QuikRead go strep A

Summary of an evaluation under the direction of SKUP Report SKUP/2015/106*

Background
Orion Diagnostica turned to SKUP for an evaluation of QuikRead go Strep A in 2013. The evaluation was performed at the Department of Clinical Microbiology, Odense University Hospital, Denmark.

The aim of the evaluation
- To describe the detection limit of the QuikRead go Strep A test and to investigate if the company's detection limit of 7×10^4 cfu/swab (colony forming units) is correct
- To describe the equivalence point (when 50% of the results are positive and 50% are negative) for the reference strain and five wild type strains and calculate the specificity
- To investigate if the detection limit, equivalence point and specificity of the evaluated instruments differ from instrument to instrument
- To investigate if the equivalence point and detection limit differ from lot to lot
- To investigate the agreement of results among evaluator(s)
- To investigate whether the equivalence point of the ATCC strain and the patient strains differ
- Selectivity: to investigate possible interference of the Strep A test with Strep C and G
- To evaluate the robustness of QuikRead go Strep A
- To evaluate the user-friendliness of QuikRead go Strep A in a hospital laboratory
- To determine the fraction of technical errors

Materials and methods
S. pyogenes ATCC strain 19615 and five wild type strains (from five patients) of *S. pyogenes*, and streptococci group C and G in different concentrations were used for determination of the equivalence point and the detection limit. In the evaluation a throat swab and 50 µL of sample is supposed to correspond to each other.

Results
The lowest positive result was $7{,}0\times10^4$ cfu/swab which correspond to the detection limit given by the manufacturer. The equivalence point, found as a geometric mean of six samples, was 4×10^4 cfu/swab. Specificity: 24 of 24 duplicate measurements analysed with two instruments from six streptococci strains were negative below the equivalence point 4×10^4 cfu/swab. Similar results were obtained when samples were analysed with three different instruments, by three evaluators or using two reagent lots. The equivalence point of the ATCC strain was $3{,}5\times10^4$cfu/swab and the equivalence point of the five wild type strains was between 2,2 and $8{,}8\times10^4$ cfu/swab. Selectivity: there was no interference on the results using haemolytic streptococci group C and G. Results were given in the display after one to three minutes. An additional experiment demonstrated that the three QuikRead go instruments could distinguish between two concentrations which differed only by a factor 1,6 ($4{,}4/2{,}8\times10^4$). It is not possible to distinguish such differences with the viable count technique. The positive and negative control materials all gave the expected results. The users were satisfied with the user manual. The operation facilities were assessed as satisfactory. The time factors and the quality control possibilities related to the QuikRead go instrument were assessed as satisfactory. The percentage of technical errors was <1,0%.

Conclusion
The following quality goals were fulfilled: The detection limit (7×10^4 cfu) given by the manufacturer was confirmed by the evaluation. The equivalence point (4×10^4 cfu/swab) of *S. pyogenes* (ATCC) and the five wild type strains did not differ. The results were similar when using different instruments, reagent lots and evaluators. There was no interference with haemolytic streptococci group C or group G.
In contrast to the viable count technique, QuikRead go instruments can distinguish between two concentrations which differ only by a factor 1,6 ($4{,}4/2{,}8\times10^4$). The positive and negative control materials all gave the expected results. The quality goal of the user-friendliness was fulfilled.The percentage of technical errors fulfilled the quality goal ≤2%.

Comments from the manufacturer
Orion Diagnostica has accepted the report without further comments.