

检验报告 Certificate of Analysis (COA)

试剂盒名称 Product Name	毕赤酵母宿主蛋白残留检测试剂盒 (酶联免疫吸附法-一步法) Pichia Pastoris Host Cell Protein (HCP) ELISA Kit	批号 LOT	20260207
		生产日期 production date	20260207
检验项目 Test Item	成品检验 Finished Product Full Inspection	有效期 expiration date	20270206
检验依据 Test Basis	企业标准 Enterprise Standard	报告日期 Report Date	20260306
规格 Specification/Model	96 Tests/盒 96 Tests/Kit	保存条件 Storage conditions	2-8 °C

检验项目 Test Item	企业标准 Enterprise Standard	检验结果 Test results
外观检验 Appearance	1、标识应清晰，易识别； 2、试剂盒内各组分应齐全、完整，液体无渗漏、无絮状物； 3、铝箔袋应无破损漏气现象。 1.Labels shall be clear and easy to identify; 2.All components in the kit shall be complete and intact, with no liquid leakage or floc; 3.Aluminum foil bags shall be free from damage and air leakage	符合标准 Qualified
包装内容及数量 Packaging contents and quantities	Pichia pastoris HCP 标准品7管，抗 Pichia pastoris HCP 酶标结合物工作液1瓶，浓缩洗液 (20×) 1瓶，显色液1瓶，终止液1瓶，抗 Pichia pastoris HCP 抗体预制酶标板1块，封板膜2张，说明书1份。 a set of <i>Pichia pastoris</i> HCP standards(7 vials), one bottle of anti- <i>Pichia pastoris</i> HCP detection antibody, one bottle of concentrated washing buffer(20×), one bottle of sample diluent, one bottle of TMB substrate, one bottle of stop solution, 96-well plate coated with anti- <i>Pichia pastoris</i> HCP, two sheets of sealing film, and one instruction manual.	符合标准 Qualified
装量 volume	试剂盒组成内，液体试剂成分的装量应不少于标示值。 In the composition of the kit, the volume of the liquid reagent components should be no less than the indicated value	符合标准 Qualified
标准曲线相关系数 Correlation coefficient of the standard curve	四参数拟合R2>0.99 Linear fitting,R2>0.99	符合标准 Qualified
最高浓度孔 Maximum concentration	检测标曲最高浓度孔 (200 ng/mL)，OD450-630nm信号均值≥1.5 The highest concentration of the detection standard curve (200 ng/mL) had an average OD value of 450-630nm ≥ 1.5	符合标准 Qualified
空白孔 Blank	检测空白孔，OD450-630nm信号均值≤0.15 Test the blank wells, and the average signal of OD450-630nm should be ≤ 0.15	符合标准 Qualified
定量限 Limit of Quantitation	标曲最低浓度孔重复10次，计算均值，回收率不超过70-130% Repeat the blank wells for 10 times, and the mean value was calculated, with a recovery rate not exceeding 70-130%	符合标准 Qualified
重复性 Repetition	标曲测试，3个平行，各浓度CV应不大于10.0% Precision on triplicate sample should yield the coefficient of variation (CV) for each concentration less than 10.0%	符合标准 Qualified

检验结论 Test conclusion	本品按企业标准检验，结果符合规定。 This product has been tested in accordance with the enterprise standards, and the results are in compliance with the
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检验人/Inspector: 王丹霞

复核人/Reviewer: 符忠恒

