

IL-15

IL-7

IL-21

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GMP Grade Cytokines

Strict Quality Control Standards

GMP Grade Quality Management System

Accelerating Global Regulatory Approval of Biological Products

GMP Grade Cytokines

Immune cell therapy, represented by CAR-T\NK cells has shown significant therapeutic effects in the treatment of various malignant tumors such as leukemia, lymphoma, and multiple myeloma. As more and more immune cell therapies enter the stage of clinical research, quality management systems have attracted more attention from the industry. During the process of immune cell therapy products, cytokines such as IL-15, IL-7, IL-21 are used as a key raw material for T\NK cell activation and amplification. FDA and Chinese Pharmacopoeia have relevant regulations about the use of these key materials. The FDA CMC recommends using FDA-approved or clinical-grade materials. For Chinese Pharmacopoeia regulations, priority should be given to the use of low-risk materials such as GMP grade materials as opposed to non-GMP grade materials. Therefore, safe, effective, and compliant cytokines are crucial for the success of R&D processes and applications of immune cell therapy drugs.

ACROBiosystems is committed to the development of high-quality reagents that are used in the clinical stage of immune cell therapy drugs. Based on the GMP-grade quality management system platform, combined with the production specifications of cell therapy drugs, we have successfully developed a series of high-quality GMP-grade cytokines such as IL-15, IL-7, IL-21. These products are produced with strict quality management and drug-level release testing standards. Our GMP-grade cytokines* can better assist the clinical research of immune cell therapy drugs and accelerate the global regulatory approval of biological products.

**ACROBiosystems GMP grade products are designed for research, manufacturing use, or ex vivo use. CAUTION: Not intended for human in vivo applications.*

ACROBiosystems GMP Quality Management System

■ Quality Management System

- ✓ Manufactured and QC tested under GMP compliance
- ✓ Designed under ISO 9001:2015 and ISO 13485:2016
- ✓ Animal-Free materials
- ✓ Materials purchased from approved suppliers
- ✓ ISO 5 cleanrooms and automatic filling equipment
- ✓ Qualified and well-trained personnel
- ✓ Fully batch production and control records
- ✓ Equipment maintenance and calibration
- ✓ Validation of analytical procedures
- ✓ Stability studies conducted
- ✓ Comprehensive regulatory support files
- ✓

Automatic filling equipment



Sterilization equipment



Strict quality standards (Example for GMP IL-15 release standard)

- ✓ SDS-PAGE purity >95%
- ✓ Endotoxin level less than 10 EU/mg
- ✓ Residual Host Cell DNA content less than 0.02ng/μg
- ✓ Residual Host Cell Protein content less than 0.5ng/ug
- ✓ Biological activity >0.8 x 10⁷ IU/mg
(Reference the WHO Human IL-15 (NIBSC code: 90/530) as standard)
- ✓ Microbial testing
- ✓ Mycoplasma testing
- ✓ In vitro virus assay
- ✓ Comprehensive stability data support
(accelerated, freeze-thaw, long-term, shipping stability verification)
- ✓ Batch-to-batch consistency
- ✓

Product Features

Strict Quality Control Standards

16 quality control standards
Excellent Safety Profile
(testing for sterility, mycoplasma, endotoxin, and residual impurities).
High stability and batch-to-batch consistency

GMP Grade Quality Management System

ISO 5 cleanrooms used for filling
Raw materials and packing materials are registered
Facilities are available for online and on-site audits

Accelerating Global Regulatory Approval of Biological Products

A comprehensive set of regulatory documents is available
Validation reports for analysis methods are available by request
FDA DMF filing in progress



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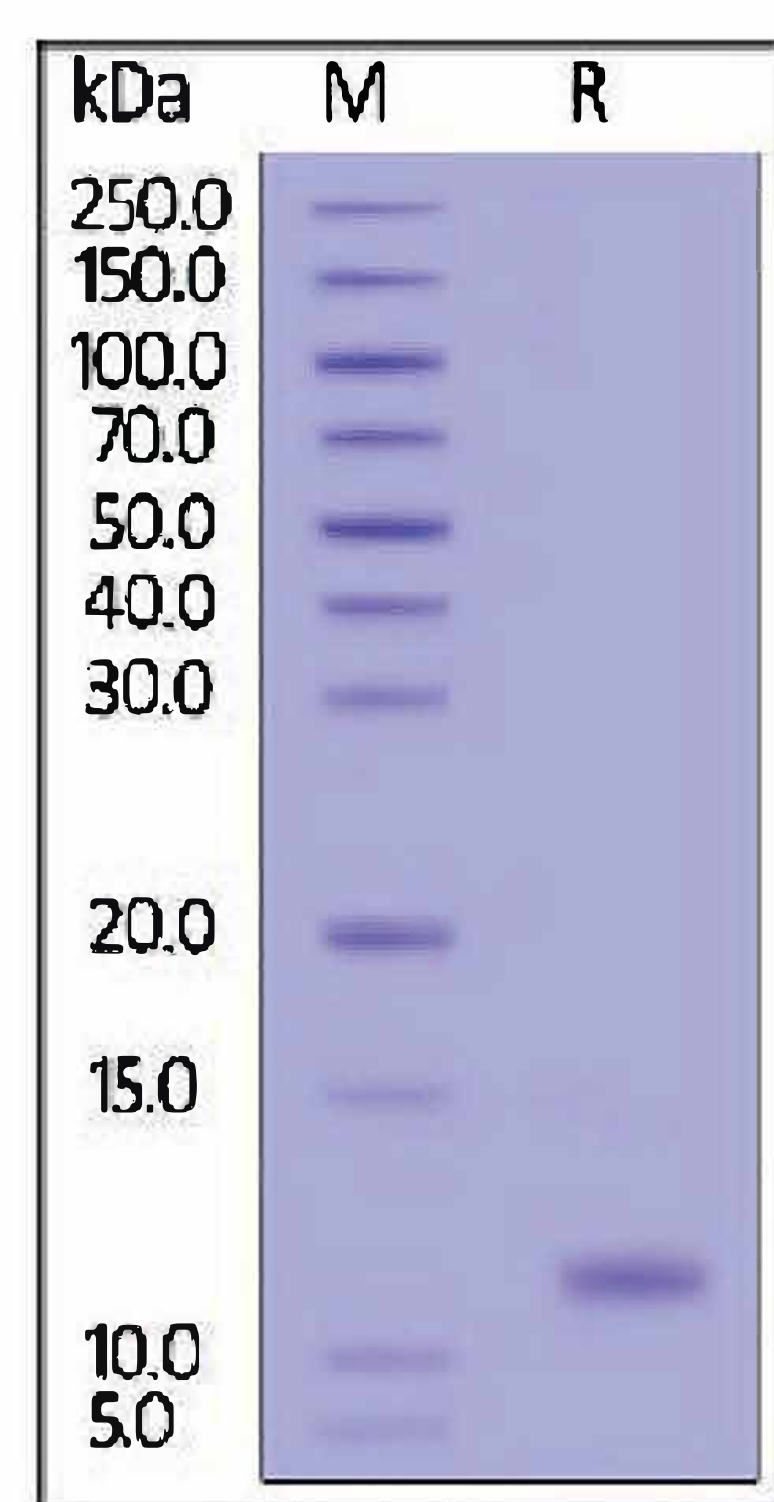
Product list

Molecule	Product description	Cat.No.
<u>IL-15</u>	<u>GMP-L15H13</u>	GMP Human IL-15
<u>IL-7</u>	<u>GMP-L07H14</u>	GMP Human IL-7
<u>IL-21</u>	<u>GMP-L21H18</u>	GMP Human IL-21

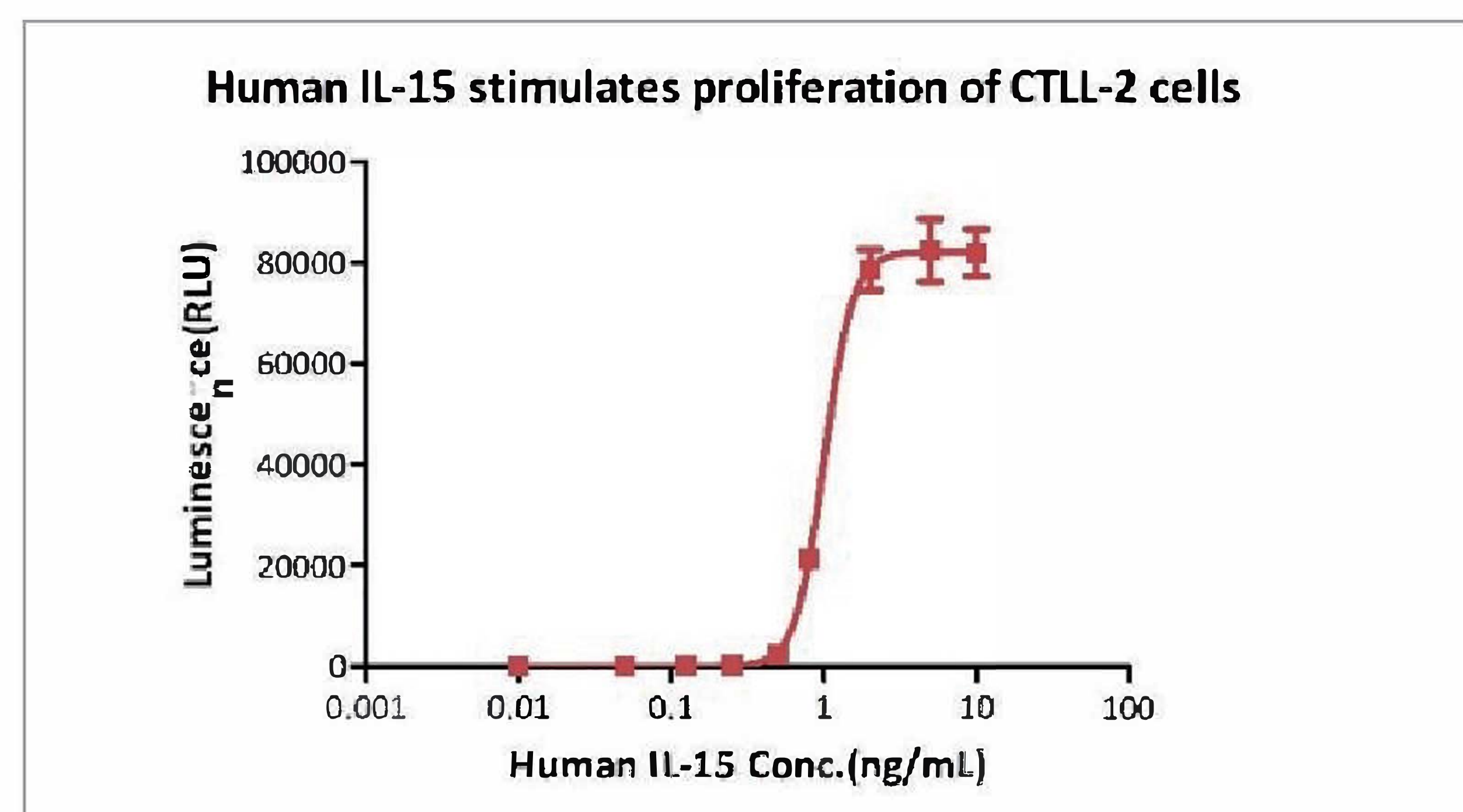
Data

► High purity

High purity than 90% of GMP Human IL-15



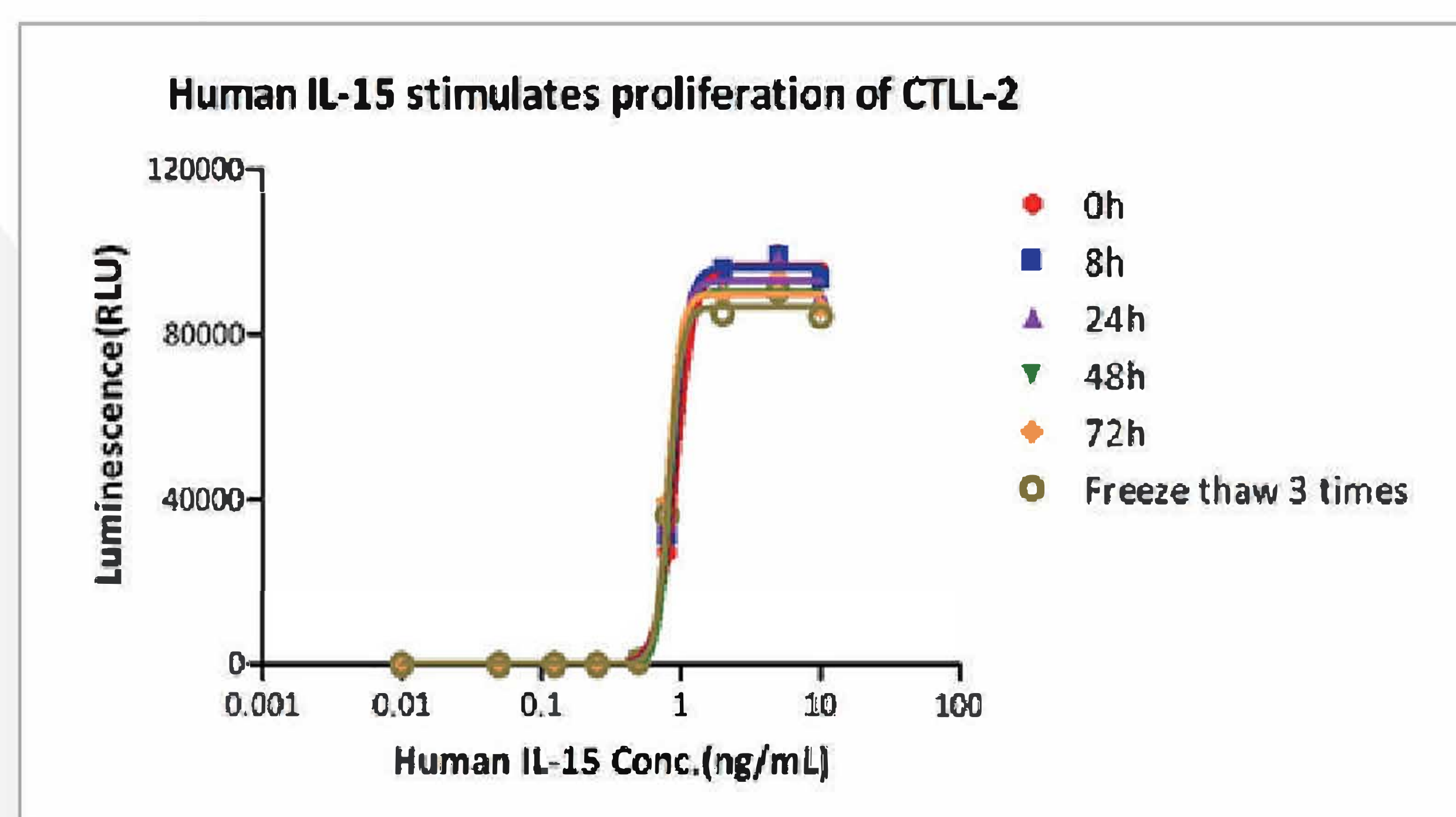
► High bioactivity



GMP Human IL-15 (Cat. No. [GMP-L15H13](#)) stimulates the proliferation of CTLL-2 cells. The EC₅₀ for this effect is 1.004 ng/mL, corresponding to a specific activity of $> 0.8 \times 10^7$ IU/mg, which is calibrated against human IL-15 WHO International Standard (NIBSC code: 95/554).

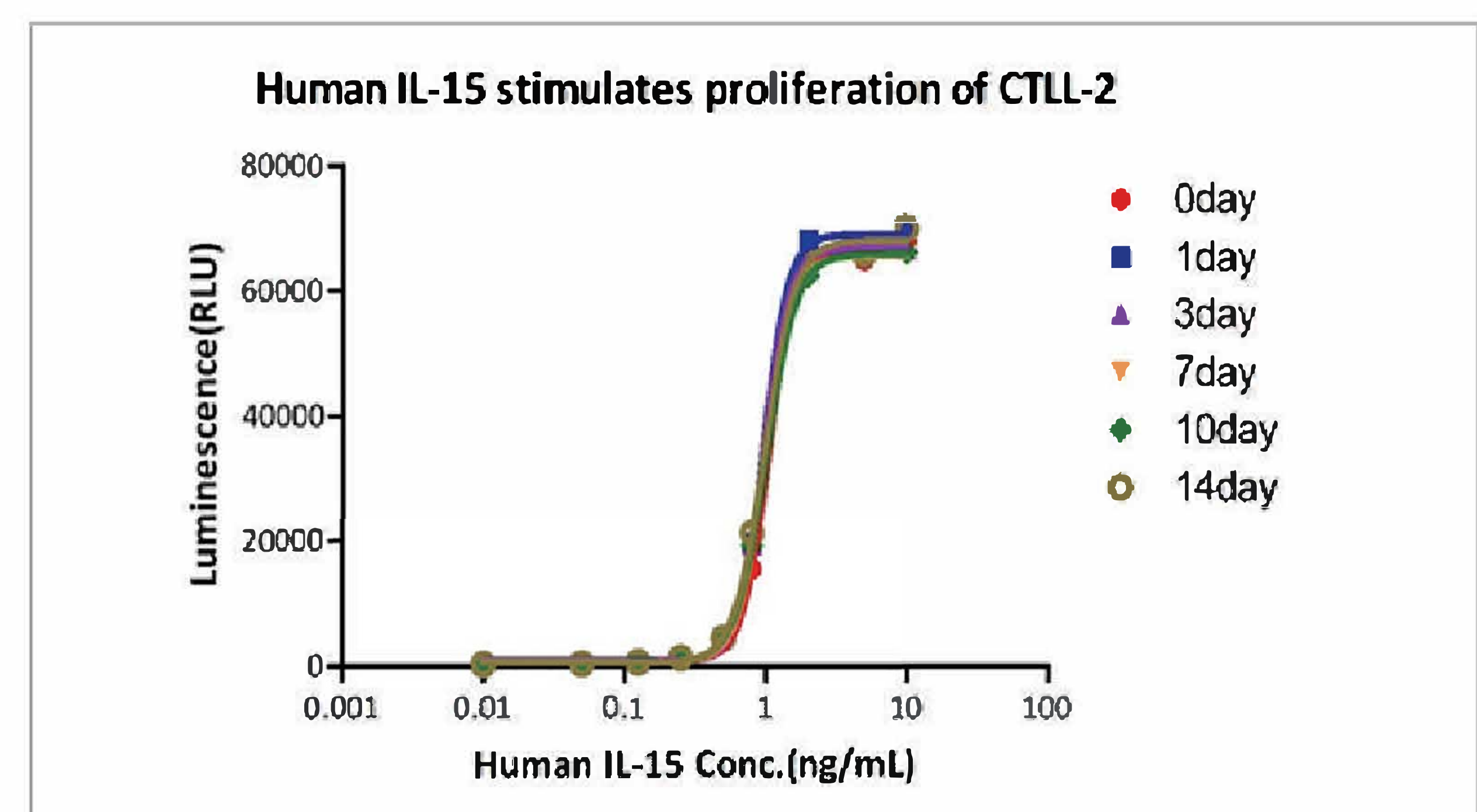
► High stability

Validation of Accelerate and Freeze-thaw stability



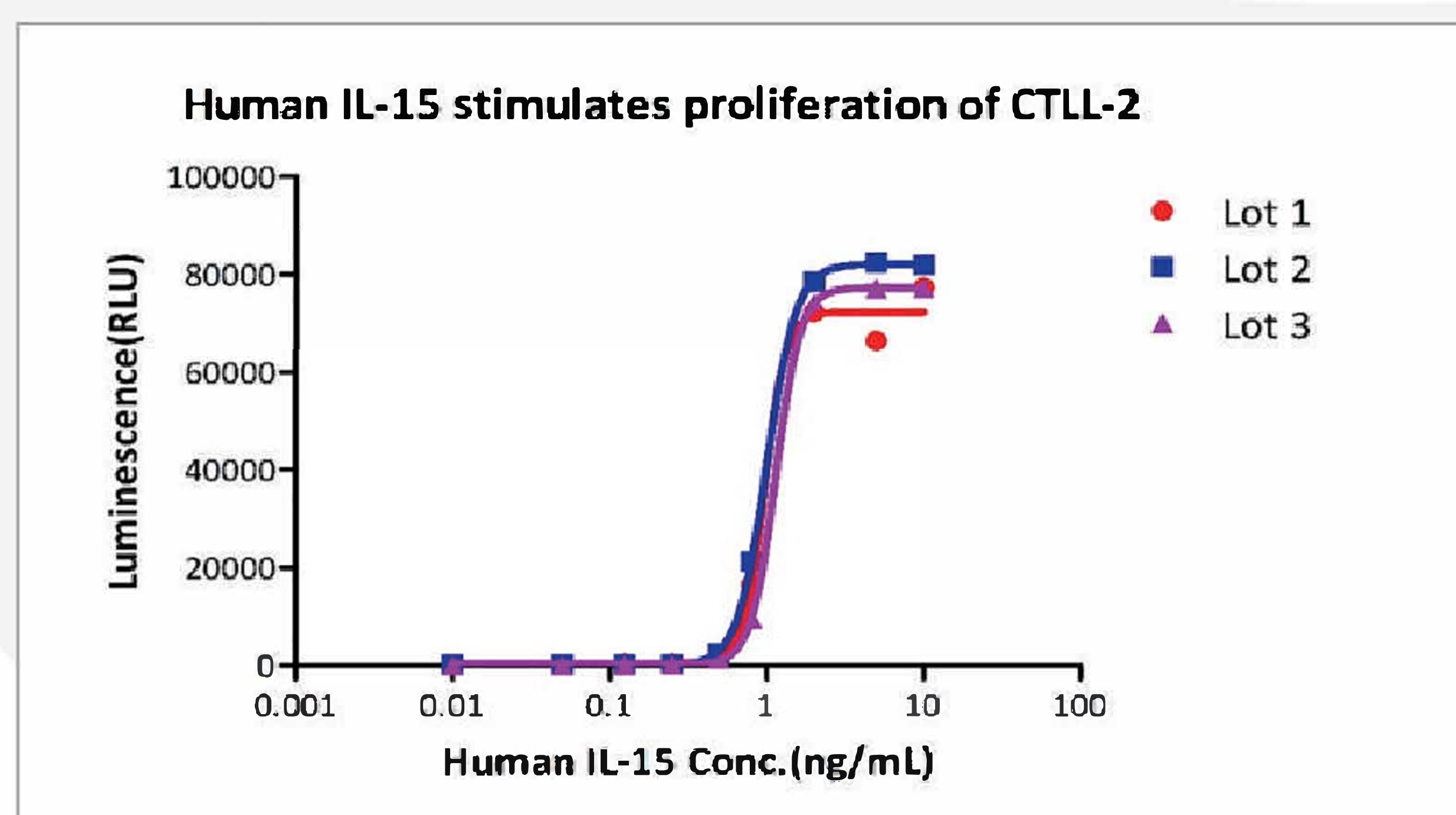
GMP Human IL-15 ([GMP-L15H13](#)) is stable in undiluted samples at 25°C for 72 hours and freeze-thaw 3 times without performance reduction.

Long-term stability testing (4°C)



GMP Human IL-15 ([GMP-L15H13](#)) is stable in undiluted samples at 4 °C for 14 days without performance reduction.

► High batch-to-batch consistency



Bioactivity of three different batches of GMP Human IL-15 ([GMP-L15H13](#)) verified by cell-based assay, and the result shows very high batch-to-batch consistency.

Her2 BAFFR IL-7
Fc Receptor Siglec-10
Biotinylated Protein
 PD-L1 VEGF165 CD3 epsilon
CD20 PD-1 BCMA
CD27 PVRIG
CD47 PSMA
CFGL1 TFPI
Siglec-15 Integrin
CD24 CD3E & CD3D IL-21
CD19 FcRn PCSK9
IL-2 R alpha
CAR-T Target Protein
Biotinylated Protein
BCMA CD200 GITR Nectin-4
VEGF165 PCSK9 IgG1 Fc CD40 VEGF165 CD73 FGLI
IL-15
SIRP alpha ADA Service Immune Checkpoint Protein
Nectin-4 Biotinylated Protein CD3E & CD3D PSMA IL-2
SPR /BLI analytical service
Glypican 3 Integrin
ADA Service CD69 MICA
LAG-3 EGF R B7-H3 BCMA CD30 MICA CD3E & CD3G CD20
Integrin TIGIT TGF-beta 1
4-1BB Siglec-15



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