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# Services

## Cell Services

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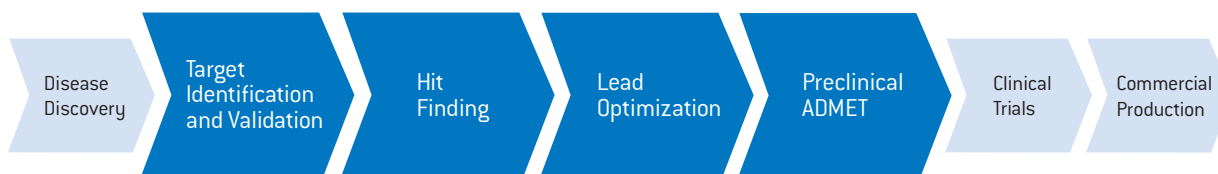
## Cell Services



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## Introduction



### Relevant Acceleration

Lonza has a reputation for expertise in many areas of cell biology, from the earliest research through biopharmaceutical production. Our presence in many pharmaceutical product and service markets helps us to understand the limitations of existing technologies and guides our efforts to find and develop better solutions for our customers.

Lonza Research Solutions is the market leader in primary cell biology. Over the past decade, the use of primary cells has been expanding. As primary cells are more difficult to handle than cell lines, we deliver complete protocols to address this. The importance of consistent tools in drug discovery is indisputable and we strive to standardize our highly relevant products.

### Our Solutions

We focus on the following areas of product and service development.

- Primary cell supply, including diseased cells, stem cell-derived cells, iPSC generation and banking, immortalized cells, cells containing biosensors, transfection of difficult cells and cell expansion services
- Improved prediction from cell models, including contextual cell-based assays for toxicity and mechanism of action assessment
- Making it easier for you, including reagent production, Cell Bio Services and Pluripotent Stem Cell Services are putting the assays you already use into biologically relevant primary cells

Our dedicated Drug Discovery Team gives you access to our expertise in many areas of cell biology. We trust that we have identified the products and services of value to drug discovery customers and we welcome the opportunity to discuss and develop them further with you.

## Cell Bio Services

Cell Bio Services was established to expand Lonza's current offering of quality primary cells. This service supports customers who require specialized cell products to meet their individual research needs and applications.

### Cell Isolation Services

We offer modifications to existing Lonza primary cells and beyond. Let us utilize our vast tissue network to provide you with the specific cell type you need.

### RAFT™ 3D Cell Culture Services

Lonza's patented RAFT™ 3D Cell Culture Systems is designed to closely mimic the *in vivo* environment of cells within 96- or 24-well plate formats. Utilizing Lonza's RAFT™ System, we can establish 3D Cell Culture Systems tailored to your needs.

### Cell Characterization

Using Lonza-generated recombinant cell lines, or a specific primary cell type in 2D or 3D cell culture systems, cell-based assays can be developed for functional testing of recombinant proteins and small molecules.

### Immortalization Services

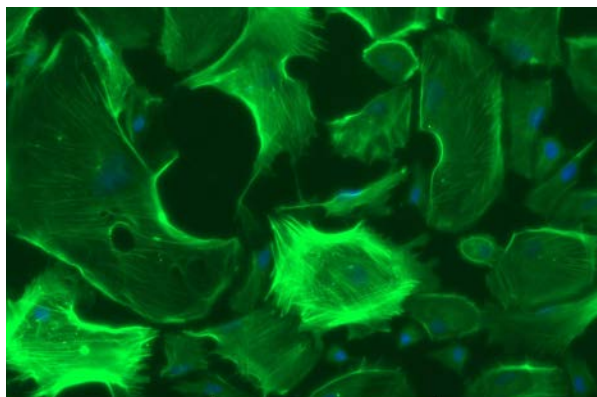
If your cell type of interest is not in our offering, the Cell Bio Services team can produce an immortalized cell line to your specifications.

### Generation of Recombinant Cells

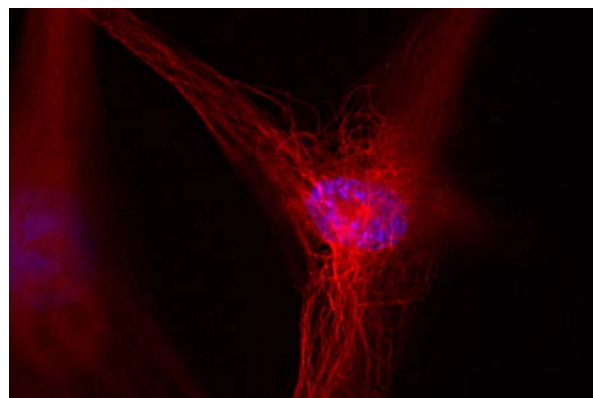
Utilize our extensive experience using difficult and hard to transfect cell lines to generate specific cell lines overexpressing your gene of interest.

### Cell Line Expansion and Banking

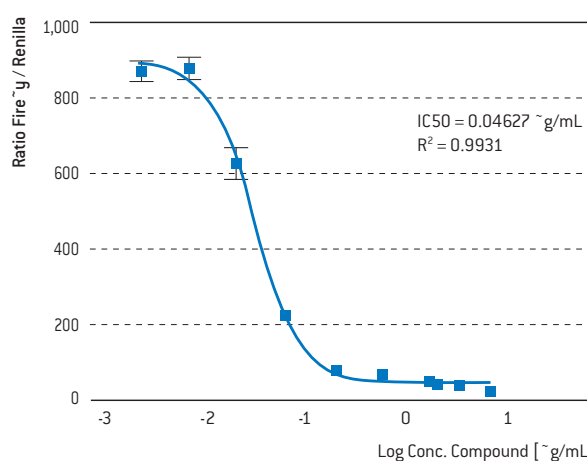
Cell line expansions are performed in accordance to your requirements and shipped to you in your preferred format, allowing you to focus on your assays and results.



Podocytes at P4, 10k a SMA overlay (20x)

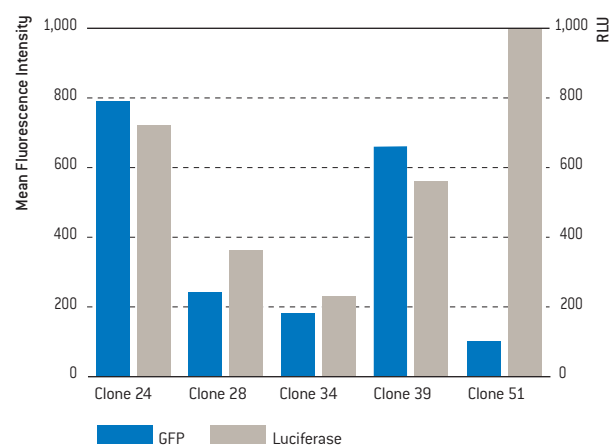


Dermal fibroblasts fixed and stained after 11 days in RAFT™ System.



Compound treatment of sarcoma cells stably expressing an inducible luciferase reporter construct.

### Double Stable Jurkat E6.1



GFP and luciferase expression level. Single-cell derived Jurkat E6.1 clones were generated by cotransfection of pmaxFP™-green N and a luciferase plasmid using Nucleofection and limited dilution.

[www.lonza.com/cellsondemand](http://www.lonza.com/cellsondemand)



## Pluripotent Stem Cell Services

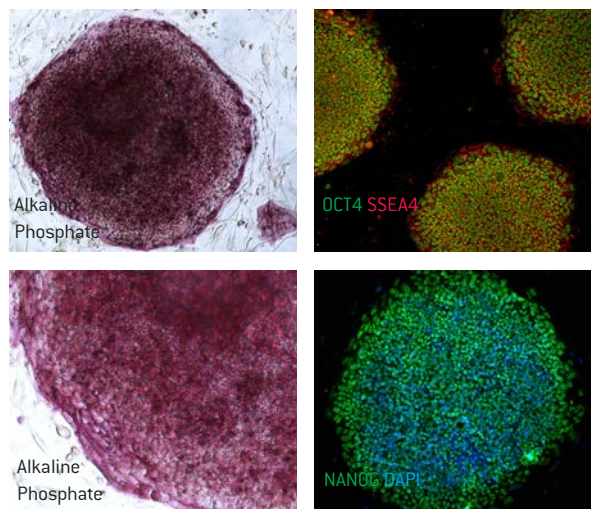
Lonza established a new strategic vision to become the leading supplier to the regenerative medicine industry. To realize this vision Lonza created the Pluripotent Stem Cell Innovation Center. Pluripotent stem cells (PSCs) have the ability to generate any of the 20<sup>+</sup> cell types in the human body. Because of this unique attribute, these cells have great potential in basic research, drug discovery, and cell replacement therapies.



Lonza has built up expertise, capacity, and capabilities in pluripotent stem cell research and their application to cGMP manufacturing. Researchers can now access this expertise through our PSC service offering from iPSC generation to process development and differentiation.

Our services span the full value chain of pluripotent stem cells from tissue acquisition to differentiation:

- **Tissue Acquisition** – We have a dedicated team that procures both research and cGMP grade tissue according to the highest ethical standards and in compliance with government regulations
- **Reprogramming** – We offer cGMP and non-cGMP iPSC generation under feeder- and feeder-free conditions using a zero-footprint technology
- **Growth / Expansion / Banking** – We have established protocols using all of the common medium, matrix, and passaging methods. We also have the infrastructure and resources to support small- and large-scale culture and banking of PSCs
- **Characterization** – We offer all the standard methods of characterizing PSCs including thawing efficiency, mycoplasma and sterility testing, karyotype analysis, short tandem repeat genotyping, pluripotency marker expression (flow cytometry and immunofluorescence), and pluripotency assays (embryoid body and teratoma formation)
- **Differentiation** – We have established protocols for the production of PSC-derived motor neurons, dopaminergic neurons, and neural stem cells. We also have development programs underway to add to our differentiation portfolio of therapeutically relevant cell types
- **Process development** – Over the years we have built up expertise in the differentiation of high purity, functional cell types. Our team is well-versed in technology transfer and optimization of manufacturing protocols



Lonza iPSCs express hESC-associated markers POU5F1/OCT4 (green) and SSEA4 (red) counterstained with DAPI (blue).

## Testing Services



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## QC Testing Solutions Services

Another means by which Lonza continues to strive to meet the needs of our QC microbiology customers is by providing complementary contract testing services for many of our QC microbiology related products.

### QC Testing Solutions Services offered:

- Endotoxin Testing Services
- Recertification Services


QC Testing Solutions Services are presently operated out of two global Lonza facilities to provide our customers with worldwide access to our current service capabilities\*:

- Lonza Walkersville, Maryland, USA
- Lonza Verviers, Belgium (Pre-paid Testing only)

\*Not all testing services are offered in both locations.

Please contact your local sales representative or Customer Service for more information about where and how to submit samples to one of our service locations above.

Register for our QC Testing Solutions e-newsletter to stay up to date on the latest endotoxin detection products and services. Featured content includes technical tips, white papers and webinar events.

 [www.lonza.com/hsc](http://www.lonza.com/hsc)



## Endotoxin Detection Testing Services

Lonza's Endotoxin Detection Testing Services offer you routine as well as customized endotoxin testing. Our facilities provide expertise in gel clot, kinetic chromogenic, and kinetic turbidimetric LAL methods, as well as the Pyrogene™ Recombinant Factor C Assay.

### USP, EP and FDA Compliant

All pharmaceutical grade endotoxin testing is performed in accordance with current regulatory documents such as the U.S. and European Pharmacopeia (USP and EP) Bacterial Endotoxins Test (BET), the 2012 U.S. Food and Drug Administration (USFDA) Guidance for Industry, and the USP monograph for medical device testing. These documents originate from or are acceptable to the major Pharmacopeia and their regulatory authorities.

Whether you are from a university, research laboratory or a Quality Control laboratory in a major pharmaceutical company, Lonza has the capabilities you need for reliable, accurate and confidential results.

### ■ Benefits

- Market leader in endotoxin detection testing systems
- Technical expertise and full service reporting
- USP and EP compliant

### STAT Testing Available\*

For customers who may need faster turn-around times, Lonza offers an expedited testing service for preliminary screening, endotoxin determination, and the Endotoxin Challenge Vial™ test. Our STAT service delivers preliminary results in 4 days or less via email. STAT requests require prior approval from Lonza's Endotoxin Testing Services.

\*STAT testing is only available in the US.

 [www.lonza.com/endotestserv](http://www.lonza.com/endotestserv)

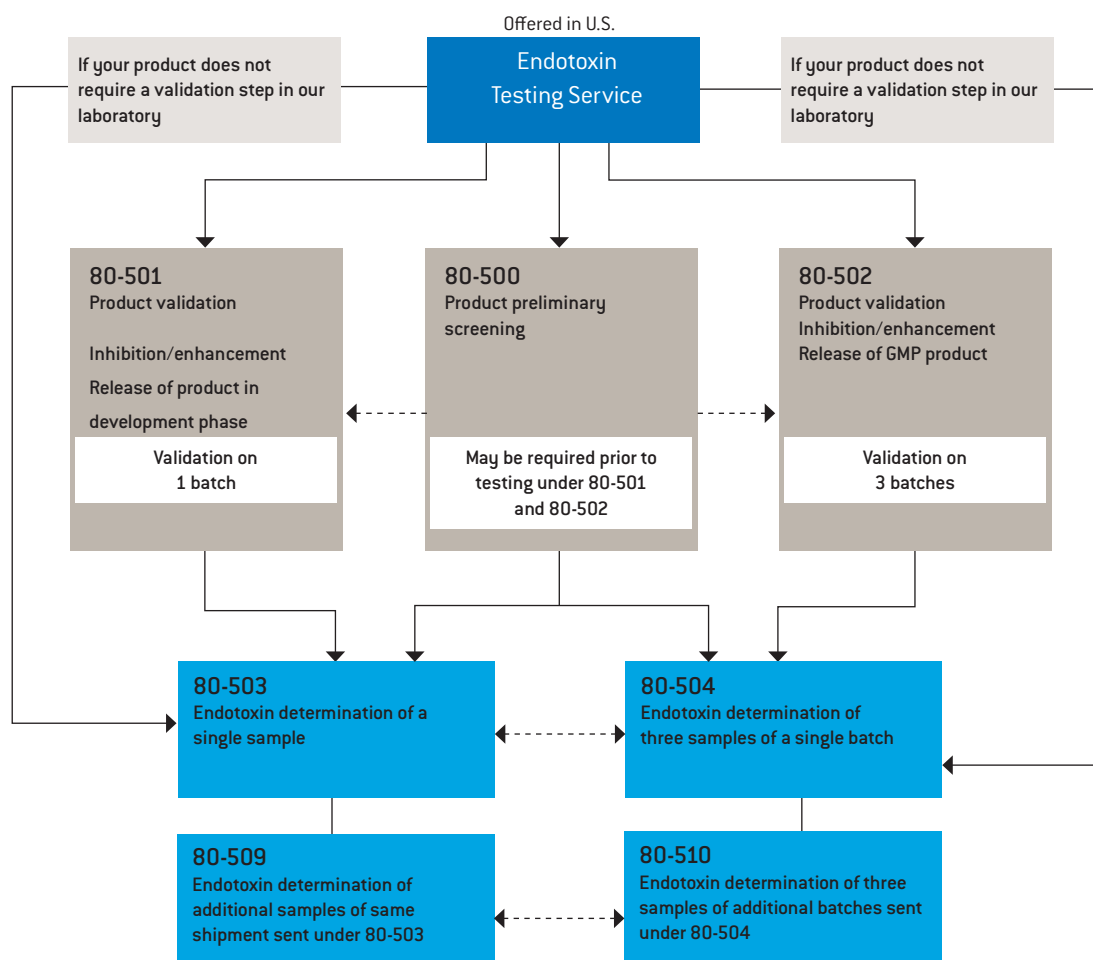


Figure 1. Endotoxin Testing Service.

## Endotoxin Detection Testing Services

Continued

### Pre-paid, Mail-in Anytime Testing Service

Available in Europe, the Endotoxin Testing Service offers a low cost mail-in anytime service for users who do not require testing according to pharmaceutical or medical device regulations.

This type of endotoxin testing is suitable for a wide range of non-standard tests such as:

- Samples from cell culture materials
- Samples of DNA plasmids
- Water samples from autoclaves or dialysis machines
- Dialysis water or fluids
- Research samples

Samples received using this service will be tested at the dilutions indicated in the Pre-paid Endotoxin Testing Service diagram below.

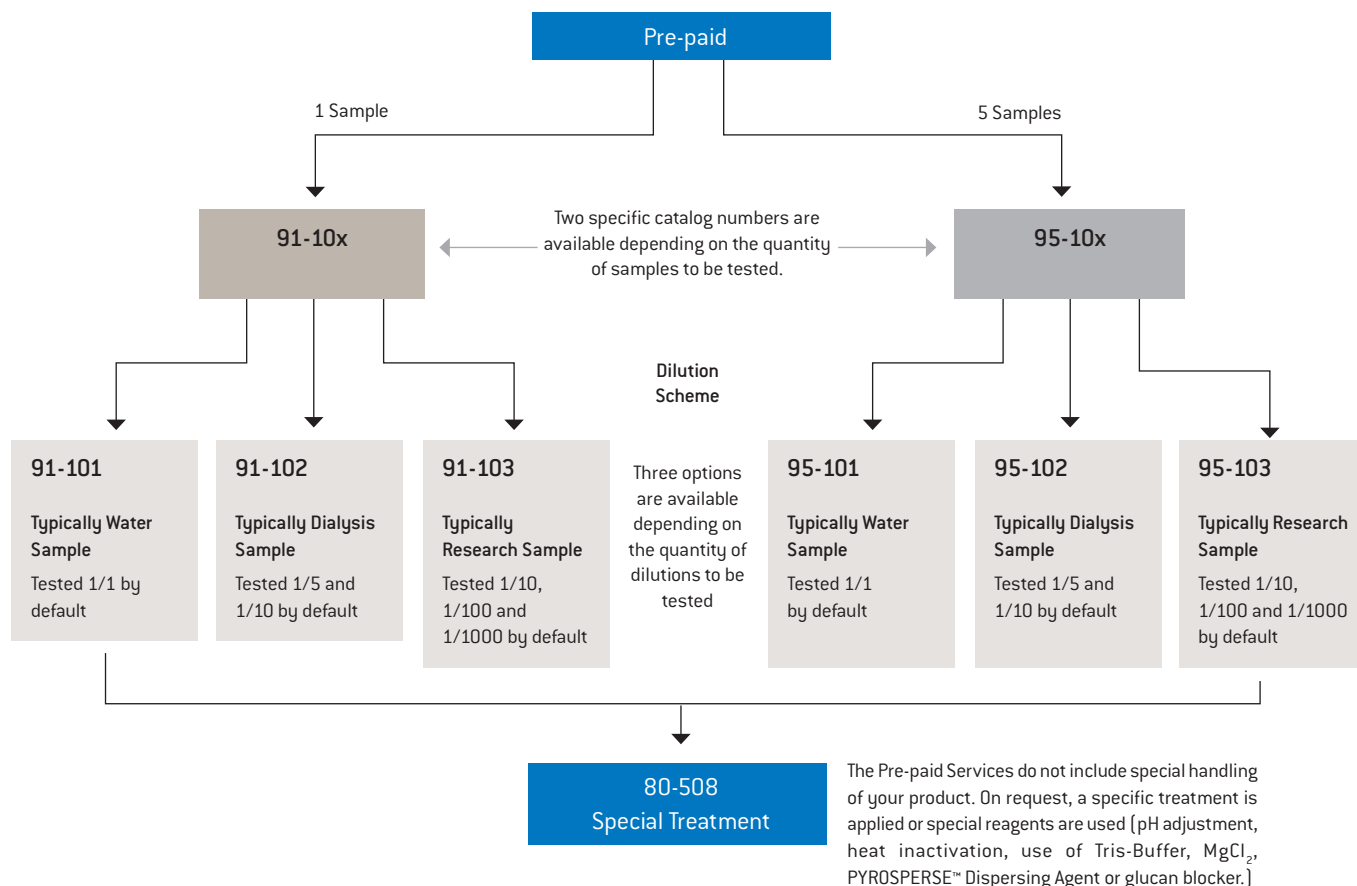
### ■ Benefits

- Low cost, convenient and quick endotoxin testing using Kinetic-QCL™ LAL Assay
- Quick, easy ordering process via web, phone, or fax
- Pre-addressed packaging for smooth delivery to Lonza's Endotoxin Testing Service

To utilize the Pre-paid Service, simply order one or more of the Rapid Endotest packs, place your sample in the sample containers provided, and mail the pre-addressed envelope back to Lonza.

Samples will be tested and results sent to the customer within 5 days of receipt.

 [www.lonza.com/endotestserv](http://www.lonza.com/endotestserv)



**Figure 2.** Pre-paid Testing Service, available in Europe. This service is not available in the US.

## Endotoxin Detection Testing Services

Continued

### Ordering Information – Endotoxin Detection Testing Services (US only)

Cat. No. NA	Cat. No. EU	Product Name	Product Description
80-500		Product Preliminary Screening	
80-501		Product Validation Inhibition/Enhancement	Release of product in development phase. Validation of one batch.
80-502		Product Validation Inhibition/Enhancement	Release of GMP product. Validation of three batches.
80-503		Endotoxin Determination of single sample	
80-509		Additional samples of same shipment sent under 80-503	
80-504		Endotoxin Determination of three samples of a single batch	
80-510		Endotoxin determination of three samples of additional batches sent under 80-504	
80-508		Unusual sample treatment or handling charge (per hour)	
80-514		Exclusion of $\beta$ -D-glucan activity testing	
80-535		Depyrogenation Endotoxin Challenge Vial™ Test	
80-544		Sample container screening	
80-500S		STAT: Product preliminary screening of one batch	
80-503S		STAT: Endotoxin determination of single sample	
80-509S		STAT: Additional samples of same shipment sent under 80-503	
80-504S		STAT: Endotoxin determination of three samples of a single batch	
80-510S		STAT: Endotoxin determination of three samples of additional batches sent under 80-504	
80-514S		STAT: Exclusion of $\beta$ -D-glucan activity testing	
80-535S		STAT: Depyrogenation Endotoxin Challenge Vial™ Test	

### Ordering Information – Pre-paid Endotoxin Detection Testing Services (Europe only)

Cat. No. NA	Cat. No. EU	Product Name	Product Description
	BE91-101	Rapid-Endotest Single Water Sample	
	BE91-102	Rapid-Endotest Single Dialysis Fluid Sample	
	BE91-103	Rapid-Endotest Single Research Sample	
	BE95-101	Rapid-Endotest Five Water Samples	
	BE95-102	Rapid-Endotest Five Dialysis Fluid Samples	
	BE95-103	Rapid-Endotest Five Research Samples	

Please contact your local Customer Service Team to obtain general information and the appropriate sample submission forms.

#### U.S. Endotoxin Testing Services

E-mail: [scientific.support@lonza.com](mailto:scientific.support@lonza.com)

#### European Endotoxin Testing Services

E-mail: [scientific.support.eu@lonza.com](mailto:scientific.support.eu@lonza.com)

## Recertification Services

### Recertification Service for Stepped Neutral Density Test Plates

The Stepped Neutral Density (SND) and Absorbance (Universal) Test plates provide the ELx808™ Microplate Reader user with the ability to manage risk and help assure the reader is functioning properly between the recommended six-month preventive maintenance visits.

The ELx808™ Readers are robust instruments designed to provide years of reliable performance for endotoxin detection and other absorbance-based assays. In following current Good Manufacturing Practices (cGMP), the reader's performance should be verified and documented at regular intervals.

In order to properly assess the reader performance, the plates used in the testing must be shown to be acceptable. Plate manufacturers recommend the SND plate be recertified at least once per year.

#### ■ Benefits

- Manages risk and helps ensure optimal performance of the ELx808™ Readers
- cGMP compliant processes, including testing of multiple parameters
- NIST-traceable testing conducted in an ISO 9001 certified facility

#### ■ Parameters tested


- Absorbance accuracy (linearity and slope)
- Precision (reproducibility of results)
- Wavelength accuracy
- Optical alignment
- Detailed physical inspection



#### ■ Reports include

- Physical inspection observations
- Coefficient of variation (%CV) for each plate standard filter
- Slope, R-value and Y-intercept linearity data
- Reader and plate uncertainty values
- Approval by a Quality Assurance representative
- Recertification due date (default is 12 months)

Please refer to the table below for additional details and ordering information. For testing parameters, reports and pricing, please contact your local sales representative.

 [www.lonza.com/recert](http://www.lonza.com/recert)

### Ordering Information – Recertification Services

Cat. No. NA	Cat. No. EU	Product Name	Product Description
85-011-SND	85-011-SND	Stepped Neutral Density Plate Recertification Service	Two filter wavelengths, 405 nm and 340 nm
85-012-SND	85-012-SND	Stepped Neutral Density Plate Recertification Service	Each additional filter wavelength
85-011BA	85-011BA	Stepped Neutral Density Plate Recertification Service	As Found and As Left testing at two filter wavelengths 405 nm and 340 nm
	85-013	Absorbance (Universal) Test Plate	Recertification Service*

SND plate recertification services offered for Lonza plate part number 25-342 only.  
\*Recertification services for BioTek® Instruments, Inc., plate part number 7260522 (Absorbance Test Plate) are only available in Europe.