

# Evaluation of STANDARD™ F test (SD Biosensor) in comparison with the BinaxNOW® (Alere) for the urine antigen detection of *Legionella pneumophila* and *Streptococcus pneumoniae*

A. Terrile<sup>1</sup>, S. Cioncolini<sup>1</sup>, E. Magnano<sup>1</sup>, V. Rabellino<sup>1</sup>, F. Lillo<sup>1</sup>  
 Laboratory of Clinical Pathology of S. Paolo Hospital, ASL 2 Liguria.  
 Via Genova 30, 17100 Savona SV.

**- Background.** *Streptococcus pneumoniae* and *Legionella pneumophila* are two of the most relevant bacterial causes of Community-Acquired Pneumoniae (CAP). *S. pneumoniae* is the leading pathogen in most of the studies around the world with a reported prevalence of up to 65% of cases. *L. pneumophila* is also an important cause of CAP (up to 15% of cases). Moreover, both *S. pneumoniae* and *L. pneumophila* account for a mortality rate as high as 30%.

In 2017, 801 samples for urinary *Legionella* Ag detection and 1002 samples for urinary Ag *S. pneumoniae* were tested in our laboratory. The incidence of positive samples was (3,74 %) for *Legionella* and (9,48 %) for *S. pneumoniae*.

**- Objectives.** A new rapid Fluorescent ImmunoAssay System (STANDARD™ F *S. pneumoniae* Ag FIA and STANDARD™ F *Legionella* Ag FIA - SD Biosensor) for the *Streptococcus pneumoniae* and *Legionella pneumophila* serogroup 1 antigen detection in urine samples, was evaluated in comparison with BinaxNOW® *Legionella* and *S. pneumoniae* test routinely used in our laboratory.

**- Materials/methods.** 280 fresh and non-concentrated urine samples were tested. 140 samples for *Legionella* and 140 for *S. pneumoniae*. Samples were first tested using BinaxNOW® *Legionella* and BinaxNOW® *S. pneumoniae* kits and results were read using Alere™ Reader instrument. Then samples underwent STANDARD™ F Ag *Legionella* and STANDARD™ F Ag *S. pneumoniae* kits testing and results were read using STANDARD™ F200 instrument.

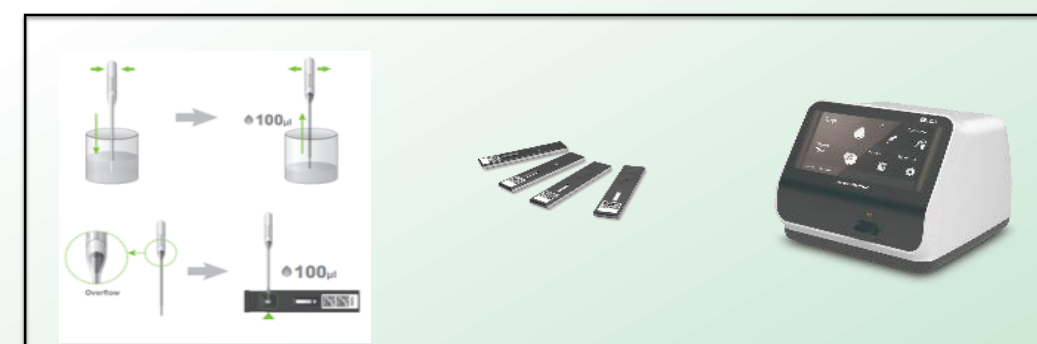


FIG. A: SD BIOSENSOR PROCEDURE

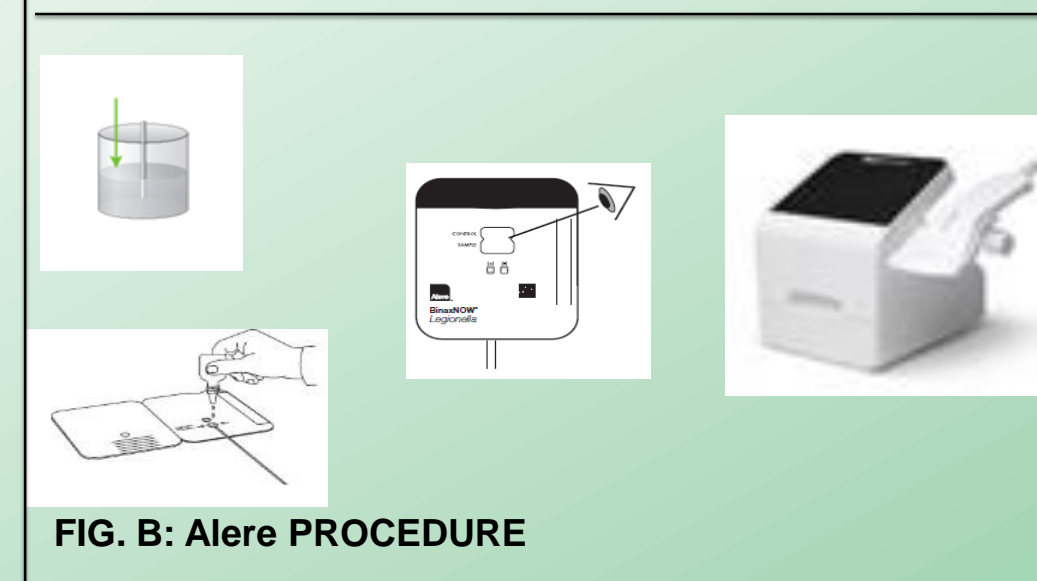


FIG. B: Alere PROCEDURE

**- Results: *Legionella pneumophila* Ag**

140 fresh and non-concentrated samples were tested for *Legionella* Ag. 135 samples resulted negative and 4 positive for both methods. 1 sample was positive by STANDARD™ F Ag *Legionella* and resulted negative using BinaxNOW® *Legionella* (Table 1).

	BinaxNOW® <i>Legionella</i> (Alere)			
		+	-	Total
STANDARD™ F <i>Legionella</i> Ag FIA (SD Biosensor)	+	4	1	5
	-	0	135	135
	Total	4	136	140

Table 1. Overall agreement: 98,6%

**- Results: *S. pneumoniae* Ag**

140 fresh and non-concentrated samples were tested for *S. pneumoniae*. 124 samples resulted negative and 12 positive for both methods. 2 samples were positive using STANDARD™ F Ag *S.pneumoniae* and resulted negative using BinaxNOW® *S. pneumoniae* and 2 samples were negative using STANDARD™ F Ag *S. pneumoniae* and resulted positive using BinaxNOW® *S. pneumoniae* (Table2).

	BinaxNOW® <i>S. pneumoniae</i> (Alere)			
		+	-	Total
STANDARD™ F <i>S. pneumoniae</i> Ag FIA (SD Biosensor)	+	12	2	14
	-	2	124	126
	Total	14	126	140

Table 2. Overall agreement: 97,14%

All the discordant samples (1 for *Legionella* and 4 for *S. pneumoniae*) were centrifuged for 15 min at 1000 rpm and retested using both systems.

After this treatment the *Legionella* sample resulted positive with both the systems (Table 3).

Two discordant samples positive using STANDARD™ F Ag *S.pneumoniae* and negative using BinaxNOW® *S. pneumoniae* resulted positive for both the systems, while the two negative using STANDARD™ F Ag *S. pneumoniae* and positive using BinaxNOW® *S. pneumoniae* confirmed the discordant results (Table 4).

	BinaxNOW® <i>Legionella</i> (Alere)			
		+	-	Total
STANDARD™ F <i>Legionella</i> Ag FIA (SD Biosensor)	+	5	0	5
	-	0	135	135
	Total	5	135	140

Table 3. Overall agreement: 100%

	BinaxNOW® <i>S. pneumoniae</i> (Alere)			
		+	-	Total
STANDARD™ F <i>S. pneumoniae</i> Ag FIA (SD Biosensor)	+	14	0	14
	-	2	124	126
	Total	16	124	140

Table 4. Overall agreement: 98,57%

**- Conclusions**

- The STANDARD™ F *Legionella* Ag FIA and *S. pneumoniae* Ag FIA system (SD Biosensor) have a workflow and a performance suitable for the routine diagnosis of *Legionella* and *S. pneumoniae* infections.
- The use of STANDARD™ F200 instrument makes the reading of the results objective and remove the human error.
- The STANDARD™ F *Legionella* Ag FIA and *S. pneumoniae* Ag FIA system (SD Biosensor) show better performances on fresh and **non-concentrated** urine sample when compares to the ones of BinaxNOW® *Legionella* and *S. pneumoniae* (Alere) detecting one more positive sample for *Legionella* and two more positive samples for *S. pneumoniae*, avoiding samples pretreatment.
- Regarding the two confirmed discordant samples (negative by STANDARD™ F Ag *S. pneumoniae* and positive by BinaxNOW® *S. pneumoniae*) these were from patients diagnosed with *pneumonia ndd* with negative blood cultures in both patients.