

生物工艺 Bioprocess

填料与细胞培养相关杂质 (Protein A & HIV-1 p24)

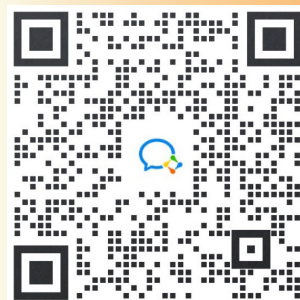
宿主细胞 DNA (HCD)

宿主细胞蛋白 (HCP)



生物工艺 (Bioprocess) 主要指抗体药物、细胞治疗、疫苗等生物药品的生产工艺及过程。由于生物制品生产过程中使用原材料的来源复杂，工艺环节可能残留宿主杂质、外源风险因子、工艺添加物等。因此，各国药监局等监管部门对工艺相关杂质有明确的法规要求！

Biogradetech 基于各国生物药物残留检测的法律法规和国际组织的指导方针，开发的一系列生物药（抗体药、CGT、疫苗等）工艺相关残留检测应用场景的试剂盒，提供工艺残留检测整体解决方案，产品包括 **Protein A、BSA、卡那霉素、慢病毒 HIV-1 p24、Benzonase 等工具酶、宿主细胞 DNA (HCD)、宿主细胞蛋白 (HCP)** 等残留检测试剂盒。



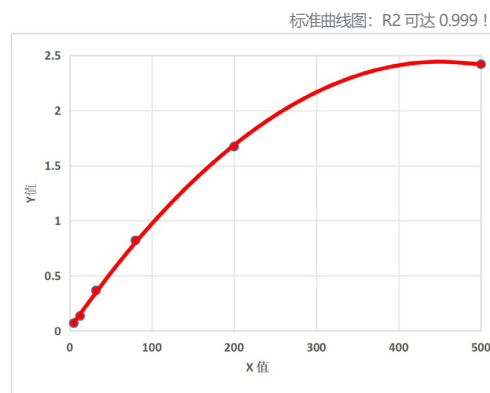
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一 填料与细胞培养相关杂质残留

🔥 爆款推荐: Protein A

在抗体药纯化过程中, 由于细胞培养液上清中含有蛋白水解酶, 上样过程中会对 Protein A 进行水解, 导致部分 Protein A 脱落, 残留在洗脱液。市面上商业化 Protein A 亲和填料种类繁多, 选择一款灵敏快速、尤其是普适兼容性强的 Protein A 残留检测工具是药物工艺质控环节需要考量的关键要素。

- ✓ **通用性强:** 天然或重组 Protein A、耐碱性 Protein A 突变体, 如 MabSelect SuRe®、TOYOPEARL®、Eshmuno® 等
- ✓ **操作便捷:** 无需加热样本, 操作更便捷, Cygnus 同款方案 (赠, 中文说明书)
- ✓ **高灵敏度:** 检测限低至 5.1pg/mL(<1ppm), 远超 FDA 建议的 10-12ppm, 重复性好
- ✓ **无种属限制:** 检测任意物种来源的样本, 特别是抗体药物物质控操作。



中文名称	英文名称	货号	规格
Protein A 残留/泄漏检测ELISA试剂盒	EZElisa™ Protein A Residual ELISA Kit	A-QEK010	96Tests
慢病毒滴度 (HIV-1 P24) 检测ELISA试剂盒	EZElisa™ HIV Lentivirus/HIV-1 P24 Titer ELISA Kit	A-QEK009	96Tests
Benzonase 核酸酶残留ELISA试剂盒	EZElisa™ Benzonase Nuclease Residual ELISA Kit	A-QEK001	96Tests
重组胰蛋白酶TrypLE ELISA试剂盒	EZElisa™ TrypLE Residual ELISA Kit	A-QEK002	96Tests
重组胰蛋白酶TrypLE ELISA试剂盒 (干细胞专用)	EZElisa™ TrypLE Residual ELISA Kit (For Stem Cell)	A-QEK003	96Tests
牛血清白蛋白BSA 残留ELISA试剂盒 (一步法)	EZElisa™ BSA Residual ELISA Kit (One-Step)	A-QEK005	96Tests
I型胶原酶 (Collagenase Type I) 残留ELISA试剂盒	EZElisa™ Collagenase Type I Residual ELISA Kit	A-QEK006	96Tests
卡那霉素 (Kanamycin) 残留ELISA试剂盒	EZElisa™ Kanamycin Residual ELISA Kit	A-QEK007	96Tests
庆大霉素 (Gentamicin) 残留ELISA试剂盒	EZElisa™ Gentamicin Residual ELISA Kit	A-QEK008	96Tests

二 宿主细胞DNA (HCD) 残留

中文名称	英文名称	货号	规格
CHO残留DNA (qPCR) 检测试剂盒	CHO Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK006	100Reactions
E.coli 残留DNA (qPCR) 检测试剂盒	E.coli Host Cell DNA Residual Detection Kit (qPCR)	A-QPK001	100Reactions
E.coli 残留DNA片段 (qPCR) 检测试剂盒	E.coli Host Cell DNA Residual Detection Kit (qPCR)	A-QPK002	4×100Reactions
E.coli 总RNA残留 (qPCR) 检测试剂盒	E.coli Host Cell Total RNA Residual Detection Assay Kit (qPCR)	A-QPK003	100Reactions
Vero残留DNA (qPCR) 检测试剂盒	Vero Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK004	100Reactions
Vero残留DNA片段 (qPCR) 检测试剂盒	Vero Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK005	4×100Reactions
HEK293残留DNA (qPCR) 检测试剂盒	HEK293 Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK007	100Reactions
HEK293残留DNA片段 (qPCR) 检测试剂盒	HEK293 Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK008	4×100Reactions
293T细胞残留DNA (qPCR) 检测试剂盒	293T Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK009	100Reactions
293T细胞残留DNA片段 (qPCR) 检测试剂盒	293T Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK010	4×100Reactions
人残留DNA (qPCR) 检测试剂盒	Human Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK011	100Reactions
人残留DNA片段分析 (qPCR) 检测试剂盒	Human Host Cell Residual DNA Fragment Detection Assay Kit	A-QPK012	4×100Reactions
Hela细胞残留DNA (qPCR) 检测试剂盒	Hela Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK013	100Reactions
Hela细胞残留DNA片段分析 (qPCR) 检测试剂盒	Hela Host Cell Residual DNA Fragment Detection Assay Kit (qPCR)	A-QPK014	4×100Reactions
E1A残留DNA (qPCR) 检测试剂盒	E1A Residual DNA Detection Assay Kit (qPCR)	A-QPK015	100Reactions
E1A&SV40LTA残留DNA (qPCR) 检测试剂盒	E1A&SV40LTA Residual DNA Detection Assay Kit (qPCR)	A-QPK016	100Reactions
质粒DNA残留 (qPCR) 检测试剂盒	Plasmid DNA Residual Detection Assay Kit (qPCR)	A-QPK017	100Reactions
毕赤酵母残留DNA (qPCR) 检测试剂盒	Pichia pastoris Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK018	100Reactions
BHK-21细胞残留DNA (qPCR) 检测试剂盒	BHK-21 Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK019	100Reactions
PG13残留DNA (qPCR) 检测试剂盒	PG13 Host Cell Residual DNA Detection Assay Kit (qPCR)	A-QPK020	100Reactions

三、宿主细胞蛋白(HCP)残留: 即将上线, 敬请期待~