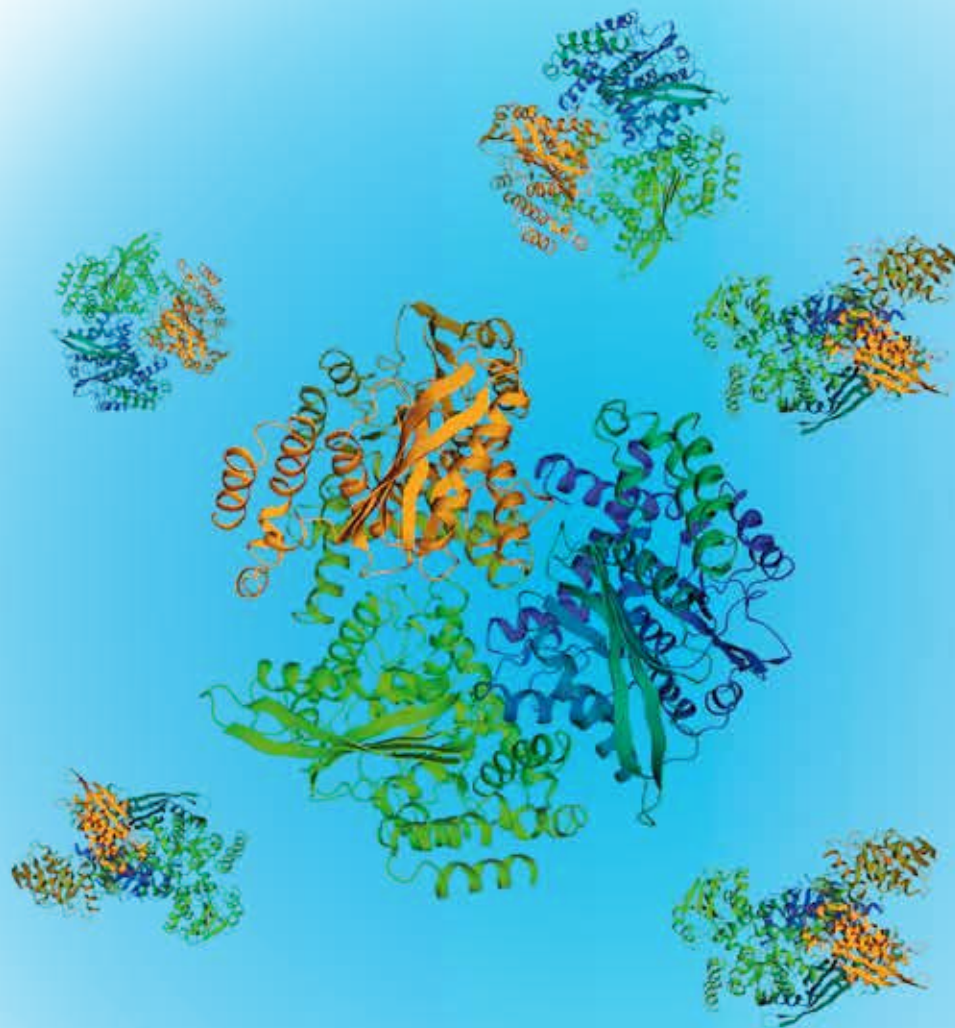


Stool testing

LIAISON[®] *C. difficile* GDH

The fully automated solution for fast and reliable
C. difficile GDH detection.



DiaSorin

The Diagnostic Specialist

FOR OUTSIDE THE US ONLY

Stool testing

LIAISON® *C. difficile* GDH

GDH is a hexameric enzyme responsible for the amination of α-ketoglutarate to glutamate and the reverse oxidative deamination of glutamate. It is also known as the *common antigen*, since all strains of *C. difficile* bacteria produce GDH.

The *C. difficile* Glutamate Dehydrogenase (GDH) assay is highly sensitive to the presence of *C. difficile* bacteria, due to the prevalence and stability of GDH in stool.

GDH determination is recommended as a preliminary screening method in most diagnostic algorithms. Its high Negative Predictive Value (NPV) makes it the ideal tool for screening out negative samples.

The LIAISON® *C. difficile* GDH is the perfect solution for achieving fast, reliable and automated results.

■ Key Assay features

Number of tests	100	Sample type	Stool
Method	Sandwich Qualitative	Throughput	180 results / hour
Solid Phase	Monoclonal antibody to GDH	Time to first result	35 minutes
Conjugate	Polyclonal antibody to GDH	Integral on board stability	8 weeks
Label / Tracer	ABEI	Calibrators availability	3 Lyophilized
Sample volume	100 µl	Calibrator stability	3 weeks

■ Performance Characteristics

A total of 200 clinical samples were tested by the LIAISON® *C. difficile* GDH assay and *C. difficile* Culture. Results are summarized in the table below.

LIAISON® <i>C. difficile</i> GDH	<i>C. difficile</i> Culture		
	Positive	Negative	Total
Positive	111	1	112
Equivocal	0	0	0
Negative	1	87	88
Total	112	88	200

Positive Agreement =	(111/112) 99.1%	95% CI (95.2 – 99.8%)
Negative Agreement =	(87/88) 98.9%	95% CI (93.9 – 99.7%)
Overall Agreement =	(198/200) 99.0%	95% CI (96.5 – 99.7%)

A total of 200 clinical samples were tested by the LIAISON® *C. difficile* GDH assay and *C. difficile* GDH ELISA assay. Results are summarized in the table below.

LIAISON® <i>C. difficile</i> GDH	Commercial <i>C. difficile</i> GDH ELISA		
	Positive	Negative	Total
Positive	109	3	112
Equivocal	0	0	0
Negative	0	88	88
Total	109	91	200

Positive Agreement =	(109/109) 100%	95% CI (96.7 – 100%)
Negative Agreement =	(88/91) 96.7%	95% CI (90.8 – 98.8%)
Overall Agreement =	(197/200) 98.5%	95% CI (95.7 – 99.5%)

■ Ordering information

LIAISON® *C. difficile* GDH (code 318910)

LIAISON® *C. difficile* GDH Control set (code 318911)

Product availability subject to required regulatory approval



The Diagnostic Specialist

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