

# The role of a rapid diagnostic test to diagnose Group A streptococcal pharyngitis in a paediatric emergency department: a diagnostic accuracy study

## Introduction

Pharyngitis is a common condition presenting to paediatric emergency departments; most have viral aetiology but 20%-40% of paediatric cases are caused by Group A streptococci (GAS). Complications are rare but serious, therefore antibiotic treatment of GAS pharyngitis is recommended. In the era of antibiotic stewardship, a point of care test to rapidly identify children with GAS pharyngitis and rationalise antibiotic use would be valuable.

Guidelines vary in their recommendations for the use of GAS rapid diagnostic tests (GAS RDT) and the need for reflex culture of negative results (particularly in a paediatric population).

Following a laboratory validation, we performed a GAS RDT (bioNexia, bioMerieux, France) diagnostic accuracy study (DAS) to assess test performance and the need for reflexive culture.

## Method

Between 23.8.15 and 16.11.15 all children presenting to Birmingham Children's Hospital emergency department with pharyngitis were assessed for inclusion to the study. Children with a Mclsaac score  $\geq 3$  or risk factors for immunosuppression went on to have a throat swab tested by GAS RDT.

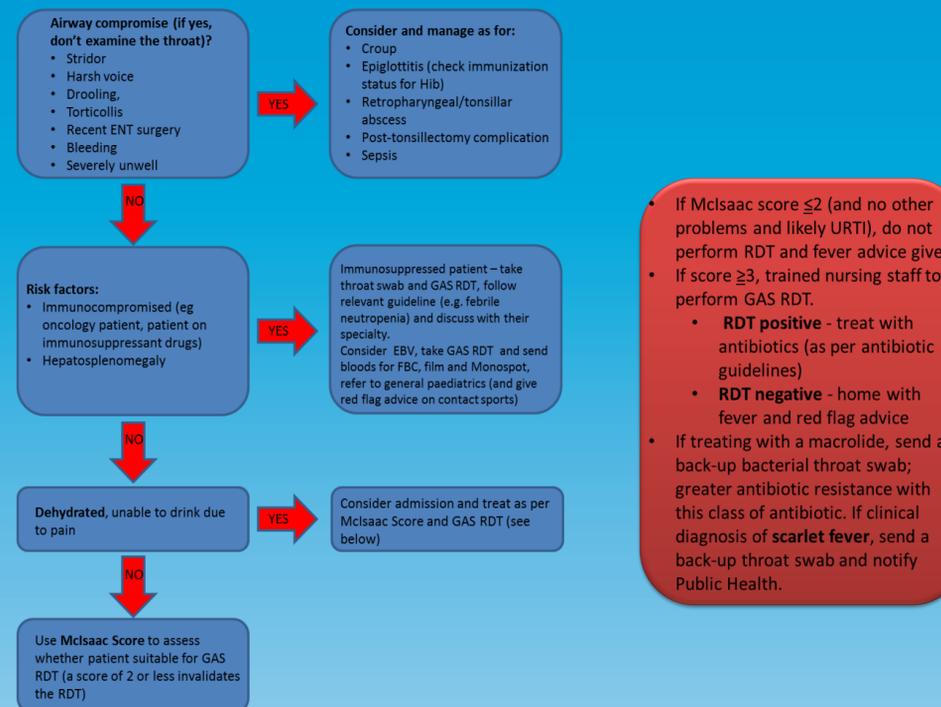
**Table 1 – Mclsaac score criteria**

Mclsaac Score criteria	Points
Temperature $> 38^{\circ}\text{C}$	1
No cough	1
Tender anterior cervical lymphadenopathy	1
Tonsillar swelling or exudate	1
Age $< 15$ years	1

Patients with a positive GAS RDT result were treated with antibiotics; a negative GAS RDT result prompted a reflex throat swab culture. Children with a negative GAS RDT and positive throat swab GAS culture were recalled and treated with antibiotics. Data was collected prospectively.

The GAS RDT had undergone technical validation within the Microbiology laboratory, finding 100% sensitivity and specificity ( $n=20$ ) compared to bacterial culture methodology. The test is already used as standard care in the USA and other European countries so ethical approval was not considered necessary (approval was gained from the hospital's Point of Care Testing Committee).

**Flow chart 1 - diagnostic algorithm for GAS RDT testing**



## Results

During the study 246 children were eligible for inclusion (age range 6 months-15 years); 29 were excluded due to incomplete data ( $n=217$ ). The GAS RDT positivity rate was 27/217 (12.4%) and overall disease incidence amongst children tested was 42/217 (19.4%).

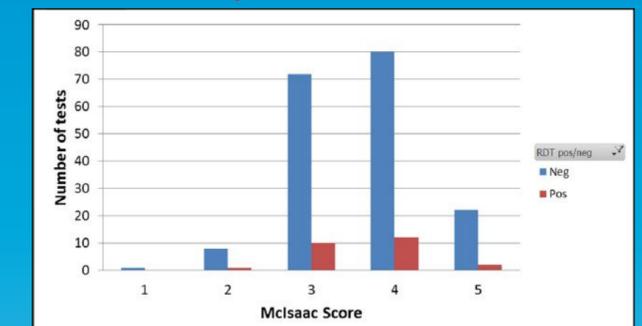
The reference standard was positivity by any method; the GAS RDT had a sensitivity of 64.3%, specificity of 100%, positive predictive value of 100% and negative predictive value of 92.1%. There was a **false negative rate of 7.9%**; temporal clustering of false negative results was noted.

GAS RDT sensitivity was highest for those children with Mclsaac score 4 and 5 (66.7% and 100% respectively). *Chart 1* shows GAS RDT results by Mclsaac score. Sensitivity was highest for children aged 6-10 (88.9%), but some age banded groups were small and this limited further analysis. *Chart 2* shows GAS RDT results by age group.

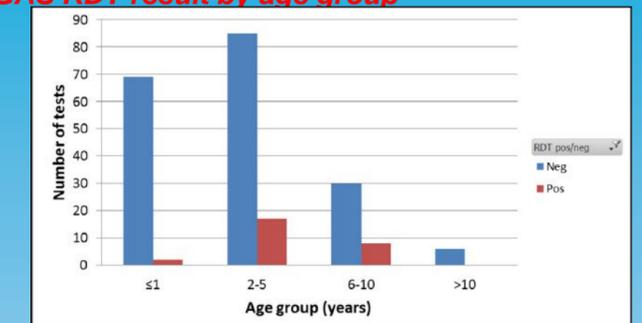
## Conclusions

- We report low GAS RDT sensitivity reported during a clinical, in-use DAS. Temporal clustering of false negative results indicates a possible user issue, related to faint positive line results.

**Chart 1 – GAS RDT result by Mclsaac score**



**Chart 2 – GAS RDT result by age group**



- The high negative predictive value indicates the GAS RDT can be used to safely exclude GAS infection. Particularly in our paediatric population; with low incidence of suppurative and non-suppurative complications.
- We conclude GAS RDT may be used to exclude GAS pharyngitis within the paediatric emergency department, and therefore rationalise antibiotic use.
- Prior to implementation a robust education and ongoing quality assurance programme must be implemented to monitor and maintain acceptable sensitivity.

## Acknowledgements & References

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