

## PRODUCT SPECIFICATIONS

<b>Name</b>	Anti- <i>C. difficile</i> GDH 11001 SPTN-5
<b>Specificity</b>	Antibody recognizes <i>Clostridium difficile</i> glutamate dehydrogenase
<b>Description</b>	Monoclonal mouse antibody, cultured <i>in vitro</i> under conditions free from animal-derived components
<b>Product code</b>	100714
<b>Product buffer solution</b>	50 mM Na-citrate, pH 6.0, 0.9 % NaCl, 0.095 % NaN <sub>3</sub> as a preservative
<b>Shelf life and storage</b>	Unspecified, storage at 2-8 °C
<b>Analyte description</b>	<i>Clostridium difficile</i> is an anaerobic Gram-positive bacterium that can cause hospital-acquired diarrhea, and is often associated with previous antibiotic use. Immunoassays detecting the <i>C. difficile</i> proteins glutamate dehydrogenase (GDH), and toxins A and B, are used to diagnose <i>C. difficile</i> infection.

## PARAMETERS TESTED ON EACH LOT

<b>Product appearance</b>	Liquid, may turn slightly opaque during storage
<b>Product concentration</b>	5.0 mg/ml (+/- 10 %)
<b>Immunoreactivity</b>	80-120 % compared to the reference sample in an FIA test
<b>IEF Profile</b>	6.9 – 8.0
<b>Purity</b>	≥ 95 %

## PARAMETERS DETERMINED DURING PRODUCT DEVELOPMENT

<b>Subclass</b>	IgG <sub>1</sub>
<b>Association rate constant</b>	Not Determined (N/D)
<b>Dissociation rate constant</b>	N/D
<b>Affinity constant</b>	N/D
<b>Determination method</b>	-
<b>Determination antigen</b>	-

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<b>Cross-reactivities</b>	N/D	
<b>Epitope</b>	N/D	
<b>Pair recommendations</b>	<b>CAPTURE ANTIBODY</b> 11001	<b>DETECTION ANTIBODY</b> 11001

Please note that pair recommendations are based on results obtained by our laboratory. Equally good results may be obtained using other pairs and therefore these recommendations are only indicative.

<b>Product stability</b>	<b>TEMPERATURE, TIME</b>	<b>RESULT</b>
	-70 °C, 21 days	OK
	-20 °C, 21 days	OK
	+4 °C, 21 days	OK
	+35 °C, 21 days	OK
	+45 °C, 3 days	OK
	+45 °C, 7 days	Reduced immunoreactivity

Stability testing is performed in the product buffer to see whether different temperatures affect the antigen binding, charge or composition of the antibody. Please note that the shelf life given on the first page is based on real time stability testing at 2-8 °C in the product buffer.

<b>Miscellaneous</b>	Reacts with recombinant <i>C. difficile</i> GDH antigen, Medix Biochemica, 610121.
<b>References</b>	-