CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW240033

II. Parent Document Number

K241188

III. CLIA Waiver Type

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant

Sekisui Diagnostics, LLC

V. Proprietary and Established Names

Acucy Influenza A&B Test with the Acucy 2 System

VI. Measurand (analyte)

Influenza A and influenza B viral nucleoprotein antigens

VII. Sample Type(s)

Direct anterior nasal and nasopharyngeal swabs

VIII. Type of Test

Qualitative immunoassay using an optoelectronic reader

IX. Test System Description

A Overview

The Acucy Influenza A&B Test is a rapid qualitative chromatographic immunoassay in the sandwich immunoassay format. The Acucy Influenza A&B Test consists of a Test Cassette that detects and differentiates influenza A and influenza B viral antigens from a patient sample. The test sample, a nasal swab or nasopharyngeal swab, is processed by inserting it into the Acucy Influenza A&B Extraction Buffer. This step elutes the nasal sample material from the swab and disrupt the virus particles to release the viral nucleoproteins. The mixture is then added to the sample well of the Test Cassette where it solubilizes reagents necessary for the detection of the viral antigens. From there, the sample migrates along the membrane surface. If influenza A or B viral antigens are present, they form a complex with the respective solubilized colloidal gold conjugated mouse monoclonal antibody to influenza A and/or B nucleoproteins. The complex will then continue to migrate until it is bound by rat anti-influenza A and/or mouse anti-influenza B antibodies that are immobilized at the test lines of the cassette's nitrocellulose membrane.

Depending upon the operator's choice, the Test Cassette is either immediately placed inside the Acucy 2 Reader for automatically timed development mode (WALK AWAY Mode) or placed on the counter or bench top for a manually timed development and then placed into the Acucy 2 Reader to be scanned (READ NOW mode). In either mode, upon completion of the development time, the Acucy 2 Reader scans the Test Cassette to measure the absorbance intensity at the test and control lines. These absorbance units are then processed to generate a final qualitative result using a method-specific algorithms.

The Acucy 2 Reader then displays the test results on the screen as either POS (+) or NEG (-) for each viral analyte, or as INVALID. As such, there are the following five possible results that can also be automatically printed on the Acucy Printer, if this option is selected:

- FLU A POS (+)/FLU B NEG (-)
- FLU A NEG (-)/FLU B POS (+)
- FLU A NEG (-)/FLU B NEG (-)
- FLU A POS (+)/FLU B POS (+)
- INVALID

B Test System Components

<u>Materials Provided</u>

- 25 Test Cassettes: individually foil pouched with desiccant
- 25 Sterile anterior nasal swabs
- 25 Extraction Buffer vials each containing 0.4 mL phosphate buffered salt solution with 0.09% sodium azide as a preservative
- 25 Extraction Vial Dropper Tips
- 1 Influenza A+/B- Control Swab (Formalin inactivated Influenza A containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture)
- 1 Influenza A-/B+ Control Swab (Formalin inactivated Influenza A containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture)

- 2 separate Instructions for Use (IFU) documents for Acucy 2 Reader and Acucy Reader
- 2 separate Quick Reference Guides for Acucy 2 Reader and Acucy Reader (each containing instructions for READ NOW and WALK AWAY Modes)
- 2 separate External Quality Control (QC) Quick Reference Guides for the Acucy and the Acucy 2 Readers
- Workstation

Materials Required but Not Provided

- Timer or watch
- Sterile nasopharyngeal swabs (refer to package insert for acceptable swabs)
- Additional external quality controls may be purchased separately (Acucy Influenza A&B Control Kit # 1011)

Instrument System

Separately from the Acucy Influenza A&B Test kit, the Acucy 2 Reader is provided with the following accessories: power cords and adapters, USB Memory Drive, and system manual.

Similar to the Acucy Reader, the Acucy 2 Reader has two modes of operation, the WALK AWAY and the READ NOW modes, described below:

a) WALK AWAY Mode:

In the WALK AWAY mode, test cassettes are inserted into the reader. Then, after the addition of the sample to the Test Cassette, the development and timing of the test occur within the reader. This allows the user to "walk away" until the test has been completed.

b) READ NOW Mode:

In the READ NOW mode, the reader analyzes the results after manually timing the development of the test cassette on a flat surface for the full 15 minutes.

Quality Control

There are three types of control mitigations for the Acucy 2 System and Acucy Influenza A&B Test:

- *Acucy 2 Reader Calibration:* The calibration test is a required function that checks the reader optics and calculation systems using the calibration zone label affixed to the drawer. The calibration procedure is performed upon installation for both Read Now and WALK AWAY functionality and is required every 30-days. The operator will be prompted by the reader to conduct calibration after 30 days has elapsed. The calibration procedure may also be performed, as directed during troubleshooting or whenever the reader date and time has been changed.
- *Internal control:* Control line integrated into the test strip of the Test Cassette (unchanged from K182001)
- *External quality controls*: Influenza A+/B- and A-/B+ control swabs (unchanged from K182001)

X. Specific Contents for CLIA Waiver

A Demonstrating "Simple":

The Acucy Influenza A&B Test with the Acucy 2 Reader was designed to be simple and easy to use by incorporating the following features:

- The test uses direct anterior nasal or nasopharyngeal swab specimens.
- The test requires basic, non-technique-dependent specimen and reagent handling to obtain accurate test results.
- The extraction buffer is premeasured and provided in individual vials.
- Dropper tips are provided to be put on the extraction buffer vials containing the eluted/extracted samples. The user inverts the vial and applies 5 drops of sample directly to the sample well of the test cassette using the dropper tip. No pipetting is required.
- The test cassettes are unitized and contain all the reagents required for analysis.
- The reagents can be stored at room temperature (15 - 30°C).
- The test does not require any operator intervention during the analysis step. In the WALK AWAY mode, once the test cassette is inserted into the Acucy 2 Reader, the extracted sample is added to the test cassette, and the reader drawer is closed, all subsequent steps are completed automatically by the reader.
- The results are interpreted by the Acucy 2 Reader which provides a direct readout of test results (i.e., positive, negative, or invalid) eliminating subjectivity associated with visual interpretation of results by the end-user.
- The reader touchscreen is designed for ease of use and features a color display that facilitates prompts and messages in simple English phrases.
- A calibration check, which is required every 30 days, is easily performed with the internal Acucy 2 calibration device and does not involve the use of a separate calibrator component.
- Error messages are unambiguous and include easy-to-interpret solutions.
- No complex troubleshooting or interpretation of error codes are required to operate the Acucy 2 Reader.
- There is no maintenance required other than wiping of the external surface of the reader.
- There are no user-serviceable parts and the instrument must be returned to Sekisui Diagnostics for repair.
- The test procedure is written at a 7th grade reading comprehension level.

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

1. Risk Analysis:

A comprehensive risk analysis of the Acucy Influenza A&B Test with the Acucy 2 Reader has been conducted in accordance with ISO 14971. The sponsor utilized the Device Hazard Analysis and the Failure Mode Effects Analysis (FMEA) methods to assess the risks of failure that may occur during use or misuse of the device. The FMEAs included identification of potential failure modes and effect of the failure, potential causes, built in design controls and evaluation of severity, frequency of occurrence, and ability to detect the failure. The elements considered included operator errors (human factors), sample and device handling and storage, and environmental factors.

Potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions 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).

The sponsor provided detailed software validation and verification documentation, including requirements related to assay performance when using the Acucy 2 Reader. The instrument software was reviewed under the parent 510(k) submission (K241188).

2. Fail-Safe and Failure Alert Mechanisms:

Fail safe/failure alert mechanisms present in the Acucy Influenza A&B Test with the Acucy 2 Reader are detailed in Table 1 below:

Table 1. Fail-Safe/ Failure Alerts in the Acucy Influenza A&B Test with the Acucy 2 Reader

Fail-Safe / Failure Alert	Present?	Comments
Lock-out functions that do not allow output of results if controls or system checks are not successfully completed.	Yes	*Self-Test:* A self-test is performed at power on and must be successfully completed for the reader to be ready for use. If the self-test does not pass, the reader will not be operable. *Calibration Test:* In the event of a failed calibration test, the error message, "FAILED CALIBRATION" will be displayed by the Acucy 2 Reader. If the calibration test fails two times in a row, the error message, "DEVICE LOCKED" will be displayed, the reader will lock, and no testing can be performed. The operator is directed to contact technical support to unlock the reader.
Lock-out functions that do not allow output if expired reagents are used.	Yes	Upon placement of an expired test cassette in the reader drawer, the reader reads the test cassette barcode and the error code "CASSETTE EXPIRED" will be displayed, preventing a test from being run.
Physical features to ensure correct placement of components, such as strips or cassettes	Yes	An arrow on each test cassette indicates the direction for inserting the cassette into the reader. In addition, the back of each cassette is notched at the top corner, this notch must be placed over a pin found in the top left corner of the reader drawer. If the cassette is not placed correctly in the drawer, the error code "TEST CANNOT BE DETECTED"

Fail-Safe / Failure Alert	Present?	Comments
		will be displayed and the test will not run.
Monitors of environmental conditions incorporated into the test system or the kit container to alert the user to environmental conditions that are outside of the recommended storage conditions.	No	Device labeling indicates acceptable environmental conditions
Internal procedural controls to flag procedural problems such as improper sample flow, incorrect use of components, or improper addition of specimen.	Yes	The test cassette contains a built-in internal control feature. Each time a test is run, the internal control zone is scanned by the Acucy 2 Reader. A "VALID" test result displayed by the reader indicates that the internal control was present, demonstrates that the test flowed correctly, and that the functional integrity of the cassette and reagents was maintained. An "INVALID" test result displayed by the reader indicates that the internal control was not present, indicating that the test did not flow correctly, and/or that the functional integrity of the Test Cassette/reagents was not maintained, and/or an operator error occurred.
Internal non-procedural controls (e.g., for checking the integrity of the reagents).	Yes	**READ NOW:** The reader scans the internal control line after the cassette is inserted and the drawer is closed. If no control line is present, an INVALID result will be displayed. **WALK AWAY:** If the reader does not detect a Control Line at the read time, an INVALID result is displayed. Detection of a control line immediately after the drawer is closed indicates a used cassette and triggers an INVALID result. INVALID Result reporting: INVALID test results indicate problem/s during testing. Display indicates the test should be repeated and, if reoccurs, to contact Technical Support.
External control material	Yes	External Controls (positive and negative) are provided with the test kit. Use of the controls helps ensure the reagents/test cassettes and Reader are functioning properly, can demonstrate proper performance by the operator, and may be used to verify reagent integrity

Fail-Safe / Failure Alert	Present?	Comments
		when a new lot or shipment is received. If either or both of the External Controls do not produce the expected result, "Failed" is displayed in the QC test results Reader display. The display indicates the controls should be repeated and if reoccurs, to contact Technical Support

3. Flex Studies:

To demonstrate the tolerance limits of the Acucy 2 reader, flex studies were conducted by simulating conditions outside the intended use instructions and environment. The flex studies were divided into two (2) categories, operational environment (e.g., temperature and humidity, vibration, lighting, air draft, non-level position, and altitude), and operator error/human factors (e.g., movement of reader, movement of cassette/vertical incubation, cassette reader window contamination, read time, cassette position in reader, and use of expired reagents and controls).

Samples used for flex study testing consisted of three (3) panel members of five (5) replicates each. Contrived low positive (LP) samples were prepared at 2X LoD by spiking negative clinical matrix (NCM) with Influenza A (Michigan/45/15) or Influenza B (Colorado/6/17) at concentrations of 5.64×10^2 $TCID_{50}$/mL and 1.41×10^3 $TCID_{50}$/mL respectively. The contrived negative sample consisted of NCM only. Fifty (50) µL of each contrived negative and positive samples were individually applied to kit swabs. Swabs were blinded, randomized, and tested according to the instructions for use except for the noted deviations dictated by the flex study parameter under evaluation. External control swabs were run on each day of testing as per the test's IFU. Results of the flex studies performed are summarized in Table 2 below:

Table 2. Summary Results of Flex Studies with Acucy 2 Reader

Acucy 2 Reader Conditions	Positive Swab Samples (Positive/Total)		Negative Swab Samples (Negative/Total)
	Flu A LP	Flu B LP	
Conducted with WALK AWAY Mode			
Temperature/Humidity			
Ambient, 15-30°C (Control)	100% (5/5)	100% (5/5)	0% (0/5)
45°C/95% RH	100% (2/2)*	N/A**	N/A**
40°C/85% RH 2-8°C/≤10% RH	100% (5/5)	100% (5/5)	0% (0/5)
* Abnormal environmental conditions resulted in reader failure for three replicates. ** Due to system failure, testing not performed at this range. Risks associated with abnormal environmental conditions were mitigated with labeling.			
Distance from Running Centrifuge			
With no centrifuge running (Control) 112 cm 88.0 cm 65.5 cm	100% (5/5)	100% 5/5)	0% (0/5)

Acucy 2 Reader Conditions	Positive Swab Samples (Positive/Total)		Negative Swab Samples (Negative/Total)
	Flu A LP	Flu B LP	
43.0 cm			
21.5 cm			
Non-levelled Surface			
No tilt (Control)	100% (5/5)	100% (5/5)	0% (0/5)
15º tilt forward			
15º tilt backward			
15º tilt to left			
15º tilt to right			
Movement of Reader During Testing			
Not moved (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Reader bumped during incubation			
Reader bumped during scanning			
Conducted with READ NOW Mode			
Environmental Lighting Source			
Normal benchtop lighting - 2,200 Lux (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Bright light under lamp - 13,700 Lux			
Direct sunlight - 14,100 Lux	N/A*	N/A*	N/A*
* Instrument/test design does not allow testing to proceed: Failed calibration			
Air Draft Conditions			
Normal benchtop (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Inside chemical fume hood			
Altitude			
134 meters	100% (5/5)	100% (5/5)	0% (0/5)
3250 meters			
Non-levelled Surface			
No tilt (Control)	100% (5/5)	100% (5/5)	0% (0/5)
15º tilt forward			
15º tilt backward			
15º tilt to left			
15º tilt to right			
Use of Expired Reagents			
Cassettes, Reagents, and Controls within Expiration in READ NOW mode or QC Mode. (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Expired Cassettes and Reagents READ NOW mode	Expiration Error	Expiration Error	Expiration Error
Expired Controls in QC Mode			
Cassette Read Window Contamination			
No contaminant (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Gloved Hand			
Bare hand			
Hand Treated with Hand Cream			

Acucy 2 Reader Conditions	Positive Swab Samples (Positive/Total)		Negative Swab Samples (Negative/Total)
	Flu A LP	Flu B LP	
Hand Treated with Hand Sanitizer			
Read Result Time			
5 Minutes	100% (5/5)	100% (5/5)	0% (0/5)
10 Minutes			
15 Minutes (Control)			
20 Minutes			
25 Minutes			
30 Minutes			
45 Minutes			
60 Minutes			
Test Cassette Incubation			
No bumping of cassette (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Cassette bumped			
Cassette placed vertically at 90º			
Test Cassette Positioning in Acucy 2 Reader Drawer			
Cassette arrow facing away from user (Control)	100% (5/5)	100% (5/5)	0% (0/5)
Backwards, with cassette arrow facing user	Invalid*	Invalid*	Invalid*
Sideways with arrow facing left/right	N/A**	N/A**	N/A**
Upside down, with bottom of cassette facing up	Invalid*	Invalid*	Invalid*
* Acucy 2 Reader displayed error, *"INVALID 9"*, which means reader was unable to detect the assay window. ** Instrument/test design does not allow testing to proceed: Drawer could not close.			

No false positive or false negatives were obtained for any of the flex studies performed. In addition, all control swabs and calibration of Acucy 2 readers passed. Of the thirteen (13) flex studies, only the flex studies for temperature and humidity, direct sunlight, expired controls and reagents, and cassette orientation resulted in system shutdown (temperature and humidity) , or lead to an invalid error (direct sunlight, expired controls and reagents, and cassette orientation). However, these risks are mitigated through the IFU, QRI and the Acucy 2 Instrument manual which instructs the end user to keep the Acucy 2 Influenza A&B Test and Acucy 2 reader out of direct sunlight, store at 15-30°C, and to check expiration dates of controls and reagents and to operate in conditions ≤ 85% RH. If any invalid results are obtained, the end user is instructed to repeat test with a new patient sample, reagents, and test cassette.

In addition to the flex testing reported here, additional testing specific to operation of the Acucy Influenza A/B test cassette was performed in support of K182001/CW18008 and leveraged for this submission as follows:

- Control Swab Storage Temperature
- Test Cassette Storage Temperature
- Swab Extraction Time

- Sample Volume
- Sample Addition Speed
- Sample Placement
- Sample Addition Angle
- Extraction Buffer Volume
- Reagent Temperature
- Sample Temperature
- Swab Stability
- Sample Storage after Elution

B Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Clinical Performance

The clinical performance of the Acucy Influenza A&B Test was determined in K182001 and was leveraged for this CLIA waiver application.

The comparative performance of the Acucy Influenza A&B Test with the Acucy Reader when used by untrained operators, testing both anterior nasal swabs (ANS) and nasopharyngeal (NP) swabs from patients with symptoms of respiratory tract infection against a composite comparator, is shown in Tables 3-4 below.

Table 3. Clinical Performance of Acucy Influenza A&B Test: Influenza A (Combined ANS and NP Swabs)

Influenza A	Comparator Positives	Comparator Negatives	Total
Acucy Positives	216	31	**247**
Acucy Negatives	8	748	**756**
Total	**224**	**779**	**1003**
Positive Percent Agreement (PPA): 96.4**%** (67/72) - 95% CI: 93/1% – 98.2% **Negative Percent Agreement (NPA):** 96.0**%** (748/779) - 95% CI: 94.4% – 97.2 %			

Table 4. Clinical Performance of Acucy Influenza A&B Test: Influenza B (Both ANS and NP Swabs)

Influenza B	Comparator Positives	Comparator Negatives	Total
Acucy Positives	130	16	**146**
Acucy Negatives	28	829	**857**
Total	**158**	**845**	**1003**
Positive Percent Agreement (PPA): 82.3% (130/158) - 95% CI: 75.6% – 87.4% **Negative Percent Agreement (NPA):** 98.1% (829/845) - 95% CI: 98.9% – 98.8%			

2. <u>Method Comparison with Predicate Device:</u>

This study evaluated the systemic differences between the Acucy and the Acucy 2 Reader.

Aliquots of 50µL each of known Influenza A or Influenza B positive or Influenza A and B negative nasopharyngeal swab (NPS) remnant samples were spiked onto sterile swabs and used as the contrived clinical samples. These samples were representative of a range of virus levels with RT-PCR values ranging from Ct 11.5 - 32.4.

Testing was performed as per Acucy Influenza A&B instructions for use. Thirty each of Influenza A and Influenza B samples and 30 Influenza A /B negative clinical samples were tested using one lot of Acucy Influenza A&B test kits. Each cassette was read on both the Acucy Reader and an Acucy 2 Reader. The Influenza A positive samples are considered as negatives for Influenza B and those positive for Influenza B are considered negative for Influenza A, thus, together with the double negative samples, for each group, there are a total of sixty (60) negatives. All the positive samples showed up as positive on both Readers. Results for the performance of the Acucy Influenza A&B Test for Influenza A and Influenza B stratified by the two Acucy Readers are in Tables 5 and 6 below:

Table 5. Influenza A performance with Archived Nasopharyngeal Swab Specimens Using READ NOW Mode on Acucy 2 Reader Compared to Acucy Reader.

Flu A by Acucy 2 Reader	Flu A by Acucy Reader		Total
	Positive	Negative	
Positive	30	1*	**31**
Negative	0	59	**59**
Total	**30**	**60**	**90**
PPA = 100.0 % (95% CI: 88.7% - 100.0 %) **NPA = 98.3 % (95% CI: 91.1% - 99.7 %)**			
*One of the Flu B positive samples returned a double positive result (positive for Flu A and Flu B) on Acucy 2 Reader but not on the Acucy Reader.			

For Influenza A, the results of the method comparison with the predicate demonstrated 100% PPA (95% CI: 88.7% -100%) and 98.3 % NPA (95% CI: 91.1% - 99.7 %) One of the Flu B positive samples returned a positive result for Flu A as well (double positive) when read on Acucy 2 Reader.

Table 6. Influenza B performance with Archived Nasopharyngeal Swab Specimens Using READ NOW Mode on Acucy 2 Reader Compared to Acucy Reader

Flu B by Acucy 2 Reader	Flu B by Acucy Reader		Total
	Positive	Negative	
Positive	30	0	**30**
Negative	0	60	**60**
Total	**30**	**60**	**90**
PPA = 100.0 % (95% CI: 88.7% - 100.0 %) **NPA = 100.0 % (95% CI: 94.0.% - 100.0 %)**			

For Influenza B, the results of the method comparison with predicate device demonstrated 100.0% PPA (95% score CI: 88.7% -100.0%) and 100% NPA (95% score CI: 94.0% - 100.0%) as compared to the Acucy 2 reader.

3. Performance Near the Assay Cutoff

A near cutoff study using CLIA waived intended users in a CLIA waived use environment was performed in support of K182001/CW180008 and leveraged for this submission.

4. Usability Study

The purpose of the usability study was to validate the use of the Acucy Influenza A&B Test with Acucy 2 System in the hands of representative CLIA waived intended users. Specifically, this testing was performed to demonstrate that representative intended use operators could:

- Set up the Acucy 2 System
- Perform a first-time log-in sequence.
- Conduct an external quality control test.
- Perform and interpret the test effectively in READ NOW or WALK AWAY Mode

Test sessions were conducted with 17 users of three levels of expertise:

Low-Level Users: These intended users had limited medical training [e.g., nursing student, certified nursing assistant (CNA), medical assistants/certified medical assistants (MA/CMA)].

Mid-Level Users: These intended users were college graduates with some medical training [e.g., licensed vocational nurse (LVN), registered nurse with an associate degree (RN- AD)].

High-Level Users: These intended users with college graduates with substantial medical training [e.g., registered nurse with a bachelor's degree or higher (RN-BSN/MSN), physician].

The testing was conducted under simulated-use conditions. Users were provided with mock patient specimens with inactivated influenza virus. Testing was conducted in a room simulated to look like a medical office, laboratory space, or point-of-care facility. All tasks were assessed under simulated conditions as they would have been during actual use. No training was provided to the users, and they did not have access to the test or supplementary materials prior to entering the testing room for the session. All user test sessions were moderated and supervised by up to two (2) experienced moderators and human factors experts. All tasks were performed without guidance or assistance by the moderators.

Each user performed the first three workflows (i.e., Setup, Cybersecurity, and External QC). The fourth and final workflow was alternated between users, with half of all participants performing a test in READ NOW mode, and half performing a test in WALK AWAY mode. The use of each mode was alternated across users.

After completing the test, users also conducted a post-test interview, and a survey. All questions and surveys were used to assess general user satisfaction level, user knowledge of the device, and to identify any areas where users felt confused or unsure.

Overall, users were successfully able to complete all tested workflows with the Acucy 2 Reader and felt the system was straightforward and easy to use with the vast majority of tasks being rated as either very easy or minimally difficult.

C Labeling for Waived Devices

The labeling consists of:

1. Acucy Influenza A&B Test with Acucy 2 System Instructions for Use (Package Insert)
2. Acucy Influenza A&B Test with Acucy 2 System Quick Reference Guide (QRG)
3. Acucy Influenza A&B Control Kit Instructions for Use
4. Acucy Influenza A&B with Acucy 2 System External Quality Control (QC) Quick Reference Guide (QRG)
5. Acucy 2 System Manual
6. Acucy 2 System Start Up Quick Reference Guide (QRG)

The following elements are appropriately present:

- The Quick Reference Guides (QRG) are written at no higher than a 7th grade reading level and, where appropriate, contain graphic representation of system components and procedure steps.
- The package insert and the Acucy Influenza A&B Test with Acucy 2 Reader QRG identifies the test as CLIA waived and contain a statement that a Certificate of Waiver is required to perform the test in a waived setting; information on how users can obtain a certificate is also provided.
- The package insert and the Acucy Influenza A&B Test with Acucy 2 Reader QRG contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
- Instructions for quality control (QC) are provided in the IFU document as well as in the Acucy Influenza A&B External Quality Control (QC) QRG and are also integrated with procedural instructions for performing the test in the package insert.
- Instructions for calibration are integrated with procedural instructions for performing the test in the package insert.
- Appropriate cautions have been added to the Package Insert and Quick Reference Guides to ensure safe use of the product.

The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.10.

XI. Benefit/Risk Considerations

A medical Benefit/Risk Analysis was done for the Acucy Influenza A&B Test as part of K182001/CW180008 and leveraged for this submission. This analysis concluded that the medical benefit/risk profile favored the decision to grant a CLIA waiver for this test.

XII. Conclusion

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