AllTest Strep A Rapid Test

A test for detection of *Streptococcus pyogenes*
manufactured by AllTest Hangzhou Biotech Co.,Ltd.

Report from the evaluation

SKUP/2023/133*

organised by SKUP at the request of AllTest Hangzhou Biotech Co.,Ltd.

*The evaluation was performed in 2023 and kept confidential upon launching on the Scandinavian market. The report was published 2025-06-06.

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1. Summary

AllTest Strep A Rapid Test

Manufacturer	AllTest Hangzhou Biotech Co.,Ltd.
Supplier in Denmark	Not disclosed
Supplier in Sweden	Not disclosed
Supplier in Norway	Not disclosed
Launched in Scandinavia	Unknown

Aim

To assess the diagnostic performance and user-friendliness of Streptococcus pyogenes group A (strep A) measurements with AllTest Strep A Rapid Test by the intended users, i.e. health care professionals in primary health care centres.

Performance specifications	Results	Conclusions
Overall diagnostic sensitivity SKUPs quality of a diagnostic sensitivity >80 % in relation to a comparison method (culturing of Strep A).	Overall diagnostic sensitivity: 87 % (90 % CI: 80-92 %)*	Fulfilled
Overall diagnostic specificity SKUPs quality of a diagnostic specificity >95 % in relation to a comparison method (culturing of Strep A).	Overall diagnostic specificity: 97,8 % (90 % CI: 95,4-99,0 %)*	Fulfilled
User-friendliness A total rating of "Satisfactory"	The user-friendliness was rated satisfactory.	Fulfilled

Additional information

Participants	319 persons suspected of having a bacterial throat infection, and displaying at least two Centor criteria, of whom 94 (30 %) tested positive on the comparison method.
Evaluated method	Alltest Strep A Rapid Test on throat samples using three lots of test cassettes.
Comparison method	Culturing of Strep A on sheep blood agar at the Department of Medical Microbiology, St. Olavs University Hospital in Trondheim, Norway.
Prevalence	30 %
Positive predictive value	94,3 %
Negative predictive value	94,8 %
Technical error	0 %. The SKUP recommendation of <2 % was achieved.

* 90 % CI included for information only

Further information about the evaluation and the organisation of SKUP can be found on www.skup.org.
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 the Health Sector
EQA	External Quality Assessment
Equalis	External quality assessment in laboratory medicine in Sweden
NA	Norwegian Accreditation
Noklus	Norwegian Organization for Quality Improvement of Laboratory Examinations
NPV	Negative Predictive Value
PHCC	Primary health care centre
POC	Point of Care
PPV	Positive Predictive Value
SKUP	Scandinavian evaluation of laboratory equipment for point of care testing
S. pyogenes	*Streptococcus pyogenes*
Strep A	*Streptococcus pyogenes* group A
UK NEQAS	United Kingdom National External Quality Assessment Service

3. Introduction

The purpose of Scandinavian evaluation of laboratory equipment for point of care testing (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 in point of care (POC) settings.

3.1. The concept of SKUP evaluations

SKUP evaluations follow common guidelines and the results from various evaluations are comparable[1]. 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 evaluation. If possible, SKUP evaluations are carried out using three lot numbers of test cassettes 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

The AllTest Strep A Rapid Test is an in vitro POC rapid test, for detection of *Streptococcus pyogenes* group A (Strep A) in mucus from the pharynx. The product is intended for near-patient and laboratory professional use. The measuring system is produced by AllTest Hangzhou Biotech Co.,Ltd. The measuring system is not launched into the Scandinavian market; therefore, the evaluation will be kept confidential as long as the measuring system is not marketed or launched in Scandinavia. The SKUP evaluation was carried out in in Norway during winter and spring of 2023, at the request of AllTest Hangzhou Biotech Co.,Ltd.

3.3. The aim of the evaluation

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

3.4. The model for the evaluation of AllTest Strep A Rapid Test

To test the performance of AllTest Strep A Rapid Test, the evaluation was carried out in primary health care centres (PHCCs), in the hands of the intended users, see flowchart in figure 1. Seven PHCCs participated in the evaluation.

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

The evaluation included:

- A comparison of the performance of AllTest Strep A Rapid Test 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. Up to 400 participants 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 participants had a positive result for *S. pyogenes* with the comparison method.
- Examination of the analytical quality (diagnostic sensitivity and diagnostic specificity) in the hands of intended users.
- Evaluation of the user-friendliness of AllTest Strep A Rapid Test and its insert.

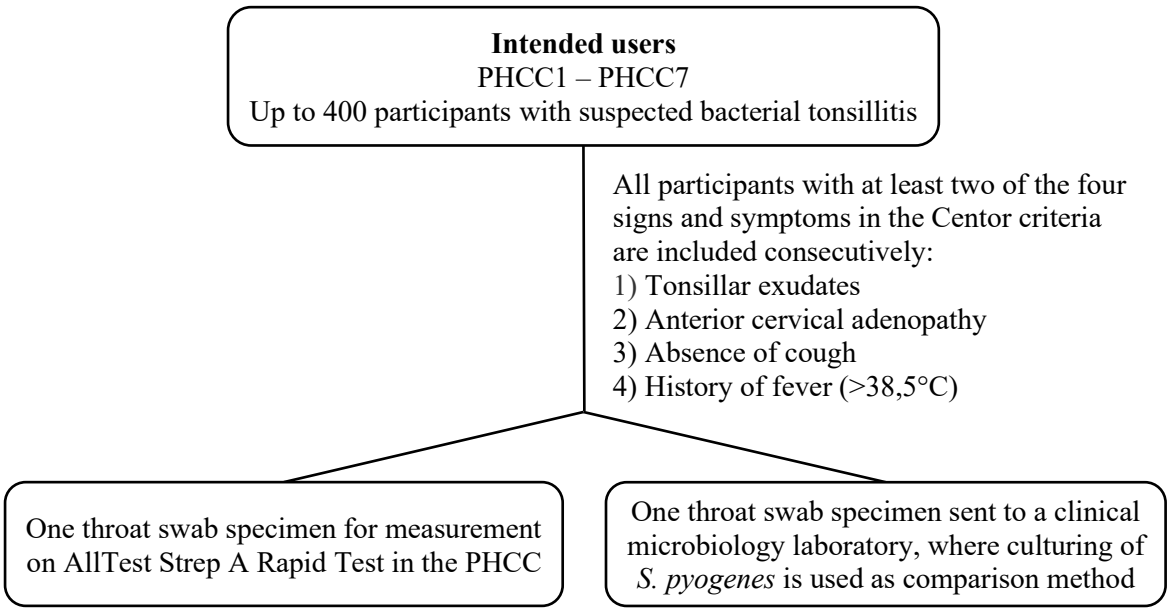

Figure 1. Flowchart illustrating the model of the evaluation. The Centor criteria are presented as 1) to 4) in the middle of the figure. Enrolment of participants continued until at least 100 positive and at least 100 negative cultures of *S. pyogenes* were achieved in the clinical microbiology laboratory, but maximum number included was initially set to 400.

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 Strep A rapid tests nor on details in the methods for culturing of *S. pyogenes*. However, the comparison method, which will be used to detect *S. pyogenes* in throat cultures, 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 >85 % and a diagnostic specificity of >95 % should, according to SKUP, be achieved for the rapid test when compared to a sensitive method for culturing of S. pyogenes.

Several evaluations were performed in Sweden in the 2000s and in Denmark during the 1980s and 1990s [4−6] 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 [7] as well as a review by Lean et al [8] further supports the quality goals set by SKUP.

4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the evaluators 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 was calculated as the fraction of true positive AllTest Strep A Rapid Test results 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 was calculated as the fraction of true negative AllTest Strep A Rapid Test results 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 is given with a 90 % CI (for information only).

Prevalence, and positive and negative predictive values
Positive predictive value (PPV) and negative predictive value (NPV) were calculated given the prevalence in the tested population. The prevalence of *S. Pyogenes* was calculated (Attachment 5), 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 were not performed. Three lot of test kits were 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 was assessed according to the answers and comments given in the questionnaire (see section 6.4). For each question, the evaluator could choose between three given ratings; satisfactory, intermediate and unsatisfactory. The responses from the evaluators were 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 registered technical errors and failed measurements during the evaluation. The fraction of tests wasted due to technical errors was calculated and taken into account in connection with the assessment of the user-friendliness. Possible technical errors included errors regarding absorption problems on the test strip and if the control line was not displayed. User errors related to the handling of the samples were excluded from the calculation.

4.4. SKUP's quality goals in this evaluation

As agreed upon in the protocol, the results from the evaluation of AllTest Strep A Rapid Test are assessed against the following quality goals:

Diagnostic sensitivity ..... ≥85 %

Diagnostic specificity ..... ≥95 %

User-friendliness, overall rating ..... Satisfactory

5. Materials and methods

5.1. Definition of the measurand

The measuring system are intended to detect Beta haemolytic Group A streptococci, or *S. pyogenes*, antigen in secrete from throat. The sample material in this evaluation was mucus from the pharynx for both the evaluated measuring system and the comparison method. For the comparison method *S. pyogenes* was identified by the ability to grow on sheep blood agar plates. The results were 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 measuring system AllTest Strep A Rapid Test

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

AllTest Strep A Rapid Test is a qualitative lateral flow immunoassay for the detection of Strep A carbohydrate antigen in throat swab specimen within 5 minutes. In the test line region, there are coated antibodies specific to Strep A carbohydrate antigen. During testing, the extracted throat swab specimen reacts with an antibody to Strep A, coated onto colloidal particles, then the mixture migrates up the membrane to react with another antibody to Strep A in the test line region. The latter reaction will generate a shift in colour in the test line region if it is a positive result, while absence of the colour indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

For technical details about the AllTest Strep A Rapid Test, see table 1. For more information about the AllTest Strep A Rapid Test measuring system, 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 AllTest Strep A Rapid Test	
Sample material	Human throat swab specimen
Sample volume	About 10 µL
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. The selected comparison method must be a recognised and well-established hospital laboratory method. Good analytical quality must be documented by results from an external quality assessment (EQA) scheme, given that external quality control is offered for the component in mention.

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 al in Trondheim, Norway.
The sample was inoculated on blood agar plates and incubated for two days in CO_2 incubator at 35°C. If needed, verification with MALDI-TOF was performed.

The clinical microbiology laboratory is accredited according to NS-EN ISO15189 (2012) by Norwegian Accreditation (NA), 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 are performed with standard methods.

Definition of positive and negative results
The results from the comparison method culturing of *S. pyogenes* are 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 prepared, a reference strain (CCUG 33061 *S. pyogenes*) was cultured on some of the plates to check that beta haemolytic streptococci grow as expected.

External analytical quality control
The clinical microbiology laboratory participates in both United Kingdom National External Quality Assessment Service (UK NEQAS) and Quality Control for Molecular Diagnostics (QCMD) EQA scheme for microbiology. Both EQA schemes concerns beta haemolytic streptococci once or twice per year. If beta haemolytic streptococci are found in a sample the bacteria will be characterized according to local procedure. The assigned value for 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 comparison method was verified with EQA results for a period circumventing the evaluation period. The EQA scheme used to verify the trueness was provided by UK NEQAS.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation

Hangzhou AllTest Biotech Co.,Ltd. via Klarety Zhao, Technical Support Specialist, applied to SKUP in August 2022 for an evaluation of AllTest Strep A Rapid Test.

Protocol, arrangements and contract

In December 2022 the protocol for the evaluation was approved, and Hangzhou AllTest Biotech Co.,Ltd. and SKUP signed a contract for the evaluation. Seven PHCCs; Kalvskinnet legesenter, Sørbyen legesenter, Midt legesenter, Gildheim legesenter, Nidaros legekontor, Byåsen legesenter and Granåsen legesenter from Trøndelag county agreed to represent the intended users in this evaluation, and the Department of Medical Microbiology, St. Olavs University Hospital, Trondheim, Norway agreed to perform the comparison measurements.

Training

The evaluating personnel were self-trained by using guidance videos supplied by Hangzhou AllTest Biotech Co.,Ltd. as well as by reading the instruction of use. When the evaluation had started, Hangzhou AllTest Biotech Co.,Ltd. was not allowed to contact or supervise the persons at the evaluation sites directly. All communication had to go through SKUP.

Recording of results

The PHCCs results were registered consecutively on a registration form prepared by SKUP and the clinical microbiology laboratory responsible for the comparison method. The results were signed by the person performing the practical work. All data was 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 participant were included in the record. The lot numbers of the AllTest Strep A Rapid Test kits and the control materials were recorded. The recorded data from the control material was sent directly to SKUP in Norway.

5.4.2. Evaluation sites and persons involved

The evaluation took place at the Department of Medical Microbiology, St. Olavs University Hospital, Trondheim, Norway and at seven PHCCs, all located in Trøndelag County, Norway. The practical work was carried out during 16 weeks, ending in April 2023.

In the PHCCs, approximately 20 medical secretaries participated in the evaluation, in total. They all use rapid tests in their routine method for detection of Strep A.

5.4.3. The evaluation procedure for intended users

Internal analytical quality control

Initially, one internal control was performed each day the PHCCs recruited participants to the evaluation, alternating between the positive and the negative control. Due to the low number of recruited participants each day, and high use of rapid tests for internal control, the frequency of internal control was changed during the evaluation. Eventually, one to two internal controls were performed each week of the evaluation, also alternating between the positive and the negative control. In addition to this, one positive control was performed upon opening a new kit.

Recruitment of patients and ethical considerations

Patients seeking care for symptoms of possible throat infection caused by bacteria were asked if they were willing to participate in the evaluation of AllTest Strep A Rapid Test. All Strep A screening samples was avoided and only participants with symptoms of pharyngitis were included. The participants were included on the background of the Centor criteria described in attachment 5. Participants that had been on antibiotic treatment during the last 14 days were not included. The following personal information were obtained from the participants; fulfilled Centor criteria. Of these, the following are disclosed in the report; number of participants fulfilling 2,3,4 Centor criteria. Privacy protection of the participants was secured. No result in the evaluation can be traced to the individual participant. Participation was voluntary, and a verbal informed consent was considered sufficient. In cases of youngsters, the parent also needed to consent for participation. The information sheet in Norwegian is attached, see attachment 6. An ethical approval was not necessary because the evaluation is considered a quality assurance project.

Handling of the samples and measurements

Three lot numbers of the test kit were distributed between the PHCCs; small evaluation sites received one or two of the lot numbers due to fixed number of tests per kit, whereas larger sites with more participants received two or three lot numbers.

Throat swab specimens were collected simultaneously for both the AllTest Strep A Rapid Test and the comparison method with the swab from the AllTest Strep A Rapid Test and a non-toxic swab without carbon.

Samples for the evaluation were collected by using two swabs simultaneously; both swabs were rolled over the tonsils simultaneously, following local guidelines of sampling, and then rubbed together before testing. One swab for the PHCC was analysed with AllTest Strep A Rapid Test in accordance with the instructions from the manufacturer, and the other swab intended for culturing were placed into sterile tube with amies medium (e-swab). The tubes were kept in a refrigerator and transported to the clinical microbiology laboratory later the same day. In the laboratory, the samples were cultured upon arrival or within 1-2 days.

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 319 participants provided duplicate samples for the evaluation. Out of the 319 samples, 152 of the participants fulfilled two or three of the Centor Criteria's. The collection was supposed to continue until 100 positive and at least 100 negative samples were detected with the comparison method. Though, the sample collection ended the 28th of April 2023, due to few potential patients available for recruitment. More than 100 negative samples were collected, and more than 90 positive samples.

Missing results

The result of one positive control was missing in the protocol.

One of the PHCC had lost their protocols for internal control, however they reported that all of their performed controls gave the correct answer. The last PHCC had not performed any internal controls due to a misunderstanding.

Omitted results

Two of the incorrect internal control results was most likely to be user error due to lack of training of a new employee at one of the PHCC.

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 Strep A 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 in accordance with the expected result of the quality control material (data not shown).

6.2.2. The trueness of the comparison method

The trueness of the comparison method was verified with EQA results for the period circumventing the evaluation report. The laboratory showed satisfactory results for culturing of beta haemolytic streptococci during and before the evaluation period.

6.3. Analytical quality of AllTest Strep A Rapid Test achieved by intended users

The results below reflect the analytical quality of AllTest Strep A Rapid Test under real-life conditions in the hands of intended users in PHCCs.

6.3.1. Internal analytical quality control

The AllTest Strep A Rapid Test includes a positive and a negative internal quality control. In total, 102 measurements were received from five PHCCs. From the 102 measurements there was 49 with the positive control and 53 with the negative control. There were 94 results that showed the correct result. The remaining five of the incorrect results were all positive controls with a negative result.

6.3.2. The diagnostic sensitivity of AllTest Strep A Rapid Test in primary health care

The diagnostic sensitivity of AllTest Strep A Rapid Test 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 AllTest Strep A Rapid Test measured in throat samples. Results achieved by intended users.

	Number of positive Strep A cultures	Number of true positive results	Number of false negative results	Diagnostic sensitivity, % (90 % CI)
n	94	82	12	87 (80-92)

Discussion

The diagnostic sensitivity of AllTest Strep A Rapid Test was 87 %, with a 90 % CI of 80-92 %. Five of the false negative results displayed sparse growth of colonies and two of the false negative results displayed abundant growth of colonies, the rest of the false negative results displayed moderate growth of colonies.

Conclusion

The quality goal of a diagnostic sensitivity of >85 % was fulfilled by AllTest Strep A Rapid Test.

6.3.3. The diagnostic specificity of AllTest Strep A Rapid Test

The diagnostic specificity of AllTest Strep A Rapid Test 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 AllTest Strep A Rapid Test measured in throat samples. Results achieved by intended users.

	Number of negative Strep A cultures	Number of true negative results	Number of false positive results	Diagnostic specificity, % (90 % CI)
n	225	220	5	97,8 (95,4-99,0)

Discussion
The diagnostic specificity of AllTest Strep A Rapid Test was 97,8 %, with a 90 % CI of 95,4-99,0 %. Three out of five false positive results were marked as a weak positive result on the evaluated rapid test by the PHCC performing the test (data not shown).

Conclusion
The quality goal of a diagnostic specificity of >95 % was fulfilled by AllTest Strep A Rapid Test.

6.3.4. The positive and negative predictive values of AllTest Strep A Rapid Test in primary health care

The PPV and NPV of AllTest Strep A Rapid Test 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 AllTest Strep A Rapid Test when measured in throat samples. Results achieved by intended users.

Number of true positive results	Number of false positive results	PPV, %
82	5	94,3

Table 5. NPV of AllTest Strep A Rapid Test when measured in throat samples. Results achieved by intended users.

Number of true negative results	Number of false negative results	NPV, %
220	12	94,8

Discussion
The PPV was 94 % and the NPV was 95 %. Note that the predictive values are affected by the prevalence of the study population (Attachment 5). A high prevalence was expected as the evaluation took place under the season for respiratory infection, as well as the use of Centor Criteria for inclusion of participants. The high prevalence of the study population affects the predictive values (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 measuring system. SKUP has prepared detailed instructions for this.

The questionnaire is divided into four subareas:

Table A) Rating of operation facilities. Is the measuring 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 measuring 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 all seven PHCCs.

Table A. Rating of operation facilities

Topic	Rating	Rating	Rating	Rating	Option
To prepare the test	**S, S, S, S, I[1], S, S**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
To prepare the sample	**S, S, S, S, I[1], S, S**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Application of specimen	**S, S, S, S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Specimen volume	**S, S, S, S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Number of procedure step	**S, S, S, S, U[1], S, S**	**Satisfactory**	Intermediate	**Unsatisfactory**	No opinion
Instrument / test design	**S, S, S, S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Reading of the test result	**E, E, E, E, E, E, E**	**Easy**	Intermediate	Difficult	No opinion
Sources of errors	**S, S, S, 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, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Size and weight of test kit	**S, S, S, S,** I[1], **S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Storage conditions for tests, unopened package	**S**	**+15 to +30°C (+2-30°C)**	+2 to +8°C	–20°C	
Storage conditions for tests, opened package	**S**	**+15 to +30°C or disposable (20-25°C)**	+2 to +8°C	–20°C	
Environmental aspects: waste handling	**S**	**No precautions**	Sorted waste	Special precautions	
Intended users	**S**	**Health care personnel or patients**	Laboratory experience	Biomedical laboratory scientists	
Total rating by SKUP		**Satisfactory**			

*Not relevant; AllTest Strep A Rapid Test does not require cleaning or maintenance.
[1]The evaluator thought it was complicated to have to mix the reagents before the application of the swab specimen. The lower rating of "Size and weight of test kit" was not described, and therefore SKUP will not include this rating in the final assessment of the test.

Table B. Rating of the information in the insert

Topic	Rating	Rating	Rating	Rating	Option
Table of contents/Index	S, S, N, N, S, N, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Preparations/Pre-analytic procedure	S, S, S, S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Specimen collection	S, S, S, S, I[1], S, I[2]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Measurement procedure	S, S, S, S, I[1], S, I[2]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Reading of result	S, S, S, S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Description of the sources of error	S, S, S, N, S, S, U[3]	Satisfactory	Intermediate	Unsatisfactory	No opinion
Help for troubleshooting*		Satisfactory	Intermediate	Unsatisfactory	No opinion
Readability / Clarity of presentation	S, S, I[4], S, S, S, U[3]	Satisfactory	Intermediate	Unsatisfactory	No opinion
General impression	S, S, S, S, S, S, S	Satisfactory	Intermediate	Unsatisfactory	No opinion
Measurement principle	S	Satisfactory	Intermediate	Unsatisfactory	
Available insert in Danish, Norwegian, Swedish**	S	Satisfactory	Intermediate	Unsatisfactory	
Total rating by SKUP		Satisfactory			

*Not relevant; AllTest Strep A Rapid Test instruction manual does not include help for troubleshooting
** AllTest Hangzhou Biotech Co.,Ltd. translated the insert to Norwegian before the evaluation.
[1]The evaluator have not described the intermediate ratings, and therefore SKUP will not include this rating in the final assessment of the test.
[2]The evaluator miss description in the illustration of extraction time of swab in buffer before application of the sample on the test cassette, in the illustration.
[3]The evaluator points out that there is no description of the sources of error in Norwegian.
[4]The text in the insert was too small.

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	**>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**		

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

Topic	Rating	Rating	Rating
Reading of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
Usefulness of the internal quality control	**Satisfactory**	Intermediate	Unsatisfactory
External quality control	**Satisfactory**	Intermediate	Unsatisfactory
Total rating by SKUP	**Satisfactory**		

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 and unsatisfactory ratings. The motivations for the lower ratings were not described and therefore not taken into account by SKUP when assessing the total rating.

Assessment of the information in the insert (table B)

The insert was assessed as satisfactory. There were some intermediate and a few unsatisfactory ratings. The lower ratings concerned the size of the text in the insert, and description of extraction time for the swab in the illustration, as well as no description of sources of error in Norwegian.

The description of extraction time for the swab is not taken into consideration, because the description is in the text instead. The rest is not considered severe enough to lower the rating.

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 AllTest Strep A Rapid Test and its insert was rated as satisfactory, although there is improvement potential pointed out.

7. References

1. Swedish Medical Products Agency, Treatment of pharyngotonsillitis in primary health care – new recomendations. 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. 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.

5. Andersen JS., Borrild NJ. & Hoffmann S. Diagnostik af halsbetændelse. En multipraksisundersøgelseaf tre antigendetektionssæt til påvisning afgruppe A-streptokokker i svælgpodninger. Ugeskrift for Læger 1994; **156** (46): 6869 − 6872.

6. Andersen JS., Borrild NJ. & Hoffmann S. Potential of antigen detection tests. BMJ 1995; **310**: 58 – 59.

7. Cohen JF et al. Rapid antigen detection test for group A streptococcus in children with pharyngitis. Cochrane Database of Systematic Reviews 2016, Issue 7.

8. Lean WL et al. Rapid Diagnostic Tests for Group A Streptococcal Pharyngitis: A Meta-analysis. Pediatrics 2014; 134 (4): 771–781.

9. The IFCC – UPAC terminology for properties and units. http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/ (accessed 2023-05-30)

Attachments

1. The organisation of SKUP
2. Facts about AllTest Strep A Rapid Test
3. Information about manufacturer, retailers and marketing
4. Product specifications for this evaluation, AllTest Strep A Rapid Test
5. Statistical expressions and calculations
6. The Centor criteria
7. Raw data, AllTest Strep A Rapid Test and the comparison method

Attachments with raw data are included only in the copy to AllTest Hangzhou Biotech Co.,Ltd.

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for point of care testing, *SKUP*, is a co-operative commitment of DEKS[1] in Denmark, Equalis[2] in Sweden and Noklus[3] in Norway. 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 laboratory equipment for point of care testing. 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.

SKUP reports are published and available at www.skup.org.

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

[2] Equalis AB (External quality assessment in laboratory medicine in Sweden) is a limited, and not for profit, company in Uppsala, Sweden, owned by the Swedish Association of Local Authorities and Regions, the Swedish Society of Medicine and the Swedish Institute of Biomedical Laboratory Science.

[3] Noklus (Norwegian Organization for Quality Improvement of Laboratory Examinations) is a national not for profit organisation 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.

Facts about Alltest Strep A Rapid Test

This form is filled in by AllTest Hangzhou Biotech Co.,Ltd.

Table 1. Facts about the test kit

Name of the test kit	Strep A Rapid Test
Number of tests in package	20 pcs
Package contents	Test, Package insert, Extraction tubes, Sterile swabs, Workstation, Dropper tips, Extraction reagent 1, Extraction reagent 2, Positive control, Negative control
Measurand	Throat Swab, Swab the posterior pharynx, tonsils and other inflamed areas.
Sample material	Throat Swab
Sample volume	About 10 μl
Measuring principle	Double antibody sandwich method
Limit of quantification	1E+07 org/ml
Test interpretation	**1.** Remove the test from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. **2.** Insert the extraction tube into the workstation, hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 μL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 μL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. **3.** Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times, and leave the swab in the extraction test tube for 1 minute. **4.** Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. **5.** Fit the dropper tip on top of the extraction tube. Place the test on a clean and level surface. Add 3 drops of the solution (approx. 100 μL) to the sample well(S) and then start the timer. **6.** Read the result at 5 minutes. Do not interpret the result after 10 minutes. **POSITIVE:*** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen. ***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen. **NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture. **Please see the illustration below.**

	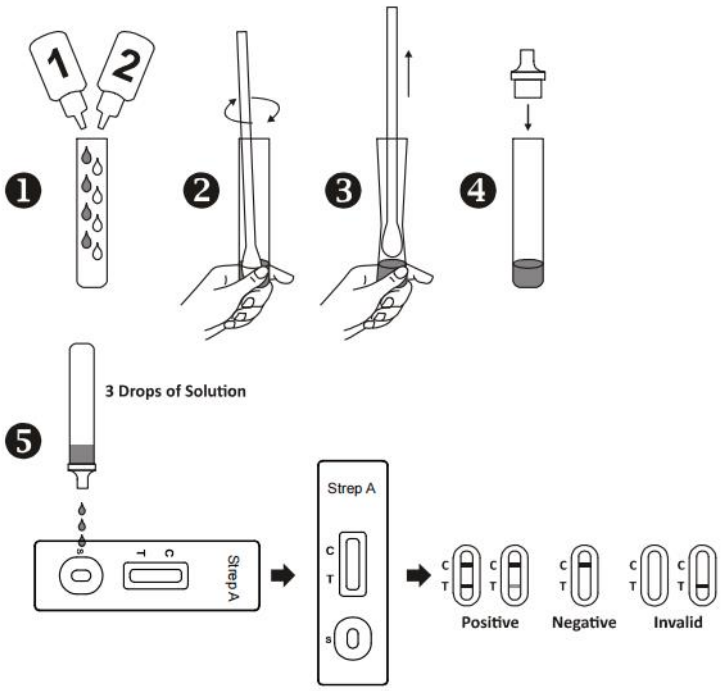
Measurement time	Read the result at 5 minutes. Do not interpret the result after 10 minutes.
Operating conditions	POC site; The Strep A Rapid Test is for near-patient and laboratory professional in vitro diagnostic use only.
Necessary equipment not included in the package	Timer
Storage temperature	Room temperature or refrigerated (2-30°C), DO NOT FREEZE.
Stability unopened test cassette	2 years
Stability opened test cassette	It is suggested to use test within one hour after removing it from the foil pouch

Table 2. Quality control

Internal control in the test cassette	Positive control and Negative control
Recommended control materials and volume	Positive control: 0.5mL, Non-viable Strep A Negative control: 0.5mL, Non-viable Strep C
Stability in unopened sealed vial	2 years
Stability in opened vial	6 months
Internal quality controls included	Yes ☑ No ☐

Information about manufacturer, retailers and marketing

This form is filled in by AllTest Hangzhou Biotech Co.,Ltd.

Table 1. Marketing information

Manufacturer	HANGZHOU ALLTEST BIOTECH CO.,LTD
Retailers in Scandinavia	Denmark: We don't have retails in Denmark. Norway: We don't have retails in Norway. Sweden: We don't have retails in Sweden.
In which countries is the system marketed	Globally ☑ Scandinavia ☐ Europe ☐
Date for start of marketing the system in Scandinavia	N/A
Date for CE-marking	2015
In which Scandinavian languages is the manual available	We have translated manuals in Danish, Swedish and Norwegian especially for this study. Please let us know if you need any of them to be included with the kits.

Product information, Alltest Strep A Rapid Test

AllTest Strep A Rapid Test

Lot name in evaluation	Lot no.	Expiry date
A	STA22120014-T	2024-11
B	STA22120023-T	2024-10
C	STA22120001-T	2024-11

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 Adjusted Walds [b]. The confidence intervals (CIs) are given for information only.

a. Documenta Geigy. Mathematics and statistics, 1971. CIBA-GEIGY Limited, Basel, Switzerland; p 186 formula # 772.
b. http://www.measuringu.com/wald.htm

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.

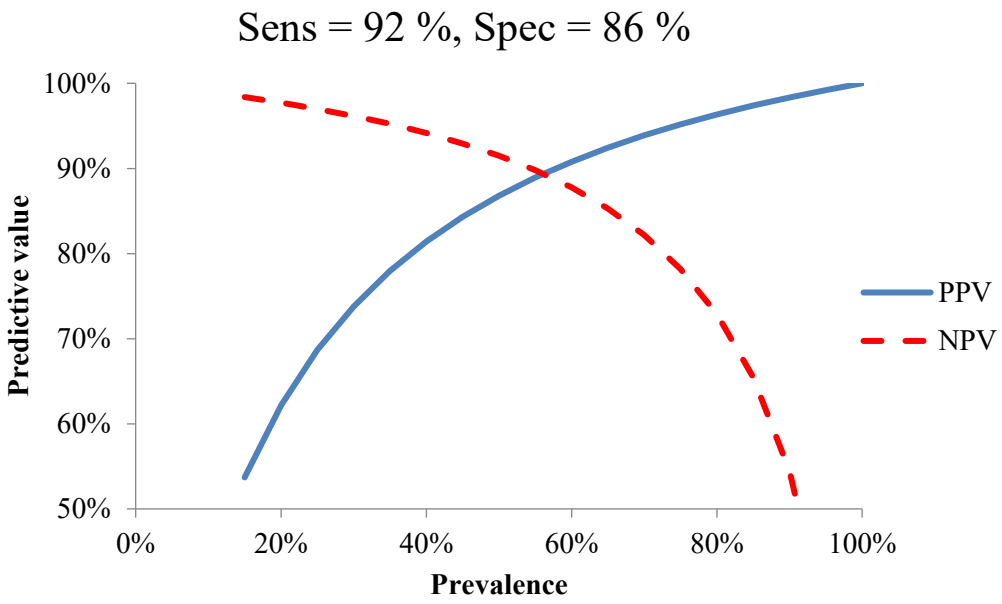

Figure 1. Relationship between PPV/NPV and prevalence.

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

Raw data, AllTest Strep A Rapid Test and the comparison method results

Raw data are included only in the copy to AllTest Hangzhou Biotech Co.,Ltd.