RAPID DIAGNOSTIC TEST FOR GROUP A STREPTOCOCCAL ANTIGEN USING QUIKREAD GO® INSTRUMENT

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AIM OF THE STUDY

The aim of this study was to demonstrate that Orion Diagnostica's new QuikRead go Strep A test is a convenient tool to support the diagnosis of pharyngitis and to show comparable sensitivity to other rapid Strep A antigen tests.

BACKGROUND

Streptococcus pyogenes or β-hemolytic group A Streptococcus (Strep A), is a major cause of upper respiratory tract infection such as tonsillitis or pharyngitis. A Strep A sore throat usually lasts less than 10 days, and the patients are infectious during the period they have symptoms and for approximately one week thereafter. The symptoms of a Strep A sore throat do not differ significantly from those of a sore throat caused by other microbes. Therefore, symptoms alone cannot be used for an accurate Strep A sore throat diagnosis and clinical and epidemiological data should be supported by laboratory tests. A rapid and accurate Strep A test supports the diagnosis and appropriate treatment decision.

The several user-friendly features of the QuikRead go instrument – portability, large touch screen guiding the user, language settings, automatic result storage into the instrument memory and LIS connectivity – make the system especially suitable for point-of-care use. Together with a ready-to-use QuikRead go Strep A test kit, the system offers an easy-to-use, fully automated solution for Strep A testing.

MATERIALS AND METHODS

QuikRead go Strep A is an immunoturbimetric test based on nanoparticles coated with rabbit anti-Strep A antibodies. Strep A antigens present in the sample react with particles, and the resultant change in the turbidity of the solution is measured by the QuikRead go instrument.

The throat sample is collected with a QuikRead go Strep A pharyngeal swab and extracted in a separate tube using extraction solutions. During extraction, the antigen is released into the swab. When the two minutes extraction is finished, the swab is inserted into the prefilled test cuvette and swirled vigorously to release the bacterial extract. After removing the swab, the cuvette is closed with a cap containing assay specific reagents. Once the cuvette is inserted into the QuikRead go instrument, the measurement starts automatically, the instrument first measuring the sample blank and then the Strep A concentration for 1–3 minutes. When the measurement is completed, the result appears on the display of the instrument as negative or positive Strep A.

The clinical performance of the QuikRead Strep A test was evaluated by using Orion Diagnostica's Streptocult® culture slide as reference.

The sensitivity of QuikRead go Strep A was also evaluated using different *Streptococcus pyogenes* bacterial suspension dilutions as samples. The QuikRead go Strep A test was compared to QuikRead 101 Strep A and four commercial lateral flow tests: TestPack Plus StrepA with OBC (Inverness Medical), Clearview Exact StrepA Dipstick (Alere), QuickVue Dipstick StrepA (Quidel Corporation) and OSOM StrepA test (Genzyme Diagnostics).

RESULTS

Performance of QuikRead go Strep A compared to culture

The clinical performance of QuikRead go Strep A was evaluated in a multi-centre study by comparing the results to the Streptocult culture method. A total of 279 patients with symptoms of pharyngitis were tested at six physician offices.

The sensitivity and specificity compared to culture was calculated. The culture slides showing rare, less than 10 colonies, were excluded when the sensitivity and specificity of the test were calculated. The results are presented in Table 1.

Table 1.

	Culture positive	Culture negative
QuikRead go Strep A positive	74	5
QuikRead go Strep A negative	15	177
Sensitivity	83% (73.7–90.2%)*	
Specificity	97% (93.7–99.1%)*	
Agreement	93%	
PPV	94%	
NPV	92%	
*95% confidence interval		

The density of group A streptococcus colonies on the culture slide was recorded. The sensitivity of the QuikRead go Strep A test in relation to the colony density on the slides is presented in table 2.

Table 2.

	Number of CFU / Sensitivity			
	< 10	≥ 10	≥ 51	≥ 100
QuikRead go Strep A positive	1	3	8	63
QuikRead go Strep A negative	7	8	4	3
Sensitivity according to number of colonies	12.5%	83.1%	91.0%	95.5%

Performance of QuikRead go Strep A compared to other commercial Strep A tests

The sensitivity of the QuikRead go Strep A test was evaluated by comparing the test to Orion Diagnostica's QuikRead 101 Strep A test and four commercial lateral flow tests using suspensions of different strains of *Streptococcus pyogenes* group A.

Eight different culture collection type strains of *Streptococcus pyogenes* were obtained and cultured. Dilution series were prepared from the cultures and the CFU/ml content of each dilution was determined using bacterial colony counting technique. The test was performed by absorbing 50 µl bacterial suspension solution onto a swab. After that the sample was extracted and tested according to the instructions of use of each test. Three parallel measurements were performed on each sample. The tested bacterial strains and qualitative results are presented in Table 3.

Table 3.

Streptococcus pyogenes strain	CFU/test	QuikRead go Strep A	QuikRead Strep A	Testpack plus	Clearview Exact	QuickVue Dipstick	Osom Strep A
CCUG 25571	0.4×10^4	-	-	-	-	-	-
	0.8×10^4	2 x neg, 1 x pos	3 x neg	3 x neg	3 x neg	3 x neg	2 x neg, 1 x weak pos
	1.3×10^4	3 x pos	3 x pos	1 x neg, 2 x weak pos	3 x neg	3 x pos	3 x pos
CCUG 32827 (M71)	3.3×10^4	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg
	5.0×10^4	3 x pos	1 x neg, 2 x pos	1 x neg, 2 x weak pos	3 x neg	1 x neg, 2 x weak pos	1 x neg, 2 x weak pos
	8.3×10^4	3 x pos	3 x pos	3 x pos	1 x neg, 2 x weak pos	3 x pos	3 x pos
CCUG 32828 (M72)	1.8×10^4	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg
	3.5×10^4	3 x pos	1 x neg, 2 x pos	3 x weak pos	3 x neg	1 x neg, 2 x weak pos	3 x weak pos
	5.8×10^4	3 x pos	3 x pos	1 x weak pos, 2 x pos	3 x neg	1 x weak pos, 2 x pos	1 x weak pos, 2 x pos
CCUG 32682 (M80)	4.3×10^4	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg	3 x neg
	8.5×10^4	1 x neg, 2 x pos	1 x neg, 2 x pos	3 x weak pos	3 x neg	3 x weak pos	3 x weak pos
	14.2×10^4	3 x pos	3 x pos	1 x weak pos, 2 x pos	3 x neg	3 x pos	3 x pos
ATCC 19615	4.8×10^4	2 x neg, 1 x pos	-	3 x neg	-	3 x neg	3 x weak pos
	9.5×10^4	3 x pos	2 x neg, 1 x pos	3 x weak pos	3 x neg	2 x neg, 1 x weak pos	3 x weak pos
	15.8×10^4	3 x pos	3 x pos	3 x pos	1 x neg, 2 x weak pos	3 x pos	3 x pos
CCUG 53553	3.0×10^4	3 x neg	3 x neg	-	-	3 x neg	3 x neg
	6.0×10^4	1 x neg, 2 x pos	2 x neg, 1 x pos	3 x neg	3 x neg	2 x neg, 1 x weak pos	3 x weak pos
	10.0×10^4	3 x pos	3 x pos	3 x pos	3 x neg	3 x pos	3 x pos
CCUG 57056	3.2×10^4	3 x neg	3 x neg	3 x neg	-	3 x neg	2 x neg, 1 x weak pos
	6.4×10^4	3 x neg	3 x neg	2 x neg, 1 x pos	3 x neg	3 x pos	3 x pos
	10.8×10^4	3 x pos	2 x neg, 1 x pos	3 x pos	2 x neg, 1 x weak pos	3 x pos	3 x pos
NCTC 9994	2.6×10^4	3 x neg	3 x neg	-	-	3 x neg	3 x neg
	5.1×10^4	3 x pos	1 x neg, 2 x pos	3 x neg	3 x neg	3 x weak pos	3 x weak pos
	8.5×10^4	3 x pos	3 x pos	3 x weak pos	3 x neg	3 x pos	3 x pos

Cross-reactivity

Cross-reactivity was tested by cultivating the bacteria and after that, by taking a sample with a swab directly from a bacterial colony. The results are presented in Table 4.

Table 4.

Tested organism	Bacterial strain	Cross-reactivity
Streptococcus B	ATCC 12386	Based on the test results, it can be concluded that these organisms possibly present in the pharynx, do not cause any cross-reactivity in the QuikRead go Strep A test.
Streptococcus C	ATCC 12388	
Streptococcus F	ATCC 12393	
Streptococcus G	ATCC 12394	
Staphylococcus aureus (Cowan)	ATCC 12598	
Candida albicans	ATCC 14053	
Neisseria sicca	ATCC 29259	
Pseudomonas aeruginosa	ATCC 27853	
Haemophilus influenzae type B	ATCC 9795	
Streptococcus pneumonia	ATCC 6303	
Branhamella catarrhalis	Clinical strain	

Antigen excess

No antigen excess has been detected in samples with exceptionally high *Streptococcus pyogenes* levels (10^9 CFU/ml).

Summary of the results

The sensitivity of the QuikRead go Strep A test was calculated based on the density of Strep A colonies on the culture slide: 95.5% (≥100 CFU/slide), 91.0% (≥51 CFU/slide), 83.1% (≥10 CFU/slide) and 12.5% (if the number of colonies was < 10 CFU/slide). The specificity was 97% and no cross-reactivity was found with other organisms typically detected in the pharynx.

The QuikRead go Strep A test detected bacteria in amounts corresponding to 7×10^4 CFU/swab, while the lateral flow type tests detected approximately $4–10 \times 10^4$ CFU/swab.

CONCLUSION

The QuikRead go Strep A tests performs comparably to other rapid Strep A tests evaluated and the result is clearly presented by the instrument as negative or positive. The QuikRead go system provides an easy-to-use, rapid and reliable tool for the diagnosis of pharyngitis.

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