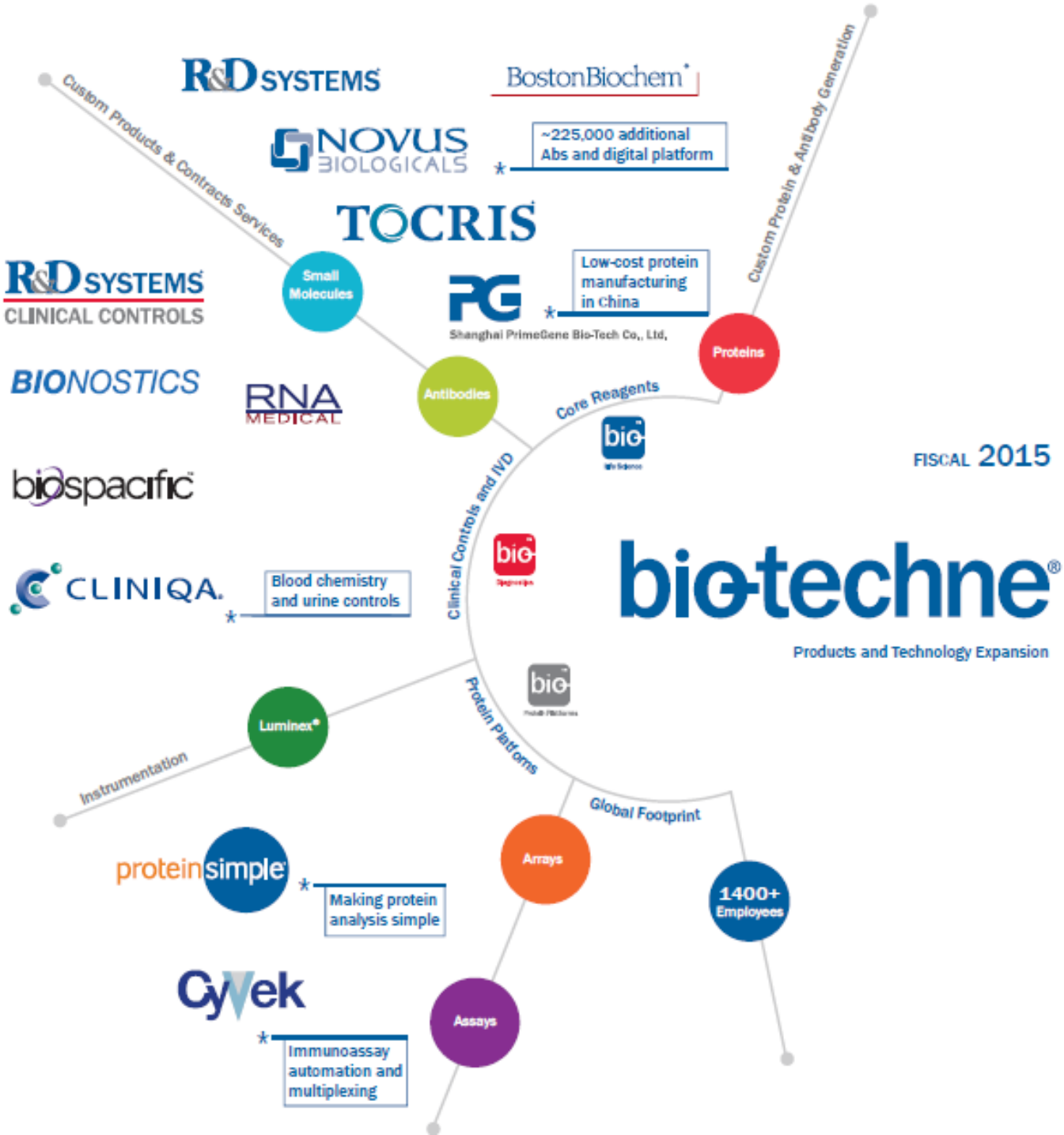
Specifications on the Datasheets are not just Numbers —

R&D Systems' High Quality Proteins

Damon Yuan, Ph. D.
Bio-Techne China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NOVUS BIOLOGICALS
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R&D SYSTEMS CLINICAL CONTROLS
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Shanghai PrimeGene Bio-Tech Co,, Ltd,
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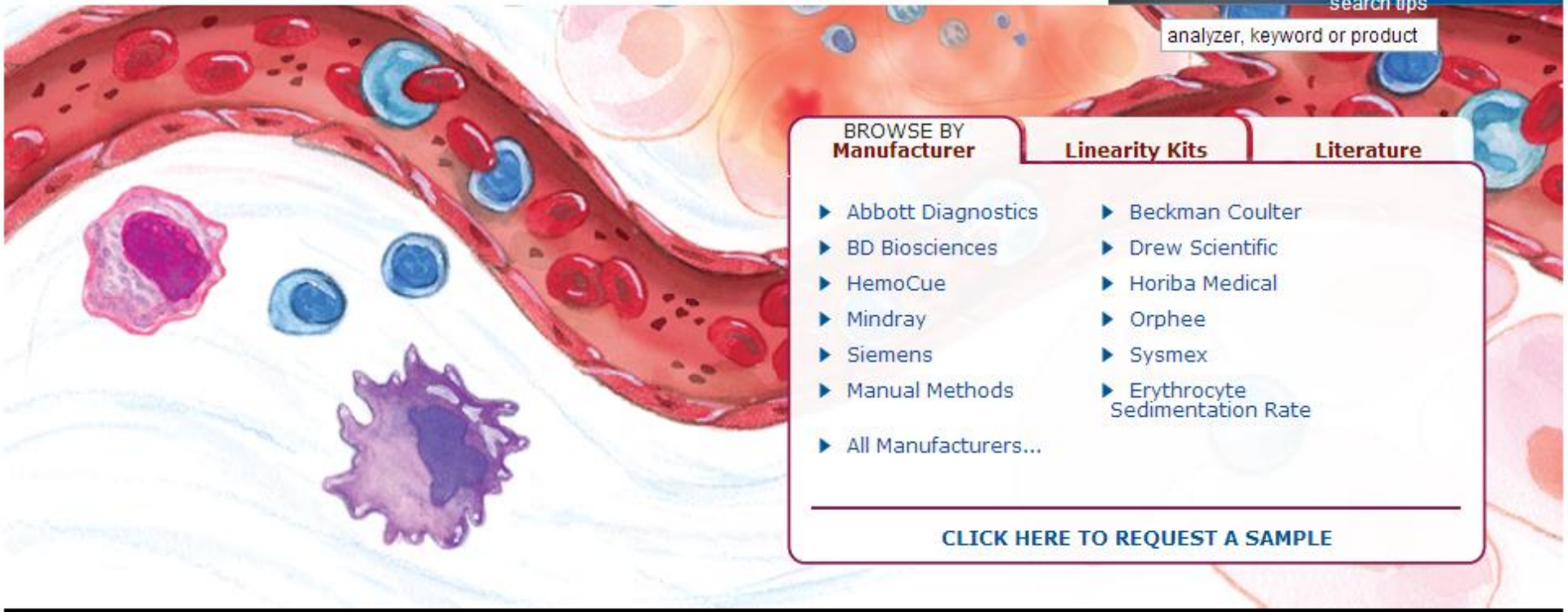

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Product Datasheet

MSDS

COA

Bulk Lots

- N端测序
- 浓度检测
- 分子量的确定
- 纯度检测
- 生物活性测试
- 总氨基酸分析
- 质谱分析

Bottling Lots

- 生物活性分析

R&D Systems
Tools for Cell Biology Research™

Recombinant Human IL-4 GMP

Catalog Number: 204-GMP

DESCRIPTION

Source	*E. coli*-derived His25-Ser153, with an N-terminal Met Accession # P05112 Produced using non-animal reagents in an animal-free laboratory. Manufactured and tested under cGMP guidelines.
N-terminal Sequence Analysis	Met-His_{25}-Lys-(Cys)-Asp-Ile-Thr-Leu-Gln-Glu
Predicted Molecular Mass	15.1 kDa

SPECIFICATIONS

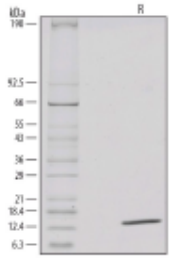
SDS-PAGE	14 kDa, reducing conditions
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323. The ED_{50} for this effect is typically 0.05-0.2 ng/mL. The specific activity of recombinant human IL-4 is approximately 2.9 x 10^4 IU/µg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE under reducing conditions and visualized by silver stain.
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS. See Certificate of Analysis for details.

PREPARATION AND STORAGE

Reconstitution	Reconstitute at 100-200 µg/mL in PBS.
Shipping	The product is shipped at ambient temperature. Upon receipt, store it immediately at the temperature recommended below.
Stability & Storage	**Use a manual defrost freezer and avoid repeated freeze-thaw cycles.** • 12 months, -20 to -70 °C as supplied. • 1 month, 2 to 8 °C under sterile conditions after reconstitution. • 3 months, -20 to -70 °C under sterile conditions after reconstitution.

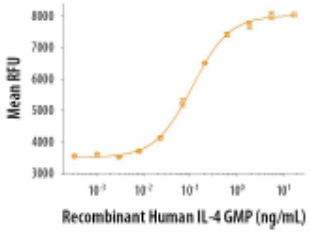
DATA

SDS-PAGE



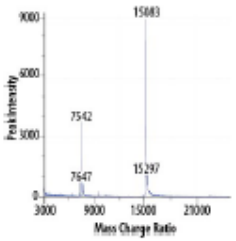
1 µg/lane of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) was resolved with SDS-PAGE under reducing (R) conditions and visualized by silver staining, showing a single band at 14 kDa.

Bioactivity



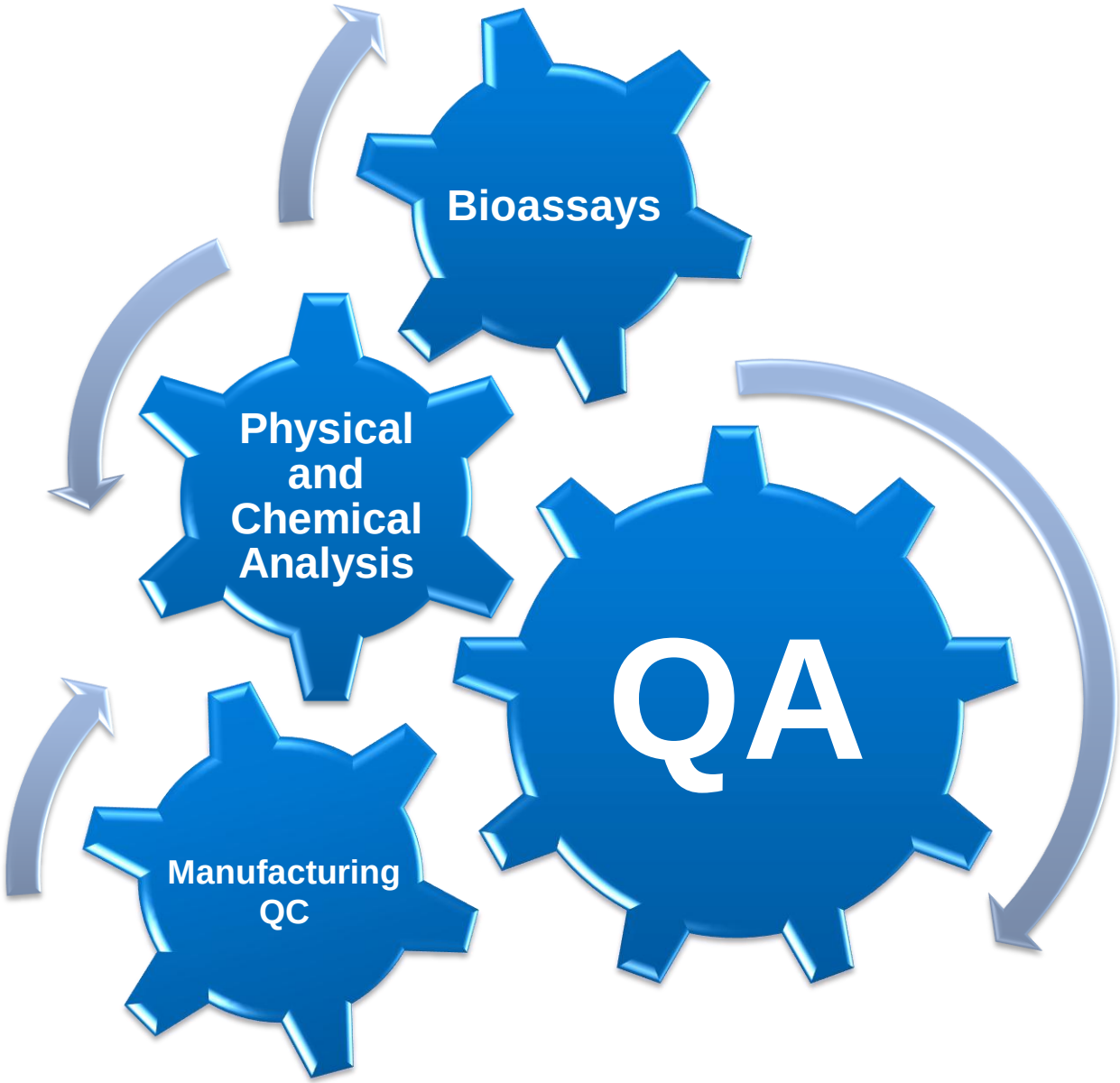
GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP) stimulates proliferation of TF-1 human erythroleukemic cells. The ED_{50} is typically 0.05-0.2 ng/mL.

Mass Spectrometry

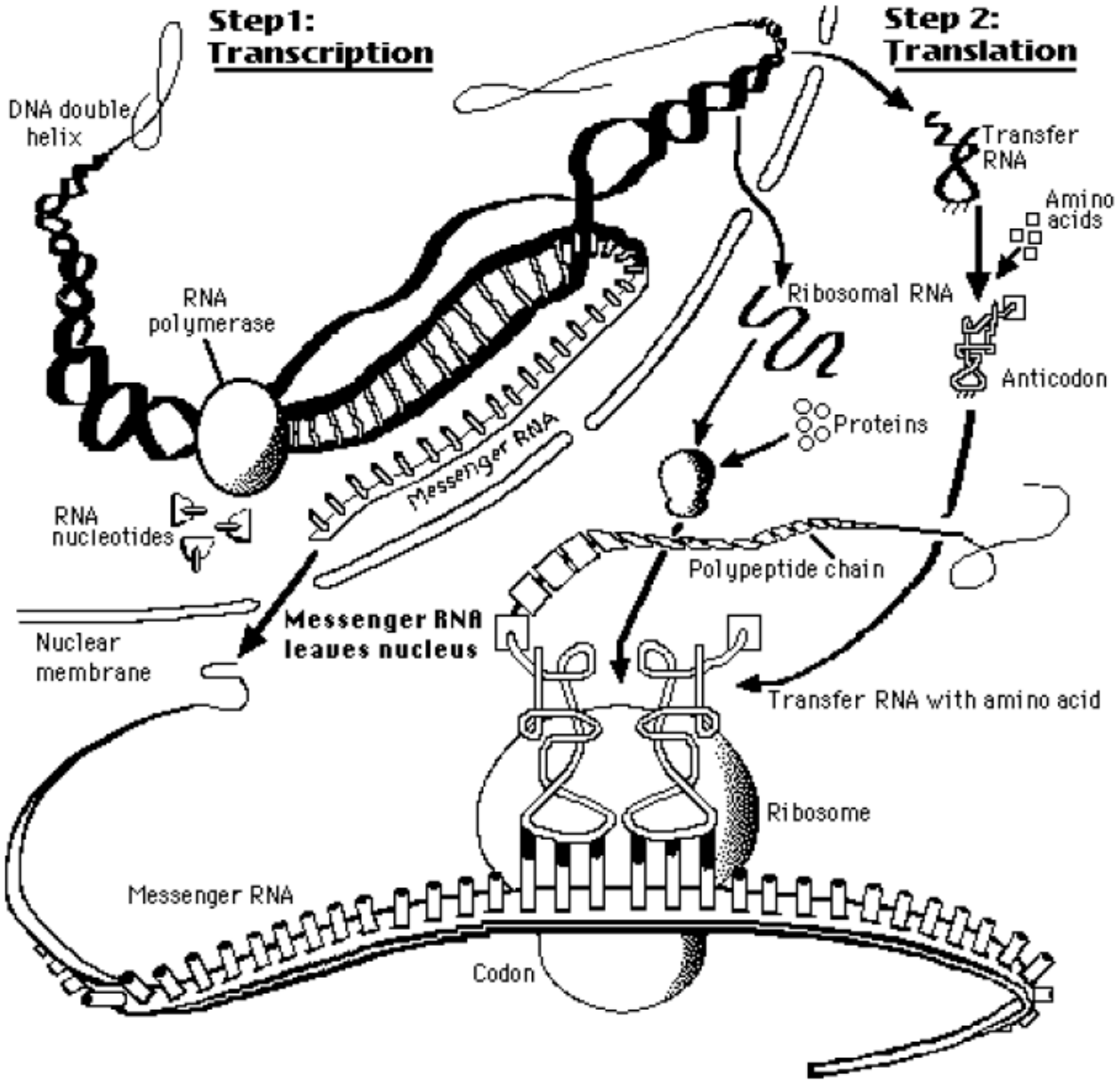


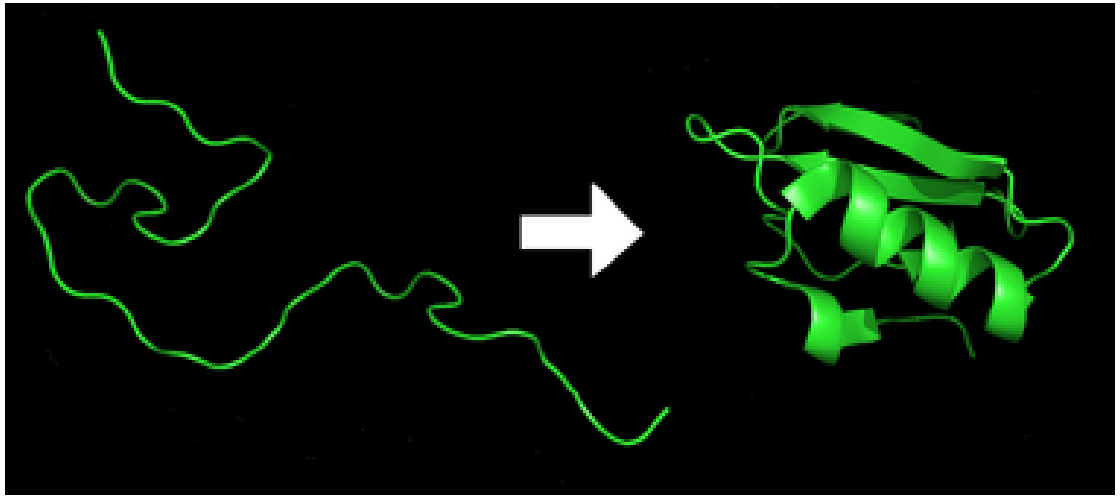
MALDI-TOF analysis of GMP-grade Recombinant Human IL-4 (Catalog # 204-GMP). The major peak at 15083 Da corresponds to the calculated molecular mass, 15094 Da. The minor peak at 15297 Da is a matrix-associated artifact of the MALDI-TOF.

Four Quality Control Departments

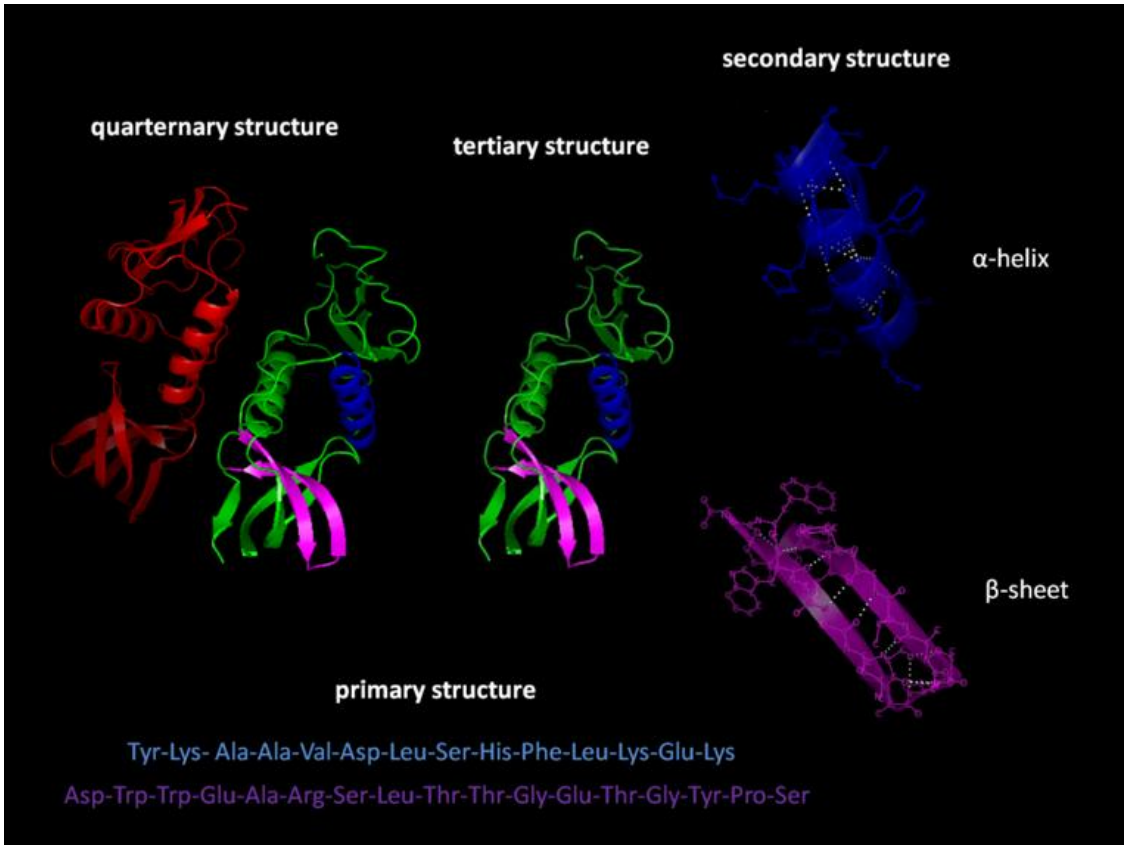


Basics of Protein Expression





线性的多肽链没有活性，蛋白质必须折叠成特定的空间结构才具有活性。



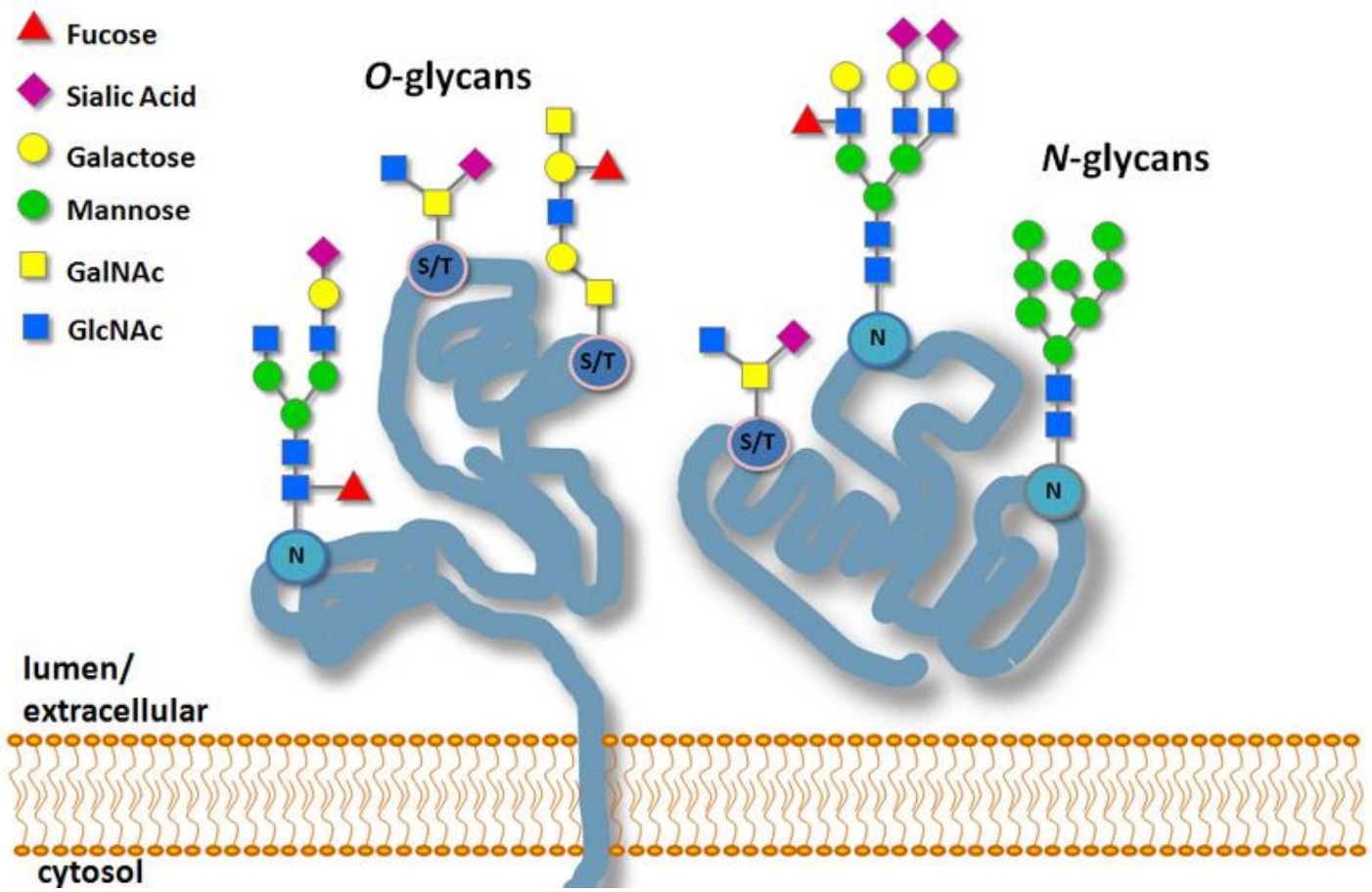
一级结构：氨基酸序列

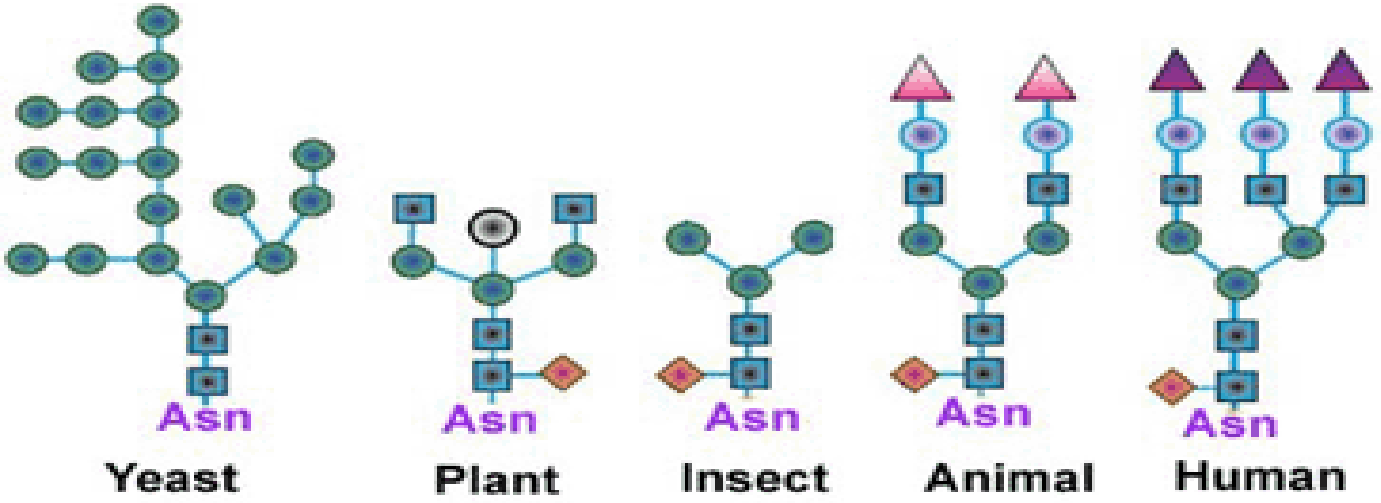
二级结构：简单重复的结构原件

三级结构：立体的空间结构

四级结构：蛋白亚基的空间布置

形成合适的空间结构是蛋白具备活性最根本的前提


Fucose
Sialic Acid
Galactose
Mannose
GalNAc
GlcNAc
O-glycans
N-glycans
S/T
S/T
S/T
N
N
N
lumen/
extracellular
cytosol


Asn
Asn
Asn
Asn
Asn
Yeast
Plant
Insect
Animal
Human

Expression Systems

大肠杆菌	NS0细胞	CHO细胞	Sf-21昆虫细胞	HEK293细胞
• 原核表达体系 • 无糖基化 • 很可能错误折叠 • 需要人工再折叠	• 小鼠骨髓瘤细胞 • 完全糖基化 • 蛋白折叠正确	• 中国仓鼠卵巢细胞 • 完全糖基化 • 蛋白折叠正确	• 昆虫细胞 • 昆虫杆状病毒表达载体 • 部分糖基化 • 通常正确折叠	• 人类细胞 • 完全糖基化 • 正确折叠

Calibrated against WHO

Conversion Table for World Health Organization (WHO) Standards

The unit status of WHO material is dependent on the testing performed. Further information regarding WHO standards can be found on the NIBSC website.

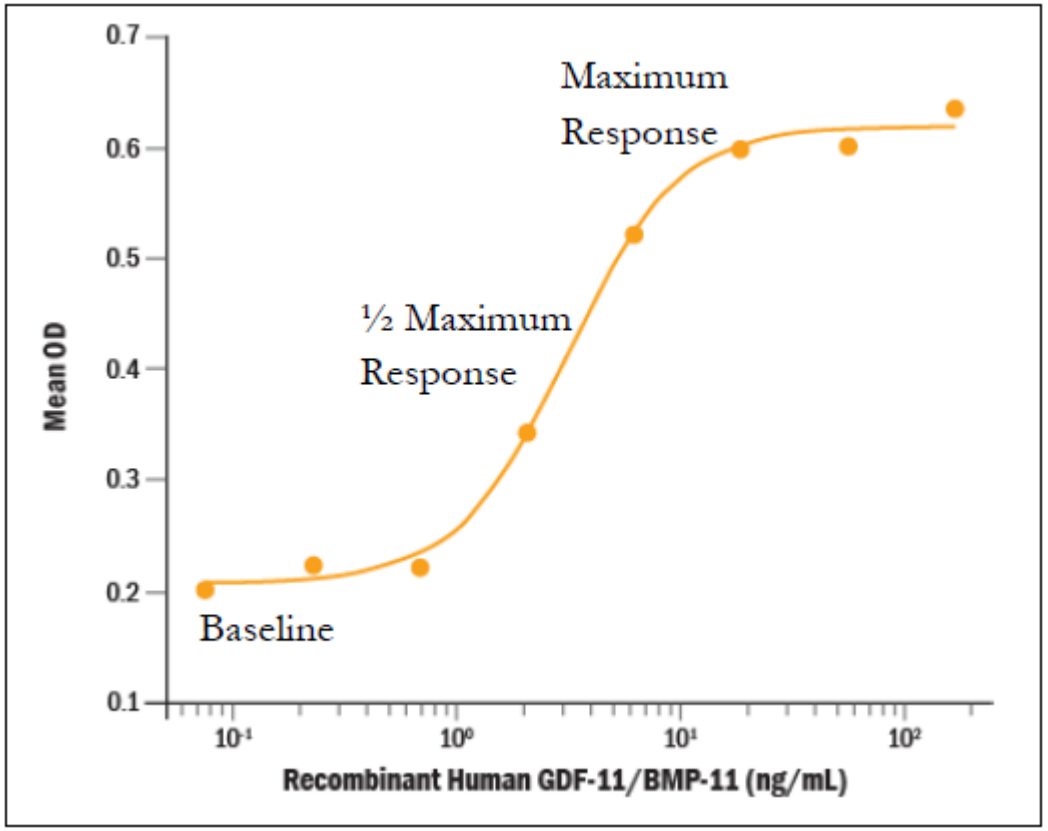
R&D Systems Cytokine	R&D Systems Catalog Number	WHO Standard Cytokine	WHO Standard Reference Number	WHO Standard Units/µg	Cell Line used for Bioassay	R&D Systems Cytokine 1 µg = WHO units	Unit Status
rhActivin A	338-AC	rhActivin A	91/626	1	K562	1	RU
rhBMP-2	355-BM	rhBMP-2	93/574	500	ATDC-5	960	IU
rhEGF	236-EG	rhEGF	91/530	1.0×10^3	Balb-3T3	3.2×10^3	IU
rhEpo	286-EP	rhEpo	11/170	150	TF-1	150 (1 U = 1 WHO U)	IU
rhFGF-7	251-KG	rhFGF-7	03/148	900	4MBr-5	520	RU
rhFGF basic	233-FB	rhFGF basic	90/712	800	NR6R-3T3	800	IU
rhFSH	5925-FS	rhFSH	92/642	13.8	HEK293/h FSH R	17.5	IU
rhFlt-3 Ligand	308-FK	rhFlt-3 Ligand	96/532	1.0×10^3	Baflt	3.1×10^3	RU
rhG-CSF	214-CS	rhG-CSF	88/502	1.0×10^5	NFS-60	2.6×10^5	IU
rhGH	1067-GH	h GH	80/505	2.6×10^{-3}	Nb2-11	5.4×10^{-3}	IU

Bioassays – Key Element of High Quality Proteins

SPECIFICATIONS	
SDS-PAGE	14 kDa, reducing conditions
Activity	Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323. The ED_{50} for this effect is typically 0.05-0.2 ng/mL. The specific activity of recombinant human IL-4 is approximately 2.9 x 10^4 IU/µg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656).
Endotoxin Level	<0.10 EU per 1 µg of the protein by the LAL method.
Purity	>97%, by SDS-PAGE under reducing conditions and visualized by silver stain.
Formulation	Lyophilized from a 0.2 µm filtered solution in PBS. See Certificate of Analysis for details.

Examples of Bioassays

- 细胞扩增分析
- 细胞生长抑制分析
- 细胞周期激活分析
- 干扰素生物分析
- 神经突触生长分析
- 钙流生物分析
- 趋化分析
- 颗粒释放和蛋白合成分析
- 蛋白因子释放分析

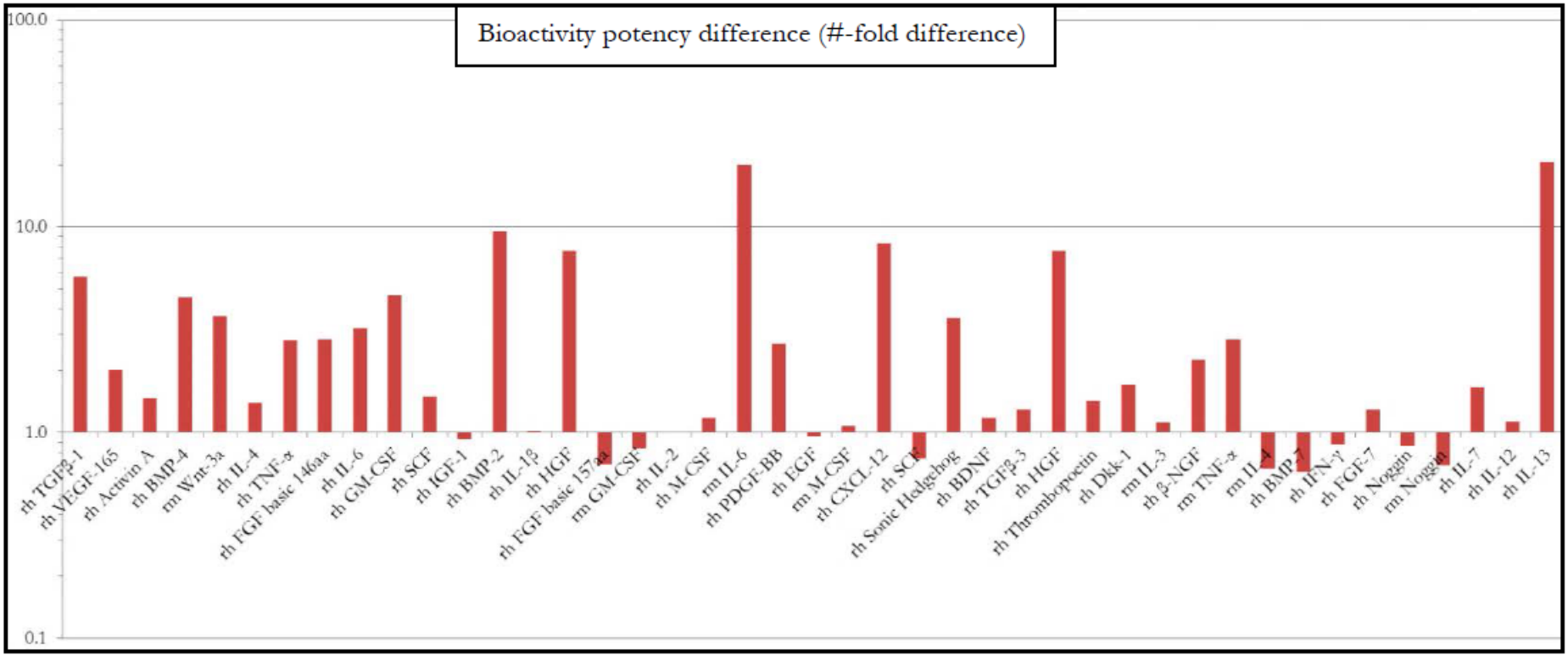


bio-techne®

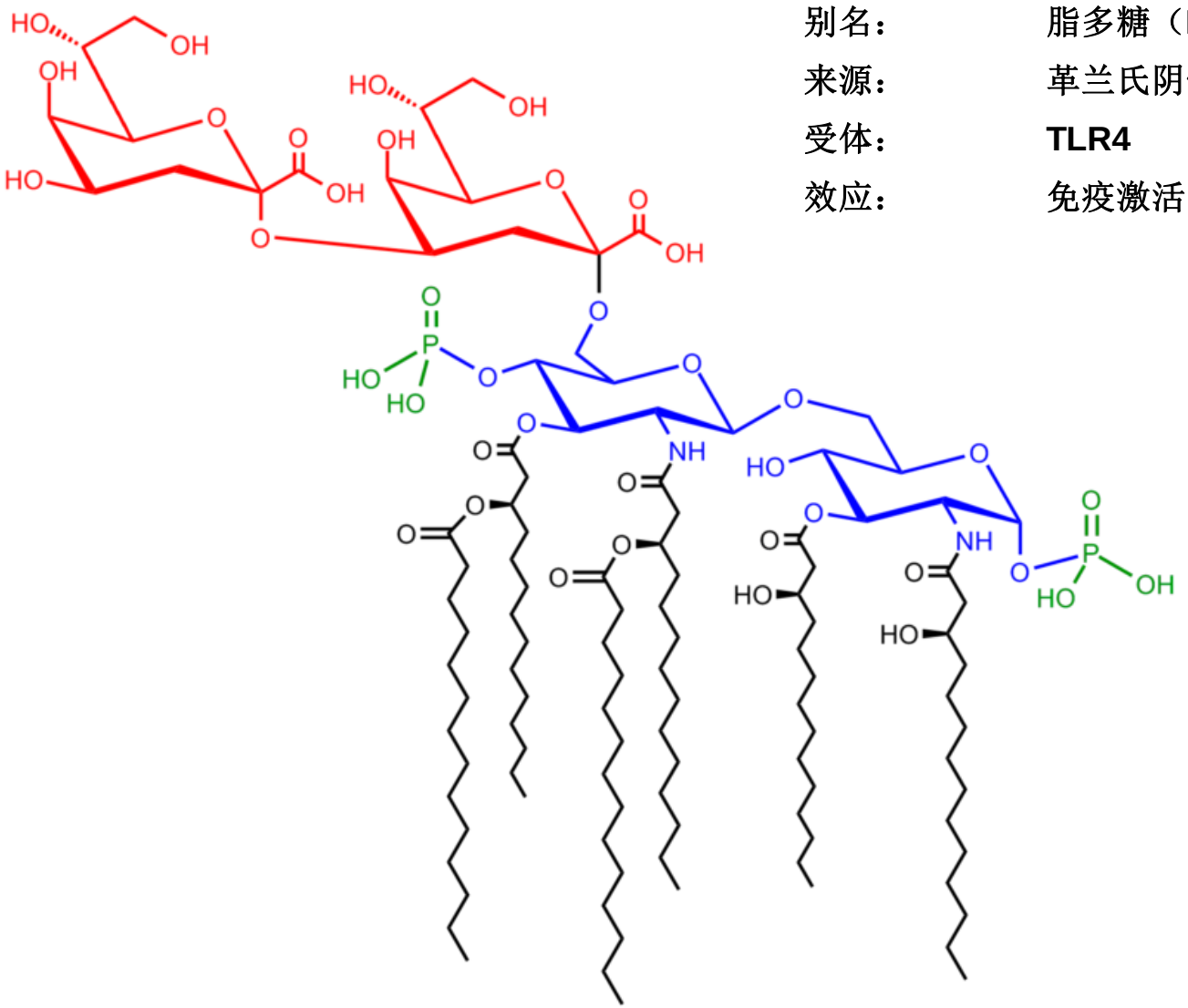
Competition

100种蛋白的随机批次平行比较，90%的R&D Systems蛋白优于竞争对手

Protein	Competitor	Competitor's ED_{50}	R&D Systems's ED_{50}	Potency over competitor
rmWnt-3a	P	1.637ng/mL	0.375ng/mL	4-fold
rhIL-4	M	0.178ng/mL	0.061ng/mL	3-fold
rhBDNF	P	2.349ng/mL	1.98ng/mL	1.2-fold
rhBMP-4	P	0.033µg/mL	0.009µg/mL	3-fold
rmIL-23	E	12.13ng/mL	0.249ng/mL	48-fold



Endotoxin



别名：	脂多糖（**LPS**）
来源：	革兰氏阴性菌细胞外壁
受体：	**TLR4**
效应：	免疫激活、致热剂

Endotoxin Levels of Human Proteins

Protein	Endotoxin Level
Activin A	<0.1EU/1µg
BMP-2	<0.1EU/1µg
BMP-4	<0.01EU/1µg
BMP-7	<0.01EU/1µg
EGF	<0.1EU/1µg
Dkk-1	<1EU/1µg
FGF basci	<0.1EU/1µg
Fibronectin	<0.1EU/1µg
Flt-3	<0.01EU/1µg
GDNF	<1EU/1µg
GM-CSF	<0.1EU/1µg
Hepsin	<1EU/1µg
IFN-gamma	<0.01EU/1µg
IGF-I	<0.1EU/1µg
IL-1beta/IL-1F2	<0.01EU/1µg
IL-2	<0.01EU/1µg
IL-3	<0.1EU/1µg
IL-4	<0.1EU/1µg
IL-6	<0.1EU/1µg
IL-7	<0.1EU/1µg
IL-11	<0.1EU/1µg

Protein	Endotoxin Level
IL-12	<1EU/1µg
IL-15	<1EU/1µg
KGF/FGF-7	<0.1EU/1µg
M-CSF	<0.01EU/1µg
Noggin	<0.1EU/1µg
Noggin Fc Chimera	<0.1EU/1µg
NRG1-beta1 EGF domain	<0.01EU/1µg
NT-3	<0.1EU/1µg
NT-4	<0.1EU/1µg
PDGF-BB	<0.01EU/1µg
SCF	<0.1EU/1µg
Shh, N-Terminus	<0.1EU/1µg
TGF-beta1	<0.1EU/1µg
Thrombopoietin	<0.1EU/1µg
TNF-alpha	<0.1EU/1µg
VEGF 165	<0.01EU/1µg
Wnt-3a	<0.1EU/1µg
BDNF	<0.1EU/1µg
GDF-8/Myostatin	<0.1EU/1µg
TGF-beta3	<0.01EU/1µg

Consistency – Most Important for Volume Users

R&D Systems
Tools for Cell Biology Research™

Recombinant Human IL-4 GMP

Catalog Number: 204-GMP

Activity

Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323.
The ED_{50} for this effect is typically 0.05-0.2 ng/mL.
The specific activity of recombinant human IL-4 is approximately 2.9 x 10^4 IU/µg, which is calibrated against human IL-4 WHO International Standard (NIBSC code: 88/656).

R&D Systems
Tools for Cell Biology Research™

Recombinant Human GM-CSF GMP

Catalog Number: 215-GMP

Activity

Measured in a cell proliferation assay using TF-1 human erythroleukemic cells. Kitamura, T. *et al.* (1989) J. Cell Physiol. **140**:323.
The ED_{50} for this effect is typically 6-30 pg/mL.
The specific activity of recombinant human GM-CSF is approximately 1.5 x 10^4 IU/µg, which is calibrated against human GM-CSF WHO International Standard (NIBSC code: 88/646).

R&D Systems
Tools for Cell Biology Research™

Recombinant Human IFN-γ GMP

Catalog Number: 285-GMP

Activity

Measured in anti-viral assays using HeLa human cervical epithelial carcinoma cells infected with encephalomyocarditis (EMC) virus. Meager, A. (1987) in Lymphokines and Interferons, a Practical Approach. Clemens, M.J. *et al.* (eds): IRL Press. 129.
The ED_{50} for this effect is typically 0.15-0.75 ng/mL.
The specific activity of recombinant human IFN-γ is approximately 2 x 10^4 IU/µg, which is calibrated against human IFN-γ Standard (NIBSC code: 87/586).

Animal-Free Proteins

Home » Products » Animal-Free™ Recombinant Proteins

Please read our complete Animal-Free Statement

严格的Animal-free体系

- 大肠杆菌表达系统
- 无动物源的原材料和培养体系
- 无动物源的设备、器材和耗材
- 专门的无动物源的实验室

Animal-Free Statement

All stages of R&D Systems' animal-free production include the following:

Dedicated Laboratories: Our Animal-Free products are manufactured in a dedicated, controlled access facility which is used exclusively for the production, purification, and bottling of Animal-Free proteins.

Standard Operating Procedures: Every stage of R&D Systems Animal-Free product manufacturing employs Standard Operating Procedures (SOPs). SOPs are fundamental to assure consistency from lot to lot and guarantee the highest quality of products.

Deviation Systems: Our quality assurance protocols involve deviation systems, which ensure that any non-conforming products (i.e., that those do not meet the requirements outlined below) are identified at the earliest opportunity. All deviations are reported, investigated, and recorded.

In addition, each stage of our established protein production methodology has been specifically modified for the manufacture of Animal-Free products:

A. **Molecular Biology:**
   1. DNA is transformed into competent bacterial cells which are generated using animal-free media

B. **Fermentation:**
   1. Fermentation processes follow approved SOPs.
   2. Raw materials and labware are animal-free* (see below).
   3. All raw materials are traceable through batch records.
   4. All batches of bacteria are grown in animal-free media.
   5. Dedicated animal-free fermentors are employed.
   6. Equipment cleaning procedures have been validated.

C. **Purification:**
   1. Purification processes follow approved SOPs.
   2. Dedicated animal-free columns are used.
   3. Column cleaning procedures have been validated specifically for animal-free manufacturing.
   4. All labware which comes in contact with the product is animal-free* (see below).
   5. Bulk purified proteins are filtered using certified animal-free filters.

bio-techne

GMP-grade Proteins

R&D Systems
Tools for Cell Biology Research™

Recombinant Human IL-15 GMP

Catalog Number: 247-GMP

BACKGROUND

R&D Systems' GMP proteins are produced according to relevant sections of the following documents: WHO TRS, No. 822, 1992 Annex 1, Good Manufacturing Practices for Biological Products; USP Chapter 1043, Ancillary Materials for Cell, Gene and Tissue-Engineered Products and USP Chapter 92, Growth Factors and Cytokines Used in Cell Therapy Manufacturing.

R&D Systems' quality focus includes:

- Manufacturing and testing under an ISO 9001:2008 and ISO 13485:2003 certified quality system
- Documented processes and QA control of documentation and process changes
- Personnel training programs
- Raw material testing and vendor qualification/monitoring
- Fully validated equipment, processes and test methods
- Equipment calibration schedules using a computerized calibration program
- Facility maintenance, safety programs and pest control
- Material review process for variances
- Monitoring of stability over product shelf-life

R&D Systems strives to provide our customers with the analytical characteristics of each product so that customers may determine whether our products are appropriate for their research. The Certificate of Analysis provided contains the following lot specific information:

- N-terminal amino acid analysis, SDS-PAGE analysis, and endotoxin level (as determined by LAL assay) performed on each bulk QC lot, not on individual bottlings of each QC lot
- Post-bottling lot-specific bioassay results (compliance with an established range) and results of microbial bioburden testing (using broth culture, Sabourand's dextrose and blood agar plates with results reported at 3 days and at 7 days)

Additional testing and documentation requested by the customer can be arranged at an additional cost. Testing may include, but is not limited to, USP sterility testing, positive identity testing, testing for adventitious agents and testing for residual host cell content.

Production records and facilities are available for examination by appropriate personnel on-site at R&D Systems in Minneapolis, Minnesota USA.

R&D Systems sells its GMP grade recombinant protein products for research use or further manufacturing use in *ex vivo* cell therapy applications. They are not for *in vivo* use or for use as therapeutic or other drugs, biologic products or devices. Please read the following End User Terms prior to using this product.

Thank You!

Technical Support: techsupport.cn@bio-techne.com

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Official Blog: http://weibo.com/rndsystems