TruQuick™ Influenza A/B 20T

A rapid test for the qualitative detection of Influenza A and Influenza B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens. For professional in vitro diagnostic use only.

REF **TQ5820** IVD **Rx Only**

INTENDED USE

The TruQuick Influenza A/B is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY AND EXPLANATION OF THE TEST

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. 1 Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus. 2 Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%. 3 However, RT-PCR is expensive, complex and must be performed in specialized laboratories.

The TruQuick Influenza A/B (Swab/Nasal Aspirate) qualitatively detects the presence of Influenza A and/or Influenza B antigen in nasopharyngeal swab or throat swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Influenza A and Influenza B to selectively detect Influenza A and Influenza B antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens.

BIOLOGICAL PRINCIPLES

The TruQuick Influenza A/B (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens. In this test, antibodies specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibodies to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibodies to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS/MATERIALS PROVIDED

The maximum number of tests obtained from this test kit is listed on the outer box.

- Test Cassettes: The Test Cassette contains anti-Influenza A and anti-Influenza B coated particles and anti-Influenza A and anti-Influenza B coated on the membrane.
- Extraction Reagent Buffer
- Extraction Tubes
- Sterile Swabs
- Extraction Tube Tips
- Workstation
- Package Insert

MATERIALS NOT PROVIDED

- Timer
- Aspiration Device

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

HAZARD and PRECAUTIONARY STATEMENTS

Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE

Store as packaged at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

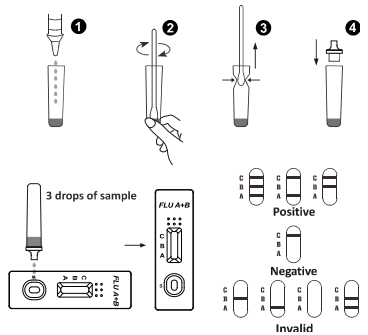
SPECIMEN COLLECTION AND PREPARATION

1. Nasopharyngeal swab sample
   Insert a sterilized swab into a nasal cavity securely through a nostril and collect mucoepidermis by wiping turbinate several times.
2. Throat swab sample
   Insert a sterilized swab into pharynx and collect mucoeoidermis mainly by wiping flare region of post-pharyngeal wall and palatine tonsil several times. Be careful not to allow saliva to attach to the swab.
3. Nasal aspirate
   Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity through a nostril, start the aspiration device and then collect nasal aspirate sample. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

TEST PROCEDURE

Allow the test, specimen, Extraction Reagent Buffer to equilibrate to room temperature (15-30 C) prior to testing.

1. Remove the Test Cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the Extraction Reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the Extraction Tube freely without touching the edge of the tube. Add 10 drops of solution (approx. 400 µL) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as it is removed to expel as much liquid as possible from the swab. Discard the swab in accordance with local biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the Extraction Tube. Place the Test Cassette on a clean and level surface. See illustration 4.
6. Add three drops of the solution (approx.120 µL) to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above.)

POSITIVE Influenza A:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear. One colored line should be in the control region (C) and colored lines should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE**: The intensity of the color in the test line regions (A or B) will vary based on the amount of influenza A or B antigen present in the sample. Any shade of color in the test regions (A or B) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test line regions (A or B).

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 Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL

This test should be performed per applicable local, state, or federal regulations or accrediting agencies.

Internal Quality Control

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Control

External controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative external controls are recommended.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES

TruQuick Influenza A/B was compared with a leading commercial RT-PCR test. The correlation between these two systems is over 97%.

LIMITATIONS OF THE PROCEDURE

1. TruQuick Influenza A/B is for in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasopharyngeal swab, throat swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus concentration can be determined by this qualitative test.
2. TruQuick Influenza A/B will only indicate the presence of Influenza A and/or B virus in the specimen from both viable and nonviable Influenza A and B strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasopharyngeal swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for influenza A and/or B does not preclude an underlying coinfection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

TruQuick Influenza A/B was evaluated with specimens obtained from the patients. RT-PCR was used as the reference method. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result

Nasopharyngeal Swab Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
TruQuick Flu A+B	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Sensitivity		99.0%			97.7%		
Specificity		98.9%			99.0%		
Correlation		98.9%			98.6%		

Throat Swab Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
TruQuick Flu A+B	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
Total		61	151	212	69	163	232
Sensitivity		95.1%			94.2%		
Specificity		99.3%			99.4%		
Correlation		98.1%			97.8%		

Nasal Aspirate Specimen

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
TruQuick Flu A+B	Positive	46	2	48	94	1	95
	Negative	0	241	241	2	158	160
Total		46	243	289	96	159	255
Sensitivity		100%			97.9%		
Specificity		99.2%			99.4%		
Correlation		99.3%			98.8%		

Reactivity with Human Influenza Strain

TruQuick Influenza A/B was tested with the following human influenza strains and a discernible line at the appropriate test-line region was observed:

Influenza A Virus	*Influenza B Virus*
A/NWS/33 10(H1N1)	B/R5
A/Hong Kong/8/68(H3N2)	B/Russia/69
A/Port Chalmers/1/73(H3N2)	B/Lee/40
A/WS/33(H1N1)	B/Hong Kong/5/72
A/New Jersey/8/76(HswN1)	
A/Mal/302/54(H1N1)	
A/chicken/Yuyao/2/2006 (H5N1)	
A/swine/Hubei/251/2001 (H9N2)	
A/Duck/Hubei/216/1983 (H7N8)	
A/Duck/Hubei/137/1982 (H10N4)	
A/Anhui/1/2013 (H7N9)	

Specificity Testing with Various Viral Strains

Description	Test Level
Human adenovirus C	5.62 x 10^5 TCID50/mL
Human adenovirus B	1.58 x 10^4 TCID50/mL
Adenovirus type 10	3.16 x 10^3 TCID50/mL
Adenovirus type 18	1.58 x 10^4 TCID50/mL
Human coronavirus OC43	2.45 x 10^6 LD50/mL
Coxsackievirus A9	2.65 x 10^4 LD50/mL 1.58 x 10^5 TCID50/mL
Coxsackievirus B5	1.58 x 10^7 TCID50/mL
Human herpesvirus 5	1.58 x 10^4 TCID50/mL
Echovirus 2	3.16 x 10^5 TCID50/mL
Echovirus 3	1 x 10^4 TCID50/mL
Echovirus 6	3.16 x 10^6 TCID50/mL
Herpes simplex virus 1	1.58 x 10^6 TCID50/mL
Human herpesvirus 2	2.81 x 10^5 TCID50/mL
Human Rhinovirus 2	2.81 x 10^4 TCID50/mL
Human Rhinovirus 14	1.58 x 10^6 TCID50/mL
Human Rhinovirus 16	8.89 x 10^6 TCID50/mL
Measles	1.58 x 10^4 TCID50/mL
Mumps	1.58 x 10^4 TCID50/mL
Sendai virus	8.89 x 10^7 TCID50/mL
Parainfluenza virus 2	1.58 x 10^7 TCID50/mL
Parainfluenza virus 3	1.58 x 10^8 TCID50/mL
Respiratory syncytial virus	8.89 x 10^4 TCID50/mL
Human respiratory syncytial virus	1.58 x 10^5 TCID50/mL
Rubella	2.81 x 10^5 TCID50/mL
Varicella-Zoster	1.58 x 10^3 TCID50/mL

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.
LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

REPRODUCIBILITY
Intra-Assay & Inter-Assay Precision
Within-run and Between-run precision was determined by using five specimens of negative, Influenza A weak, Influenza B Weak, Influenza A Strong and Influenza B Strong and three different lots of TruQuick Influenza A/B were tested. Five replicates of each level were tested each day for three consecutive days. The specimens were correctly identified>99% of the time.

CROSSREACTIVITY
The following organisms were tested at 1.0x10^8 org/mL and all found to be negative when tested with TruQuick Influenza A/B:

Arcanobacterium
Candida albicans
Corynebacterium
Enterococcus faecalis
Enterococcus faecium
Escherichia coli
Haemophilus
Moraxella catarrhalis
Neisseria gonorrhoeae
Neisseria lactamica
Nesseria subllava
Proleus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus subspaureus
Staphylococcus epidermidis
Staphylococcus saprophylicus
Streptococcus agalactiae
Streptococcus bovis
Streptococcus dysgalatiae / subsp. dysgalatiae
Streptococcus oralis formerly *Streptococcus*
Streptococcus pneumoniae
Streptococcus pygenes
Streptococcus salivarius
Streptococcus sp group F.type 2

ANALYTICAL SENSITIVITY
Titration studies performed with antigen-positive samples diluted in PBS have shown the assay will detect influenza to 3.0 x 10^4 $TCID_{50}$/test and influenza B to 1.5 x 10^5 $TCID_{50}$/test.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to samples spiked with 0.5% BSA-PBS, 200 HA/mL influenza A virus, 330 HA/mL influenza A virus, 30 HA/mL influenza B virus and 60 HA/mL influenza B virus. None of the substances interfered in the assay:

Cherry Halls® cough drops
Menthol Halls® cough drops
Robitussin® cough syrup
Dimetapp® cough syrup
Vicks® Chloroseptic spray
Cepacol® Chloroseptic spray
Listerine® mouthwash
Scope® mouthwash

REFERENCES

1. Williams KM, Jackson MA, Hamilton M. Rapid diagnostic testing for URIs in children; Impact on physician decision making and cost. Infec Med. 2002;19(3):109-111.
2. Betts RF. Influenza virus. In Mandell GL, Douglas RG Jr, Bennett JE. (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y. 1995;p. 1546-1567.
3. WHO recommendations on the use of rapid testing for influenza diagnosis, WHO. July 2005.

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.