

12 PERFORMANCE CHARACTERISTICS

The performance of the PathoDxtra Streptococcal Grouping Kit was evaluated at a hospital laboratory in Paris, France. A total of 419 isolates were tested, including 311 Lancefield grouped streptococci, 79 non-groupable streptococci/enterococci and 29 non-streptococci. The results obtained were compared to a commercially available nitrous acid extraction kit.

The sensitivity and specificity of the kits examined was calculated from the trial data, as follows:

	PathoDxtra Streptococcal Grouping Kit	Predicate device
Mean sensitivity (%)	89.1	85.2
Mean specificity (%)	97.8	97.5

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