

# Clinical sensitivity and specificity

## Vitassay Clostridium difficile GDH+Toxin A+B

CT.01.EN 7715024 Ed01

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

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

Versus a commercial available test:

- **C. DIFF QUIK CHEK Complete®** (Techlab, USA)
- **Wampole™ C. Diff Check™-60** (Techlab, USA)

In order to detect Clostridium difficile glutamato deshidrogenase (GDH) and Toxin A and B of Clostridium difficile in stool samples .

TRIAL LOCATION

This evaluation was performed in an independent laboratory.

Positive samples were confirmed with an ELISA assay at the Hospital.

SAMPLES

Samples were provided from patients collected by local Hospital (Zaragoza, Spain).

EVALUATION AND RESULTS

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

- **Vitassay Clostridium difficile GDH+Toxin A+B** (Vitassay Healthcare, S.L.U. Spain)
- **C. DIFF QUIK CHEK Complete®** (Techlab, USA)
- **Wampole™ C. Diff Check™-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 GDH+Toxin A+B** compared with others comercial tests, C. DIFF QUIK CHEK Complete® y Wampole™ C. Diff Check™-60.

C. DIFF QUIK CHEK Complete®				
Vitassay Clostridium difficile GDH+Toxin A+B (GDH)				
		Positive	Negative	Total
	Positive	26	0	26
	Negative	0	48	48
	Total	26	48	74

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

Wampole™ C. Diff Check™-60				
Vitassay Clostridium difficile GDH+Toxin A+B (GDH)				
		Positive	Negative	Total
	Positive	39	0	39
	Negative	2	47	49
	Total	41	47	88

Vitassay Clostridium difficile GDH+Toxin A+B vs Wampole™ C. Diff Check™-60			
Sensitivity	Specificity	PPV	NPV
>95%	>99%	>99%	96%

Kappa value: 1

# Clinical sensitivity and specificity

## Vitassay Clostridium difficile GDH+Toxin A+B

CT.01.EN 7355024 Ed00

C. DIFF QUIK CHEK Complete®				
		Positive	Negative	Total
Vitassay Clostridium difficile GDH+Toxin A+B (Toxin A+B)	Positive	6	0	6
	Negative	0	44	44
	Total	6	44	50

Vitassay Clostridium difficile GDH+Toxin A+B vs C. DIFF QUIK CHEK Complete®			
Sensitivity	Specificity	PPV	NPV

>99%                      >99%                      >99%                      >99%

Kappa: 1

CONCLUSION:

Vitassay Clostridium difficile GDH+Toxin A+B showed a high sensitivity (>99%, >95%, >99%) and a high specificity (>99%,>99%, >99%) to detect GDH+Toxin A+Toxin B compared with other assays.

Spain, 24<sup>th</sup> March 2016

  
Javier Garfella  
Technical manager

Vitassay Healthcare, S.L.U.  
Parque Tecnológico WALQA  
Ctra. N.330, Km.566  
22197-Cuarte (Huesca, SPAIN)  
www.vitassay.com