



Product Brief Form: Rapid Response Production™

Dear Customer,

As an ISO 9001:2000 certified company, we want to provide you with the exact product you wish to order. This document serves as our Product Brief and your definition of the product and its packaging. Your signature at the bottom of this document is our confirmation that you have carefully read and reviewed the information contained within, and it is both accurate and complete.

HyClone's Rapid Response Production facility is an entity within its Research and Product Development group. It is neither governed by cGMP guidelines nor a regulated part of HyClone's manufacturing facilities. Therefore, products manufactured by the Rapid Response Production facility are intended for research use only and, unless specifically stated otherwise, will incorporate the following aspects:

- Label will state "For Research Use Only"
- Sterile filtered using 0.2 μ filters
- QC testing by request only (see item 8)
- Product Information Sheet provided on lots with QC testing

1. Product History

- New Product (not manufactured by HyClone previously)
 Previously manufactured product: Project No.: _____ Lot No.: _____

2. Product Description

- General Product Application (indicate):
 Liquid Medium/Supplement Dry Powdered Medium/Supplement

3. Lot Size Information

- Liquid Medium/Supplement: Size: _____ L
 Dry Powdered Medium/Supplement: Size: _____ gm

4. Packaging Information

- Liquid Medium/Supplement**
 Bottle Size: _____ Fill Volume: _____ mL
 BPC Size: _____ Fill Volume: _____ L
 Custom/Description: _____ Fill Volume: _____ mL
-
- Dry Powder Medium/Supplement**
 Bottle Size: _____ Fill Volume: _____ grams
 Custom/Description: _____ Fill Volume: _____ grams

5. Label Requirements

List exact information desired on label:

6. Temperature Requirements

Store at: _____ °C Ship at: _____ °C

7. Formulation

- Formulation Attached Same as Project No.: _____
(with changes listed below)

Component	Amount	Component	Amount
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8. Quality Control Testing Waive all QC testing Perform QC testing as indicated below**Liquid Medium/Supplement****Target Value**

Appearance _____

Sterility _____

pH _____

Osmolality _____

Endotoxin _____

Other _____

Dry Powdered Medium/Supplement**Target Value**

Appearance _____

Sterility _____

pH _____

Osmolality _____

Endotoxin _____

Other _____

9. Customer Information

Company: _____

Date: _____

Client: _____

Client Title: _____

Tel.: _____

Fax: _____

E-mail: _____

Address: _____

City: _____

State/Province: _____

Country: _____

ZIP/Postal Code: _____

Approval Signature: X _____

HyClone Use OnlyHyClone Pilot Plant Manufacturing Approval: Yes No

Manufacturing Cost: _____

Component Cost: _____

QC Cost: _____

Packaging Cost: _____

Cost/Unit: _____

Lot Cost: _____

Project No.: _____

GL Code: _____

Manufacturing Date: _____

Shipping Date: _____