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IMMUNOQuick®

IMMUNOQUICK®

Clostridium difficile GDH and Tox A/B

Rapid

Results in minutes

Convenient

Easy handling

Reliable

Constant quality

Efficient

One step Assay

Clostridium difficile (*C.difficile*) is a bacterium of the Clostridium family. This bacterium may naturally reside in the intestines or in other cases people may ingest spores of the bacteria, especially in hospital or nursing home facilities. When the bacteria are in a colon in which the normal gut flora has been destroyed, by for instance a wide spectrum of antibiotics, the intestines will become overrun with *C.difficile*. The release of the bacteria's toxins may cause an infection of the colon. The symptoms of *C.difficile* infection could include, but are not limited to: bloating, diarrhea and abdominal pain. In rare cases an infection may progress to a life threatening toxic megacolon.

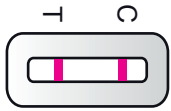
Mild cases of an infection are often cured by discontinuing the antibiotic treatment. In more serious cases, oral administration of metronidazole and if not successful vancomycin may be required.

The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America

(IDSA) and European Society of Clinical Microbiology and Infectious Diseases (ESCMID) suggest the use of a two-step process, which includes an initial screening of stool samples with an immunoassay test for GDH, a sensitive test for the detection of *C.difficile* bacteria, followed, if GDH positive, by a second, specific test to determine if the toxin that causes damage to the colon is present, since not all *C.difficile* may produce the toxin.

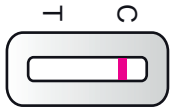
The IMMUNOQUICK® Clostridium difficile GDH test qualitatively detects glutamate dehydrogenase, produced by the bacteria, in stool samples. This is a 1-step, 15 minutes assay. The new IMMUNOQUICK® Tox A/B test qualitatively detect the toxins A and B produced by toxigenic strains of *C.difficile* in stool samples in only 15 minutes. The IMMUNOQUICK® Clostridium difficile GDH and the new IMMUNOQUICK® Tox A/B test are two additional tests in the BIOSYNEX's Gastro-Enterology product portfolio.

Protocol & Interpretation



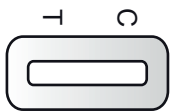
POSITIVE RESULT

In the test (T) and in the control (C) zones purple bands appear.



NEGATIVE RESULT

Only one purple band appears in the control (C) zone.



INVALID RESULT

When there is no band visible in the control (C) zone the test is invalid and should be repeated with a new device.



The Test Line (T) correspond to the detection of the Glutamate Deshydrogenase in the IMMUNOQUICK® C. difficile GDH test or to the detection of Toxins A & B in the IMMUNOQUICK® Tox A/B test.

For the complete procedure, please refer to the Instruction For Use (IFU) supplied with each kit.

Performance

IMMUNOQUICK® C.difficile GDH

		TOXIGENIC CULTURE	
		Positive	Negative
IMMUNOQUICK®	Positive	23	14
C.difficile GDH	Negative	1	266
		Sensitivity:	Specificity:
		95.8%	95.0%

Negative Predicted Value (NPV): 99.6%

IMMUNOQUICK® Tox A/B

		C. difficile Toxin A/B EIA*	
		Positive	Negative
IMMUNOQUICK®	Positive	112	1
Tox A/B	Negative	15	154
		Sensitivity:	Specificity:
		88%	99%

*EIA : Enzyme Immunoassay

Additional Informa-

IMMUNOQUICK® C.difficile GDH

REF 0537_K25: each kit contains 25 tests

Shelf life: 18 months

Storage Conditions: 2-30°C



IMMUNOQUICK® Tox A/B

REF 0561_K20: each kit contains 20 tests

Shelf life: 12 months

Storage Conditions: 2-30°C



The BIOSYNEX Group is one of the most significant manufacturers of rapid membrane tests on the in-vitro diagnostic market.

We offer high quality, easy to use Drugs of Abuse, Tropical Disease, Virology, Bacteriology, Autoimmune Disease, Oncology, Cardiology, Fertility, Obstetrics and Emergency Medicine kits.

Our Research and Development laboratories in Germany and France and our state of the art manufacturing facilities are dedicated to continuously meet the needs of our customers.

Our aim is to provide diagnostic tests to help physicians make faster and better medical and therefore lifesaving decisions.