

Product Description

The MicroPlex® Microspheres regions 1 thru 100 are offered at the standard concentration of 1.25×10^7 /mL on a build-to-order basis in custom volume increments of 1mL ranging from 100 to 1000 mL to more efficiently accommodate large volume demand.

Ordering Guidelines

The available range of volume sizes are restricted to 4 bottle sizes with allowable 1mL increment fill ranges to choose from, reference Table 1.

Table 1

MicroPlex Custom Volume Order Numbers	MicroPlex Regions offered (XXX)	Bottle Size (mL)	# of Bottles		Available Custom Volume Ranges (mL/bottle)
			Limit per Lot @ MIN vol	Limit per Lot @ MAX vol	
LC10XXX-C125	001 thru 100	125	7	7	100-125
LC10XXX-C250		250	7	7	126-250
LC10XXX-C500		500	7	6	251-500
LC10XXX-C1000		1000	7	3	501-1000

XXX = 3 digit region number

- Order by the Region & Bottle size specific order number and state the custom volume for each bottle size and the quantity requested. Refer to Order example below.
- Minimum Order volume = 100 mL/region
- Maximum volume per dyed lot = 3000 mL/region. Volumes larger than maximum can be ordered but are produced from more than one dyed lot.
- There is a Max limit to the number of bottles allowed per each lot packaged in same size bottle. Reference Table 1.
- MicroPlex Custom Volumes are priced per UOM “mL” according to contracted price.
- All orders are packaged in standardized round, amber, HDPE, wide mouth bottles according to the order numbers above.
 - Build-to-order lead time: Estimated 6 - 8 week lead time. Lead time may vary depending on the total order line items.
- Note: There is no planned volume overage to the custom fill. All volumes will be within -2% to +5% of the order volume.

Order example: Customer would like 460 mL of the same lot of Region 050. This could be ordered in a number of different configurations. Note: Lot numbers are assigned per bottle size part number **and** volume requested. A single region ordered with multiples of the same bottle size will be processed under a single lot number (**Example B**) or multiple lot numbers if the requested volume varies (**Example C**). If requesting a single region of same dyed lot to be configured into more than one volume or bottle size, the single region will have different lot numbers per bottle size (**Example D**).

Example	Order information on P.O. (Should also include Product Descriptions)			Ordered Volumes filled as indicated per P.O.	
	Line Item	Order #	Qty (mL)	Fill Vol (mL)	Lot #
A	1	LC10050-C500	460	460	B12345
	or				
B	1	LC10050-C250	230	230	B12345
	2	LC10050-C250	230	230	B12345
	or				
C	1	LC10050-C125	120	120	B12345
	2	LC10050-C125	120	120	B12345
	3	LC10050-C125	120	120	B12345
	4	LC10050-C125	100	100	B12356
	or				
D	1	LC10050-C500	335	335	B12345
	2	LC10050-C125	125	125	B12356

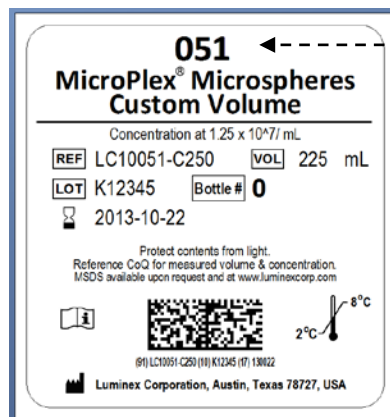
Ordering information

Order Number	Luminex Product Descriptions
LC10XXX-C125	MicroPlex Microsphere, Region XXX, 125mL btl, 100 - 125 mL
LC10XXX-C250	MicroPlex Microsphere, Region XXX, 250mL btl, 126 - 250mL
LC10XXX-C500	MicroPlex Microsphere, Region XXX, 500mL btl, 251 - 500mL
LC10XXX-C1000	MicroPlex Microsphere, Region XXX, 1000mL btl, 501-1000mL

Labels

Example bottle label and CoQ presented to show information accompanying order.

Bottle Label Example shown approximate size.




XXX = Region Number

CoQ Example not shown actual size.

Certificate of Quality

MicroPlex® Microspheres, Custom Volume

REF	Product Number	LC10050-C125
LOT	Product Lot Number	B12345
	Product Expiration Date	YYYY-MM-DD
	Dyed Intermediate Lot	B12300
	Progenitor Lot ¹	003
	Classification Identifier	050
	Classification Efficiency (%) ^{2,3,5}	95.4
	Misclassification (%) ^{2,4,5}	0.20
	Doublet Discrimination (DD) Peak ^{2,5}	9959
	Reporter (RP1) Background Mean ^{2,5}	12.0

Bottle Number	Bottle Volume (mL)	Concentration (microspheres/mL)
1	120	1.250 x 10 ⁷
2	120	1.259 x 10
3	120	1.245 x 10
4	120	1.253 x 10
4	120	1.241 x 10
6	120	1.248 x 10
7	120	1.256 x 10

This certificate provides descriptive lot information, measured values, and assurance that quality requirements have been met for the components, intermediates, and finished product. Luminex Corporation certifies that the MicroPlex® Microspheres, Custom Volume lot defined above conforms to all prescribed acceptance criteria and is fit for its intended use.

QC Signature 31, December, 2000

- ¹ Reference applicable Progenitor Certificate of Quality for Progenitor lot information
² Measured at Luminex100/200 calibrated settings in PBS pH 7.4 with 1 mg/mL BSA
³ Gated Target Region Events - DD Gated Events
⁴ Gated Non-target Region Events - DD Gated Events
⁵ DD gate setting 8000 - 13500

Luminex**An ISO 13485:2003 Quality Certified Company**

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