

# Summary / DIAQUICK Strep A Blue Dipstick for measurement of *Streptococcus pyogenes*



**Manufacturer:** DIALAB GmbH

**Supplier:** Medic24 in Denmark, Norway and Sweden

*Summary of an evaluation provided by SKUP*

## **Conclusion**

- **The quality goal for diagnostic sensitivity was not fulfilled by intended users.**
- **The quality goal for diagnostic specificity was fulfilled by intended users.**
- **The quality goal for user-friendliness was fulfilled.**

## **Background**

DIAQUICK Strep A Blue Dipstick is an in vitro diagnostic rapid test for detection of *Streptococcus pyogenes* (Strep A). The product is intended for professional use and the sample material is human mucus from the pharynx and tonsils. The test is produced by DIALAB GmbH. The SKUP evaluation was carried out in winter/spring 2018 at the request of Medic24 in Sweden.

## **The aim of the evaluation**

The aim of the evaluation was to assess the analytical quality and user-friendliness of DIAQUICK Strep A Blue Dipstick, when used under real-life conditions by intended users in primary health care.

## **Materials and methods**

In four primary health care centres (PHCCs), two throat swab samples were taken at the same time from 348 individuals with symptoms of pharyngitis. One swab was used for measurement with DIAQUICK Strep A Blue Dipstick, and the other swab was sent to the clinical microbiology laboratory for analysis on a comparison method (culturing of *Streptococcus pyogenes*). The user-friendliness of the rapid test was assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory. The results and user-friendliness were assessed according to pre-set quality goals. The analytical quality goals were a diagnostic sensitivity >80 % and a diagnostic specificity >95 %, when compared to the results from the comparison method, and the quality goal for user-friendliness was a total rating of “satisfactory”. In addition, the prevalence and positive and negative predictive values were calculated.

## **Results**

The diagnostic sensitivity of DIAQUICK Strep A Blue Dipstick was 72 % and the diagnostic specificity was 98 %, when compared to the results from the comparison method. The prevalence of Strep A among the patients was 30 %, and the positive and negative predictive values of the rapid test were 94 % and 89 %, respectively. The user-friendliness was rated as satisfactory.

## **Comments from DIALAB GmbH/Medic24**

A letter with comments from DIALAB GmbH/Medic24 is attached to the report.

*This summary is also published in Danish, Norwegian and Swedish at [www.skup.org](http://www.skup.org).*