TruQuick™ Strep A Blue 20T

A rapid test for the qualitative detection of Strep A antigens in throat swab specimens.

REF **TQ5120** IVD **Rx Only**

INTENDED USE

TruQuick Strep A Blue is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY AND EXPLANATION OF THE TEST

Streptococcus pyogenes are nonmotile gram-positive cocci, which contain the Lancefield Group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3, 4]

TruQuick Strep A Blue is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within five minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

BIOLOGICAL PRINCIPLES

TruQuick Strep A Blue is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a blue line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

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 Strep A antibody-coated particles and Strep A antibodies coated on the membrane.
- Extraction Reagent 1 (2M $NaNO_2$)
- Extraction Reagent 2 (0.027M Citric acid)
- Positive Control (Nonviable Strep A; 0.01% ProClin 300)
- Negative Control (Nonviable Strep C; 0.01% ProClin 300)
- Extraction Tubes
- Dropper tips
- Workstation
- Sterile swabs
- Package insert

MATERIALS NOT PROVIDED

- Timer

PRECAUTIONS

1. All reagents are for in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.
8. Reagent 2 contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
9. The Positive and Negative Controls contain ProClin 300 as a preservative.
10. Do not interchange reagent bottle caps.
11. Do not interchange external control solution bottle caps.

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 in the sealed pouch 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.

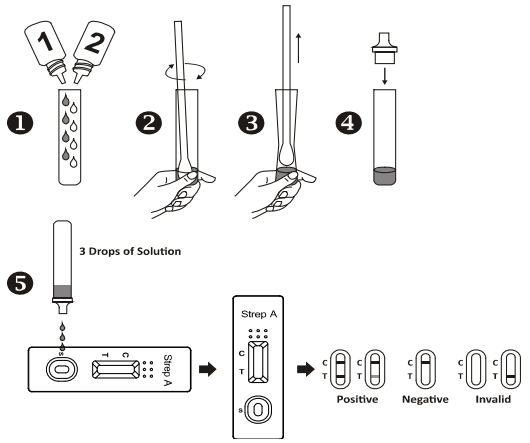
SPECIMEN COLLECTION AND PREPARATION

1. Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
2. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to eight hours at room temperature or 72 hours at 2-8 C.
3. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in TruQuick Strep A Blue.

TEST PROCEDURE

Allow the test, reagents, throat swab specimen, 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. Hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent 1 to an Extraction Tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the Extraction Tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
3. Immediately add the swab into the Extraction Tube, agitate the swab vigorously 15 times, Leave the swab in the Extraction Tube for **1 minute**. See illustration 2.
4. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. See illustration 3
5. Fit the dropper tip on top of the Extraction Tube. Place the Test Cassette on a clean and level surface. Add 3 drops of the solution (approx.100 µL) to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 4 and illustration 5.



INTERPRETATION OF RESULTS

(Please refer to the illustration above.)

POSITIVE:* Two lines appear. One blue line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen.

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

NEGATIVE: One blue line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

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 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 blue line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

Procedure for External Quality Control Testing

1. Add 4 full drops of Extraction Reagent 1 and 4 full drops of Extraction Reagent 2 into an Extraction Tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of Positive or Negative Control solution into the tube, holding the bottle upright.
3. Place a clean swab into this Extraction Tube and agitate the swab in the solution by rotating it at least 15 times. Leave the swab in the Extraction Tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the Extraction Tube and squeezing the Extraction Tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the Extraction Tube. Place the Test Cassette on a clean and level surface. Add three drops of the solution (approx. 100 µL) to the sample well and then start the timer.
5. Read the results at five minutes; do not interpret the result after 10 minutes.

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

Approximately 15% of pharyngitis in children ages three months to five years is caused by Group A beta hemolytic Streptococcus.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

LIMITATIONS OF THE PROCEDURE

1. TruQuick Strep A Blue is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and nonviable Group A Streptococcus bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

SPECIFIC PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Using three medical centers for evaluation, a total of 526 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by TruQuick Strep A Blue. The plates were further streaked for isolation, and then incubated at 37 C with 5-10% CO_2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination grouping kit. Of the 526 total specimens, 404 were confirmed to be negative and 122 were confirmed to be positive by culture. During this study, four Strep F specimens yielded positive results with the test. One of these specimens was recultured, then retested and yielded a negative result. Three additional different Strep F strains were cultured and tested for crossreactivity and also yielded negative results.

Method		Culture		Total Results
	Results	Positive	Negative	
TruQuick Strep A Blue	Positive	116	9	125
	Negative	6	395	401
Total Results		122	404	526

Sensitivity: 95.1% (95% CI*: 89.6%-98.2%)
Specificity: 97.8% (95% CI*: 95.8%-99%)
Correlation: 97.1% (95% CI*: 95.3%-98.4%) *Confidence Interval

Positive Culture Classification	TruQuick Strep A Blue Culture	% Agreement
Rare	8/10	80.0%
1+	18/20	90.0%
2+	19/20	95.0%
3+	33/34	97.1%
4+	38/38	100.0%

REPRODUCIBILITY

Intra/Inter-Assay Precision

10 µL of 0.5% BSA-PBS, 1 x 10^7 org/mL Strep A or 1 x 10^8 org/mL Strep A were spiked onto swabs and tested. Five replicates of each level were tested each day for three consecutive days using twelve lots. The correct results were obtained < 99% of the time.

CROSSREACTIVITY

The following organisms were tested at 1.0 x 10^7 org/mL per test and were all found to be nonreactive when tested with TruQuick Strep A Blue. No mucoid-producing strains were tested.

Group B *Streptococcus*	*Neisseria meningitidis*	*Serratia marcescens*
Group F *Streptococcus*	*Neisseria sicca*	*Klebsiella pneumoniae*
Streptococcus pneumoniae	*Branhamella catarrhalis*	*Bordetella pertussis*
Streptococcus mutans	Group C *Streptococcus*	*Neisseria gonorrhea*
Staphylococcus aureus	Group G *Streptococcus*	*Neisseria subflava*
Corynebacterium diphtheria	*Streptococcus sanguis*	*Hemophilus influenza*
Candida albicans	*Staphylococcus epidermidis*	*Pseudomonas aeruginosa*
Enterococcus faecalis		

ANALYTICAL SENSITIVITY
The Limit of Detection for this assay, as determined in tests with Strep A strain ATCC 12365, is 1.0 x 10^7 org/mL.

HIGH DOSE HOOK EFFECT
Concentrations of Strep A antigen up to 1.0 x 10^{12} org/mL did not cause high dose hook effect.

TESTS FOR INTERFERING SUBSTANCES
The swabs were spiked with 100 µL of potentially interfering substances below at the starting concentration of 1% and then spiked with 10 µL 0.5% BSA-PBS, 2.5 x 10^7org/mL or 1 x 10^8 org/mL of sample. None of the following substances showed any interference with the test.
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

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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.