Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F

Influenza A/B FIA

REF FINF01G

STANDARD™ F Influenza A/B FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

Influenza, commonly known as the flu, is a highly contagious and acute viral infection of the respiratory tract caused by an influenza virus. Three types of influenza viruses affect people, called Type A, Type B, and Type C. Type A viruses are the most prevalent and are associated with most serious epidemics. The clinical symptoms by the infection of Type A viruses are more severe than symptoms caused by Type B viruses. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season. Type C viruses have never been connected with a large epidemic of human disease. Influenza can take on a variety of appearances, ranging from isolated respiratory findings that resemble the common cold, to severe pneumonia requiring hospitalization and death. STANDARD F Influenza A/B FIA, containing a highly specific and sensitive antibody, provides significantly fast, easy and accurate system to identify the target antigen in a nasopharyngeal specimen.

[Intended use]

The STANDARD F Influenza A/B FIA is the fluorescence immunoassay to detect influenza infection in human nasal swab and nasopharyngeal swab, wash, or aspirate specimens, identifying existence of influenza type A and B viral nucleoprotein antigens. STANDARD F Influenza A/B FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD F Influenza A/B FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect influenza virus nucleoproteins. STANDARD F Influenza A/B FIA has two test lines ("A" and "B") and a control line which is coated with monoclonal anti-influenza A, monoclonal anti-influenza B and polyclonal mouse Ig G each. The patient's sample is applied into the sample well of the test device and the sample migrates through the membrane. If influenza A/B viral antigen is present in patient sample, it will react with europium conjugated monoclonal anti-influenza A/monoclonal anti-influenza B in the conjugation pad and form antibody-antigen fluorescence particle complexes. These complexes move along to the membrane to be captured by the anti-influenza A/anti-influenza B on the test line and make fluorescence signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the influenza A/B virus in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test device ② Extraction buffer tube ③ Sterile swab ④ Filter cap ⑤ Positive control (option)
⑥ Negative control (option) ⑦ Fixed volume dropper (300µl) (option) ⑧ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the extraction buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Use the STANDARD F Influenza A/B FIA at 15-32°C / 59-90°F and 10-90%RH.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
12. Immediately use the test device after taking out of aluminum foil pouch.
13. If the test result with positive/negative control swab is abnormal, do not use the kit.
14. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
15. The bar code of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
16. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
17. Improper specimen collection, handling or transport may yield inaccurate results.
18. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN PREPARATION, STORAGE AND TRANSPORT

[Methods of sample collection]

Nasal Swab | Nasopharyngeal Swab | Nasopharyngeal Aspirate | Nasopharyngeal Wash (Syringe method) | Nasopharyngeal Wash (Bulb method)

[Specimen preparation]

- **Nasal swab**

1. To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).
3. Rotate the swab a few times against the nasal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at refrigerated (2-8°C/36-46°F) or at room temperature (15- 30°C/59-86°F), in a clean, dry, closed container for up to 48 hours at refrigerated (2-8°C / 36-46°F) or 24 hours at room temperature (15-30°C / 59-86°F) prior to testing.

- **Nasopharyngeal swab**

1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinate.
3. Rotate the swab a few times against the nasopharyngeal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours in a clean, dry, closed container prior to testing.

- **Nasal/nasopharyngeal swab in transport media**

1. Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system.
2. The BD Universal Viral Transport and Copan Universal Transport Medium have been tested and found to be compatible with STANDARD F Influenza A/B Test.
3. For nasal/nasopharyngeal swabs in transport media, use the 1-3 ml of transport media.

CAUTION

- Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.

- **Nasopharyngeal wash**

1. Fill the syringe or aspiration bulb with the minimal volume of nonbacteriostatic saline (pH 7.0) required per the subject's size and age.
2. Instill the saline into one nostril while the head is tilted back.
3. Aspirate the wash specimen back into the syringe or bulb.
4. Repeating procedure for the second nostril will deliver optimal combined specimens.
5. Specimen should be tested as soon as possible after collection. If not use the specimen immediately, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours after collection.

- **Nasopharyngeal aspirate**

1. Have the patient sit with head tilted slightly backward.
2. Instill 1-1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril.
3. Flush a plastic catheter or tubing with 2-3 ml of saline.
4. Insert the tubing into the nostril parallel to the palate (not upwards).
5. Aspirate nasopharyngeal secretions. Collect the specimens in sterile vials. If permitted, repeat this procedure for the other nostril.
6. Specimen should be tested as soon as possible after collection. If not use the specimen immediately, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours after collection.

- **Transport media**

The following viral transport media listed in Table 1 were tested by SD BIOSENSOR R&D team and determined to be compatible with the STANDARD F Influenza A/B FIA. However, lot-to-lot variation of viral transport media may impact the performance.

Table.1 Recommended Viral Transport Media (VTM)

Viral Transport Medium(VTM)	Recommended Storage Condition	
	2°C to 8°C	25°C
Copan UTM™ Universal Transport Media	72 hours	12 hours
BD™ Universal Viral Transport	72 hours	12 hours
Copan eSwab	72 hours	12 hours
Hank's Balanced Salt Solution	72 hours	12 hours
M4	72 hours	12 hours
M4-RT	72 hours	12 hours
M5	72 hours	12 hours
Starplex Multitrans	72 hours	12 hours
Sigma Virocult Media	72 hours	12 hours
Normal saline	72 hours	12 hours
1x PBS	72 hours	12 hours
ASAN PHARM UTM	72 hours	12 hours
Noble Bio REST™ UTM	72 hours	12 hours
AMIES AGAR GEL - NO CHARCOAL[1)]	72 hours	12 hours
STANDARD™ Transport Medium	72 hours	12 hours

AMIES AGAR GEL - NO CHARCOAL[1)]
The swab which is placed into the agar gel medium is used for testing of Influenza A/B. So, follow the test procedure such as nasal/nasopharyngeal swab.

NOTE

When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

TEST PROCEDURE

[Preparation]

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) prior to testing.
2. Carefully read the instructions for using the STANDARD F Influenza A/B FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.

<Foil pouch> <Test device> <Silica gel>

CAUTION

- If a violet colored band (check band) does not appear in the result window of the test device, do not use it.

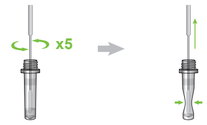
CAUTION

- Do not write on the bar code or damage the bar code of the test device.

[Collection of sample]

- **Nasal/nasopharyngeal swab**

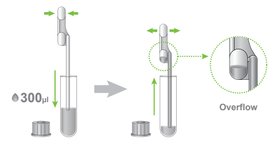
1. Allow test device to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Insert the nasopharyngeal swab sample of patient into an extraction buffer tube. Swirl the swab at least five times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.



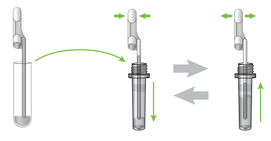
4. Tightly screw the filter cap onto the tube.

- **Nasopharyngeal aspirate/wash or specimens in transport media**

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Compress the top bulb of a fixed volume dropper (300µl) and place the tip of the dropper into the collected sample.
3. Slowly release the top bulb of the dropper dipping the tip of the dropper into the sample.



4. Completely squeeze the sample into an extraction buffer tube pressing hardly the top bulb of the dropper.
5. Repeat carefully pressing and releasing the top bulb of the dropper a few times to mix the sample and the extraction buffer.



6. Remove the dropper and tightly screw the filter cap onto the extraration buffer tube.

NOTE

- Fixed volume dropper is designed to aspirate the correct amount of solution by collecting overflowed liquid in the bottom bulb of dropper.

- **Positive/Negative control**

1. Insert the positive/negative control swab in the kit into an extraction buffer tube. Swirl the swab at least five times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

3. Tightly screw the filter cap onto the tube.

[Analysis of sample]

- **Using a 'STANDARD TEST' mode**

- **Applied STANDARD F100, F200 and F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'.
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.

4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

5. Apply 4 drops of mixed sample to the sample well in the test device.

6. After applying the sample, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

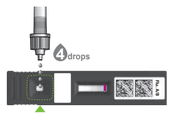
7. The analyzer will automatically display the test result within 10 minutes.
- With F100 and F200 analyzers, if the tested sample is strongly positive, the analyzer shows intermediate results(in 90 sec, 3 minutes and 5 minutes) before the test is finishes(10 minutes).

- **Using a 'READ ONLY' mode**

- **Applied STANDARD F100 and F200 analyzer**

1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a sample information on the label of test device.

2. Apply 4 drops of mixed sample to the sample well in the test device.



3. Incubate the test device for 10 minutes outside of the analyzer. Incubation must not be more than 20 minutes.

4. Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual. Insert the test device to the test slot of the analyzer.

5. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Influenza A	COI ≥ 1.0	Positive for Influenza A
Influenza B	COI ≥ 1.0	Positive for Influenza B
Influenza A/B	Influenza A COI ≥ 1.0 Influenza B COI ≥ 1.0	Positive for Influenza A and B
Negative	COI < 1.0	Negative for Influenza A or B
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient sample

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI(cutoff index) value. The COI is a numerical representation of the measured fluorecence signal.

QUALITY CONTROL

[STANDARD F Analyzers calibration check]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzer's manual.

When to use calibration set

1. Before using the analyzer for the first time
2. When you drop the analyzer
3. Whenever you do not agree with your result
4. When you want to check the performance of an analyzer and test device

How to use calibration set

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

CAUTION

- The STANDARD F100 Analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[Internal procedural control]

1. The internal procedural control zone is in the end of the membrane of the test device. STANDARD F Analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F analyzers shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

[External quality control]

1. Positive and negative controls may be supplied with each kits or can be purchased from the distributors.
2. It is recommended that positive and negative controls be run:
   - once for each new lot.
   - once for each untrained operator.
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of influenza A/B viruses in the specimen and should not be used as the sole criteria for the diagnosis of influenza A/B virus infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of influenza A/B viruses concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

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PERFORMANCE CHARACTERISTICS

The following studies were performed with STANDARD F Influenza A/B FIA and STANDARD F200.

1. **Analytical Reactivity:** Analytical reactivity was demonstrated with STANDARD F Influenza A/B FIA and STANDARD F200 using a total 59 strains of Influenza A and B were tested by STANDARD F Influenza A/B FIA. All of the strains were detected at the concentrations listed in the below table.

Table.2 STANDARD F Influenza A/B FIA results

Viral Strain	Viral Type	Strain (sub type)	Minimum detectable level (ugHA/ml)
A/Beijing/262/95	A	H1N1	0.01
A/Brazil/11/78	A	H1N1	0.01
A/Brisbane/59/2007 (IVR-148) (H1N1)	A	H1N1	0.0013
A/California/7/09 (H1N1) (NYMC-X181)	A	H1N1	0.1125
A/California/7/09 (H1N1)v (NIBRG-121xp) (Egg Derived)	A	H1N1	0.0012
A/California/7/09 (H1N1)v (NYMCX-179A)(Cell Derived)	A	H1N1	0.0008
A/California/7/2009 (H1N1) Like (A/Brisbane/10/2010- cell derived)	A	H1N1	0.0052
A/California/7/2009 (H1N1pdm)(NYMC X-179A)	A	H1N1	0.4375
A/California/7/2009-like(NIB-74)	A	H1N1	0.0145
A/Johannesburg/82/96	A	H1N1	0.0098
A/Michigan/45/2015 (NYMC X-275)	A	H1N1	0.38
A/New Caledonia/20/99	A	H1N1	0.0016
A/New Caledonia/20/99 (IVR-116)	A	H1N1	0.26
A/New Caledonia/71/2014 (NYMCX-257A)(Egg derived antigen)	A	H1N1	0.0038
A/Puerto Rico/8/34 (HINI)	A	H1N1	0.0063
A/Singapore/GP1908/2015 (IVR-180)	A	H1N1	0.005
A/Solomon Islands/3/2006 (H1N1)(IVR-145)	A	H1N1	0.0057
A/Texas/36/91	A	H1N1	0.0035
A/USSR/92/77	A	H1N1	0.0108
A/Singapore/1/57 (H2N2)	A	H2N2	0.0028
A/Brisbane/10/2007-like (Prepared from A/Uruguay/716/2007 (NYMC X-175C))	A	H3N2	0.0018
A/Hiroshima/52/2005 (H3N2) (IVR-142)	A	H3N2	0.008
A/Hong Kong/4801/2014 (NYMC X-263B)	A	H3N2	0.075
A/Johannesburg/33/94	A	H3N2	0.0043
A/New York/55/2004 (H3N2) (NYMC X-157)	A	H3N2	0.0069
A/South Australia/55/2014 Cell derived	A	H3N2	0.0051
A/Sydney/5/97	A	H3N2	0.49
A/Texas/1/77	A	H3N2	0.0288
A/Texas/50/2012 (NYMC X-223)	A	H3N2	0.0046
A/Victoria/210/2009 (H3N2) (NYMCX-187)	A	H3N2	0.0023
A/Victoria/361/2011 (H3N2) (IVR-165)	A	H3N2	0.0247
A/Wyoming/03/03	A	H3N2	0.0625
A/Equine/Newmarket/1/93	A	H3N8	0.0513
A/Equine/Newmarket/2/93	A	H3N8	0.4
A/Anhui/1/05 (H5N1) IBCDC-RG-6	A	H5N1	0.0248
A/turkey/Turkey/1/2005 (H5N1) NIBRG-23	A	H5N1	0.0781
A/Vietnam/1194/2004 (H5N1) NIBRG-14	A	H5N1	0.0042
A/Duck/Singapore-Q/F119-3/97 (H5N3)	A	H5N3	0.0048
A/mallard/Netherlands/12/00(H7N3) NIBRG-60	A	H7N3	0.0288
A/Anhui/1/2013 (NIBRG-268) (H7N9)	A	H7N9	0.0119
A/chick/Hong Kong/G9/1997 (H9N2) NIBRG-91	A	H9N2	0.0013
A/Switzerland/9715293/2013 (NIB88)	A	H3N2	0.1375
A/Texas/50/2012 (NYMC X-223A) (Cell derived)	A	H3N2	0.0045
B/ Jiangsu/10/2003	B		16
B/Brisbane/60/08	B		2.1
B/Brisbane/60/2008 (NYMC BX-35) (Egg Derived)	B		11
B/Brisbane/60/2008 (NYMCBX-35)(Cell Derived)	B		0.0043
B/Brisbane/9/2014 (Egg Derived)	B		2.625
B/Florida/4/2006	B		0.0056
B/Guangdong/120/2000	B		0.005
B/Harbin/7/94	B		0.007
B/Hubei-Wujiagang/158/2009 (NYMCBX-39)	B		4.4
B/Johannesburg/5/99	B		1.9
B/Malaysia/2506/2004	B		1.25
B/Massachusetts/02/2012	B		7.5
B/Phuket/3073/2013	B		7.5
B/Utah/9/2014 (Cell Derived)	B		0.0006
B/Wisconsin/1/2010 (cell derived)	B		0.0036
B/Yamanashi/166/98	B		0.21
B/Colorado/06/2017 (B/Victoria/2/87 lineage)	B		0.063

* ugHA/ml = micro-gram hemagglutination dose

2. **Clinical sensitivity:** Total 164 samples were evaluated for Influenza A sensitivity. The clinical sensitivity of STANDARD F Influenza A/B FIA, got a high correlation with real time-PCR test, is presented below in table 3.

Table. 3 Clinical sensitivity of STANDARD F Influenza A/B FIA

Influenza A		PCR		Total
		Positive	Negative	
STANDARD F Influenza A/B FIA	Positive	159	0	159
	Negative	5	0	5
Total Result		164	0	164
Sensitivity		97.0% (93.0 - 99.0%)*		

* 95% confidence interval

Total 105 samples were evaluated for Influenza B sensitivity. The clinical specificity of STANDARD F Influenza A/B FIA, got a high correlation with real time-PCR test, is presented below in table 4.

Table. 4 Clinical sensitivity of STANDARD F Influenza A/B FIA

Influenza B		PCR		Total
		Positive	Negative	
STANDARD F Influenza A/B FIA	Positive	99	0	99
	Negative	6	0	6
Total Result		105	0	105
Sensitivity		94.3% (88.0 - 97.9%)*		

* 95% confidence interval

3. **Clinical specificity:** Total 124 samples were evaluated for Influenza A specificity. The clinical specificity of STANDARD F Influenza A/B FIA, got a high correlation with real time-PCR test, is presented below in table 5.

Table. 5 Clinical specificity of STANDARD F Influenza A/B FIA

Influenza A		PCR		Total
		Positive	Negative	
STANDARD F Influenza A/B FIA	Positive	0	3	3
	Negative	0	121	121
Total Result		0	124	124
Specificity		97.6% (93.1 - 99.5%)*		

* 95% confidence interval

Total 124 samples were evaluated for Influenza B specificity. The clinical specificity of STANDARD F Influenza A/B FIA, got a high correlation with real time-PCR test, is presented below in table 6.

Table. 6 Clinical specificity of STANDARD F Influenza A/B FIA

Influenza B		PCR		Total
		Positive	Negative	
STANDARD F Influenza A/B FIA	Positive	0	3	3
	Negative	0	121	121
Total Result		0	124	124
Specificity		97.6% (93.1 - 99.5%)*		

* 95% confidence interval

ANALYTICAL SPECIFICITY

1. **Cross Reactivity**
The STANDARD F Influenza A/B FIA and STANDARD F200 were evaluated with a total of 33 microorganisms and 17 non-influenza viral isolates.

- Thirty three(33) bacterial and fungal microorganisms(106cfu/ml).
- Seventeen(17) non-influenza viral isolates(10^{5}TCID50/ml).

STANDARD F Influenza A/B FIA did not show any sign of cross reactivity with microorganisms or non-influenza viral isolates listed below in table 7.

Table. 7 Cross reactivity of STANDARD F Influenza A/B FIA

NO	Microorganism/Virus	Concentration	Results (3 times repeat test)			Conclusion
			1	2	3	
1	*Bacteriodes fragilis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
2	*Bordetella pertussis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
3	*Candida albicans*	10^6 cfu/ml	- / -	- / -	- / -	Negative
4	*Corynebacterium diphtherium*	10^6 cfu/ml	- / -	- / -	- / -	Negative
5	*Escherichia coli*	10^6 cfu/ml	- / -	- / -	- / -	Negative
6	*Fusobacterium nucleatum*	10^6 cfu/ml	- / -	- / -	- / -	Negative
7	*Haemophilus influenzae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
8	*Haemophilus parainfluenzae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
9	*Klebsiella pneumoniae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
10	*Lactobacillus sp.*	10^6 cfu/ml	- / -	- / -	- / -	Negative
11	*Legionella sp.*	10^6 cfu/ml	- / -	- / -	- / -	Negative
12	*Moraxella catarrhalis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
13	*Mycobacterium tuberculosis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
14	*Mycoplasma pneumoniae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
15	*Neisseria gonorrhoeae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
16	*Neisseria meningitidis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
17	*Neisseria mucosa*	10^6 cfu/ml	- / -	- / -	- / -	Negative
18	*Neisseria sp.(Neisseria perflaus)*	10^6 cfu/ml	- / -	- / -	- / -	Negative
19	*Neisseria subflava*	10^6 cfu/ml	- / -	- / -	- / -	Negative
20	*Peptostreptococcus anaerobius*	10^6 cfu/ml	- / -	- / -	- / -	Negative
21	*Porphyromonas asaccharolyticus*	10^6 cfu/ml	- / -	- / -	- / -	Negative
22	*Propionibacterium acnes*	10^6 cfu/ml	- / -	- / -	- / -	Negative
23	*Proteus mirabilis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
24	*Pseudomonas aeruginosa*	10^6 cfu/ml	- / -	- / -	- / -	Negative
25	*Serratia marcescens*	10^6 cfu/ml	- / -	- / -	- / -	Negative
26	*Staphylococcus aureus*	10^6 cfu/ml	- / -	- / -	- / -	Negative
27	*Staphylococcus epidermidis*	10^6 cfu/ml	- / -	- / -	- / -	Negative
28	*Streptococcus mutans*	10^6 cfu/ml	- / -	- / -	- / -	Negative
29	*Streptococcus pneumoniae*	10^6 cfu/ml	- / -	- / -	- / -	Negative
30	*Streptococcus pyogenes*	10^6 cfu/ml	- / -	- / -	- / -	Negative
31	*Streptococcus sp. Group C*	10^6 cfu/ml	- / -	- / -	- / -	Negative
32	*Streptococcus sp. Group G*	10^6 cfu/ml	- / -	- / -	- / -	Negative
33	*Streptococcus salivarius*	10^6 cfu/ml	- / -	- / -	- / -	Negative
34	Adenovirus type 1	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
35	Adenovirus type 7	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
36	Human coronavirus (OC43)	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative
37	Human coronavirus (229E)	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
38	Human coxsackievirus	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
39	Cytomegalovirus	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative
40	Epstein Barr Virus	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
41	Human parainfluenza type 1	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
42	Human parainfluenza type 2	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative
43	Human parainfluenza type 3	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
44	Measles	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
45	Human metapneumovirus	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative
46	Mumps virus	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
47	Respiratory syncytial virus type A	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
48	Respiratory syncytial virus type B	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative
49	Rhinovirus type 1B	10^5 $TCID_{50}$/ml	- / -	- / -	- / -	Negative
50	Enterovirus	10^5 $TCID_{50}$/mll	- / -	- / -	- / -	Negative

2. **Interfering Substances**
Several over-the-counter substances, chemicals and body fluids (whole blood, mucin) were evaluated with STANDARD F Influenza A/B FIA and STANDARD F200. There are no interfering reactions with substances below listed in Table 8.

Table. 8 Non-interfering Substance

No.	Potential interfering substances	Conc. of substances
1	Acetaminophen	10 mg/ml
2	Acetylsalicylic acid	20 mg/ml
3	Guaiacol glyceryl ether	20 mg/ml
4	Oxymetazoline	0.05 mg/ml
5	Whole blood	2%
6	Mucin	1 mg/ml
7	Tobramycin	500 ng/ml
8	Mupirocin	10 mg/ml
9	Fluticasone Propionate	500 ng/ml
10	Tamiflu (Oseltamivir Phosphate)	5 mg/ml

* Each potential interfering substance was spiked in influenza A, B positive and negative specimens according to the concentration set out above.

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