New QuickStrepA test of automated mariPOC® system provides culture sensitivity in 15 minutes

Antikainen P.[1], Ruonamo R.[1], Soukka J.[1], Hotakainen K.[2], Vakkila J.[2], Koskinen J.O.[1]

[1] ArcDia International Ltd, Turku, Finland
[2] Clinic for Children and Adolescents, Mehiläinen Oy Ltd, Helsinki, Finland

Introduction

mariPOC® (Figure 1) is an automated test system for rapid multianalyte decentralized testing of acute infectious diseases. mariPOC® pharyn antigen detection test for tonsillitis covers Group A streptococcus (GAS) and adenovirus. mariPOC® GAS test has shown superior sensitivity compared to culture and even to PCR[1)]. Higher accuracy enables optimization of antibiotic use. The limitation of the pharyn test has been its turnaround time, 20 minutes for positive samples and two hours for low positive and negative samples.

We aimed to redesign the pharyn test to speed up the analysis and to revalidate the faster GAS test against bacterial culture and the old test.

Figure 1. mariPOC® test system (ArcDia International Ltd, Finland)

Methods

A new GAS test was developed by screening for novel antibody reagents with specificity against the Lancefield group A carbohydrate. Optimization of the method was followed by thorough validation. Analytical sensitivity of the new GAS test was studied against the old GAS test with dilution series of purified bacteria. The specificity of the new test was validated by excluding potential cross-reactions against several pathogens and normal flora bacteria, and testing a cohort of asymptomatic subjects (N=44).

The evaluation of the new GAS test with clinical samples was carried out in two Mehiläinen medical centers (Turku and Helsinki Töölö, Finland). Throat samples with cotton and flocked swabs were collected simultaneously from patients (N=193) with tonsillitis. The cotton swabs were tested using the standard culture and agglutination test procedures of Mehiläinen. The flocked swabs were tested according to manufacturers` instructions with the old and the new mariPOC® pharyn tests.

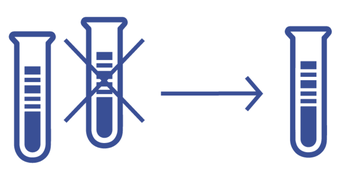
Results

The analytical sensitivity of the new GAS test was 150 CFU/ml (2000 bct/ml) and equal to the old test. High sensitivity was reached in less than one hour from the start of the assay. The new test did not cross-react with any of the tested non-GAS microbes and all the samples from asymptomatic subjects gave negative results.

The sensitivity for adenovirus in one hour assay point remained the same compared to two hours assay due to the fast reaction kinetics of the method. In addition to the faster turnaround time, the new pharyn test is easier to perform because it no longer requires sample dilution tube.

In the evaluation with clinical samples bacterial culture detected 39 GAS positive samples (Table 1). The new GAS test detected 38 out of 39 culture positive samples and one additional positive sample already in the first 15 minute reporting phase. One culture positive sample was negative both with the old and new GAS tests. In the final reporting phase (55 minutes), the new GAS test detected further 16 positive samples. **The additional findings were confirmed to be analytically correct by signal levels higher than six standard deviations from the mean of negative controls. Simultaneous positivity in the old GAS test, validated against culture, clinical findings and PCR[1)], further confirmed the positivity.**

Workflow



Pretreatment without dilution tube

Reporting time

Preliminary: 20 min → 15 min
Final: 120 min → 55 min

Table 1. Comparison of the new mariPOC® GAS test against bacterial culture.

		Culture		
		Positive	**Negative**	**Total**
New maripoc GAS test	**Positive**	38	17	55
	Negative	1	137	138
	Total	39	154	193

Culture sensitivity in 15 minutes

Higher sensitivity than culture in 55 minutes

Conclusions

The redesigned mariPOC® pharyn test provides results significantly faster than before. **Already in 15 minutes the sensitivity for GAS exceeds the culture sensitivity.** The theoretical sensitivity of culture is very close or even better than that of mariPOC® GAS test. However, as well demonstrated in the literature, it can hardly ever be reached in clinical samples containing commensal flora.

Thanks to fast kinetics and high sensitivity already in 15 minutes, it was possible to introduce mariPOC® QuickStrepA test along with the new pharyn test. QuickStrepA test is a single pathogen test for detection of GAS and reports final results in 15 minutes with culture sensitivity. The faster tests will fit better in the clinical processes of users and bring the speed to the same level as that of rapid lateral flow tests.

1) Vakkila et al., J Clin Microbiol. 2015;53(7):2079-2083

NSCMID 2017
Tórshavn, Faroe Islands

maripoc