

Native Clostridium Difficile Toxoid A

Cat. No. CLO-082 **Lot. No.** (See product label)

SPECIFICATION

Product Overview

Clostridium difficile Toxoid A is a highly purified, non-toxic preparation derived from C. difficile toxin A. It has been developed either for use as an immunogen to raise antibodies or for use in clinical diagnostic assays. Formaldehyde is used to convert the toxin into Toxoid A and quality control data illustrates that this treatment has no significant effect on the antigenicity of the resultant preparation.

Background

Clostridium difficile (C. difficile) is a Gram-positive spore-forming anaerobic bacterium, first described in the mid-1930s. Recent studies have shown that C. difficile is predominantly associated with cases of infectious diarrhoea in patients after treatment with antibiotics (antibiotic-associated diarrhoea, AAD), or have imbalanced commensal gastrointestinal flora. C. difficile infection can cause severe disease and death in a significant number of cases and is recognised as a leading cause of severe gastrointestinal disease and AAD in hospitalised patients (Voth, DE). The severity of the disease in each case is determined by various factors, including the virulence of the C. difficile strain, the condition of the patient's normal gut flora and the individual's immune response to intestinal damage.

Toxins A and B have been identified as major C. difficile virulence factors, which are encoded by the tcdA and tcdB genes respectively. Both toxin A and toxin B have pro-inflammatory and cytotoxic activity, which disrupt the intestinal epithelium leading to extensive damage and cell death in the large intestine (Carter, GP).

In recent years, new hypervirulent strains of C. difficile, including ribotype 027 and 078, have emerged causing new epidemics of C. difficile in the developed world, and are a cause for significant concern within the global health care community (Ghose, C).

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	The product is presented in a choice of pack sizes and is lyophilised for ease of use.
Purity	>95% pure by SDS-PAGE
Sequence Strain	VPI10463
Inactivation	Inactivated using formaldehyde. No cell rounding in the sensitive verocytotoxicity assay at 2 µg/mL compared to active toxin lethal dose of 0.2 ng/mL.
Formulation	Contents when reconstituted in 250µl sterile distilled water will contain: Toxoid A at a concentration of 0.4 mg/mL in 0.05M Hepes, 0.15M NaCl and 5% sucrose
Stability	Lyophilised vial: 1 year after date of receipt. Reconstituted liquid: 1 month
Freezing	Reconstituted liquid can be frozen at -80 centigrade to extend stability to 1 year; however every freeze/thaw cycle will cause increased aggregation. Avoid multiple freeze/thaw cycles and multiple temperature fluctuations.
Storage	Lyophilised vial: +4 centigrade. Reconstituted liquid: +4 centigrade.
Shipping	Ambient
Notes	This product is intended for research and manufacturing uses only. It is not a diagnostic device. The user assumes all responsibility for care, custody and control of the material, including its disposal, in accordance with all regulations.
Type	Native
ClassID 1	Infectious Disease

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GENE INFORMATION

Synonyms	Clostridium Difficile Toxoid A
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