P0773 – ECCMID 2015

Clinical evaluation of a novel *Clostridium difficile* molecular one step test system

M. Hell[1] and R. Brunauer[2]

[1]Paracelsus Medical University Salzburg, [2]Private Laboratories Dr. Georg Mustafa/Dr. Hans Richter, 5020 Salzburg, Austria

Objectives: ESCMID guidelines for the diagnosis of C. *difficile* infections (CDI) recommend a two- or three-step algorithm and promote nucleic acid amplification test (NAAT) as being superior to toxins A/B enzyme immunoassay (EIA) however, stating that false positives are of concern. We tested a new NAAT system that combines *C. difficile*-specific GDH gene amplification with toxin A, B and binary toxin gene amplification to provide a one-step method with a computed algorithm to prevent false positive results.

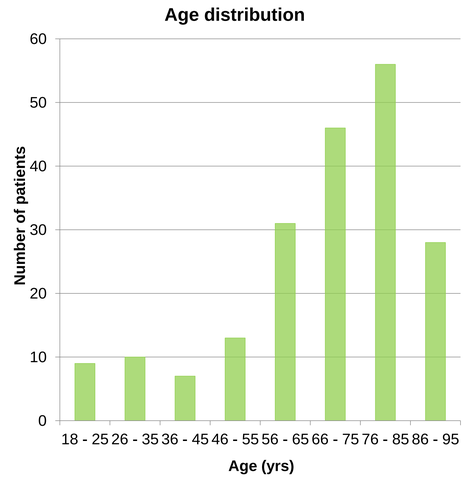

Fig. 1: Age distribution in suspected CDI

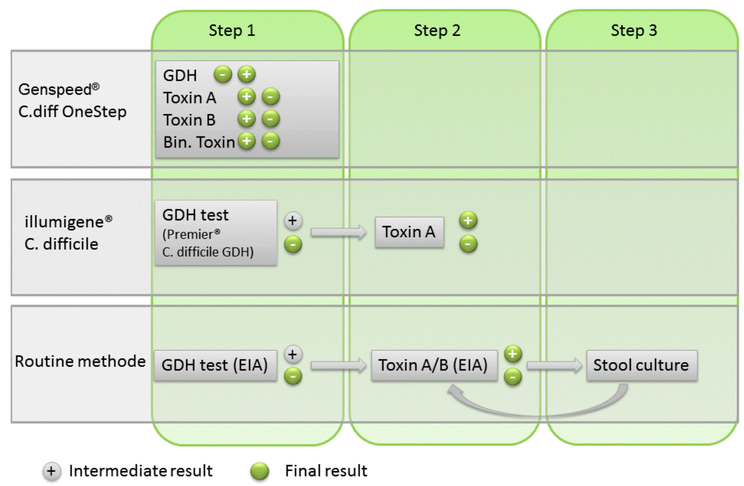

Fig. 2 Comparison of testing algorithms

Materials and methods: One hundred and ninety-nine stool samples were analysed by the routine method as well as by Genspeed® C.diff OneStep and another molecular biological test system (both two-step algorithms) in 2-months-period. Inclusion criteria were liquid or semi-liquid stool samples and suspected CDI and age >18 years (figure 1). Samples were first tested by the routine, culture-based method before they were evaluated by Genspeed® C.diff OneStep and illumigene® C. difficile test systems (figure 2). The Genspeed® test comes with a simple preanalytics set up and does not need DNA-extraction.

Results: Of the 199 analysed samples 15 were determined positive for toxigenic C. difficile by the routine method. There was a quite some disagreement among the three different methods tested (see Figure 3). Overall only 12 samples were consistently identified as positive by at least two of the methods. Based on these data the performance characteristics of the novel Genspeed® C.diff OneStep test system were calculated (table 1).

Table 1: Performance characteristics

Genspeed® result	*Consensus results positive	negative	Total	
pos.	10	0	10	
neg.	2	187	189	**PPV = 100.0%**
	12	187	199	**NPV = 98.9%**

Sensitivity = 83.33% **Prevalence = 6.0%**
Specificity = 100.00%

	Toxigenic *C. difficile* positive:	Number of *discordant samples:	Number of concordant samples:
Genspeed® C.diff OneStep	N=10 (2 positive for binary toxin)	N=0	N=10 (100 %)
illumigene® C. difficile	N=16	N=4	N=12 (75 %)
Routine methode	N=15	N=3	N=12 (80 %)

*identified as positive by only one method
**identifed as positive by at least two methods

Fig. 3: Results overview

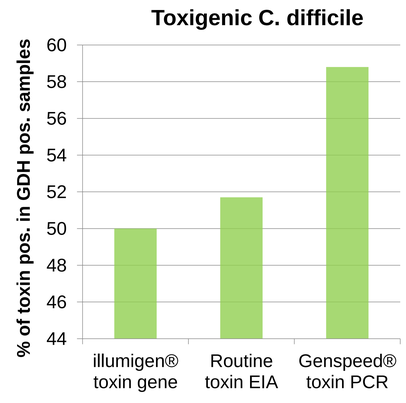

Fig. 4: Percentage of toxigenic *C. difficile* in GDH positive samples

Conclusion: The Genspeed® C.diff OneStep test system showed an excellent positive predictive value with no false positives. It is an easy to handle, single step test that provides comprehensive results with a high specificity and an acceptable sensitivity.