CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW250010

B. Parent Document Number

K250398

C. CLIA Waiver Type

CLIA Waiver by Application

D. Applicant

Innovita (Tangshan) Biological Technology Co., Ltd.

E. Proprietary and Established Names

Innovita Flu A/B Antigen Rapid Test

F. Measurand (analyte)

Influenza A and influenza B nucleoprotein antigens

G. Sample Type(s)

Nasopharyngeal Swab Samples (NPS)

H. Type of Test

Qualitative lateral flow immunoassay

I. Test System Description

1. Overview:

The Innovita Flu A/B Antigen Rapid Test is intended for the qualitative detection of influenza virus type A (Flu A) and influenza virus type B (Flu B) nucleoprotein antigens directly from nasopharyngeal swab samples (NPS) when collected from symptomatic patients. The Innovita Flu A/B Antigen Rapid Test is validated for testing nasopharyngeal swab without transport media. The test cassette in the test kit is assembled with a test strip in a plastic housing that contains a nitrocellulose membrane with three lines: two test lines (Flu A line and Flu B line) and a control line (C line).

The Innovita Flu A/B Antigen Rapid Test is a double antibody sandwich immunochromatographic assay which consists of the following parts: sample pad, conjugate pad, nitrocellulose membrane and absorbing pad. The conjugate pad contains monoclonal antibody against the Flu A/Flu B antigen labeled with latex microspheres and chicken IgY antibody conjugated with latex microspheres. The nitrocellulose membrane contains the other monoclonal antibody against Flu A/Flu B antigen at the respective test lines or the rabbit anti-chicken IgY antibody at the control line. Excess liquid and reagents are absorbed by the absorbing pad.

A schematic representation of the lateral flow test strip is shown below.

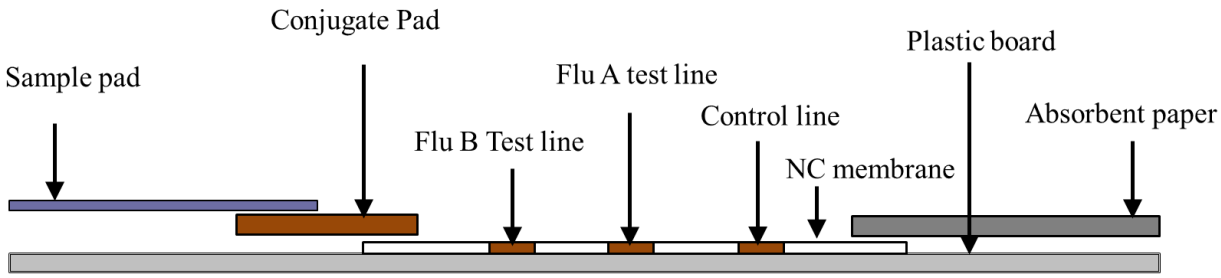

Figure 1: Schematic representation of the Innovita Flu A/B Antigen Rapid Test

After the specimen is applied into the sample well of the device, antigen from the specimen (if present) forms an immune complex with the monoclonal antibodies specific for A and B labeled with latex microspheres within the conjugate pad. The complex/sample migrates from the conjugate pad to the test zone where either the Flu A or Flu B labeled complexes will be captured by monoclonal antibodies at the Flu A or Flu B test line forming a red-purple line which indicates a positive result.

The test also contains an internal control system. The chicken IgY antibody conjugated with latex microspheres form an immune complex with the rabbit anti-chicken IgY antibody at the control line forming a red purple line. A red-purple control line (C) should always appear after the test is completed and should be interpreted as negative in the absence of red-purple line at the Flu A and Flu B test line. Absence of a red-purple control line indicates an invalid result.

2. <u>Test System Components:</u>

The Innovita Flu A/B Antigen Rapid Test consists of the following components:

- Test cassette
- Extraction diluent
- Nasopharyngeal swab
- Package Insert
- Quick Reference Instructions (QRI)
- External Controls
    - o Influenza A Positive Control
    - o Influenza B Positive Control

o Negative Control

J. Demonstrating "Simple":

Innovita Flu A/B Antigen Rapid test is designed to be simple and easy to use incorporating the following key features:

- The test is self-contained.
- The test uses an unprocessed nasopharyngeal swab specimen only.
- The test needs only basic, non-technique-dependent specimen manipulation and reagent handling.
- The supplied reagents are premeasured and provided in single-use vials.
- The test does not require any operator intervention during the analysis step.
- The test does not require technical or specialized training for troubleshooting or interpretation of multiple or complex error codes.
- The test does not require any electronic or mechanical maintenance beyond simple tasks.
- The test produces results that do not require operator calibration, interpretation, or calculation.
- The test produces easily determinable results, such as positive, negative, or invalid.
- The kit is packaged with a Quick Reference Instructions (QRI) guide that outlines the test process in easy-to-follow steps with illustrations.

K. Demonstrating "Insignificant Risk of an Erroneous Result" – Failure Alerts and Fail-safe Mechanisms:

1. Risk Analysis:

Risk analysis was performed using the Failure Modes and Effects Analysis (FMEA) Method in accordance with ISO 14971. 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 Innovita Flu A/B Antigen Rapid Test. The elements considered include operator error, environmental factors, specimen and reagent handling, storage, device calibration, and external controls.

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 Innovita Flu A/B Antigen Rapid Test was designed to include numerous features and fail-safe mechanisms built into the system to prevent erroneous results.

a. Design Features:

- Each test cassette is packaged in a foil pouch with desiccant to maintain the integrity of the test device and reagents.
- The foil pouch is printed with the assay name, lot number, production date, and expiration date to ensure clarity and appropriate use.
- Each test cassette features distinct position marks within the results window to facilitate clear and accurate result interpretation. The control line is denoted as "C", the Flu A antigen line is denoted as "Flu A" and the Flu B antigen line is denoted as "Flu B".

b. Fail-safe features:

1. Internal Quality Control:

The Innovita Flu A/B Antigen Rapid Test contains built-in procedural control features. The result format provides a simple interpretation for positive and negative results. The appearance of a red-purple procedural control line demonstrates that sufficient flow of reagents and adequate samples migration has occurred, and the functional integrity of the test strip was maintained. If a red-purple procedural control line does not develop within 30 minutes, the test result is considered invalid and retesting with a new sample and new device is recommended.

2. External Quality Control:

External quality controls are used to demonstrate that the reagents and assay procedures perform properly. Each Innovita Flu A/B Antigen Rapid Test contains two external positive control swabs (one Influenza A and one Influenza B swab) and one negative control swab. The positive control swabs and negative control swab are recommended for testing when receiving a new lot of reagents or when a new operator uses the test. The swabs are tested following the same procedure used for patient samples.

Each control swab should produce the expected positive or negative results to verify test performance. Each control swab is individually packaged in a foil pouch. The pouch is printed with information such as the control swab type and the expiration date. Users are instructed not to use expired external controls.

If the controls do not perform as expected, users are instructed to contact INNOVITA Technical Support before testing patient specimens.

3. Flex Studies:

The operational limits of the candidate device were evaluated in a series of experiments of "stress", including conditions outside of those recommended in the instructions for use. The strains and concentrations of viruses (1.5x LoD) used in flex studies are shown in the Table 1 below. 50µL of negative clinical matrix with or without spiked virus were used as positive and negative swab samples respectively. Three replicates were tested by

three operators using three different lots. The studies and data demonstrate that the test is robust in the claimed intended use condition with an insignificant risk of erroneous result. Results are summarized in Table 2 below followed by a summary of flex studies along with their respective risk mitigations as shown in Table 3 below.

Table 1: Strains and Concentrations of Viruses used in Flex Studies

Strain Type	Strain Subtype	Concentration of stock ($TCID_{50}$/mL)	Concentration of 1.5× LOD ($TCID_{50}$/mL)
Flu A virus (H1N1)	A/Dominican Republic/7293/ 2013 pdm09	5×10^5	7.5×10^2
Flu B virus (Victoria lineage)	B/Michigan/01/ 2021	5.7×10^5	2.15×10^3

Table 2: Summary Results of Flex Studies

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
Interference during detection	Drop the cassette from table to ground, immediately pick up and return to the table	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Move the cassette to another surface during specimen flow	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Place vertically along the short side (specimen well at top)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Place vertically along the short side (specimen well at bottom)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Place vertically along the long side	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Place horizontally	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
Swab storage time after sampling and before placing into extraction buffer	0 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	30 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	60 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	90 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Swab storage time in extraction buffer before testing	0 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	30 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	60 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	90 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Sample volume transferred to the specimen well	1 drop	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	2 drops	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	3 drops	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
	4 drops	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	6 drops	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	8 drops	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Lighting Conditions	Fluorescent Lighting	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Incandescent	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Natural Daylight (Outdoor)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Dim lighting (100 Lux)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Natural Lighting (300 Lux)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Strong Light (500 Lux)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Reading time	5 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	10 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
	15 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	30 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	45 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	60 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Number of times of stirring the swab	5 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	10 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	15 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	20 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Temperature and Humidity conditions	Normal temperature (15-30°C) and normal humidity (10%-80% RH)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Low temperature (5±2°C) and low humidity (5%±3% RH)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	Low temperature (5±2°C) and high humidity	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
	(95%±3% RH)	Negative	0/9	0/9
	High temperature (45±2°C) and low humidity (5%±3% RH)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	High temperature (45±2°C) and high humidity (95%±3% RH)	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Equilibrate to room temperature after cold storage	10 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	20 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	30 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	40 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	50 min	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Swab was placed into the extraction buffer and shaken	0 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	1 time	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	3 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	5 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9

Condition		Sample	Positive Replicates/Total Replicates	
			Flu A	Flu B
		Negative	0/9	0/9
	7 times	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
Squeezing the outside of tube after 10 stirring of the swab	Yes	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9
	No	Influenza A Positive	9/9	0/9
		Influenza B Positive	0/9	9/9
		Negative	0/9	0/9

Table 3: Summary of Flex Studies Performed and Risk Mitigations

Category	Failure Mode	Results and Conclusion	Risk Control Measure
Operator Error	Impact of the inclination angle	Acceptable performance was observed when the cassette was moved to another surface immediately after sample application or placed vertically along the short or long side or placed horizontally.	N/A
	Physical Impact Resistance	Acceptable performance was observed when the cassette was dropped to the ground after sample application and immediately picked and returned to the table.	N/A
	Sample Drop Volume Tolerance	Acceptable assay performance was observed when 1, 2, 3, 4, 6 or 8 drops of specimen was added to the specimen well.	QRI/IFU includes the statement, "*Apply 3 drops of diluted specimen into the specimen well*."
	Result Interpretation time	Acceptable performance was observed when results were read between 5 to 60 minutes	QRI/IFU includes the warning statement, "*Do not read the results before 10 minutes or after 30 minutes.*"
	Extraction-Number of times of stirring the swab	Acceptable performance was observed when the swab was stirred 5 to 20 times in the extraction buffer.	QRI/IFU includes the instructions, "*The swab tip should be completely immersed in the solution and then stir 10-15 times to ensure the sample is properly mixed.*"

Category	Failure Mode	Results and Conclusion	Risk Control Measure
	Extraction-Number of shaking of diluted specimen	Acceptable performance was observed when the swab was placed into the extraction buffer and shaken for 0-7 times.	N/A
	Extraction-Squeezing the outside of tube after 10 stirring of the swab	Acceptable performance was observed either after squeezing the outside of the tube or not squeezing the outside of the tube after 10 stirring of the swab.	QRI/IFU instructs the user as follows: "*Remove the swab while squeezing the middle of the vial to remove the liquid from the swab*"
Environmental factor	Temperature	Acceptable performance was observed when the temperature ranged from 10°C to 40°C.	IFU includes the precautionary statement, "*Allow test device, specimen and diluent to equilibrate to room temperature (15–30℃) prior to opening the pouch.*"
	Humidity	Acceptable performance was observed when the humidity conditions ranged between 5% to 95% RH.	N/A
	Impact of light source	Acceptable performance was observed when results were read at fluorescent lighting environment, incandescent environment, natural daylight, dim lighting environment (100 Lux), natural lighting (300 Lux) or strong lighting (500 Lux).	N/A
Specimen Integrity	Swab storage time after sampling and before placing into extraction buffer	Acceptable assay performance was observed when swab samples were stored for 0, 30, 60 or 90 minutes at RT and at 2-8℃ for 0, 12, 24 and 36h.	QRI/IFU includes the statement, "*Freshly collected specimens should be tested immediately*."
	Swab storage time in extraction buffer before testing	Acceptable assay performance was observed when swab samples were placed in extraction buffer and stored for 0, 30, 60 or 90 minutes at RT and at 2-8℃ for 0, 12, 24 and 36h.	QRI/IFU includes the statement, "*Freshly collected specimens should be tested immediately.*"
	Swab samples frozen and then extracted	Acceptable assay performance when swab samples were frozen for 0, 3, 6, 9, 12, 15, 18 and 21 months before placing in extraction buffer.	QRI/IFU includes the statement, "*Freshly collected specimens should be tested immediately*."
	Freeze-thawing	Acceptable assay performance when swab samples underwent 0, 1, 2, 3 and 4 freeze-thaw cycles before placing in extraction buffer.	QRI/IFU includes the statement, "*Freshly collected specimens should be tested immediately*."

Category	Failure Mode	Results and Conclusion	Risk Control Measure
Reagent Integrity	Equilibrate to room temperature after cold storage	Acceptable assay performance when swab samples and test kits were stored refrigerated for 24h and then placed in RT for 10 min, 20 min, 30 min, 40 min and 50 min for testing according to the IFU.	IFU includes the precautionary statement, "*Allow test device, specimen and diluent to equilibrate to room temperature (15–30°C) prior to opening the pouch.*"
	In-Use (Open Pouch) Stability	Acceptable assay performance after opening the foil pouch for 90 minutes at 40%~60% RH conditions and for 60 minutes at 80% RH conditions.	QRI/IFU includes the precautionary statement, "*The user should not open the foil pouch of the Test Cassette until the cassette is ready for immediate use."*

L. 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 when compared to a 510(k)-cleared influenza RT-PCR assay with an extraction step. The study prospectively enrolled symptomatic subjects at three CLIA waived clinical study sites between December 2023 and July 2024 with a total of 12 operators representative of CLIA-waived users (i.e., not formally trained in a laboratory setting).

A nasopharyngeal sample for the RT-PCR comparator was collected first from one nostril and a nasopharyngeal sample for the candidate test was then collected from the other nostril. This order of sample collection was consistent across the entire study. Comparator test samples were collected at the clinical study site and inserted into viral transport media per the IFU of the comparator test and transported to a central laboratory for testing. Samples for the candidate device were collected and were immediately tested with the Innovita Flu A/B Antigen Rapid Test according to the instructions for use by each operator and with no training specifically with the candidate test.

A total of 1109 subjects were enrolled, of which 8 samples were excluded due to loss of samples during transit to the laboratory for comparator testing. Hence, 1101 subjects were evaluable.

The summary of demographics of the clinical subjects are shown in Table 4 below.

Table 4: Subject Demographics

Age Group	Female		Male		Total	
	No. of sample	%	No. of Sample	%	No. of Sample	%
≤ 5 years	224	39.4	239	44.9	463	42.1
6 to 21 years	198	34.8	201	37.8	399	36.2
22 to 60 years	120	21.1	78	14.7	198	18.0
≥ 61 years	27	4.7	14	2.6	41	3.7
Total	569	100	532	100	1101	100
	Female: 51.6% (569/1101)		Male: 48.3% (532/1101)			

The clinical performance of the Innovita Flu A/B Antigen Rapid Test were compared with results obtained by a highly sensitive influenza RT-PCR comparator assay, demonstrating the following performance estimates as shown in Table 5 and Table 6 below:

Table 5: Clinical Performance Estimates - Influenza A

	Comparator Positives	***Comparator Negatives***	***Total***
Candidate Positives	203	4	207
Candidate Negatives	34	860	894
Total	237	864	1101
Positive Percent Agreement (PPA) = 85.7% (95% CI: 80.6%-89.5%)			
Negative Percent Agreement (NPA) = 99.5% (95% CI: 98.8%-99.8%)			

Table 6: Clinical Performance Estimates - Influenza B

	Comparator Positives	**Comparator Negatives**	**Total**
Candidate Positives	36	0	36
Candidate Negatives	6	1059	1065
Total	42	1059	1101
Positive Percent Agreement (PPA) = 85.7% (95% CI: 72.2%-93.3%)			
Negative Percent Agreement (NPA) = 100% (95% CI: 99.6%-100%)			

2. Device Performance with Analyte Concentrations Near the Cutoff:

A combined precision and reproducibility study was conducted for the Innovita Flu A/B Antigen Rapid Test. Three concentrations of each Flu A: H1N1 A/Dominican Republic/7293/2013 pdm09, and Flu B: Victoria/ B/Michigan/01/2021 were spiked into pooled nasal fluid of which 50µL of each sample were applied to dry nasal swabs to prepare the following test sample panel members:

- Negative Sample
- High Negative Sample at 0.1x LoD for each strain
- Low Positive Sample at 1x LoD for each strain

- Positive Sample at 3x LoD for each strain

The study was conducted at three (3) different CLIA waived sites to assess variability between days, runs, operators, reagent lots and site, with the following study design: 3 sites x 2 operators per site x 1 lot per site x 5 days x 1 run x 5 replicates yielding 150 results/sample panel. Samples were blinded and randomized before allotting them to the operators and processed per the IFU of the candidate device.

The results were in 100% agreement with the expected results for negative, 1x LoD, and 3x LoD samples by lot/site, by operator, by day, and overall for both analytes. All results were negative when tested with high negative samples. The results are summarized in Table 7 below by lot/site and are presented as percent positive agreement.

Table 7: Reproducibility Study results

Sample	No. of Positives / No. of Samples tested (%)						Total no. of Positives/ Total no. of Samples (%)	
	Site 1/Lot 1		Site 2/Lot 2		Site 3/Lot 3			
	Flu A	Flu B	Flu A	Flu B	Flu A	Flu B	Flu A	Flu B
Negative swab sample	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%)	0/150 (0%)
Flu A high negative swab sample (0.1×LoD)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%)	0/150 (0%)
Flu A Low positive swab sample (1×LoD)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	150/150 (100%)	0/150 (0%)
Flu A moderate positive swab sample (3×LoD)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	150/150 (100%)	0/150 (0%)
Flu B high negative swab sample (0.1×LoD)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/150 (0%)	0/150 (0%)
Flu B Low positive swab sample (1×LOD)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/150 (0%)	150/150 (100%)
Flu B moderate positive swab sample (3×LOD)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/50 (0%)	50/50 (100%)	0/150 (0%)	150/150 (100%)

3. Operator Questionnaire:

At the end of the study, each operator involved in the CLIA waiver clinical evaluation and reproducibility/precision studies was given a questionnaire to provide feedback on the ease of use of the Innovita Flu A/B Antigen Rapid Test. The questionnaire had 12 questions that assessed the following general topics:

- Ease of use of the test
- Ability to follow the test instructions
- Ability to properly interpret test results

The operators performing the testing at each site also filled out a questionnaire about their professional training and background. Based on the operators' feedback, the Innovita Flu A/B Antigen Rapid Test 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 Innovita Flu A/B Antigen Rapid Test were clear and easy to follow.

M. Labeling for Waived Devices

The labeling consists of:

1. Package Insert
2. Quick Reference Instructions
3. Package Labeling – Kit box label, pouch label.

The following elements are appropriately present:

- The QRI is written at 7th grade comprehension level.
- The QRI and the IFU identify the test as CLIA waived.
- The IFU contains a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The QRI and the IFU contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- The IFU contains a statement that any modification to the test or the manufacturer's instructions will result in the test being classified as high complexity.
- The IFU and QRI provide instructions for conducting quality control procedures.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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