TruQuick™ RSV 20T

A rapid test for the qualitative detection of Respiratory Syncytial Virus Antigen in nasopharyngeal swab or nasal aspirate specimens.

REF **TQ5320** IVD **Rx Only**

INTENDED USE
TruQuick RSV is a qualitative, lateral flow chromatographic immunoassay for the detection of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of respiratory syncytial virus viral infections.

SUMMARY AND EXPLANATION OF THE TEST
Respiratory Syncytial Virus (RSV), which causes infection of the lungs and breathing passages, is a major cause of respiratory illness in young children. In adults, it may only produce symptoms of a common cold, such as a stuffy or runny nose, sore throat, mild headache, cough, fever, and a general feeling of being ill. But in premature babies and kids with diseases that affect the lungs, heart, or immune system, RSV infections can lead to other more serious illnesses.[1] RSV is highly contagious and can be spread through droplets containing the virus when someone coughs or sneezes. It also can live on surfaces (such as countertops or doorknobs) and on hands and clothing, so it can be easily spread when a person touches something contaminated. RSV can spread rapidly through schools and childcare centers. Babies often get it when older kids carry the virus home from school and pass it to them. Almost all kids are infected with RSV at least once by the time they're 2-3 years old.[2] RSV infections often occur in epidemics that last from late fall through early spring. Respiratory illness caused by RSV — such as bronchiolitis or pneumonia — usually lasts about a week, but some cases may last several weeks.

TruQuick RSV qualitatively detects the presence of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Respiratory Syncytial Virus to selectively detect Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens.

BIOLOGICAL PRINCIPLES
TruQuick RSV is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab or nasal aspirate specimens. In this test, antibody specific to the Respiratory Syncytial Virus nucleoproteins is coated on the test line regions of the Test Cassette. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored line in the test regions. The presence of this colored line in 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-Respiratory Syncytial Virus particles and anti-Respiratory Syncytial Virus coated on the membrane.
- Extraction Reagent
- Extraction Tubes
- Extraction Tube Tips
- Sterile Swabs
- Workstation
- Package insert

MATERIALS NOT PROVIDED
- Timers
- Aspiration Device

PRECAUTIONS
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.

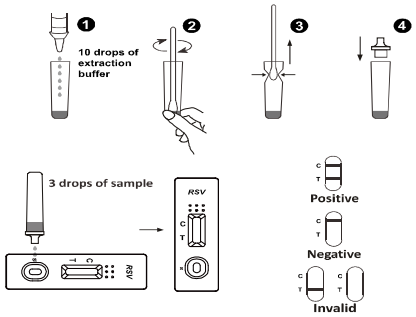
HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

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 from a nostril and collect mucoepidermis wiping turbinate several times.

2. Nasopharyngeal aspirate
Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from 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 Buffer and/or controls to reach 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.
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.
4. 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.
5. Fit the dropper tip on top of the Extraction Tube. Place the Test Cassette on a clean and level surface.
6. Add 3 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:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). A positive result in the test region indicates that Respiratory Syncytial Virus antigen was detected in the sample.
NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test line regions (T).
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 procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that a positive control and a negative external control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

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
The TruQuick RSV has been compared with a leading commercial RT-PCR test. The correlation between these two systems is over 95%.

LIMITATIONS OF THE PROCEDURE
1. TruQuick RSV is for in vitro diagnostic use only. The test should be used for the detection of Respiratory Syncytial Virus in nasopharyngeal swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Respiratory Syncytial Virus concentration can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. TruQuick RSV is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with Respiratory Syncytial Virus.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
5. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
6. 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity, Specificity and Correlation
TruQuick RSV was evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for TruQuick RSV. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result

TruQuick RSV		Nasopharyngeal swab Specimen			Nasal Aspirate Specimen		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
	Positive	76	2	78	87	2	89
	Negative	6	99	105	7	128	135
Total		82	101	183	94	130	224
Sensitivity		92.7%			92.6%		
Specificity		98.0%			98.5%		
Correlation		95.6%			96.0%		

Reaction with Various Serotype of Respiratory Syncytial Virus
The current test kit is able to detect the following serotype of the Respiratory Syncytial Virus: Subtype A (A2,long), Subtype B (9320, wild-type).

REPRODUCIBILITY
Intra-Assay and Inter-Assay Precision
Within-run and Between-run precision was determined by using three specimens of Respiratory Syncytial Virus standard control. Three different lots of TruQuick RSV have been tested using 0.5% BSA-PBS, 200 HA/mL RSV and 330 HA/mL RSV specimens. Ten replicates of each level were tested. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY
No crossreaction has been confirmed of TruQuick RSV with the following pathogens:
1. Bacteria
   Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum, Escherichia coil，Group C *streptococcus*, Group G *streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae, Peptococcus asaccharolyticus, Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae* (group B), *Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes* (group A), *Veillonella parvula*
2. Virus
   Influenza A, Influenza B, Adenovirus Type 1~8,11,19,37, Coxsackie virus Type A16, B1~5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Type I simple herpes virus, Parainfluenza virus Type 1~3, Poliovirus Type 1~3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14
3. Mycoplasma etc.
   No crossreaction with *Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae*.

TESTS FOR INTERFERING SUBSTANCES
The following substances were tested with TruQuick RSV and no interference was observed:
Cherry Halls® cough drops, Menthol Halls® cough drops, Robitussin® cough syrup, Dimetapp® cough syrup, Vicks Chloraseptic® spray, Cepacol Chloraseptic® spray, Listerine® mouthwash, Scope® mouthwash.

REFERENCES

1. Glezen WP, Taber LH, Frank AL, Kasel JA. Risk of primary infection and reinfection with respiratory syncytial virus. American journal of diseases of children. 1986;(1960)140(6): 543–6.
2. Hall CB, Weinberg GA, Iwane MK, Blumkin AK, Edwards KM, Staat MA, et al. The burden of respiratory syncytial virus infection in young children. New Engl J of Med. 2009;360(6):588–98.

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SNTQ5320 **REV. 05/17**

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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	R_x 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.