JOY TEST

Bordetella pertussis Antigen Rapid Test (Nasopharyngeal Swab) Instructions

REF IBP-502

English

A rapid test for the qualitative detection of Bordetella pertussis Antigens in human Nasopharyngeal swab specimen.

For professional in vitro diagnostic use only.

INTENDED USE

The *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Bordetella pertussis* Antigens in human Nasopharyngeal swab as an aid in the diagnosis of *Bordetella pertussis* infection.

SUMMARY

Pertussis, "severe cough", also known as pertussis or "cough for 100 days", was originally described in the Paris epidemic in 1578. Pertussis is a highly infectious respiratory tract infection, mainly caused by bacteria.[1-2]

It is characterized by a "hacking" cough, followed by a high-pitched intake of breath, or a" whoop" (hence the common names of whooping cough). The disease is most dangerous in infants and young children, and can give rise to complications and even lead to death. The bacterium *Bordetella pertussis*, that causes the disease, can be found in all countries. Pertussis spreads easily from person to person mainly through droplets produced by coughing or sneezing. [2]

PRINCIPLE

The *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab) is a qualitative, membrane based immunoassay for the detection of antigens to *Bordetella pertussis* in nasopharyngeal swab. The membrane is pre-coated with anti-*Bordetella pertussis* antibodies. During testing, the *Bordetella pertussis* antigen in swab specimen reacts with *Bordetella pertussis* antibody particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-*Bordetella pertussis* antibodies on the membrane in the test line region. If the specimen contains antigen to *Bordetella pertussis*, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain *Bordetella pertussis* antigen, a colored line will not appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-*Bordetella pertussis* antibodies coated particles and anti-*Bordetella pertussis* antibodies coated on the membrane.

PRECAUTIONS

Please read all the information in this instructions before performing the test.

1. For professional *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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either 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 after the expiration date.

MATERIALS

Materials provided

- Test device
- Tube with buffer
- Swab
- Instructions

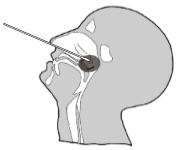
Materials required but not provided

- Timer

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Nasopharyngeal Swab Specimen Collection

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx 5-10 times.
3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.



Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

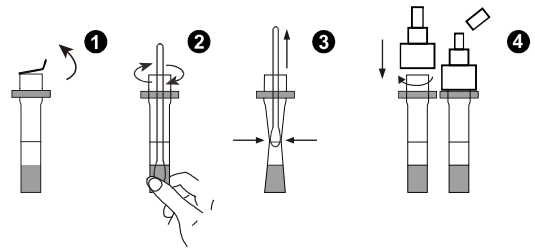
Specimen Transport and Storage

Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8°C.

SPECIMEN PREPARATION

Only the extraction buffer provided in the kit is to be used for swab specimen preparation.

1. Remove the cover on the specimen collection tube.
2. Place the swab specimen in the Extraction Tube with Extraction Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen 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. Tighten the cap onto the specimen collection tube. Hold the specimen collection tube upright then unscrew the tip of the specimen collection tube.

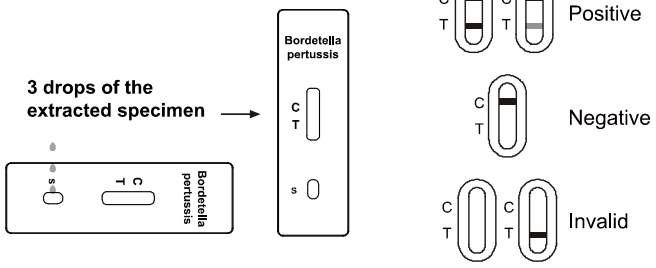


*__NOTE__: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8 °C.

DIRECTIONS FOR USE

Allow the test, specimen swab, 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 within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen extraction tube and add **3 drops of extracted specimen** to specimen well(S) and then start the timer.
3. Wait for the colored line(s) to appear. **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 colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *Bordetella pertussis* antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (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. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

QUALITY CONTROL

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 specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of *Bordetella pertussis* antigens in nasopharyngeal swab specimens. Neither the quantitative value nor the rate of increase in *Bordetella pertussis* antigens can be determined by this qualitative test.
2. The *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab) will only indicate the presence of *Bordetella pertussis* antigens in the specimen and should not be used as the sole criteria for the diagnosis of *Bordetella pertussis* infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Bordetella pertussis* infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab) was evaluated with clinical swab specimens whose status was confirmed using RT-PCR. The results are presented in the following tables.

Method		RT-PCR		Total Results
***Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab)**	**Results**	Positive	Negative	
	Positive	49	3	52
	Negative	4	66	70
Total Results		53	69	122

Relative sensitivity: 92.5% (95%CI*: 81.8%~97.9%);
Relative specificity: 95.7% (95%CI*: 87.8%~99.1%);
Accuracy: 94.3% (95%CI*: 88.5%~97.7%). *Confidence Intervals

Cross-reactivity

The following microbial all found to be negative when tested with the *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab):

Description	Test Level
Influenza A H1N1	1×10^7 $TCID_{50}$/mL
Influenza A H3N2	1×10^7 $TCID_{50}$/mL
SARS-CoV-2 Culture Fluid	3.8×10^6 $TCID_{50}$/mL
Respiratory syncytial virus	1×10^7 $TCID_{50}$/mL
Human Rhinovirus	1.41×10^5 $TCID_{50}$/mL
Streptococcus group F	1.0×10^8 org/mL
Staphylococcus epidermidis	6.07×10^8 CFU/mL
Escherichia coli	1.0×10^8 org/mL
Streptococcus pyogenes	2.39×10^8 CFU/mL
Neisseria subflava	1.0×10^8 org/mL
Moraxella catarrhalis	1.0×10^8 org/mL
Candida albicans	4.76×10^7 CFU/mL

Pseudomonas aeruginosa	$1.0x10^8$ org/mL
Streptococcus pneumoniae	$1.34x10^8$ CFU/mL
Neisseria lactamica	$1.0x10^8$ org/mL
Staphylococcus aureus	$8.35x10^8$ CFU/mL

Interfering Substances

The interfering substances below were spiked with negative, *Bordetella pertussis* weak positive. No substances showed any interference with the *Bordetella pertussis* Antigen Rapid Test (Nasopharyngeal Swab):

Substance	Concentration
Mucin	50 µg/mL
Dexamethasone	0.8 mg/mL
Mupirocin	12 mg/mL
Oxymethazoline Hydrochloride Spray	12 mg/mL
Whole Blood	5 µL/mL

BIBLIOGRAPHY

1. Kilgore, P. E., Salim, A. M., Zervos, M. J. & Schmitt, H. J. Pertussis: microbiology, disease, treatment, and prevention. Clin. Microbiol.Rev. 29, 449–486 (2016).
2. Rohani, P. & Scarpino, S.V. Pertussis: Epidemiology, Immunology & Evolution (Oxford University Press, Oxford, 2019).

	Caution
IVD	*In vitro* diagnostic medical device
	Temperature limit
	Do not use if package is damaged and consult instructions for use
EU REP	Authorized representative in the European Community/European Union
REF	Catalogue number
	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Importer
	Distributor


Manufacturer

Hangzhou Alltest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EU REP
VidaQuick Biotech S.L.
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Barcelona Province, 08036, Spain
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JOYMED.cz - ID: 08595771

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Statement: Information about manufacturer of sterile swab is placed on the packaging.

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