

510k Submission
K962296
Requested Revisions - 11-24-96
STREPTOLEX-STAT™
UNIPATH LIMITED

DEC 16 1996

510K SUMMARY

Date: November 24, 1996

Product Name:
STREPTOLEX-STAT™

Sponsor's Name:
UNIPATH LIMITED
Wade Road
Basingstoke Hants
RG24 8PW England

Product to be distributed in the US by:

Orion Diagnostica, Inc.
71 Verconica Ave.
Somerset, NJ 008873

Unipath, Oxoid Division
217 Colonade Rd.
Nepean Ontario

SUBSTANTIAL EQUIVALENCE

STREPTOLEX-STAT™ is substantially equivalent to several commercially available products utilizing similar methodology for the identification of streptococcal groups A, B, C, F and G.

Manufacturer : Murex Diagnostics, Inc.

Product: **Streptex and Streptex - Acid Extraction Kit -**
Provide an alternative method for the extraction and identification of Streptococcal Lancefield group antigens from cultured organisms. This test offers a nitrous acid extraction procedure that is substantially equivalent to the STREPTOLEX-STAT™ procedure.

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Manufacturer: Diagnostic Products Corporation

Product: PathoDx® Strep Grouping - a latex agglutination test designed to identify beta-hemolytic streptococci of Lancefield groups A, B, C, F, and G. This test offers a nitrous acid extraction procedure that is substantially equivalent to the STREPTOLEX-STAT™ procedure.

Manufacturer: Unipath Limited, Oxoid

Streptococcal Grouping Kit - A latex agglutination test for the identification of Streptococcal groups, A, B, C, D, F and G. This kit does not include a nitrous acid extraction method, but performance of the Unipath STREPTOLEX-STAT™ was compared to this substantially equivalent product for the qualitative grouping of streptococcal organisms. (K854929), and is currently being marketed by Unipath (Orion Diagnostica, Inc.)

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PERFORMANCE DATA

The performance of the STREPTOLEX-STAT™ was compared to three commercially available, substantially equivalent grouping kits listed above. Studies were done at three test sites. The following is a summary of the performance data.

The data compiled from one clinical laboratory in the US, one in Canada and one in the UK. The following is a summary of the test results.

Strep Group/No. Tested	Unipath (Oxoid) Acid Extraction Sensitivity
Group A 111	111/111 (100%)
Group B 120	117/120¹ (98%)
Group C 83	80/83² (96%)
Group F 66	59/66³ (89%)
Group G 90	90/90 (100%)
Total 470	457/470 (97%)

1. At one site, upon initial testing, 3 negative reactions were observed. Discrepancies were related to insufficient number of colonies used. Discrepancies were resolved upon retest.

2. At one site, upon initial testing, 3 negative reactions were observed. Discrepancies were related to insufficient number of colonies used. Discrepancies were resolved upon retest.

3. At one site, upon initial testing, 7 negative reactions were observed. Discrepancies were related to insufficient number of colonies used. 5 of the 7 discrepancies were resolved upon retest.

Data comparing the STREPTOLEX-STAT™ Group Reagent with other commercially available grouping kits demonstrated an overall agreement of 97%.

These data clearly demonstrate the safety and efficacy and substantial equivalence of the STREPTOLEX - STAT™.

These data will be made available to any person within 30 days of a written request.