

Summary of an evaluation provided by SKUP

QuickVue Dipstick Strep A Test for measurement of Strep A

Manufacturer: Quidel Corporation

Supplier in Scandinavia: Alere

Conclusion

The quality goals set for QuickVue Dipstick Strep A Test were fulfilled for diagnostic sensitivity, interference, user-friendliness and technical errors. The quality goal for diagnostic specificity was not fulfilled.

Background

QuickVue Dipstick Strep A Test is a rapid test for detection of *Streptococcus pyogenes* group A (Strep A) in patient throat samples. The Strep A test is produced by Quidel Corporation that also requested the evaluation. QuickVue Dipstick Strep A Test has been evaluated by SKUP in 2003, but only in a clinical microbiology laboratory. The present evaluation is a full evaluation.

The aim of the evaluation

The aim of the evaluation was to determine the analytical quality and the user-friendliness of QuickVue Dipstick Strep A Test. The results were assessed according to the quality goals set for the evaluation. The evaluation was carried out in a clinical microbiology laboratory and by the intended users at seven primary health care centres.

Materials and methods

In the clinical microbiology laboratory two types of evaluations were performed; 1) analysis of the swabs from patients from the evaluating primary health care centres on the comparison method (culturing), and 2) analysis of dilution series of a Strep A reference strain, five Strep A patient strains, one Strep C strain, one Strep G strain and a blank sample. The clinical microbiology laboratory also examined inter-person reading agreement by comparing the results from two evaluators reading all samples double blinded, and robustness of the test result by re-reading the results from the least and most diluted samples of each strain five minutes after recommended reading time. The swabs from patients from the primary health care centres were also analysed with real time polymerase chain reaction (real-time PCR).

In the primary health care centres two throat swabs were taken from all consenting patients ($n = 322$) with symptoms of bacterial throat infection; one for direct measurement with QuickVue Dipstick Strep A Test, and the other to be sent to the clinical microbiology laboratory for culturing. The quality goals set in the evaluation was a diagnostic sensitivity $>80\%$ and a diagnostic specificity $>95\%$ using the results from culturing as comparison method, as well as no interference with Strep C and G, satisfactory user-friendliness, and a fraction of technical errors (failed measurements) $\leq 2\%$. The prevalence and positive and negative predictive values were calculated.

Results

The diagnostic sensitivity of QuickVue Dipstick Strep A Test was 92% and the diagnostic specificity was 86%, when compared to the results from culturing. The prevalence of Strep A among the patients was 38% and the positive and negative predictive values were 80% and 95%, respectively. There was no interference with Strep C and G in the diluted samples in the clinical microbiology laboratory. The user-friendliness was rated as satisfactory and there were no technical errors reported. Other variables that were estimated, but had no quality goals were; the equivalence point, which was estimated to lie in the range $1,5 \times 10^4 - 1,5 \times 10^5$ cfu/mL; inter-person reading agreement, that showed complete agreement; and the robustness of the test results, which showed that the results remained unchanged after five minutes late reading. Results from real-time PCR compared with the culturing of the patient samples showed more positive results for the PCR technique.

Comments from Quidel Corporation

Comments from Quidel Corporation are attached in the end of the report.