Clinical sensitivity and specificity Vitassay RSV

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An evaluation was performed in order to compare the characteristics of functionality of the evaluated inmunocromatographic tests:

- Vitassay RSV (Vitassay Healthcare, S.L.U., Spain)

And other commercial kit

- BinaxNOW®RSV (Alere)

For the detection of RSV in nasal swaps.

TRIAL LOCATION

This evaluation was performed in an independent laboratory.

SAMPLES

Samples were provided for the independent laboratory,

EVALUATIONS AND RESULTS

Samples were procesed following up the instructions for use related to each commercial kit.

- -Vitassay RSV (Vitassay Healthcare, S.L.U., Spain)
- BinaxNOW®RSV (Alere)

Sensitivity and specificity was obtained using standard methods and the measure of concordance was calculated by Cohen's Kappa coefficient.

The interpretation of the Kappa value should be as follows:

- Kappa value (IK) <0.4 weak concordance
- -Kappa value (IK) between 0.4 and 0.6 High concordance.
- Kappa value(IK) > 0.6 Excellent concordance

- Vitassay RSV compared with other commercial kit, BinaxNOW®RSV:

BinaxNOW®RSV					
		18	0	18	
Vitassay RSV		1	10	11	
		19	10	29	

Vitassay RSV vs BinaxNOW®RSV					
95%	>99%	>99%	91%		

Kappa value: 0,93

CONCLUSION:

Vitassay RSV showed a high sensitivity (95%) and a high specificity (>99%) for the detection of RSV antigens compared with other assay.

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