

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**

K051638

**B. Purpose of Submission:**

To obtain clearance for the Inverness Medical TestPack + Plus  
Strep Test

**C. Analyte:**

Group A Streptococcal antigen

**D. Type of Test:**

Horizontal-flow enzyme immunoassay

**E. Applicant:**

Unipath Limited

**F. Proprietary and Established Names:**

Inverness Medical TestPack + *Plus* Strep A with OBC

**G. Regulatory Information:**

1. Regulation section:

21 CFR Part 866.3740 Streptococcus spp. serological reagents

Limitation: 21 CFR 866.9 (6)

2. Classification:

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3. Product Code:

GTY – Streptococcus spp.

4. Panel:

83 Microbiology

**H. Intended Use:**

1. Intended use(s):

INVERNESS MEDICAL TESTPACK PLUS STREP A with On Board Controls (OBC) (TESTPACK STREP A) is a rapid immunoassay for the qualitative detection of Group A Streptococcal (Group A Strep) antigen in throat swab specimens from patients with suspected Group A Strep associated pharyngitis and for confirmation of presumptive Group A Strep colonies isolated on culture plates. For Professional and Laboratory use only.

2. Indication(s) for use:

INVERNESS MEDICAL TESTPACK PLUS STREP A with (OBC) TEST is intended for the qualitative detection of Group A Streptococcal (Group A Strep) antigen in throat swab specimens from patients with suspected Group A Strep associated pharyngitis and for confirmation of presumptive Group A Strep colonies isolated on culture plates. The test is intended for Professional and Laboratory use only.

3. Special condition for use statement(s):

For Prescription Use Only

4. Special instrument Requirements:

Not applicable

**I. Device Description:**

The device consists of a chromatography strip membrane housed in a plastic frame. The membrane carries immobilized polyclonal anti-Strep A antibody coupled to colloidal gold dye particles. The test line contains sheep and rabbit anti-group A streptococcus antibody. The control line consists of an immobilized antibody to the anti-Strep A indicator antibody. At the control line, anti-Strep A indicator antibody-unbound/bound colloidal gold complexes form a control line in the control window which indicates that the device is functioning properly. Additionally, the test device consists of negative and positive on board controls that also serve as indicators that the test reagents are working correctly.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Quidel QuickVue<sup>®</sup> Dipstick Strep A Test
2. Predicate K number(s):  
K011097
3. Comparison with predicate(s):

Similarities		
Item	Device	Predicate
Intended use	For the qualitative detection of group A streptococcal antigen directly from throat swabs.	same
Specimen type	Throat swab or culture colonies	same
technology	Immunochromatographic	same
antibodies	Polyclonal anti-Strep A	same
Limit of detection	$1.5 \times 10^5$ CFU mL	same
Difference		
Item	Device	Predicate
Extraction method	Extraction applied to device test well	Dipstick placed in tube of extract
Clinical sensitivity	97.6% CI (93.1-99.5%)	92% CI (86-96%)
Clinical specificity	98.4% CI (95.9-99.6%)	98% CI (95-99%)
Positive and negative on board controls	Yes	No
End of assay control	Yes	No
Extraction reagents	3	2

**K. Standard/Guidance Document referenced (if applicable):**

Not applicable

**L. Test Principle:**

The test device is a lateral flow immunoassay consisting of a chromatography strip membrane housed in a plastic frame. The membrane carries immobilized sheep and rabbit polyclonal antibodies bound to colloidal gold dye particles. The Streptococcal Group A specific antigen is extracted from the throat swab using Reagent 1 and Reagent 2. Following this, Reagent 3 is added to neutralize the acid formed by Reagents 1 and 2. The mixture is then dropped into the Sample Well of the reaction disc and allowed to migrate through the membrane until it reaches the End of Assay Window. As the specimen extract migrates through the membrane, it mobilizes the Group A Strep antibody-coated colloid. If Group A Streptococcal antigen is present in the specimen it will form a complex with the antibody-colloid. The antibody colloid complex migrates through the membrane and is then captured by the Group A Strep antibody in the result window, providing a visual indication of the presence of antigen. The test can be read when the End of Assay Window has turned pink/red. A pink/red Plus Sign (+) appearing in the Result Window indicates the presence of the Group A Strep antigen. A Minus Sign (–) indicates no antigen was detected.

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

Within lot, between lot and between operator reproducibility were tested over a 3 day period. Five replicates of a negative, weak positive and positive control were tested by 3 operators on each occasion. No differences were seen between runs, and all controls produced the expected results.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Not applicable

d. *Detection limit:*

The test device has a minimum limit of detection of  $1.5 \times 10^5$  CFU/mL.

e. *Analytical specificity:*

The analytical specificity was determined by testing organisms expected to be found in the respiratory tract at  $1 \times 10^8$  organisms per mL, with the exception of *Staphylococcus aureus*, which was tested at  $1 \times 10^9$  organisms per mL. No cross reactivity was found when TESTPACK STREP A was tested with the bacteria listed below:

*Arcanobacterium haemolyticum**Bordetella pertussis**Candida albicans**Corynebacterium diphtheria**Escherichia coli**Fusobacterium necrophorum**Klebsiella pneumoniae*

*Haemophilus influenzae*  
*Haemophilus parahaemolyticus*  
*Moraxella catarrhalis*  
*Moraxella lacunata*  
*Neisseria gonorrhoeae*  
*Neisseria lactamica*  
*Neisseria meningitidis*  
*Neisseria sicca*  
*Neisseria subflava*  
*Proteus vulgaris*  
*Pseudomonas aeruginosa*  
*Serratia marcescens*  
*Staphylococcus aureus* (Cowan's serotype I)  
*Staphylococcus aureus*  
*Staphylococcus epidermidis*  
*Staphylococcus haemolyticus*  
*Staphylococcus saprophyticus*  
*Streptococcus* groups B, C, D, F, G  
*Streptococcus oralis*  
*Streptococcus salivarius*  
*Streptococcus sanguis*  
*Streptococcus mitis*  
*Streptococcus mutans*  
*Streptococcus pneumoniae*  
*Yersinia enterocolitica*

TESTPACK STREP A was found to perform as expected with both positive and negative samples in the presence of benzocaine and lidocaine, which are active ingredients found in a number of commercially available sore throat treatments.

f. *Assay cut-off*

Using ATCC strain 12344, the limit of detection of TESTPACK STREP A (at which Streptococci were detected 100% of the time) was shown to be  $1.05 \times 10^5$  CFU/swab.

2. Comparison studies:

a. *Method comparison with gold standard:*

For visually positive SBA (Sheep Blood agar) plates, clinicians recorded the density and growth of presumptive group A Streptococcus colonies. The results from SBA culture and the corresponding TESTPACK STREP A rapid results are compared below:

	<i>SBA plates</i>		
	Pos	Neg	Total
Testpack Strep A (+)	122	4	126
Testpack Strep A (-)	3	240	243
Total	125	244	369

  

		95% CI
Clinical sensitivity	122/125 (97.6%)	93.1-99.5%

Clinical specificity	240/244 (95.9%)	95.9-99.6%
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*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical sensitivity:*

The clinical performance of TESTPACK STREP A was compared with standard sheep blood agar culture. In a multi-center field evaluation, two throat swabs were collected simultaneously from children and adults presenting to clinics with symptoms of pharyngitis. One swab was tested by clinic staff according to each clinic's normal standard of care. The remaining swab was retained for evaluation of TESTPACK STREP A and was either tested immediately or stored at 2-8°C in transport tubes prior to testing. All swabs were tested on the day of collection. Swabs retained for evaluation of TESTPACK STREP A were used to inoculate a sheep blood agar (SBA) plate, prior to being tested using the TESTPACK STREP A test. Plates were incubated for 24-48 hours at 35°C with 5-10% CO<sub>2</sub>. Presumptive group A Streptococcus colonies on SBA culture plates were confirmed using a commercially available Streptococcal latex grouping test. Results were obtained for 369 (335 pediatric and 34 adult) patients, of which 125 were found positive by standard SBA culture and 244 were found negative. The sensitivity of the TESTPACK STREP A test was 97.6% when compared to standard SBA culture (95% confidence interval [CI]: (93.1-99.5%). The specificity of the TESTPACK STREP A test was 98.4% when compared to standard SBA culture (95% Confidence Interval [CI]: (95.9-99.6%).

*b. Clinical specificity:*

Refer to (e.) above

*c. Other clinical supportive data (when a and b is not applicable):*

Not applicable

4. Clinical cut-off:

The lower limit of detection of this assay is  $1.5 \times 10^5$  cfu/ml.

5. Expected values/Reference range: (Interpretive Criteria)

It is believed that approximately 19% of all upper respiratory tracts infections are caused by Group A Streptococcus. A prevalence of 33.7% was observed in the clinical performance evaluation of TESTPACK STREP A. Group A Strep associated pharyngitis displays a seasonal variation and is most prevalent during the Winter and early Spring. Certain populations are at higher risk of infection, for example, schools, nursing homes and hospitals. Clustering of cases occurs.

**N. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.