Comparative Evaluation of the Novel STANDARDTM F S.pneumoniae Ag FIA test (SD BIOSENSOR) with the Uni-GoldTM S. pneumoniae assay (TrinityBiotech) and the BinaxNOW® S. pneumoniae antigen card (Alere) for detection of pneumococcal urinary antigen

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29th ECCMID Amsterdam, Netherlands 13–16 April 2019

ABSTRACT

Community-acquired pneumonia (CAP) are one of the major causes of morbidity, mortality and hospitalization. A rapid laboratory diagnosis is of paramount importance to guide an appropriate antibiotic therapy. The pneumococcal urinary antigen test (PUAT) is recommended to identify the causative agent in CAP. It's an easy to use and rapid test and the urine samples can be collected easily from most patients. STANDARD F S. pneumoniae is a new rapid fluorescent immunochromatographic test supplied with an analyzer for objective results.

OBJECTIVES

Evaluate the performances of STANDARD F comparing with Uni-Gold reference test (routinely used in our laboratory) and with BinaxNow comparative device.

METHODS

To evaluate the performances of STANDARD F we compared it with Uni-Gold reference test (routinely used in our laboratory) and with BinaxNow comparative device. A total of 218 (200 fresh and 18 frozen) urine samples (US) submitted for pneumococcal urinary antigen testing between January and November 2018 were evaluated. All the samples were collected from patients with high clinical suspicion of pneumonia. The three assays were performed simultaneously according to the manufacturers' instructions. An interesting feature of Standard F is the presence of a COI (cut off index). COI is a quantification of fluorescence signal. A COI ≥1 means positive result, whereas a COI <1 means a negative result.

Uni-GoldTM S. pneumoniae (TrinityBiotech) | S.pneumoniae Ag FIA (SD Biosensor) | S.pneumoniae BinaxNOW (Alere)

RESULTS

From 160 US and from 40 US we obtained respectively a negative and a positive concordant results for all three assays. A total of 18 discrepant US were found. 15 were positive to Uni-Gold but negative with the other two methods.

For these 15 US a very weak positive signal was identified by the Uni-Gold test line and a very low COI (ranging from 0 to 0,25) was detected by SD BIOSENSOR. Among these 15 discrepant US one was obtaiend from a patient with *S.pneumoniae* bacteremia identified in the same day of urine testing. Two days later a US from the same patient was resubmitted to our laboratory and gave a positive result with all the three assays under evaluation, thus suggesting that the Uni-Gold test was correctly positive at the first test.

The remaining 14 US of this discrepant category were boiled and retested in order to remove potential interference. After the heat treatment only 4 US resulted negative for all the three methods. Of the remaining 10 US, one belong to a patient with *P. aeruginosa* and *E. coli* bacteremia and 10^6 CFU/mL *E. coli* isolated in urine in the same day of collection of the US. Another US belong to a P. multocida bacteremia patient and third one to patient suffering from *P. aeruginosa* urinary tract infection with a 10^6 CFU/mL bacterial load. These false positive results could be explained by a likely cross-reactivity between *S. pneumoniae* and other bacterial species. The last 7 patients in this group of subjects whose US gave discrepant results did not show any increase of the most commonly detected pneumonia biomarkers such as the white blood cells count and the level of the C reactive protein. No microrganisms were found in the urine, blood cultures or sputa from these patients.

Another 2 discrepant US were positive when tested with the Unigold and SD BIOSENSOR (COI 1.76 and 1.12), but totally negative with the BinaxNOW test. In order to resolve these discrepancies and trying to enhance the sensitivity of BinaxNOW the US were centrifuged and the three assays repeated. After centrifugation one US (COI 1.76) gave a positive result with all the three methods, but the another one (COI 1.12) remain Binax NOW negative.

The last discrepancy concern one US resulted positive to Unigold and BinaxNOW, but negative to SD BIOSENSOR (COI 0.01). Also, neither with centrigufation nor heat treatment resolved this discrepancy. The US belong to a patient with no increase in pneumonia biomarkers (like C reactive protein and White Blood Cells count) and no isolation of microrganisms from blood culture or sputa.

The sensitivity, specificity of STANDARD F compared with reference device (Uni-Gold) was respectively of 72.4%, 100%. Cohen's kappa coefficient and Overall percent agreement of STANDARD F compared with comparative device (BinaxNOW) was respectively of 0.954 and 98.6%.

		STANDARDTM F S.pneumoniae +	STANDARDTM F S.pneumoniae -
Uni-GoldTM S. pneumoniae	+	42	16
	-	0	160

		STANDARDTM F S.pneumoniae +	STANDARDTM F S.pneumoniae -
BinaxNOW® S. pneumoniae	+	40	1
	-	2	175

	Uni-GoldTM S. pneumoniae	STANDARDTM F S.pneumoniae	BinaxNOW® S. pneumoniae
+	58 (40)+[18]	42 (40)+[2]	41 (40)+[1]
-	160	176 (160)+[16]	177 (160)+[17]

Concordants (Round Brackets) and discrepants (Square Brackets) results obtained on US by the three methods used. In yellow is reported the total of concordant and discrepant results.

CONCLUSIONS

STANDARD F S.pneumoniae appears to be a promising supplement to pneumococcal CAP diagnosis. The assay demonstrated an excellent specificity and good sensitivity in pneumonia patients'. The automatic analyzer eliminates the subjectivity of a visual result and the ability to interface with laboratory information system (LIS) reduce the risk of reporting errors during manual data entry. Recentemente è stata introdotta sul mercato un modello + avanzato di