AIM OF THE STUDY
The aim of the study was to demonstrate that Orion Diagnostic'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 – makes 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 immunochromatographic test based on nanoparticles coated with rabbit anti-Strep A antibodies. Strep A antigen 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 parallel flow test cassette and reagents were released to release the bacterial extract. After removing the swab, the cassette is closed with a cap containing assay specific reagents. Once the cassette 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 1–5 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 go Strep A test was evaluated by using Orion Diagnostic's Streptococcal culture slide as reference.

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 Streptococcal 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.

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.

The mean density of colonies on the culture slide was counted as 51,5 CFU/swab and the sensitivity of the QuikRead go Strep A test was 97% (93.7–99.1%) when the concentration was equal to 109 CFU/swab and no cross-reactivity was found with other organisms.

Table 4.

<table>
<thead>
<tr>
<th>Tested organism</th>
<th>ATCC strain</th>
<th>Clinical strain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Streptococcus A</td>
<td>ATCC 9348</td>
<td>Clinical strain</td>
</tr>
<tr>
<td>Streptococcus B</td>
<td>ATCC 10085</td>
<td>Clinical strain</td>
</tr>
<tr>
<td>Streptococcus C</td>
<td>ATCC 10310</td>
<td>Clinical strain</td>
</tr>
<tr>
<td>Streptococcus D</td>
<td>ATCC 10312</td>
<td>Clinical strain</td>
</tr>
<tr>
<td>Streptococcus E</td>
<td>ATCC 10314</td>
<td>Clinical strain</td>
</tr>
</tbody>
</table>

Antigen excess
No antigen excess has been detected in samples with exceptionally high Streptococcus pyogenes levels (109 CFU/swab).

CONCLUSION
The QuikRead go Strep A test 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.

REFERENCES