

# Request form for Gibco™ custom media and buffers

Request date

## Section 1: Customer information

Company name

Customer name

Shipping address

Customer phone

Thermo Fisher account manager

Customer email

## Section 2: Product information and customization type

### Manufacturing

Gibco™ custom products are manufactured at ISO 13485–certified sites and in conformity with cGMP for medical devices, 21 CFR Part 820.

### Gibco™ Rapid Prototyping

Products produced by our non-GMP rapid prototyping lab are for research use only and not for use in diagnostic procedures. We are unable to guarantee biological performance of the manufactured product.

### Product use restrictions

Gibco custom media and buffers are for use only in laboratory research or for further manufacturing. Products have not been qualified for animal or human diagnostic or therapeutic applications. Uses other than the label intended use (e.g., human, animal, therapeutic, diagnostic, or clinical applications) have not been established as safe and effective. Certain product uses may require further evaluation. We reserve the right to accept or decline an order based on the customer's intended use.

Research Use Only (RUO, including biochemical repack)

Yes

No

Product use classification (make selection if not RUO)

Manufacturing process (make selection)

Product format (make selection)

Reference Cat. No.

Prior quote number (optional)

## Formulation modifications

For complex changes, please fill out the additional spreadsheet provided by [CustomMedia@thermofisher.com](mailto:CustomMedia@thermofisher.com).

Change type	Component and concentrations	Unit of measurement	CAS Registry Number (optional)	Comments
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Additional customization comments

## Section 3: Batch volumes and package offerings

For each batch, decide between liquid, powder, or Gibco™ Advanced Granulation Technology™ (AGT™) format. Then click either Gibco Rapid Prototyping or cGMP under the desired column, and then select the desired packaging format.

### Batch 1

Quantity	Unit size fill volume	Liquid packaging	Powder packaging	AGT format packaging	Total volume
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## Batch 2

Quantity	Unit size fill volume	Liquid packaging	Powder packaging	AGT format packaging	Total volume

## Batch 3

Quantity	Unit size fill volume	Liquid packaging	Powder packaging	AGT format packaging	Total volume

## Section 4: Product testing

### Gibco Rapid Prototyping (non-cGMP) testing

Limited Gibco Rapid Prototyping testing is available for a fee. The test results are provided without a Certificate of Analysis (CoA) and are not used as criteria for releasing the product. Please select from the testing options below:

pH

Osmolality

Sterility (liquid) or solubility  
(powder or AGT format)

No testing

## cGMP testing

cGMP liquids are QC tested for pH, osmolality, and sterility; powder and AGT formats are QC tested for pH, osmolality, and solubility. The test results are provided with a Certificate of Analysis (CoA). Please select from the additional testing options below provided for a fee:

Same cGMP testing as the product catalog number:

No additional testing

Customer-specified cGMP testing as provided below:

## Section 5: Labeling and documentation

Gibco Rapid Prototyping (non-cGMP)	cGMP		
Include manufacture date	Include manufacture date	Include expiration date	Private label required

### Shelf life

The shelf life of this product has not been determined. It is the responsibility of the end user to determine an appropriate shelf life. If requested, shelf life is given as a guide and is not guaranteed by Thermo Fisher Scientific. Please attach stability information if expiration date is required. Real-time stability studies can be provided as a custom service.

### Labeling and documentation notes

Please email your request to [CustomMedia@thermofisher.com](mailto:CustomMedia@thermofisher.com).

All orders made following this request are subject to our confirmation of final requirements and related feasibility review, and are also subject to **Thermo Fisher Scientific Terms and Conditions of Sale** at [thermofisher.com/us/en/home/global/terms-and-conditions.html](https://www.thermofisher.com/us/en/home/global/terms-and-conditions.html), or upon request. Thank you for choosing Gibco custom products.

#### Gibco Program Management Office

3175 Staley Road  
Grand Island, NY 14072 USA

Tel: +1 (716) 774-6966  
Toll-Free: +1 (800) 584-0545

[CustomMedia@thermofisher.com](mailto:CustomMedia@thermofisher.com)

#### Gibco Program Management Office

3 Fountain Drive  
Inchinnan Business Park  
Paisley, PA4 9RF, U.K.

Tel: +44 (141) 814-6100

[EUCustomMedia@thermofisher.com](mailto:EUCustomMedia@thermofisher.com)

# Differences between Gibco Rapid Prototyping and cGMP custom media manufacturing

## Gibco Rapid Prototyping



Research Use Only (RUO)



### Batch volumes

- 1–600 L liquid medium
- 1–30 kg powder medium
- 1–8 kg AGT format medium



### Packaging options

Standard packaging available



### Product testing

Limited testing available for a fee:

- | Liquid medium | Powder medium |
|---------------|---------------|
| • pH          | • pH          |
| • Osmolality  | • Osmolality  |
| • Sterility   | • Solubility  |

Results provided without a CoA.



### Production lead times

Lead times vary based on request



RUO and other intended use options available



### Batch volumes

- 10–10,000 L liquid medium
- 1–7,500 kg powder medium
- 50–1,000 kg AGT format medium



### Packaging options

Standard and custom packaging options available



### Product testing

Price includes the following tests:

- | Liquid medium | Powder medium |
|---------------|---------------|
| • pH          | • pH          |
| • Osmolality  | • Osmolality  |
| • Sterility   | • Solubility  |

Additional tests available. Results provided with a CoA.



### Production lead times

Lead times vary based on request

Please contact [CustomMedia@thermofisher.com](mailto:CustomMedia@thermofisher.com) for more information on Gibco custom media products.

**gibco**