

Clinical sensitivity and specificity

Vitassay Clostridium difficile Toxin A+B

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

- **Vitassay Clostridium difficile Toxin A+B** (Vitassay Healthcare, S.L.U., Spain)

Versus a commercial kit:

- **C. DIFF QUIK CHECK Complete®** (Techlab, USA)

In order to detect Toxin A and Toxin B of Clostridium difficile in stool samples to make a presumptive diagnosis of *Clostridium difficile* infection.

TRIAL LOCATION

This evaluation was performed in an independent laboratory.

SAMPLES

The stool samples were provided from local Hospital patients (Zaragoza, España).

EVALUATION AND RESULTS

Samples were processed following up the instructions for use related to each commercial kit:

- **Vitassay Clostridium difficile Toxin A+B** (Vitassay Healthcare, SPAIN)

- **C. DIFF QUIK CHECK Complete®** (Techlab, USA)

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

The interpretation of the kappa value should be as follows:

- **Valor Kappa (IK) <0.4 – Weak concordance**

- **Valor Kappa (IK) between 0.4 to 0.6 – High concordance**

- **Valor Kappa (IK) >0.6 – Excellent concordance**

- **Vitassay Clostridium difficile Toxin A+B** compared with other comercial kit, C. DIFF QUIK CHECK Complete®:

C. DIFF QUIK CHECK Complete®				
Vitassay Clostridium m difficile Toxin A+B	Positive	Positive	Negative	Total
	Negative	0	44	44
	Total	6	44	50

Vitassay Clostridium difficile Toxin A+B vs C. DIFF QUIK CHECK Complete®			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

Kappa value: 1

CONCLUSION:

Vitassay Clostridium difficile Toxin A+B showed a high sensitivity (>99%) and a high specificity (>99%) to detect Toxins A and B of the *Clostridium difficile* compared with other assays.

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