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FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette

Instructions For Use

REF **R225T020B0C0** 20 Tests/kit **R225T025B0C0** 25 Tests/kit

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of influenza A (FLU A), influenza B (FLU B), COVID-19 (SARS-CoV-2), respiratory syncytial virus(RSV), adenovirus (Adeno) and mycoplasma pneumoniae (MP) antigen in nasopharyngeal swab specimens. This test is intended for use as an aid in the differential diagnosis of influenza A, influenza B, COVID-19, respiratory syncytial virus, adenovirus viral and mycoplasma pneumoniae infections in humans in conjunction with clinical and epidemiological risk factors.

Summary

The FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of influenza A, influenza B, COVID-19, respiratory syncytial virus (RSV), adenovirus and mycoplasma pneumoniae antigen in nasopharyngeal swab specimens from individuals with suspected influenz A&B/COVID-19/RSV/adenovirus/MP infection in conjunction with clinical presentation and the results of other laboratory tests. Results are for the detection of influenza A+B, COVID-19, RSV, adenovirus and MP antigen. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigen, but clinical correlation with patient medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial/viral infection. Negative results should be treated as a presumption and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, medical history and the presence of clinical signs and symptoms consistent with influenza A+B, COVID-19, RSV, adenovirus and MP. The FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette is intended for use by trained clinical laboratory personnel.

TEST PRINCIPLE

The FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette is a qualitative membrane strip based immunoassay for the detection of influenza A virus, and influenza B virus, COVID-19 virus, respiratory syncytial virus(RSV), adenovirus and mycoplasma pneumoniae (MP) antigen in nasopharyngeal swab specimens.

In this test procedure, influenza A antibody, influenza B antibody, COVID-19-N antibody, RSV virus antibody adenovirus antibody and mycoplasma pneumoniae antibody is immobilized in the different test line regions of the device. After a nasopharyngeal swab specimen is placed in the specimen well, it reacts with influenza A antibody, influenza B antibody, COVID-19-N antibody, respiratory syncytial virus antibody, adenovirus antibody and mycoplasma pneumoniae antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized influenza A antibody, influenza B antibody, COVID-19-N antibody, respiratory syncytial virus, adenovirus antibody and mycoplasma pneumoniae antibody. If the specimen contains influenza A virus antigen, influenza B virus antigen, COVID-19 virus antigen, respiratory syncytial virus antigen, adenovirus antigen or mycoplasma pneumoniae antigen, a colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain influenza A virus antigen, influenza B virus antigen, COVID-19 virus antigen, respiratory syncytial virus antigen, adenovirus antigen or mycoplasma pneumoniae antigen, a colored line will not appear in these regions indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Material Provided

Kit size: 20 tests/kit

Test Cassette - 20	Instructions for use - 1	Workstation - 1
Disposable swab - 20	Extraction tube with buffer solution - 20	

Kit size: 25 tests/kit

Test Cassette - 25	Instructions for use - 1	Workstation - 1
Disposable swab - 25	Extraction tube with buffer solution - 25	

Materials not provided:

Timer, specimen collection container, centrifuge, disposable latex gloves, sealed bag and disinfectant.

STORAGE AND STABILITY

- Stored at 2-30℃, the validity period of the product is 24 months. Do not freeze.
- The test cassette should be used within 1 hour after opening the sealed pouch. If the temperature is higher than 30℃ or in high humidity environment, it should be to use immediately.
- Kit contents are stable until the expiration date printed on the package.
- Keep away from sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only. Do not use after expiration date. Do not reuse the test cassette.
2. Do not eat, drink, or smoke in the area where the samples or kits are handled.
3. Handle all samples as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
5. The test cassette should remain in a sealed foil pouch until use. Do not use the test cassette if the pouch is damaged or opened.
6. Allow the test device and specimens to equilibrate at room temperature (15-30℃) and humidity (<80%)prior to testing.
7. After use, the test cassette can be disposed of with household waste in a sealed bag.
8. Follow local standard biosafety guidelines for handling and disposal of potential infective materials.

SPECIMEN COLLECTION AND HANDLING

- Only the swab provided in the kit is to be used for nasopharyngeal swab collection.
- To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasopharyngeal wall and then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods.
- Bring specimens to room temperature prior to testing.
- If it is not possible to test immediately, it is strongly recommended that the swab is placed in a clean, unused plastic extraction tube labelled with patient information to maintain best performance and avoid possible contamination. The sample can be kept tightly sealed in this extraction tube at room temperature (15-30℃ or 59-86℉) for a maximum of one hour. Make sure that the swab is firmly seated in the extraction tube and that the cap is tightly closed. If a delay of more than one hour occurs , discard the sample. A new sample must be taken for the test.
- If specimens are to be transported, they should be packaged according to local regulations for the transport of pathogens.

TEST PROCEDURE

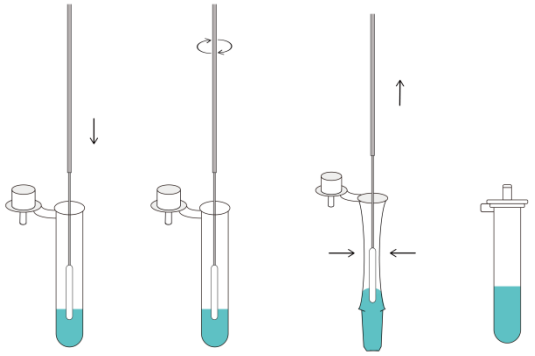
Please read the instructions for use carefully before use.

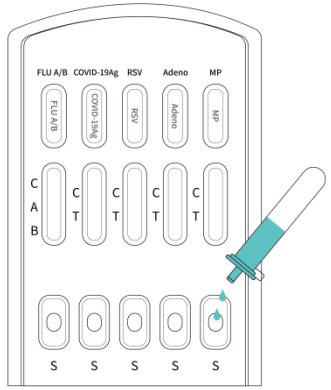
Allow the test cassette, buffer to room temperature 15-30 ℃ (59-86 ℉) before testing.

1. Place the extraction tube in the workstation. Peel off aluminum foil seal from the top of the extraction tube containing the extraction buffer .
2. Place the swab into the extraction tube. Rotate the swab for 10-15 seconds while pressing the head against the inside of the tube to release the specimens in the swab.
3. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. When ready to test, open the pouch at the notch and take out the test cassette. Place the test cassette on a clean, flat surface.
5. Fit the tube tip or close the cap onto the tube, then invert the extraction tube and add 3 drops of specimen (approximately 90μL) into each of the specimen well (S) and then start the timer.
6. Read the result at 15 minutes. If left unread for 20 minutes or more, the results are invalid and a repeat test is recommended.

Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of specimen.





INTERPRETATION OF RESULTS

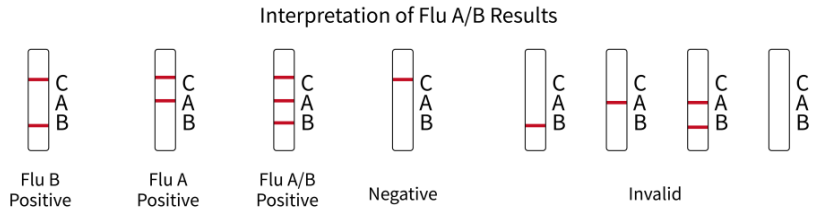
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking, and correct procedural technique.

1. Interpretation of Flu A/B Results:

Positive: Control line and at least one test line appear on the membrane. The appearance of A test line indicates the presence of Flu A antigen. The appearance of B test line indicates the presence of Flu B antigen. And if both A and B line appear, it indicates that the presence of both Flu A and Flu B antigen.

Negative: One colored line appears in the control region(C). No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device . If the problem persists, discontinue using the test kit immediately and contact your local distributor.

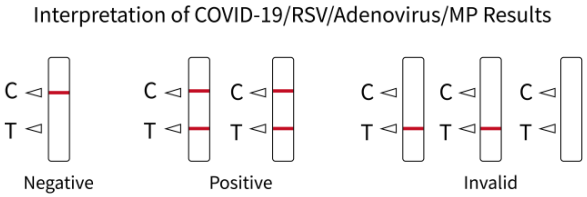


2. Interpretation of COVID-19/RSV/Adenovirus/MP Results

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

Negative: One colored line appears in the control region(C). No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device . If the problem persists, discontinue using the test kit immediately and contact your local distributor.



***NOTE:** The intensity of the color in the test line regions may vary depends on the concentration of virus antigen. Therefore, any shade of color in the test line region should be considered positive.

PROCEDURAL CONTROL

There are internal procedural controls in the test. A colored line displayed in the control area (C) is an internal procedural control. It confirms the presence of a sufficient amount of sample and correct procedure.

LIMITATIONS OF THE TEST METHOD

1. This test detects both viable (live) and non-viable, FLU A/B, SARS-CoV, COVID-19, respiratory syncytial virus(RSV), adenovirus and mycoplasma pneumoniae(MP) antigen. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample .
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of FLU A&B &COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected , transported, or handled.
5. False results may occur if specimens are tested past 1 hour of collection. Specimen should be test as quickly as possible after specimen collection .
6. Positive test results do not rule out co-infections with other pathogens
7. Positive test results do not differentiate between SARS-CoV and COVID-19 antigen .
8. Negative test results are not intended to rule in other viral or bacterial infections .
9. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
10. If the differentiation of specific influenza A virus , influenza B virus and COVID-19 virus and respiratory syncytial virus(RSV), adenovirus and mycoplasma pneumoniae(MP) antigen is needed, additional testing, in consultation with local public health departments.
11. A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing if required.

PERFORMANCE CHARACTERISTICS

1. Clinical performance

1.1 The evaluation assay results for Influenza A are as below:

Table 1. Influenza A: Comparison of evaluation assay and reference assay:

Reference		A leading Commercial FLU A test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	108	2	110
	Negative	2	818	820
TOTAL RESULTS		110	820	930

The coincidence rate of sensitivity:98.18% (95%CI*: 93.59 %-99.78%)
The coincidence rate of specificity: 99.76% (95%CI*: 99.12%-99.97%)
Total coincidence rate: 99.57% (95%CI*:98.90%-99.88%)

1.2 The evaluation assay results for Influenza B are as below:

Table 2. Influenza B: Comparison of evaluation assay and reference assay

Reference		A leading Commercial FLU B test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	101	1	102
	Negative	2	826	828
TOTAL RESULTS		103	827	930

The coincidence rate of sensitivity: 98.06% (95%CI*: 93.16%-99.76%)
The coincidence rate of specificity: 99.88% (95%CI*: 99.33%-100.00%)
Total coincidence rate: 99.68% (95%CI*: 99.06%-99.93%)

1.3 The evaluation assay results for SARS-CoV-2 are as below:

Table 3. SARS-CoV-2: Comparison of evaluation assay and reference assay

Reference		A leading Commercial COVID-19 Test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	134	3	137
	Negative	3	790	793
TOTAL RESULTS		137	793	930

The coincidence rate of sensitivity: 97.81% (95%CI*: 93.73%-99.55%)
The coincidence rate of specificity: 99.62% (95%CI*: 98.90%-99.92%)
Total coincidence rate:99.35% (95%CI*: 98.60%-99.76%)

Table 4. SARS-CoV-2: Subjects on Days Post-Symptom Onset

Days post Symptom onset	Number of samples	Commercial Test Positive Result	FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette (COVID-19 Test Positive Result)	95% Confidence Interval
1	4	4	4（100.00%）	47.29%-100.00%
2	15	15	15（100.00%）	81.90%-100.00%
3	15	15	15（100.00%）	81.90%-100.00%

4	17	17	17（100.00%）	83.84%-100.00%
5	25	25	24（96.00%）	79.65%-99.90%
6	27	27	26（96.30%）	81.03%-99.91%
7	34	34	33（97.06%）	84.67%-99.92%
Total	137	137	134（97.81%）	93.73%-99.55%

1.4 The evaluation assay results for RSV are as below:

Table 5. RSV: Comparison of evaluation assay and reference assay

Reference		A leading Commercial RSV test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	127	6	133
	Negative	3	794	797
TOTAL RESULTS		130	800	930

The coincidence rate of sensitivity: 97.69% (95%CI*: 93.40%-99.52%)

The coincidence rate of specificity: 99.25% (95%CI*:98.37%-99.72%)

Total coincidence rate: 99.03% (95%CI*: 98.17%-99.56%)

1.5 The evaluation assay results for Adenovirus are as below:

Table 6. Adenovirus: Comparison of evaluation assay and reference assay

Reference		A leading Commercial Adenovirus test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	109	2	111
	Negative	1	818	819
TOTAL RESULTS		110	820	930

The coincidence rate of sensitivity: 99.09% (95%CI*: 95.04%-99.98%)

The coincidence rate of specificity: 99.76% (95%CI*: 99.12%-99.97%)

Total coincidence rate: 99.68% (95%CI*:99.06% -99.93%)

1.6 The evaluation assay results for MP are as below:

Table 7. MP: Comparison of evaluation assay and reference assay

Reference		A leading Commercial MP test		Total Results
Method	Result	Positive	Negative	
FLU A&B & COVID-19 & RSV & Adeno & MP Antigen Combo Test Cassette	Positive	99	6	105
	Negative	1	824	825
TOTAL RESULTS		100	830	930

The coincidence rate of sensitivity: 99.00% (95%CI*: 94.55%-99.97%)

The coincidence rate of specificity: 99.27% (95%CI*: 98.43%-99.73%)

Total coincidence rate: 99.25%(95%CI*: 98.45% -99.70%)

2. Interference

For Flu A

The following compounds have been tested using the Flu A test and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μL/mL	Oxymetazoline	0.6mg/mL
Mucin	50μg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200μL/mL	Rebetol	4.5μg/mL
Dexamethasone	0.8mg/mL	Relenza	282ng/mL
Fluni solide	6.8ng/mL	Tamiflu	1.1μg/mL
Mupirocin	12mg/mL	Tobryamycin	2.43mg/mL

For Flu B

The following compounds have been tested using the Flu B test and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μL/mL	Oxymetazoline	0 6mg/mL
Mucin	50μg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200μL/mL	Rebetol	4 5μg/mL
Dexamethasone	0.8mg/mL	Relenza	282ng/mL
Fluni solide	6. 8ng/mL	Tamiflu	1.1μg/mL
Mupirocin	12mg/mL	Tobryamycin	2.43mg/mL

For COVID-19

The following compounds have been tested using the COVID-19 test and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μL/mL	Oxymetazoline	0.6mg/mL
Mucin	50μg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200μL/mL	Rebetol	4 5μg/mL
Dexamethasone	0 8mg/mL	Relenza	282ng/mL

For RSV

The following compounds have been tested using the respiratory syncytial virus test and no interference was observed.

Mucin	Meropenem	Lopinavir	Dexamethasone
Blood	Tobramycin	Ritonavir	Flunisolide
α-Interferon	Histamine hydrochloride	Abidol	Triamcinolone Acetonide
Zanamivir	Benfulin	Levofloxacin	Budesonide
Ribavirin	Oxymetazoline	Azithromycin	Momitsone
Oseltamivir	NaCl(including preservative)	Human Anti-mouse Antibody(HAMA)	Fluticasone
Palamivir	Beclomethasone	Cefatriaxone	Biotin

For Adenovirus

The following compounds have been tested using the adenovirus antigen test and no interference was observed.

Mucin	Meropenem	Lopinavir	Dexamethasone
Blood	Tobramycin	Ritonavir	Flunisolide
α-Interferon	Histamine hydrochloride	Abidol	Triamcinolone Acetonide
Zanamivir	Benfulin	Levofloxacin	Budesonide
Ribavirin	Oxymetazoline	Azithromycin	Momitsone
Oseltamivir	NaCl(including preservative)	Human Anti-mouse Antibody(HAMA)	Fluticasone
Palamivir	Beclomethasone	Cefatriaxone	Biotin

For MP

The following compounds have been tested using the Mycoplasma Pneumoniae Antigen Test and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μl/mL	Oxymetazoline	0.6mg/mL
Mucin	50μg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200μl/mL	Rebetol	4.5μg/mL
Dexamethasone	0.8mg/mL	Relenza	282ng/mL
Fluni solide	6.8ng/mL	Tamiflu	1.1μg/mL
Mupirocin	12mg/mL	Tobramycin	2.43mg/L

3. Cross-reactivity

For Flu A

The Flu A Antigen Test has been tested for other virus(Table below). The results showed no cross-reactivity.

Influenza B	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Pseudomonas aeruginosa	Mumps	Escherichia coli	Streptococcus pygenes
Nesseria subllava	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius

Respiratory syncytial virus	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	COVID-19 virus		

For Flu B

The Flu B Antigen Test has been tested for other virus(Table below). The results showed no cross-reactivity .

Influenza A H3N2	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Pseudomonas aeruginosa	Mumps	Escherichia coli	Streptococcus pygenes
Nesseria subllava	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Respiratory syncytial virus	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	COVID-19 virus	Influenza A H1N1	

For COVID-19

The COVID-19 Antigen Test has been tested for other virus(Table below). The results showed no cross - reactivity.

Pseudomonas aeruginosa	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Influenza A H1N1	Mumps	Escherichia coli	Streptococcus pygenes
Influenza A H3N2	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Influenza B	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	Respiratory syncytial virus	Nesseria subllava	

For RSV

The respiratory syncytial virus Antigen Test has been tested for other virus(Table below). The results showed no cross-reactivity.

Nesseria subllava	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Influenza A H1N1	Mumps	Escherichia coli	Streptococcus pygenes
Influenza A H3N2	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Influenza B	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	Pseudomonas aeruginosa		

For Adenovirus and MP

The adenovirus Antigen Test and MP Antigen Test has been tested for other virus(Table below). The results showed no cross-reactivity.

Pseudomonas aeruginosa	Human Rhinovirus 14	Arcanobacterium	Staphylococcus aureus subspaureus
Human coronavirus OC43	Human Rhinovirus 16	Candida albicans	Staphylococcus epidermidis
Coronvirus NL63	Measles	Corynebacterium	Streptococcus pneumoniae
Influenza A H1N1	Mumps	Escherichia coli	Streptococcus pygenes
Influenza A H3N2	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Influenza B	Parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Human Rhinovirus 2	Nesseria subllava		

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INDEX OF SYMBOLS

	Consult Instructions for Use	Σ	Contains sufficient for <n> tests		Temperature limit
IVD	In vitro diagnostic medical device		Use by date		Manufacturer
REF	Catalogue number	LOT	Batch code		Date of manufacture
CE	CE conformity marking	EC REP	Authorized representative in the European Community/ European Union		Do not re-use
	Do not use if package is damaged and consult instructions for use				

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