

Certificate of Analysis

Name: Clostridium difficile ribotype R027 Toxoid B

Product Code: NAT41675-50 / NAT41675-100 / NAT41675-500

Batch #: 25060515D

Date of Manufacture: 14th August 2025

Product Description: Native toxin purified from *Clostridioides difficile* (syn. *Clostridium difficile*) ribotype R027, converted to toxoid through processing with formaldehyde.

Strain/Isolate: ribotype R027

Amount: 0.05 mg / 0.10 mg / 0.50 mg

Presentation: Lyophilised. May appear bubbly/glassy due to product stabilisation in sucrose.

Buffer: 50 mM HEPES pH8.0, 150 mM NaCl, 10% (w/v) sucrose.

Reconstitution:

NAT41675-50	100ul sterile pure water	final concentration 500ug/ml
NAT41675-100	200ul sterile pure water	final concentration 500ug/ml
NAT41675-500	1000ul sterile pure water	final concentration 500ug/ml

Verocytotoxicity assay result: 4pg/ml (lowest point at which rounded cells are observed)

Usage Guidelines

Short Term Storage: 2°C to 8°C lyophilised

Long Term Storage: -80° C after reconstitution

Stability: Lyophilised vial 1 year after date of receipt.
Reconstituted liquid 1 month at 2°C to 8°C, up to 12 months at -80°C.

Freezing: Avoid multiple freeze-thaw cycles and temperature fluctuations of reconstituted product.
Freezing and thawing may cause aggregation and reduce activity.

Mixing: Mix gently to avoid causing aggregation.

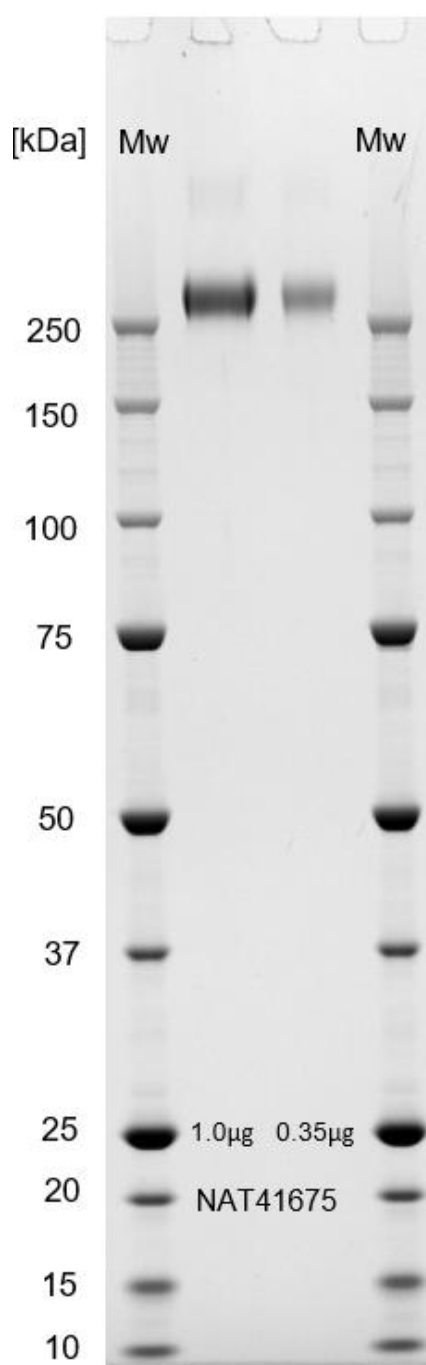
Sterility: This product has reduced bioburden through 0.2µm filtration, but is not sterile.

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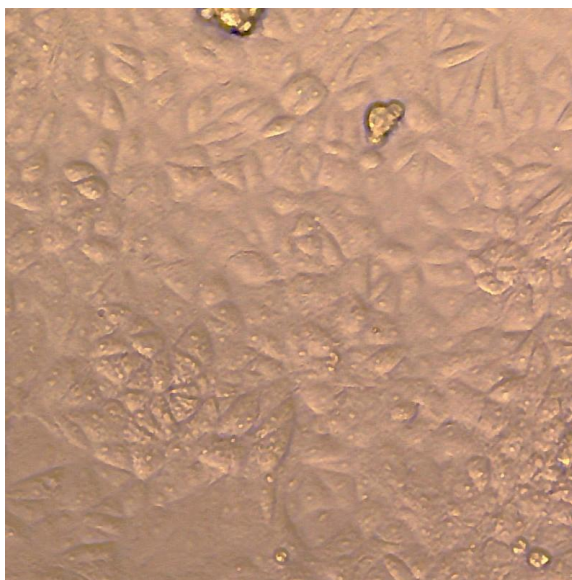
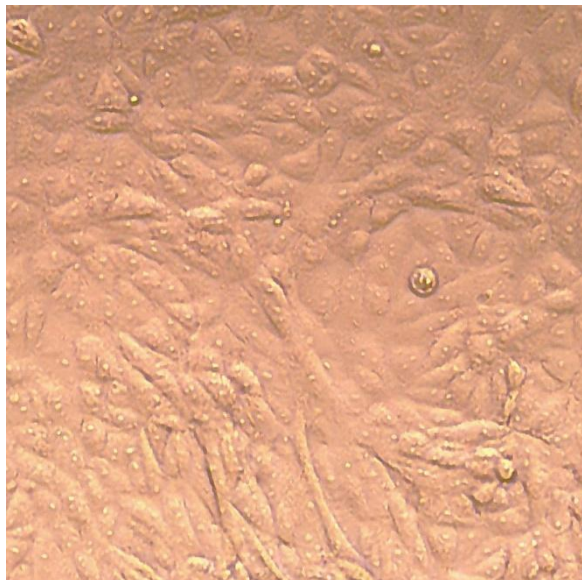
Batch #: 25070915D

SDS-PAGE: Coomassie-stained reducing SDS-PAGE showing purified Clostridium difficile Toxoid B.



Verocytotoxicity results

The Toxoid was negative by Verotoxicity up to 7.81µg/ml.



Negative control

Toxoid 7.81µg/ml

14/08/2025

X



QC

Signed by: Toni.Ertl@lgcgroup.com

21/08/2025

X



QA

Signed by: Estelle.Tressens@LGCGroup.com

Products are for Research Use or for Further Manufacturing Use only. Not for Diagnostic or Therapeutic Use.