-CoV-2 positive	5/5

The flex studies demonstrate that the test is robust in the claimed intended use condition with an insignificant risk of erroneous results.

C. Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Comparison Study

A prospective clinical study was conducted to assess the performance of the candidate test in a simulated at-home setting when compared to a highly sensitive 510(k)-cleared SARS-CoV-2 RT-PCR assay with an extraction step. The study enrolled symptomatic subjects at nine (9) clinical study sites between April 2023, and February 2024, when Omicron was the most prevalent SARS-CoV-2 strain in the U.S.

Both the comparator and the candidate test used anterior nasal swab samples, and the sample collection order was alternated (randomized) for each study subject. Comparator test samples were collected by health care professionals at the clinical study site and inserted into Universal Transport Media per the IFU of the comparator test. Samples for the candidate antigen test were collected per the test's QRI and were either self-collected by a lay user aged ≥14 years or collected by an adult (parent/guardian) from individuals aged 2 to <14 years.

This study enrolled a total of 1,053 individuals. Of the 1,053 results obtained, 21 were excluded and 1,032 were considered evaluable. The clinical performance estimates are based on these 1,032 study subjects with symptoms upto 5 days post symptom onset (DPSO). The 1,032 results consisted of 128 positive and 904 negative study subjects as defined by the comparator result. The WELLlife COVID-19 Antigen Test Rx demonstrated the following performance, when compared to the result of the SARS-CoV-2 RT-PCR comparator assay:

- Positive Percent Agreement (PPA) of 84.38% (108/128) (95% CI: 77.10%, 89.65%)
- Negative Percent Agreement (NPA) of 99.67% (901/904) (95% CI: 99.03%, 99.89%).

Table 2. Demographics of Clinical Study Participants – Age, Sex and Self-collection distribution.

Characteristic	Number of Evaluable Subjects	Percentage of Total
Age		
2-13 years of age	117	11.34%
14-21 years of age	86	8.33%
22-64 years of age	698	67.64%
> 64years of age	131	12.69%
Total	**1,032**	**100%**
Sex		
Male	414	40.12%

Characteristic	Number of Evaluable Subjects	Percentage of Total
Age		
Female	618	59.88%
Total	**1,032**	**100%**
Sample Collector		
Self-collected sample	900	87.21%
Sample collected by other	132	12.79%
Total	**1,032**	**100%**

Table 3. Clinical Performance Estimates

Candidate Test	Comparator Test		
	Positive	**Negative**	**Total**
Positive	108	3	111
Negative	20	901	921
Total	**128**	**904**	**1,032**
Positive Percent Agreement (PPA) = 84.38% (108/128) *95% CI: (77.10%, 89.65%)*			
Negative Percent Agreement (NPA) = 99.67% (901/904) *(95% CI: 99.03%, 99.89%)*			

Table 4. Clinical Performance Stratified by DPSO

Days Post Symptom Onset	PPA
0	100% (5/5)
1	90.91% (20/22)
2	82.35% (28/34)
3	83.33% (25/30)
4	86.36% (19/22)
5	73.33% (11/15)
Total	**84.38% (108/128)**

2. <u>Device Performance with Analyte Concentrations Near the Cutoff:</u>

The precision and reproducibility studies were conducted separately.

a. Precision

A precision study was conducted to assess variability with respect to days, operators, and device lots. The study included three device lots, each tested every day by three operators for 20 days; testing was conducted in duplicates for each sample concentration (i.e., 3 operators x 20 days x 3 lots x 2 runs per day x 2 replicates per sample per run = 720 results per sample panel member). One (1) negative sample and two (2) samples with heat inactivated SARS-CoV-2 Omicron Variant lineage BA.5 (Isolate USA/COR-22-063113/2022) were spiked into negative clinical nasal swab matrix (NCM) to prepare a sample panel consisting of:

- Negative sample
- Low positive sample (1.5x LoD)
- Positive sample (3x LoD)

Fifty (50) microliters of each sample was applied to dry nasal swabs. After blinding and randomizing, samples were processed per the IFU of the candidate device.

Precision was observed to be 100% for all replicates prepared at 1.5x LoD and 3x LoD, demonstrating no variability in the performance of the candidate assay across the conditions, operators, lots, and days tested.

Precision study samples were also prepared at 0.9x LoD (below LoD) using the same materials for sample preparation as for the original study. These samples were then tested as follows: 2 operators x 3 lots x 3 days x 2 runs per day x 2 replicates per sample per run and resulted in a total of 72 replicates. The precision for the 0.9x LoD sample was less than 100%, which is expected based on the random error for a sample below the LoD. However, the performance was consistent across all three lots tested.

Table 5. Precision Study Summary Results

	Negative (n/Total N)*			**Below LoD (0.9xLoD) (p/Total P)***		**Low Positive (1.5xLoD) (p/Total P)#**			**Positive (3xLoD) (p/Total P)#**		
Operator	**1**	**2**	**3**	**1**	**2**	**1**	**2**	**3**	**1**	**2**	**3**
Lot 1	0/80	0/80	0/80	11/12	9/12	80/80	80/80	80/80	80/80	80/80	80/80
Lot 2	0/80	0/80	0/80	10/12	10/12	80/80	80/80	80/80	80/80	80/80	80/80
Lot 3	0/80	0/80	0/80	12/12	12/12	80/80	80/80	80/80	80/80	80/80	80/80
Agreement	**100% (720/720)**			**88.89% (64/72)**		**100% (720/720)**			**100% (720/720)**		
95%CI	99.47%, 100%			79.58%, 94.26%		99.47%, 100%			99.47%, 100%		

* - **(n/Total N)** = number of positives/total number tested
\# - **(p/Total P)** = number of positives/total number tested

b. Reproducibility

A reproducibility study was conducted to assess any site-dependent variability in the performance of the candidate device. The study included one (1) device lot that was tested at three CLIA waived sites by three (3) untrained operators over 5 days and 3 replicates per sample (i.e., 1 lot x 3 sites x 3 operators x 5 days x 3 replicates = 135 results per sample panel member).

One (1) negative sample and four (4) levels of heat inactivated SARS-CoV-2 XBB (hCoV-19/USA/CA-Stanford-109_S21/2022) were spiked into negative clinical nasal swab matrix (NCM) to prepare a sample panel consisting of:

- Negative Sample
- High negative (0.1xLoD)
- Below LoD (0.8xLoD)
- Low positive (1xLoD)
- Moderate positive (3xLoD)

Fifty (50) microliters of each sample was applied to dry nasal swabs. After blinding and randomizing, samples were processed per the IFU of the candidate device.

Reproducibility was observed to be 100% for all panels tested (except 0.8xLoD and 1xLoD), demonstrating no variability in the performance of the candidate assay across the sites, operators, days and replicates tested.

Table 6. Reproducibility Study Summary Results

	Negative (n/N) (n/Total N)*			High Negative (0.1xLoD) (n/Total N)*			Low Positive (0.8xLoD) (p/Total P)#			Weak Positive (1xLoD) (p/Total P)#			Moderate Positive (3xLoD) (p/Total P)#		
Operator	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
Site A	15/15	15/15	15/15	15/15	15/15	15/15	13/15	13/15	14/15	15/15	15/15	14/15	15/15	15/15	15/15
Site B	15/15	15/15	15/15	15/15	15/15	15/15	13/15	14/15	13/15	15/15	15/15	15/15	15/15	15/15	15/15
Site C	15/15	15/15	15/15	15/15	15/15	15/15	12/15	14/15	13/15	15/15	15/15	15/15	15/15	15/15	15/15
Agreement	**100% (135/135)**			**100% (135/135)**			**88.15% (119/135)**			**99.26% (134/135)**			**100% (135/135)**		
95% CI	97.23%, 100%			97.23%, 100%			81.61%, 92.57%			95.92%, 99.87%			97.23%, 100%		

* - **(n/Total N)** = number of negatives/Total number tested
\# - **(p/Total P)** = number of positives/Total number tested

The results obtained from these studies demonstrated that the WELLlife COVID-19 Antigen Test Rx produces reproducible results with untrained operators in CLIA waived settings and consistent performance across multiple lots with organism concentrations near the assay LoD.

c. Operator Questionnaire

At the end of the reproducibility study, each of the 9 untrained operators (3 from each of the 3 CLIA waived sites) was given a questionnaire to provide feedback on the ease of use of the WELLlife COVID-19 Antigen Test Rx. The questionnaire had 8 questions that evaluated the following general topics:

- The Quick Reference Instructions were easy to read and understand.
- The Instruction for Use was easy to read and understand.
- Ease to prepare the sample for testing and performing the test.
- Ease of interpreting the results.
- Ability to read test and control line.

Based on the operators' feedback, the overall WELLlife COVID-19 Antigen Test Rx was found to be easy to use without the help of an expert. Processing the sample, applying it to the cassette correctly, and seeing and understanding the results were easy. Operators also found the written instructions for the test were clear and easy to follow.

D. Labeling for Waived Devices

The labeling submitted for the WELLlife COVID-19 Antigen Test Rx consists of:

1. Quick Reference Instructions (QRI)
2. Instructions for Use (IFU)
3. Package Labeling – kit box labels, device pouch label, and extraction buffer label

The following elements are appropriately present:

- The test procedures is written at no higher than a 7th grade reading level:

- The name of the test and a statement that labs with a Certificate of Waiver may use it.
- A statement clearly states the specimen type.
- A statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- The IFU and QRI provides instructions for conducting quality control.
- Interpretation of results, including diagrams on how to read and assess validity of test results and control results.
- A warning addressing color blindness when waived tests use color-coded reagents and/or endpoints.
- Safety considerations for test operation that particularly apply to untrained users.
- Telephone number to contact manufacturer for technical assistance or troubleshooting the test system and to direct the user to call for assistance when the device or the control materials do not work as specified by the manufacturer.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

XI. Conclusion

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.