

Clinical sensitivity and specificity

Vitassay Clostridium difficile antigen GDH

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Several evaluations were performed to determine the performance characteristics of a rapid immunocromatographic test:

- **Vitassay Clostridium difficile antigen GDH** (Vitassay Healthcare, S.L.U., Spain)

Versus a commercial test:

C. DIFF QUIK CHEK Complete® (Techlab, USA)

C. DIFF CHEK™-60 (Techlab, USA)

In order to detect Clostridium difficile antigen GDH in stool samples.

TRIAL LOCATION

Evaluation performed in an independent laboratory.

SAMPLES

Stool samples were prepared from local Hospital patients (Zaragoza, Spain)

EVALUATION AND RESULTS

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

- **Vitassay Clostridium difficile antigen GDH** (Vitassay Healthcare, S.L.U., Spain)

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

- **Wampole™ C. DIFF CHEK™-60** (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 antigen GDH** compared with others comercial kits, **C. DIFF QUIK CHEK Complete®** y **C. DIFF CHEK™-60** :

C. DIFF QUIK CHEK Complete®				
Vitassay Clostridium difficile antigen GDH		Positive	Negative	Total
	Positive	26	0	26
	Negative	0	48	48
	Total	26	48	74

Vitassay Clostridium difficile antigen GDH vs C. DIFF QUIK CHEK Complete®			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

Wampole™ C. DIFF CHEK™-60				
Vitassay Clostridium difficile antigen GDH		Positivo	Negativo	Total
	Positivo	39	0	39
	Negativo	2	47	49
	Total	41	47	88

Vitassay Clostridium difficile antigen GDH vs Wampole™ C. DIFF CHEK™-60			
Sensitivity	Specificity	PPV	NPV
>95%	>99%	>99%	96%
Valor Kappa: 1			

CONCLUSION:

Vitassay Clostridium difficile antigen GDH showed a high sensitivity (>99%, >95%) and a high specificity (>99%, >99%) to detect the *Clostridium difficile* compared with other assays.

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