

Testing with confidence

Inverness Medical
TESTPACK®+Plus

Group A Streptococcus is a major cause of upper respiratory infections in humans, but is often misdiagnosed leading to:

- The over prescribing of antibiotics, which can lead to an increase in antibiotic resistant strains of bacteria.
- The risk of extended illness and secondary complications including rheumatic fever and glomerulonephritis caused by delayed antibiotic treatment.

Clinical performance of TestPack Strep A

- Throat swabs were collected from children and adults presenting with symptoms of pharyngitis.
- Swabs were used for SBA culture and were tested with TestPack Strep A.
- Results were obtained for 369 patients, of which 125 were found positive by standard SBA culture and 244 were found negative. The sensitivity of TestPack Strep A was 97.6% when compared to standard SBA culture and the specificity was 98.4%.

Culture	TestPack Strep A	
	+	-
+	122	3
-	4	240



- Made in Japan, high quality

TestPack Strep A

Features	Benefits
Easy to use	No training required
Easy to interpret results; positive (+) or negative (-)	The test tells you when it is ready to read - no need for a timer
Rapid - results in approximately 5 minutes	Rapid results allow immediate antibiotic therapy, reducing severity of symptoms and the likelihood of further clinical complications
In-built controls to monitor: <ul style="list-style-type: none"> • Assay time - the test tells you when it is ready to read • Extraction procedure - a colour change reassures that the correct procedure has been followed • Specimen migration - indicated by presence of the Minus Bar • Antibody functionality - indicated by presence of the Positive On Board Control • Non-specific binding - indicated by presence of the Negative On Board Control 	Unique in-built controls give complete confidence throughout
Highly sensitive and specific	

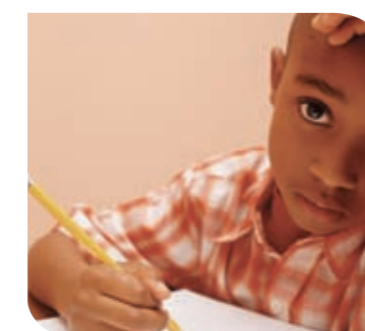


Product Information

Inverness Medical TestPack® Strep A

Catalogue No	505715 (20 Tests) 505796 (40 Tests)
Kit Size	20 or 40 Tests
Storage	2-30°C
Sample Type	Throat Swab
Time to Result	Approximately 5 minutes
Sensitivity	97.6%*
Specificity	98.4%*

*Compared to standard SBA culture



Distributed by:

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Inverness Medical
TESTPACK®+Plus



STREP A

with unique in-built
positive and negative controls



The professionals' choice in diagnosing
Strep A pharyngitis

Why TestPack?

Inverness Medical TestPack® offers unique features that make it stand out from the competition. It is designed specifically to give complete reassurance to our users.

With proven performance in the field, TestPack has continually shown excellent sensitivity and specificity with clear '+' or '-' results.

Unlike other rapid tests which only incorporate a procedural control, TestPack has a built in positive and negative control – giving complete confidence in the result every time.

The unique on-board controls monitor sample flow, disc functionality and check for non specific binding. The End of Assay removes the need to time the test as it indicates when the test is ready to read.

With all the benefits of a premium product TestPack Strep A is suitable for use in most situations.

- hospitals and doctor's surgeries
- laboratories or point of care

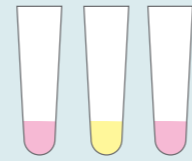
TestPack Strep A allows informed decision making for doctors and patients alike.

TestPack is the professionals' choice in diagnosing Strep A pharyngitis



On-board controls

TestPack Strep A has on-board controls to ensure confidence in the results of every test. No other test provides this level of reassurance in every result.



Colour Change Reagents

- When each reagent is added to the extraction tube there is a colour change. This provides reassurance that the reagents have been added in the correct order and that the sample extract has been properly neutralised.



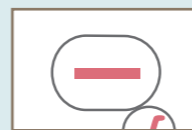
The Positive Control

- The Positive Control must be present for every test result. If it is not present the result is **invalid**.
- The Positive Control shows that the test has worked correctly. It is always produced in a valid test whether Strep A antigen is present or not.
- The presence of the Positive Control on every disc eliminates the need for external controls.



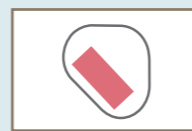
The Negative Control

- If the Negative Control is present, the test result is **invalid**.
- The presence of the Negative Control indicates the possibility of an interfering substance in the sample that could cause a misleading result.
- The presence of the Negative Control on every disc eliminates the need for external controls, and provides reassurance that a positive result is caused by presence of Strep A antigen.



The Minus Bar

- The Minus Bar must be present for a valid test result.
- The presence of the Minus Bar indicates that the test has been performed correctly and that the sample has flowed through the disc.



The End of Assay

- The End of Assay window changes to a pink / red colour when the test is ready to read.
- The End of Assay is a built in time check: no need for a timer.



The Patient Bar

- The appearance of the vertical Patient Bar indicates a positive test result irrespective of its intensity.

Performing a test

- 1 Add 3 drops of Reagent 1 (pink) to an extraction tube.
- 2 Add 3 drops of Reagent 2. Solution must turn yellow. Place swab in tube, swirl and mix well. Let stand for between 1-30 minutes.
- 3 Add 3 drops of Reagent 3. Swirl swab and mix well. Solution must turn pink. Express the liquid from swab - squeeze and rotate as it is withdrawn. Apply dropper tip to extraction tube. **Immediately before use, remove test from foil pouch.**
- 4 Add entire contents of extraction tube drop-wise to sample well.
- 5 When End of Assay window changes to pink/red read result. Do not interpret results after 10 minutes.

