



DIAQUICK Strep A Blue Dipstick

A system for measurement of *Streptococcus pyogenes*
manufactured by DIALAB GmbH

Report from the evaluation

SKUP/2018/114

organised by SKUP at the request of Medic24

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The report was written by SKUP, summer 2018. The main author was Sara Ekvall, SKUP in Sweden. In order to use the SKUP name in marketing, it has to be referred to www.skup.org and the report code in question; SKUP/2018/114. For this purpose, the company can use a logotype containing the report code, available for the requesting company together with the final report. A correct format of referral in scientific publications will be “SKUP. Report from the evaluation SKUP/2018/114. DIAQUICK Strep A Blue Dipstick (DIALAB GmbH), a system for measurement of *Streptococcus pyogenes* group A, www.skup.org (assessed date).” The organisation of SKUP is described in attachment 1.

Table of contents

1. SUMMARY	5
2. ABBREVIATIONS AND ACRONYMS	6
3. INTRODUCTION	7
3.1. THE CONCEPT OF SKUP EVALUATIONS	7
3.2. BACKGROUND FOR THE EVALUATION.....	7
3.3. THE AIM OF THE EVALUATION	7
3.4. THE MODEL FOR THE EVALUATION OF DIAQUICK STREP A BLUE DIPSTICK.....	7
4. QUALITY GOALS	9
4.1. ANALYTICAL QUALITY	9
4.2. USER-FRIENDLINESS.....	9
4.3. PRINCIPLES FOR THE ASSESSMENTS	9
4.4. SKUP’S QUALITY GOALS IN THIS EVALUATION	10
5. MATERIALS AND METHODS	11
5.1. DEFINITION OF THE MEASURAND.....	11
5.2. THE EVALUATED RAPID TEST DIAQUICK STREP A BLUE DIPSTICK	11
5.3. THE SELECTED COMPARISON METHOD.....	12
5.4. THE EVALUATION.....	13
6. RESULTS AND DISCUSSION	15
6.1. NUMBER OF SAMPLES.....	15
6.2. ANALYTICAL QUALITY OF THE SELECTED COMPARISON METHOD.....	15
6.3. ANALYTICAL QUALITY OF DIAQUICK STREP A BLUE DIPSTICK ACHIEVED BY INTENDED USERS.....	16
6.4. EVALUATION OF USER-FRIENDLINESS	18
7. REFERENCES	23
ATTACHMENTS	
1. The organisation of SKUP	
2. Facts about DIAQUICK Strep A Blue Dipstick	
3. Information about manufacturer, retailers and marketing	
4. Product specifications for this evaluation, DIAQUICK Strep A Blue Dipstick	
5. Statistical expressions and calculations	
6. The Centor criteria	
7. Raw data, DIAQUICK Strep A Blue Dipstick versus the comparison method	
8. List of previous SKUP evaluations	
9. Comments from DIALAB GmbH/Medic24	

Attachments with raw data are included only in the copy to Medic24.

1. Summary

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.

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.

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.

2. Abbreviations and Acronyms

BLS	Biomedical Laboratory Scientist
C-NPU	Committee on Nomenclature, Properties and Units
Cfu	Colony forming units
CI	Confidence Interval
DEKS	Danish Institute of External Quality Assurance for Laboratories in Health Care
EQA	External Quality Assessment
Equalis	External quality assessment in laboratory medicine in Sweden
Noklus	Norwegian Quality Improvement of Laboratory Examinations
NPV	Negative Predictive Value
PHCC	Primary health care centre
PPV	Positive Predictive Value
SKUP	Scandinavian evaluation of laboratory equipment for point of care testing
<i>S. pyogenes</i>	<i>Streptococcus pyogenes</i>
Strep A	<i>Streptococcus pyogenes</i> group A
Swedac	Swedish Board for Accreditation and Conformity Assessment
UK NEQAS	United Kingdom National External Quality Assessment Service

3. Introduction

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia by providing objective information about analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP evaluations.

3.1. The concept of SKUP evaluations

SKUP evaluations follow common guidelines and the results from various evaluations are comparable¹. The evaluation set-up and details are described in an evaluation protocol and agreed upon in advance. The analytical results and user-friendliness are assessed according to pre-set quality goals. To fully demonstrate the quality of a product, the end-users should be involved in the evaluations. If possible, SKUP evaluations are carried out using three lot numbers of test kits from separate and time-spread productions. Some evaluation codes are followed by an asterisk (*), indicating an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

3.2. Background for the evaluation

DIAQUICK Strep A Blue Dipstick is an in vitro diagnostic rapid test for detection of *Streptococcus pyogenes* group A (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.

3.3. 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.

3.4. The model for the evaluation of DIAQUICK Strep A Blue Dipstick

The evaluation was carried out in primary health care centres (PHCCs) to test the performance of DIAQUICK Strep A Blue Dipstick in the hands of the intended users, see flowchart in figure 1. Four PHCCs participated in the evaluation.

The evaluation included:

- A comparison of the performance of DIAQUICK Strep A Blue Dipstick in PHCCs with a comparison method, i.e. culturing of *Streptococcus pyogenes* (*S. pyogenes*) of samples from the same patients. Patients who consulted their general practitioner were tested with both methods. 348 individuals with tonsillitis suspected to be bacterial and at least two of the Centor criteria (figure 1 and attachment 6) fulfilled [1, 2] were included. The evaluation continued until at least 100 patient samples had positive results for *S. pyogenes* with the comparison method. A prevalence of approximately 25 % was expected.
- Examination of the analytical quality (diagnostic sensitivity and diagnostic specificity) in the hands of intended users.
- Evaluation of the user-friendliness of DIAQUICK Strep A Blue Dipstick and its insert.

¹SKUP evaluations are under continuous development. In some cases, it may be difficult to compare earlier protocols, results and reports with more recent ones.

In addition, the prevalence, positive predictive value (PPV) and negative predictive value (NPV) were calculated on the achieved diagnostic sensitivity and diagnostic specificity.

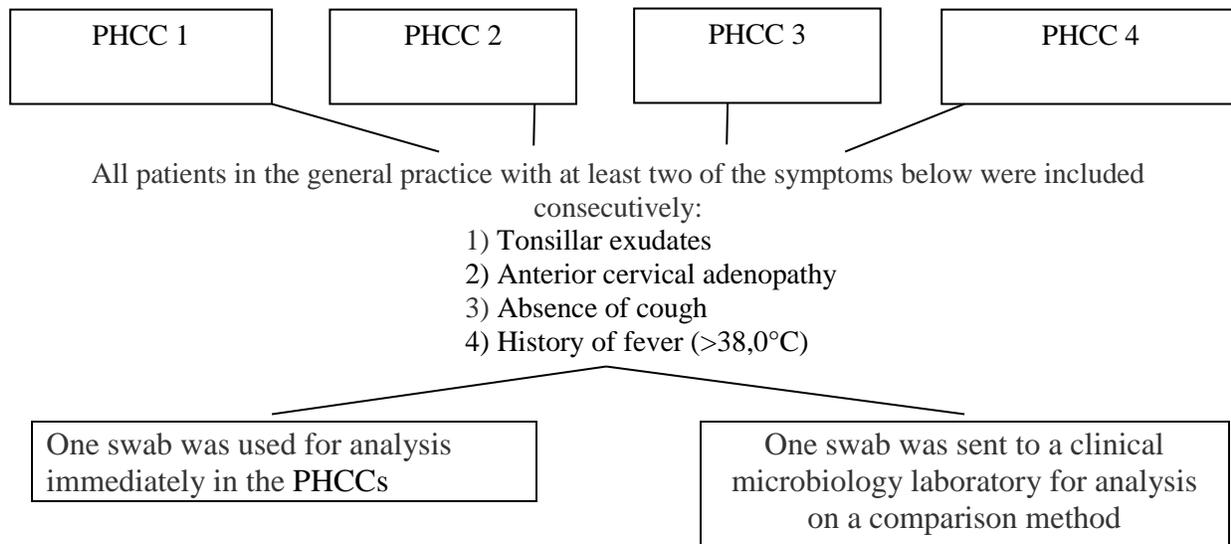


Figure 1. Flowchart illustrating the model for the evaluation of DIAQUICK Strep A Blue Dipstick. The Centor criteria are presented as 1) to 4) in the middle of the figure. Enrolment of patients continued until at least 100 positive and at least 100 negative cultures of *S. pyogenes* were achieved in the clinical microbiology laboratory.

4. Quality goals

4.1. Analytical quality

At present, no gold standard for the rapid testing of *S. pyogenes* exists. There is neither consensus on the detection procedures used for rapid Strep A tests nor on details in the methods for culturing of *S. pyogenes*. However, culturing is still considered the diagnostic standard and was the comparison method used in this evaluation. The comparison method should be accredited and performed as described by Kellogg [3] or shown to be equivalent.

Present recommendations for the rapid tests for S. pyogenes

A diagnostic sensitivity of >80 % and a diagnostic specificity of >95 % should, according to SKUP, be achieved when compared to a sensitive method for culturing of *S. pyogenes*. Several evaluations were performed in Sweden in the 2000s [4] and in Denmark during the 1980s and 1990s [5–7] among general practitioners. It has been shown that rapid Strep A tests can fulfil SKUP's quality goal of both diagnostic sensitivity and diagnostic specificity. A more recent review in the Cochrane Library of rapid Strep A tests further supports the quality goals set by SKUP [8].

4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the evaluating persons in the PHCCs to fill in a questionnaire, see section 6.4.

Technical errors

SKUP recommends that the fraction of tests wasted due to technical errors should not exceed 2 %.

4.3. Principles for the assessments

To qualify for an overall good assessment in a SKUP evaluation, the rapid test must show satisfactory analytical quality as well as satisfactory user-friendliness.

4.3.1. Assessment of the analytical quality

The analytical results were assessed according to pre-set quality goals.

Diagnostic sensitivity

The diagnostic sensitivity is based on the fraction of positive results with DIAQUICK Strep A Blue Dipstick in the PHCCs in proportion to the positive results with culturing of *S. pyogenes* in the clinical microbiology laboratory.

The achieved diagnostic sensitivity is presented as fulfilling or not fulfilling the quality goal. The calculated result is given with a 90 % confidence interval (CI) (for information only).

Diagnostic specificity

The diagnostic specificity is based on the fraction of negative results with DIAQUICK Strep A Blue Dipstick in the PHCCs in proportion to the negative results with culturing of *S. pyogenes* in the clinical microbiology laboratory.

The achieved diagnostic specificity is presented as fulfilling or not fulfilling the quality goal. The calculated result will be given with a 90 % CI (for information only).

Prevalence, and positive and negative predictive values

Positive and negative predictive values are dependent on prevalence. Based on previous evaluations performed in autumn, winter or early spring, the prevalence of *S. pyogenes* is estimated to about 25 % in the population tested for *S. pyogenes*. The prevalence of *S. Pyogenes* is calculated, as well as the PPV and the NPV; and will be mentioned in the conclusion of the report for information purpose.

Assessment of three lots

Separate lot calculations are not performed. Three lot of test kits is used for the purpose of having an evaluation less sensitive to the risk of a poor batch.

4.3.2. Assessment of the user-friendliness

The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 6.4). For each question, the evaluator chooses between three given ratings; satisfactory, intermediate and unsatisfactory. The responses from the evaluators are reviewed and summed up. To achieve the overall rating “satisfactory”, the tested equipment must reach a total rating of “satisfactory” in all four subareas of characteristics described in section 6.4.

Technical errors

The evaluating persons register technical errors and failed measurements during the evaluation. The fraction of tests wasted due to technical errors is calculated and taken into account in connection with the assessment of the user-friendliness.

4.4. SKUP’s quality goals in this evaluation

As agreed upon when the protocol was drawn up, the results from the evaluation of DIAQUICK Strep A Blue Dipstick are assessed against the following quality goals:

Diagnostic sensitivity >80 %
Diagnostic specificity >95 %
User-friendliness, overall rating Satisfactory

5. Materials and methods

5.1. Definition of the measurand

The measurement system intends to detect Beta haemolytic Group A streptococci, or *S. pyogenes*, antigen in secrete from throat. The sample material in this evaluation is mucus from the pharynx for both the evaluated system and the comparison method. For the comparison method *S. pyogenes* is identified by the ability to grow on sheep blood agar plates. The results are expressed on an ordinal scale (positive or negative) for both methods. The Committee on Nomenclature, Properties and Units (C-NPU) systematically describes clinical laboratory measurands in a database [9]. The NPU codes related to the measurands in this evaluation are NPU12293 (for the comparison method, the sample location has to be specified) and NPU18729 (the sample location is specified to pharynx). In this protocol, the term Strep A will be used for this measurand.

5.2. The evaluated rapid test DIAQUICK Strep A Blue Dipstick

The information in this section derives from the company's information material.

The DIAQUICK Strep A Blue Dipstick is a qualitative, lateral flow immunoassay for the detection of Strep A antigen in human throat swab specimens within 5 minutes.

In this test, antibodies specific to Strep A carbohydrate antigens are coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with a second Strep A antibody, which is coated onto colloidal particles. This mixture migrates up the membrane to react with the antibody there and generates a red coloured line in the test region. The presence of this red coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a blue coloured line will always appear in the control line region, indicating that proper specimen volume has been added and membrane wicking has occurred. See figure 2, for the test procedure of DIAQUICK Strep A Blue Dipstick.

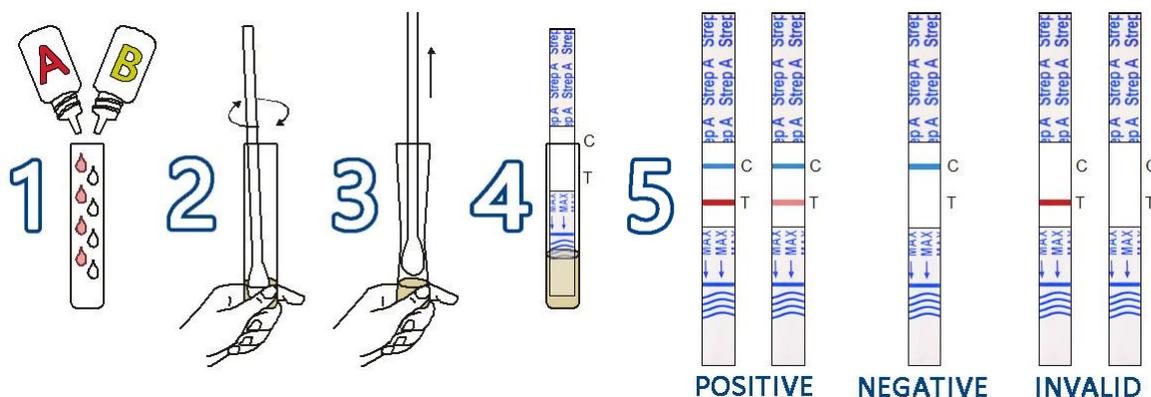


Figure 2. The test procedure of DIAQUICK Strep A Blue Dipstick

For technical details about the DIAQUICK Strep A Blue Dipstick test, see table 1. For more information about the DIAQUICK Strep A Blue Dipstick test, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 2 and 3. For product specifications in this evaluation, see attachment 4.

Table 1. Technical details from the manufacturer

Technical details for DIAQUICK Strep A Blue Dipstick	
Sample material	Human throat swab specimen
Measuring time	5 minutes
Measuring results	Positive / Negative

5.3. The selected comparison method

A selected comparison method is a fully specified method which, in the absence of a Reference method, serves as a common basis for the comparison of the evaluated method.

5.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation was culturing of *S. pyogenes*, hereafter called “the comparison method”.

In the clinical microbiology in Lund, Sweden, the following method for culturing was used: 30 µL of the sample was inoculated on a double-layered agar plate (Columbia II agar, BD) without and with 5 % sheep blood, and then incubated in an anaerob environment at 37°C between 18 and 20 hours. β-hemolytic colonies were tested with an agglutination test (Streptex™, Thermo Scientific). If needed, verification with MALDI-TOF (Bruker Daltronics, Germany) was performed.

The clinical microbiology laboratory is accredited by the Swedish Board for Accreditation and Conformity Assessment (Swedac) for qualitative culturing of beta haemolytic Group A, C and G streptococci. Interpretation of the growth of bacteria and identification of the type of growing bacteria were performed with standard methods [10].

Definition of positive and negative results

The results from the comparison method culturing of *S. pyogenes* were given as colony forming units (cfu) and assessed as follows:

0 cfu	No growth	Negative
1–9 cfu	Sparse growth	Positive
10–99 cfu	Moderate growth	Positive
>100 cfu	Abundant growth	Positive

Internal analytical quality control

For every new batch of agar plates prepared, a reference strain was cultured on some of the plates to check that beta haemolytic streptococci grew as expected.

External analytical quality control

The clinical microbiology laboratory participates in United Kingdom National External Quality Assessment Service (UK NEQAS) EQA scheme for microbiology that once or twice a year concern beta haemolytic Group A streptococci. If beta haemolytic streptococci are found in a sample, the bacteria will be characterized according to local procedure. The assigned value for beta haemolytic Group A streptococci is based on known bacteria strains added in a fixed concentration.

5.3.2. Verification of the analytical quality of the comparison method

Trueness

The trueness of the method for culturing and identification of *S. pyogenes* and other streptococci was verified with EQA results for a period circumventing the evaluation period. The EQA samples were provided by UK NEQAS.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation

Medic24 via Kari Røsand applied to SKUP in April 2017 for an evaluation of DIAQUICK Strep A Blue Dipstick.

Protocol, arrangements and contract

In February 2018, the protocol for the evaluation was approved, and Medic24 and SKUP signed a contract for the evaluation. Four PHCCs (Hörby, Norra Fäladen, Svalöv and Södervärn) from Skåne county, Sweden, agreed to represent the intended users in this evaluation.

Training

The training in the PHCCs reflected the training usually given to the end-users. Medic24 or DIALAB GmbH were not allowed to contact or supervise the evaluators during the evaluation period.

Recording of results

The PHCCs results were registered consecutively on a registration form prepared by SKUP. The results were signed by the person performing the practical work. All data were reported (time of specimen collection, days of analysis, controls taken in use, technical errors, failed measurements, mistakes etc.). The Centor criteria used for inclusion of each patient were included in the record.

The results from the comparison method were registered in the clinical microbiology laboratory, and then sent to SKUP.

5.4.2. Evaluation sites and persons involved

The evaluation took place at the Department of Clinical Microbiology, Division of Laboratory Medicine, Skånes University Hospital, Lund, Sweden and four PHCCs, all located in Skåne County, Sweden. The practical work was carried out during 10 weeks, ending in April 2018. At the hospital laboratory, resident physician Afamia Jabbour was main responsible for the evaluation. She also acted as the contact person towards the PHCCs.

In the PHCCs, approximately 12 assistant nurses and one biomedical laboratory scientist (BLS) participated in the evaluation in total. They all use rapid tests in their routine method for detection of Strep A. Three out of four participating PHCCs do not have a BLS as the person responsible for analysing the samples for the evaluation.

5.4.3. The evaluation procedure for intended users

Internal analytical quality control

Internal analytical quality control samples for DIAQUICK Strep A Blue Dipstick were performed each evaluation day, alternating between the positive and the negative control (included in the kit). In addition, built-in procedural control features were checked during each analysis.

External analytical quality control

Each PHCC in this evaluation participated with DIAQUICK Strep A Blue Dipstick in one EQA round from Equalis during the evaluation. The Strep A EQA scheme at Equalis is intended for rapid tests only. The EQA round consisted of three materials with different concentrations of non-viable Strep A bacteria. The target values were assigned by the producer of the material.

Recruitment of patients

Patients seeking care for symptoms of possible throat infection caused by bacteria were asked if they were willing to participate in the evaluation of DIAQUICK Strep A Blue Dipstick. Participation was voluntary and verbal consent was considered to be sufficient. In case of youngsters, the parent also needed to consent.

Inclusion of all Strep A screening samples was avoided and only patients with severe symptoms of pharyngitis were included. The patients were included by the Centor criteria described in attachment 6. They were not included if they had been on antibiotic treatment during the last 14 days, due to the risk of false positive result as also dead *S. pyogenes* bacteria can be detected with the rapid test.

Handling of the samples and measurements

The four PHCCs collected throat swab samples in duplicates until 100 positive and at least 100 negative samples had been measured on the comparison method.

During the evaluation, the rapid Strep A test normally used in the PHCCs was not used. This was because two swabs were needed for the evaluation, and it seemed that three swabs would be too much for the patients. Samples were collected by using two swabs simultaneously; one swab for the PHCC for analysis with DIAQUICK Strep A Blue Dipstick in accordance with the instructions from the manufacturer, and the other swab for the comparison method. The swabs were rolled over the tonsils simultaneously, following local guidelines of sampling, and then rubbed together before running the tests.

The sample intended for analysis with DIAQUICK Strep A Blue Dipstick was collected with the swab included in the test kit and processed as described in the kit insert. The reading time was given to 5 minutes, which was followed at most times. A few of the positive results were read after 1–4 minutes.

The swab intended for culturing was swirled in a tube with transport medium, and the tube was kept in a refrigerator until it was sent in a cooling bag to the clinical microbiology laboratory later the same day. The cultures were started upon arrival of the samples. The referral form sent in connection with the samples indicated the results from DIAQUICK Strep A Blue Dipstick. Should DIAQUICK Strep A Blue Dipstick show an incorrect result, this would appear during culturing and would be reported to the PHCC the day after sampling.

6. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 5.

6.1. Number of samples

Patient samples

In total 351 patients provided duplicate samples. The youngest patient enrolled was 8 months old and the oldest was 88 years old. The average age was 23 years and the median age 18 years. Patients of female sex comprised 56 % of the 351 patients.

Missing results

Culturing of three of the patient samples were missing, leaving 348 samples for the calculations.

Omitted results

There were no omitted results.

Recorded technical errors or failed measurements

No technical errors or failed measurements were reported.

Prevalence

The prevalence was calculated by dividing the number of positive cultures with the total number of the cultures of patient samples. The prevalence was 30%.

6.2. Analytical quality of the selected comparison method

6.2.1. Internal analytical quality control

All results from the internal analytical quality control were as expected (data not shown).

6.2.2. The trueness of the comparison method

The clinical microbiology laboratory participates in an EQA scheme at UK NEQAS. The laboratory showed satisfactory results for culturing of beta haemolytic streptococci during the evaluation period (first half of 2018).

6.3. Analytical quality of DIAQUICK Strep A Blue Dipstick achieved by intended users

The results below reflect the analytical quality of DIAQUICK Strep A Blue Dipstick under real-life conditions in the hands of intended users in PHCCs.

6.3.1. Internal analytical quality control

The DIAQUICK Strep A Blue Dipstick test kit includes a positive and a negative internal quality control. One quality control sample was run each evaluation day, alternating between the positive and the negative control, at each of the PHCCs. In total, 147 measurements were done, 74 with the positive control and 73 with the negative control. 144 results showed the correct result, the remaining four results (two positive and two negative) were missing in the protocols.

6.3.2. External analytical quality control

The PHCCs received three external control materials intended for Strep A rapid tests from Equalis during the evaluation. All PHCCs achieved the correct results with DIAQUICK Strep A Blue Dipstick on all three samples (data not shown).

6.3.3. The diagnostic sensitivity of DIAQUICK Strep A Blue Dipstick in primary health care

The diagnostic sensitivity of DIAQUICK Strep A Blue Dipstick was calculated by comparing the test results in the PHCCs with the culturing from the same patients showing positive results, see table 2. The calculations were done as described in Attachment 5 using the culturing results as true values. The raw data is presented to the requesting company only (Attachment 7).

Table 2. Diagnostic sensitivity of DIAQUICK Strep A Blue Dipstick

Number of true positive results	Number of false negative results	Diagnostic sensitivity
76	29	0,724

Number of positive Strep A cultures: 105

Discussion

The diagnostic sensitivity was 72 %, with a 90 % CI of 65-79 %. 16 of the false negative results displayed sparse growth of colonies; 8 of the false negative results displayed moderate growth of colonies and 5 of the false negative results displayed abundant growth of colonies.

Conclusion

The quality goal of a diagnostic sensitivity of >80 % was not fulfilled.

6.3.4. The diagnostic specificity of DIAQUICK Strep A Blue Dipstick in primary health care

The diagnostic specificity of DIAQUICK Strep A Blue Dipstick was calculated by comparing the test results in the PHCCs with the culturing from the same patients showing negative results, see table 3. The calculations were done as described in Attachment 5 using the culturing results as true values. The raw data is presented to the requesting company only (Attachment 7).

Table 3. Diagnostic specificity of DIAQUICK Strep A Blue Dipstick

Number of true negative results	Number of false positive results	Diagnostic specificity
238	5	0,979

Number of negative Strep A cultures: 243

Discussion

The diagnostic specificity was 98 %, with a 90 % CI of 96-99 %.

Conclusion

The quality goal of a diagnostic specificity of >95% was fulfilled.

6.3.5. The positive and negative predictive values of DIAQUICK Strep A Blue Dipstick in primary health care

The PPV and NPV of DIAQUICK Strep A Blue Dipstick was calculated by comparing the positive and negative test results in the PHCCs with the culturing from the same patients showing positive and negative results, respectively, see table 4 and 5. The calculations were done as described in Attachment 5 using the culturing results as true values. The raw data is presented to the requesting company only (Attachment 7).

Table 4. PPV of DIAQUICK Strep A Blue Dipstick

Number of true positive results	Number of false positive results	PPV
76	5	0,938

Table 5. NPV of DIAQUICK Strep A Blue Dipstick

Number of true negative results	Number of false negative results	NPV
238	29	0,891

Discussion

The PPV was 94 % and the NPV was 89 %. Note that the predictive values are affected by the prevalence (Attachment 5).

6.4. Evaluation of user-friendliness

6.4.1. Questionnaire to the evaluators

The most important response regarding user-friendliness comes from the intended users themselves. The end-users often emphasise other aspects than those pointed out by more extensively trained laboratory personnel.

At the end of the evaluation period, the intended users filled in a questionnaire about the user-friendliness of the measurement system. SKUP has prepared detailed instructions for this.

The questionnaire is divided into four subareas:

Table A) Rating of operation facilities. Is the system easy to handle?

Table B) Rating of the information in the manual / insert / quick guide

Table C) Rating of time factors for the preparation and the measurement

Table D) Rating of performing internal and external analytical quality control

The intended users filled in table A and B. SKUP filled in table C and D and in addition, topics marked with grey colour in table A and B.

In the tables, the first column shows what is up for consideration. The second column in table A and B shows the rating by the users at the evaluation sites. The rest of the columns show the rating options. The overall ratings from all the evaluating sites are marked in coloured and bold text. The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

Unsatisfactory and intermediate ratings are marked with a number and explained below the tables. The intermediate category covers neutral ratings assessed as neither good nor bad.

An assessment of the user-friendliness is subjective, and the topics in the questionnaire may be emphasised differently by different users. The assessment can therefore vary between different persons and between the countries. This will be discussed and taken into account in the overall assessment of the user-friendliness.

Comment

In this evaluation, the user-friendliness was assessed by evaluators from four PHCCs.

Table A. Rating of operation facilities

Topic	Rating	Rating	Rating	Rating	Option
To prepare the test / instrument	I ¹ , S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
To prepare the sample	I ¹ , S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Application of specimen	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Specimen volume*		Satisfactory	Intermediate	Unsatisfactory	No opinion
Number of procedure step	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Instrument / test design	I ¹ , S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Reading of the test result	E, E, E, I ²	Easy	Intermediate	Difficult	No opinion
Sources of errors	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Cleaning / Maintenance**		Satisfactory	Intermediate	Unsatisfactory	No opinion
Hygiene, when using the test	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Size and weight of package	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Storage conditions for tests, unopened package	S	+15 to +30°C	+2 to +8°C	-20°C	
Storage conditions for tests, opened package ³	S	+15 to +30°C	+2 to +8°C	-20°C	
Environmental aspects: waste handling	U ⁴	No precautions	Sorted waste	Special precautions	
Intended users	S	Health care personnel or patients	Laboratory experience	Biomedical laboratory scientists	

Total rating by SKUP**Satisfactory**

*Sample material is throat swabs.

**Cleaning and maintenance not needed.

¹The diameter of the extraction tube is too small, making it difficult to put drops and swab into it. Difficult to take out the single-packed test sticks.²A bit too weak lines sometimes.³Dipsticks must remain in sealed pouch until use.⁴Viable bacteria always have to be handled with special precautions.

Additional positive comments: The test functions as good as the one regularly in use. Good size package

Table B. Rating of the information in the insert

Topic	Rating	Rating	Rating	Rating	Option
Table of contents/Index*		Satisfactory	Intermediate	Unsatisfactory	No opinion
Preparations/Pre-analytic procedure	N, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Specimen collection	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Measurement procedure	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Reading of result	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Description of the sources of error	S, S, N, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Help for troubleshooting	S, S, N, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Readability / Clarity of presentation	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
General impression	S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Measurement principle	S	Satisfactory	Intermediate	Unsatisfactory	
Available insert in Danish, Norwegian, Swedish	I ¹	Satisfactory	Intermediate	Unsatisfactory	
Total rating by SKUP		Satisfactory			

*Insert do not contain Table of contents/Index

¹Not available in Danish

Table C. Rating of time factors (filled in by SKUP)

Topic	Rating	Rating	Rating
Required training time	<2 hours	2 to 8 hours	>8 hours
Durations of preparations / Pre-analytical time	<6 min.	6 to 10 min.	>10 min.
Duration of analysis	<10 min.	10 to 20 min.	>20 min.
Stability of test, unopened package	>5 months	3 to 5 months	<3 months
Stability of test, opened package ¹	>30 day or disposable	14 to 30 days	<14 days
Stability of quality control material, unopened	>5 months	3 to 5 months	<3 months
Stability of quality control material, opened	>6 days or disposable	2 to 6 days	≤1 day

Total rating by SKUP**Satisfactory**

¹ The stability of the reagent solutions does not change when opened. Dipsticks are individually packed, and opened right before use.

Table D. Rating of analytical quality control (filled in by SKUP)

Topic	Rating	Rating	Rating
Reading of the internal quality control ¹	Satisfactory	Intermediate	Unsatisfactory
Usefulness of the internal quality control	Satisfactory	Intermediate	Unsatisfactory
External quality control	Satisfactory	Intermediate	Unsatisfactory

Total rating by SKUP**Satisfactory**

¹ In addition to the positive and negative controls included in the kit, several procedural control steps are built in to the test.

6.4.2. Assessment of the user-friendliness*Assessment of the operation facilities (table A)*

The operation facilities were in total assessed as satisfactory, but there were a few intermediate ratings. The motivations for the lower ratings were that one PHCC felt that the diameter of the extraction tube was too small, which made it a bit difficult to put the drops and the swab into it, and they also found it a bit difficult to take out the single-packed test sticks from the package. Another PHCC commented that it was a bit too weak lines sometimes. Considering waste handling; viable bacteria should always be handled with special precautions.

Assessment of the information in the insert (table B)

The insert was assessed as satisfactory.

Assessment of time factors (table C)

The time factors were assessed as satisfactory.

Assessment of analytical quality control possibilities (table D)

The analytical quality control possibilities were assessed as satisfactory.

Conclusion

In all, the user-friendliness of DIAQUICK Strep A Blue Dipstick and its insert was rated as satisfactory. The quality goal for user-friendliness was fulfilled.

7. References

1. Swedish Medical Products Agency, Treatment of pharyngotonsillitis in primary health care – new recommendations. In Swedish. Handläggning av faryngotonsilliter i öppenvård – ny rekommendation. Information från Läkemedelsverket 2012; **23** (6): 18 – 25.
2. Centor RM. *et al.* The diagnosis of strep throat in adults in the emergency room. Medical Decision Making 1981; **1** (3): 239 – 246.
3. Kellogg JA. Suitability of throat culture procedures for detection of group A streptococci and as reference standards for evaluation of streptococcal antigen detection kits. J Clin Microbiology 1990; **28**: 165 – 159.
4. Karlsson P. Dept. of Microbiology, Ryhov hospital, Jönköping, Sweden, personal communication.
5. Hoffmann S. Detection of group A streptococcal antigen from throat swabs with five diagnostic kits in general practice. Streptococcus Department, Statens Seruminstitut, Copenhagen, Denmark. Diagn Microbiol Infect Dis 1990; **13**: 209 – 215.
6. Andersen JS., Borrild NJ. & Hoffmann S. Diagnostik af halsbetændelse. En multipraksisundersøgelse af tre antigen-detektionssæt til påvisning af gruppe A-streptokokker i svælghodninger. Ugeskrift for Læger 1994; **156** (46): 6869 – 6872.
7. Andersen JS., Borrild NJ. & Hoffmann S. Potential of antigen detection tests. BMJ 1995; **310**: 58 – 59.
8. Cohen JF *et al.* Rapid antigen detection test for group A streptococcus in children with pharyngitis. Cochrane Database of Systematic Reviews 2016, Issue 7.
9. The IFCC – IUPAC terminology for properties and units. <http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/>
10. Swedish Society for Clinical Microbiology (FKM). Recommended reference methods (In Swedish). http://referensmetodik.folkhalsomyndigheten.se/w/Betahemolyserande_streptokocker_grupp_A,_B,_C_och_G (accessed August 2018)

Attachments

1. The organisation of SKUP
2. Facts about DIAQUICK Strep A Blue Dipstick
3. Information about manufacturer, retailers and marketing
4. Product specifications for this evaluation, DIAQUICK Strep A Blue Dipstick
5. Statistical expressions and calculations
6. The Centor criteria
7. Raw data, DIAQUICK Strep A Blue Dipstick versus the comparison method
8. List of previous SKUP evaluations
9. Comments from DIALAB GmbH/Medic24

Attachments with raw data are included only in the copy to Medic24.

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for point of care testing, SKUP, is a co-operative commitment of Noklus¹ in Norway, DEKS² in Denmark, and Equalis³ in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at Noklus in Bergen, Norway.

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information about analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of equipment for primary health care, hospitals and also of devices for self-monitoring. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. The analytical results are assessed according to *pre-set quality goals*. To fully demonstrate the quality of a product, the *end-users* should be involved in the evaluations.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year the report was completed and a serial number. A report code, followed by an asterisk (*), indicates an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

SKUP reports are published at www.skup.org.

¹ Noklus (Norwegian Quality Improvement of Laboratory Examinations) is a national not for profit organisation offering activities for quality improvement to all medical laboratory services in Norway. Noklus was established in 1992 and is governed by a management committee consisting of representatives from the Norwegian Government, the Norwegian Medical Association and the Norwegian Society of Medical Biochemistry, with the Norwegian Association of Local and Regional Authorities (KS) as observer.

² DEKS (Danish Institute for External Quality Assurance for Laboratories in Health Care) is a non-profit organisation owned by the Capital Region of Denmark on behalf of all other Regions in Denmark.

³ Equalis AB (External quality assessment in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by "Sveriges Kommuner och Landsting" (Swedish Association of Local Authorities and Regions), "Svenska Läkaresällskapet" (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

Facts about DIAQUICK Strep A Blue Dipstick

Parts of this form are filled in by Medic24. NA = not applicable.

Table 1. Basic facts

Name of the measurement system:	DIAQUICK Strep A Blue Dipstick
Dimensions and weight:	Width: 235 mm Depth: 130 mm Height: 80 mm Weight: 230 g
Components of the measurement system:	20 Tests, individually packed in foil pouches 20 Extraction Tubes (plastic) 20 Sterile Swabs, individually packed 1 Work Station (cardboard) 1 x 10 mL Extraction Reagent 1: 2 M NaNO ₂ 1 x 10 mL Extraction Reagent 2: 0.027 M citric acid 1 x 1 mL Positive Control: non-viable Strep A 1 x 1 mL Negative Control: non-viable Strep C
Measurand:	Strep A antigen
Sample material:	Human throat swab specimen
Sample volume:	NA
Measuring principle:	Qualitative, lateral flow immunoassay for the detection of Strep A antigen
Traceability:	NA
Calibration:	NA
Measuring range:	Positive/Negative
Linearity:	NA
Measurement time:	5 minutes
Operating conditions:	Room temperature
Electrical power supply:	NA
Recommended regular maintenance:	NA
Package contents:	Dipsticks coated with antibodies specific to Strep A, extraction reagents 1 and 2, sterile throat swabs, positive and negative controls, extraction tubes, work station, package insert
Necessary equipment not included in the package:	Gloves, timer

Table 2. Post analytical traceability

Is input of patient identification possible?	No
Is input of operator identification possible?	No
Can the instrument be connected to a bar-code reader?	NA
Can the instrument be connected to a printer?	NA
What can be printed?	NA
Can the instrument be connected to a PC?	NA
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	NA
What is the storage capacity of the instrument and what is stored in the instrument?	NA
Is it possible to trace/search for measurement results?	NA

Table 3. Facts about the reagent/test strips/test cassettes

Name of the reagent/test strips/test cassettes:	DIAQUICK Strep A Blue Dipstick
Stability in unopened sealed vial:	24 months from production date
Stability in opened vial:	24 months from production date (dipsticks must remain in the sealed pouch until use)
Package contents:	Dipsticks are individually packed

Table 4. Quality control

Electronic self-check:	NA
Recommended control materials and volume:	External positive and negative control included. 1 drop of each external control material added into separate extraction tubes between step 4 and 5 in the directions for use.
Stability in unopened sealed vial:	24 months from production date
Stability in opened vial:	24 months from production date
Package contents:	1 x 1 mL Positive Control: non-viable Strep A 1 x 1 mL Negative Control: non-viable Strep C

Information about manufacturer, retailers and marketing

Parts of this form are filled in by Medic24.

Table 1. Supplier and manufacturer in Scandinavia

Manufacturer:	DIALAB GmbH
Retailers in Scandinavia:	<u>Denmark:</u> Medic24 <u>Norway:</u> Medic24 <u>Sweden:</u> Medic24
In which countries are the system marketed:	Not marketed in any country
Date for start of marketing the system in Scandinavia:	2018-10-11
Date for CE-marking:	2017-10-22
In which Scandinavian languages is the manual available:	Norwegian and Swedish

Product information, DIAQUICK Strep A Blue Dipstick

DIAQUICK Strep A Blue Dipstick kit

Kit lot number STA1712002-S, expiry date 2019-12

Kit lot number STA1712003-S, expiry date 2019-12

Kit lot number STA1712004-S, expiry date 2019-12

Kit content

1x10 mL Extraction reagent A, includes sodium nitrite 2 mol/L

1x10 mL Extraction reagent B, includes citric acid 0,027 mol/L

1x1 mL Internal quality control Positive; non-viable Strep A, includes sodium azide 0,09 %

1x1 mL Internal quality control Negative; non-viable Strep C, includes sodium azide 0,09 %

20 Dipsticks, covered with antibodies against Strep A

20 Sterile swabs

20 Test tubes

1 Work station

Kit insert

Statistical expressions and calculations

This attachment is valid for evaluations of qualitative test methods with results on the ordinal scale.

Statistical terms and expressions

The definitions and formulas in this section originate from the Geigy document [a].

Statistical calculations

Diagnostic sensitivity is true positive/(true positive + false negative)

Diagnostic specificity is true negative/(false positive + true negative)

Positive predictive value (PPV) is true positive/(true positive + false positive)

Negative predictive value (NPV) is true negative/(true negative + false negative)

Prevalence is true positive/(true positive + true negative + false positive + false negative)

See table 1 for an illustration.

Table 1. Illustration of statistical calculations

	Truth		
	Positive	Negative	
Evaluated test positive	a	b	PPV = a/(a+b)
Evaluated test negative	c	d	NPV = d/(d+c)
	Diagnostic sensitivity = a/(a+c)	Diagnostic specificity = d/(b+d)	

Calculation of confidence intervals

Estimation of CI for fractions/proportions is performed according to the formula 772 in Documenta Geigy [a] / Adjusted Walds [b]]. The confidence intervals (CIs) are given for information only.

Relationship between PPV / NPV and prevalence

Contrary to diagnostic sensitivity and specificity, the PPV and NPV are related to the prevalence of the disease in a specific population (figure 1). PPV and NPV are also related to the diagnostic sensitivity and specificity of a diagnostic test.

a. Documenta Geigy. Mathematics and statistics, 1971. CIBA-GEIGY Limited, Basel, Switzerland; p 186 formula # 772.

b. <http://www.measuringu.com/wald.htm>

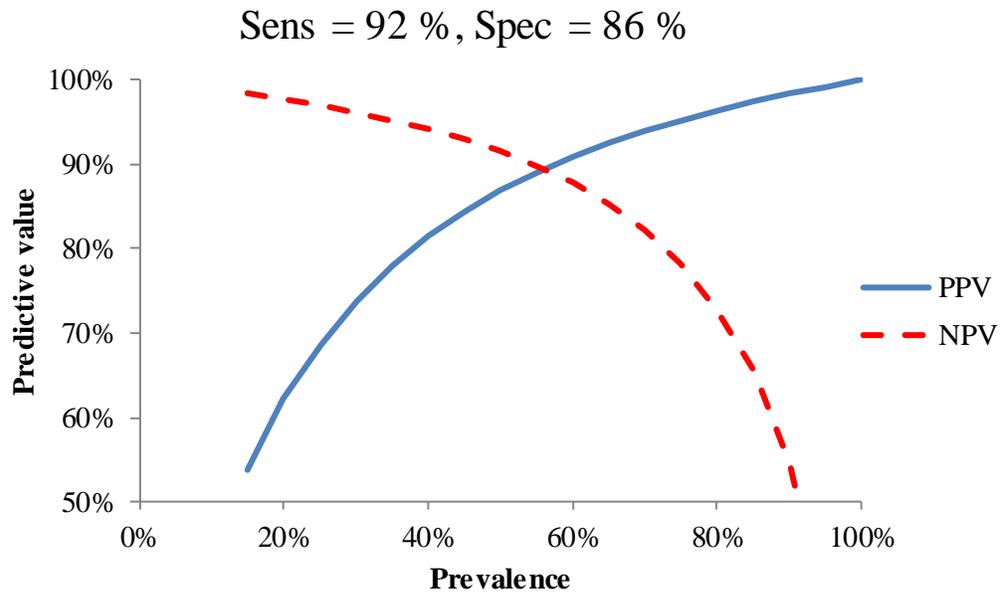


Figure 1. Relationship between PPV/NPV and prevalence.

In figure 1, a diagnostic sensitivity of 92 % and a diagnostic specificity of 86 % are used to illustrate the decrease of NPV (dashed line) and increase of PPV (solid line) as the prevalence of the disease increases.

The Centor criteria

The patients are judged on four criteria, with one point added for each positive criterion [a]:

- History of fever
- Tonsillar exudates
- Tender anterior cervical adenopathy
- Absence of cough

The Modified Centor criteria add the patient's age to the criteria [b]:

- Age <15 add 1 point
- Age >44 subtract 1 point

The point system is important in that it dictates management. Guidelines [a] for management state:

- <2 points – No antibiotic or throat culturing of *S. pyogenes* necessary (risk of Strep A infection <10 %)
- 2-3 points – Should receive a throat culturing and be treated with an antibiotic if the culturing of *S. pyogenes* is positive (risk of Strep A infection 32 % if 3 criteria, 15 % if 2)
- >3 points – Treat empirically with an antibiotic (risk of Strep A infection 56 %)

The presence of all four variables indicates a 40–60 % positive predictive value for culturing of samples from the throat to test positive for Group A Streptococcus bacteria. The absence of all four variables indicates a negative predictive value of greater than 80 % [c]. The high negative predictive value suggests that the Centor criteria can be more effectively used for ruling out a Strep A infection than for diagnosing it.

- a. Centor RM. *et al.* The diagnosis of strep throat in adults in the emergency room. *Medical Decision Making* 1981; **1** (3): 239 – 246.
- b. McIsaac WJ. *et al.* Empirical validation of guidelines for the management of pharyngitis in children and adults. *J Am Med Assoc* 2004; **291** (13): 1587 – 1595.
- c. Chan TV. The patient with sore throat. *Med Clin North Am* 2010; **94** (5): 923 – 943.

Raw data are included only in the copy to Medic24.

List of previous SKUP evaluations

The 30 latest SKUP evaluations

Evaluation no.	Component	Instrument/testkit	Producer
SKUP/2018/114	Strep A	DIAQUICK Strep A Blue Dipstick	DIALAB GmbH
SKUP/2018/115*	PT (INR)	<i>Confidential</i>	
SKUP/2017/113	Glucose ¹	Accu-Chek Instant	Roche Diabetes Care GmbH
SKUP/2017/111	Glucose ¹	<i>Confidential</i>	
SKUP/2017/112	Glucose ¹	Accu-Chek Guide	Roche Diabetes Care GmbH
SKUP/2016/110	PT (INR)	Xprecia Stride Coagulation system	Siemens Healthcare Diagnostics INC
SKUP/2015/107	Strep A	QuickVue Dipstick Strep A Test	Quidel Corporation
SKUP/2015/109	PT (INR)	microINR portable coagulometer	iLine Microsystems S.L.
SKUP/2015/108	HbA1c	<i>Confidential</i>	
SKUP/2015/102	HbA1c	<i>Confidential</i>	
SKUP/2015/106*	Strep A	QuikRead go	Orion Diagnostica Oy
SKUP/2014/101	HbA1c	InnovaStar analyzer	DiaSys Diagnostic Systems GmbH
SKUP/2014/104	PT (INR)	ProTime InRhythm	ITC International Technidyne Corporation
SKUP/2014/105	Glucose ¹	Accu-Chek Aviva	Roche Diagnostics
SKUP/2014/103	PT (INR)	<i>Confidential</i>	
SKUP/2013/87	Glucose ¹	Wella Calla Light	Med Trust Handelsges.m.b.H.
SKUP/2013/100	Glucose ¹	Mylife Unio	Bionime Corporation
SKUP/2013/97	NT-proBNP	Cobas h 232 POC system	Roche Diagnostics GmbH
SKUP/2013/92	CRP	Eurolyser smart 700/340	Eurolyser Diagnostica GmbH
SKUP/2013/99*	Glucose	Accu-Chek Mobile	Roche Diagnostics
SKUP/2013/98*	Glucose	Accu-Chek Aviva	Roche Diagnostics
SKUP/2013/85	Glucose, β -Ketone	Nova StatStrip	Nova Biomedical Corporation, USA
SKUP/2013/96	Hemoglobin	DiaSpect Hemoglobin T	DiaSpect Medical GmbH
SKUP/2013/68	Allergens	ImmunoCap Rapid	Phadia AB Marknadsbolag Sverige
SKUP/2012/95	Glucose ¹	Mendor Discreet	Mendor Oy
SKUP/2012/94	Glucose ¹	Contour XT	Bayer Healthcare
SKUP/2012/91	HbA1c	Quo-Test A1c	Quoient Diagnostics Ltd
SKUP/2011/93*	Glucose	Accu-Chek Performa	Roche Diagnostics
SKUP/2011/90	CRP	i-Chroma	BodiTech Med. Inc.
SKUP/2011/84*	PT (INR)	Simple Simon PT and MixxoCap	Zafena AB

Some evaluation codes are followed by an asterisk (), indicating an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

¹ Including a user-evaluation among diabetes patients

Comments from DIALAB GmbH/Medic24



Comments from DIALAB

06 September 2018
SKUP,
BOX 977
SE-751 09
Uppsala

Regarding the SKUP Evaluation Report no. SKUP/2018/114 about the DIAQUICK Strep.A Blue Dipstick, we would like to give the following comments:

The target sensitivity set by SKUP (> 80 %) could not be reached within this evaluation. As there is no International Reference Standard for Strep.A tests, we did an extensive evaluation with eight different Strep.A strains (ATCC strains no. 12202, 12203, 12204, 12365, 14289, 19615, 49399, 51399) to define the sensitivity of our test. All tested Strep.A strains performed very well.

There is no visible pattern about the false negative results. Out of the 29 false negative results, there are 16 culture results which are weak, eight moderate and five strong positive. Therefore, a too weak sensitivity of the test cannot be the problem.

Nevertheless, the specificity was excellent for the test. It reached 98 %, which is above the target of > 95 % set by SKUP.

In terms of user friendliness, the rating was very good overall, including the rating of operation facilities, information provided in the package insert, rating of time factors and rating of analytical quality control. The test received satisfactory for all the above-mentioned criteria.

Regarding Appendix 5, Figure 1 SKUP confirmed that Appendix 5 is only a general attachment to the statistics SKUP uses in general. The graph in Figure 1 is not specific for the DIAQUICK Strep.A Blue Dipstick in any way but is just a general display on the NPV and PPV change related to the prevalence of the disease.

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