

Summary of the evaluation of 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 seven 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.

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