

Nalgene containers developed specifically for the risk-averse

Clean containers that meet the demands of your workflow and the regulatory bodies that govern it

Making sure the equipment and materials used in critical environments meet the demanding standards of cleanliness can be a challenging process. Reduce the risk of failing to meet USP <788> requirements by using the cleanest validated containers on the market.

Packaging in the right configuration

The Thermo Scientific™ Nalgene™ multi-tiered portfolio provides bioproduction facilities with a variety of high-quality, sterile storage and transport solutions. This enables you to choose the appropriate product necessary to suit your application—through the step-down process and into your clean room.

Tier	PETG	PC	HDPE
Standard clean	•	•	•
Certified clean	•	•	
Platinum certified clean	•	•	•

Key features

- Multiple tiers
 - Platinum certified clean containers are certified to contain less than 1/3 of the allowable particulate limits specified in USP <788>
 - Certified clean containers meet USP <788> low particulate requirements
- Multiple resins available
 - Polycarbonate (PC)
 - Polyethylene terephthalate (PETG)
 - High-density polyethylene (HDPE)
- Sterile, ready-to-use products with robust triple-layer packaging for your step-down process
 - 2 heat-sealed bags create dual sterile barriers
 - 1 carton liner
 - Double-walled cartons
 - Improved labeling
- Produced in clean room (ISO class 7)
- Certified leakproof* to protect valuable contents

* Our guarantee for a leakproof seal is subject to our standard product warranty, as set forth in the Thermo Fisher Scientific Terms and Conditions of Sale. Our products are leakproof at ambient temperature and pressure when used with their corresponding closures. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned applications. Please contact technicalsupport@thermofisher.com if you need additional information about our products.

	Certified clean	Platinum certified clean
Packaging		
Triple-layer outer packaging	Container(s) in a labeled heat-sealed bag and then packed in an additional heat-sealed bag. Multiple packs are gathered in a carton liner bag, placed in a carton, and closed with a cable tie.	
Labeling	Visible through each packaging layer	
Double-walled cartons	Yes	Yes
Shelf life		
Expiration (years)	5	5*
Certifications/compliance		
Visual inspection	Yes	Yes
Particle specification	USP <788>	Below 1/3 of USP <788> limits
Endotoxin requirement (per USP <85>)	<0.5 EU/mL	<0.25 EU/mL
Certified sterile (SAL of 10 ⁻⁶)*	Yes	Yes
Nonpyrogenic	Yes	Yes
Compendial and extraction testing		
Noncytotoxic	Yes	Yes
Nonhemolytic	ISO 10993-3	ISO 10993-3
USP Class VI compliant/certificate	Yes	Yes
USP <661> physicochemical tests—compliant	Yes, rev 37 physicochemical	Yes, rev 37 physicochemical
Animal components according to BSE/TSE** regulatory statements	Certain SKUs contain animal-derived components; uncolored closure	Certain SKUs contain animal-derived components; white closure
EMA 410/01—compliant	Yes	Yes
Melamine	No	No
Validation reports available	Yes	Yes

* Certain products are currently 2 years and undergoing validation to extend shelf life.

** SAL: sterility assurance level; BSE/TSE: bovine spongiform encephalopathy/transmissible spongiform encephalopathies.

PETG

PETG containers have robust gas-barrier properties and offer low permeability to gases such as O₂ and H₂O₂.

- Suitable for storage in conditions from –70°C to 70°C
- White, low-density polyethylene (LDPE)-lined, radiation-stable polypropylene (PP) closure

Ordering information

Thermo Scientific™ Nalgene™ PETG Certified Clean Biotainer™ Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
125 mL	38 mm	52 mm	105 mm	5/100	383025-42
500 mL	38 mm	77 mm	176 mm	5/70	383005-42
1,000 mL	48 mm	98 mm	201 mm	5/35	383110-42
2,000 mL	48 mm	116 mm	265 mm	20/20	383230-20
2,000 mL	48 mm	116 mm	265 mm	5/20	383230-42
5,000 mL	48 mm	166 mm	299 mm	1/6	383415-16*
5,000 mL	48 mm	166 mm	299 mm	1/6	383415-42

* With polyethylene handle.

Thermo Scientific™ Nalgene™ Square PETG Platinum Certified Clean Biotainer Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
125 mL	38 mm	52 mm	105 mm	5/100	CE-N3025-42
500 mL	38 mm	77 mm	176 mm	5/70	CE-N3005-42
1,000 mL	48 mm	98 mm	201 mm	5/35	CE-N3110-42
2,000 mL	48 mm	116 mm	265 mm	5/20	CE-N3230-42

Thermo Scientific™ Nalgene™ Square PETG Certified Clean Media Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
30 mL	20 mm	38 mm	64 mm	6/72	382019-0030
60 mL	24 mm	41 mm	82 mm	6/72	382019-0060
125 mL	38-430	52 mm	108 mm	6/48	382019-0125
250 mL	38-430	59 mm	144 mm	6/48	382019-0250
500 mL	38-430	73 mm	178 mm	4/24	382019-0500
1,000 mL	38-430	92 mm	219 mm	2/24	382019-1000
2,000 mL	53B	116 mm	271 mm	1/12	382019-2000

Thermo Scientific™ Nalgene™ Square PETG Platinum Certified Clean Media Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20 mm	22 mm	46 mm	52/416	CE-N2035-0005
20 mL	20 mm	30 mm	65 mm	84/504	CE-N2035-0020
30 mL	20 mm	38 mm	64 mm	7/70	CE-N2019-0030
60 mL	24 mm	41 mm	82 mm	6/72	CE-N2019-0060
125 mL	38-430 mm	54 mm	110 mm	5/50	CE-N2019-0125
250 mL	38-430 mm	59 mm	144 mm	12/48	CE-N2019-0250
500 mL	38-430 mm	74 mm	177 mm	5/70	CE-N2019-0500
1,000 mL	38-430 mm	92 mm	219 mm	5/35	CE-N2019-1000
2,000 mL	53B	116 mm	271 mm	5/20	CE-N2019-2000

Thermo Scientific™ Nalgene™ PETG Certified Clean Validation Bottle					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20-415 mm	22.25 mm	45.9 mm	52/416	382035-0005
20 mL	20-415 mm	29.72 mm	64.5 mm	84/504	382035-0020

PC

The robustness and impact resistance of PC at cold temperatures make PC bottles and carboys ideal for freezing all of your high-value products.

- White, silicone-lined, radiation-stable PP closure
- Recommended temperature range of –100°C to 100°C
- Validation vials available in 5 mL and 20 mL sizes

Ordering information

Thermo Scientific™ Nalgene™ PC Certified Clean Biotainer™ Bottles and Carboys					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
125 mL	38 mm	52 mm	105 mm	5/50	383030-42
1,000 mL	48 mm	98 mm	201 mm	5/35	383120-42
2,000 mL	38 mm	116 mm	265 mm	5/20	383233-42
5,000 mL	38 mm	166 mm	299 mm	1/6	383405-16*
5,000 mL	48 mm	166 mm	299 mm	1/2	383405-42
10,000 mL	48 mm	255 mm	337 mm	1/2	383410-08*
10,000 mL	48 mm	255 mm	337 mm	1/2	383410-42
20,000 mL	48 mm	255 mm	495 mm	1/3	383423-42

* With attached handle.

Thermo Scientific™ Nalgene™ PC Platinum Certified Clean Biotainer™ Bottles and Carboys					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20 mm	22 mm	46 mm	52/416	CE-N3500-05
20 mL	20 mm	30 mm	69 mm	84/504	CE-N3500-20
125 mL	38 mm	52 mm	105 mm	5/50	CE-N3030-42
1,000 mL	48 mm	98 mm	201 mm	5/35	CE-N3120-42
2,000 mL	38 mm	116 mm	265 mm	5/20	CE-N3233-42
5,000 mL	48 mm	166 mm	299 mm	1/6	CE-N3405-42
10,000 mL	48 mm	255 mm	337 mm	1/2	CE-N3410-42

Thermo Scientific™ Nalgene™ PC Certified Clean Validation Bottle					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20-400 mm	22.4 mm	46.7 mm	52/416	383500-05
20 mL	20-400 mm	29.7 mm	65.3 mm	84/504	383500-20

HDPE

HDPE containers offer excellent chemical resistance, and the wide range of chemical compatibilities makes them a great option for storage of harsh materials.

- Support storage conditions of –100°C to 120°C
- LDPE-lined, radiation-stable PP closure (sizes 10 L and above with white PP closures)

Ordering information

Thermo Scientific™ Nalgene™ Platinum Certified Clean HDPE Bottles and Carboys						
Description	Volume	Closure size	Optical density (OD)	Height with closure	No. per pack/case	Cat. No.
Narrow-mouth bottle	30 mL	20-415	34.3 mm	61 mm	12/72	CE-E2099-0001
	250 mL	24-415	61 mm	133 mm	12/72	CE-N2099-0008
	500 mL	28-415	72.6 mm	170.4 mm	12/48	CE-N2099-0016
	1 L	38-430	91.4 mm	215.9 mm	6/24	CE-N2099-0032
Wide-mouth bottle	250 mL	43-415	61 mm	99.3 mm	12/72	CE-N2199-0008
	500 mL	53-415	72.6 mm	168.2 mm	12/48	CE-N2199-0016
	1 L	63-415	91.44 mm	199.2 mm	6/24	CE-N2199-0032
Carboy with integrated handles	10 L	83B	250.2 mm	389 mm	1/6	CE-N2289-0020
	20 L		284.2 mm	501.7 mm	1/4	CE-N2289-0050
	33 L		381 mm	546 mm	1/1	CE-N2289-0075

Manufactured, tested, and supported for critical applications

- Forced extraction studies and validation binders* can be requested by emailing our technical support staff at rocregsupport@thermofisher.com.
- Certificates on demand: Customers can obtain a lot-specific Nalgene product certificate on demand at any time from our website. Enter the lot number in the field at the bottom of each product webpage, and a PDF of the certificate is instantly available for print or download.
- Sign up for notifications: Receive electronic notification of changes to product form, fit, function, manufacturing location, and tooling as well as major process changes by registering in our customer change notification database. To register for change notifications for a specific list of Nalgene products, go to thermofisher.com/registercustomernotifications.

Find out more at thermofisher.com/usp-clean

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* Forced extraction studies and validation binders from Thermo Fisher Scientific are provided, where available, under a confidentiality agreement to assist customers in product selection. Customers are responsible for determining which studies are recommended for its specific applications. Forced extraction studies and validation binders may be requested by contacting us at rocregsupport@thermofisher.com.