



# Servicebio

## 产品检验报告

## Product Test Report

产品名称 Product name	样品保存器皿 Sample storage container	产品材质 Material	PP (聚丙烯)
产品型号 Product model	冻存管 Cryotube (V 型底、V Bottom)	产品规格 Specification	2.0mL
产品批号 Lot number	XC20211016	生产日期 Production Date	2021.10.16
产品状态 Status	无菌无酶 Dnase/Rnase free &Sterile	储存条件 Storage condition	常温 Room temperature
灭菌日期 Sterilization date	见辐照证明 Refer to the Irradiation Certificate	灭菌批号 Sterilization lot number	见辐照证明 Refer to the Irradiation Certifi
辐照剂量 Irradiation dose	15.0-20.0KGy	有效期 Validity	2 年 2 years

检验依据:《中华人民共和国药典》2020 版、GB/T 2828.1-2012

Test basis: Pharmacopoeia of the People's Republic of China 2020 edition, GB/T 2828.1-2012

抽样原则: GB/T 2828.1-2012; 外观性能的接收质量限 AQL=0.40、其它接收质量限 AQL=0.01

Sampling principle: GB/T 2828.1-2012; The receiving quality limit of appearance performance is AQL=0.40, and the other receiving quality limit is AQL=0.01

### 检验项目 Test items

检验指标 Test index	检验标准 Test standard	检验结果 Test result	判定 Decision
外观 Appearance	毛刺 Burr 产品内部均不能有大于 0.25mm 的毛刺, 外部不能有大于 0.35mm 的毛刺。There should be no burr larger than 0.25mm inside the product, and no burr larger than 0.35mm outside	所有产品均合格 All the products are qualified	合格 Qualified
	缺损 Defect 产品有任何部分的缺损均属于不合格品。 Any defect in any part of the product is unqualified.	所有产品均无缺损 All the products are free of defects	合格 Qualified
	变形 Distortion 产品表面的各种缺损如开裂、扭曲变形、污点以及肉眼可见 (日光灯下距离 30 厘米) 气泡均属于不合格产品。All kinds of defects on the surface of the product, such as cracking, distortion, stains and visible to the naked eye (30cm away from the fluorescent lamp) bubble are unqualified products.	所有产品均无变形 All the products are free of distortion	合格 Qualified
	污染 Contamination 产品有类似于油脂等物质的均属于不合格品; 黑点: 产品有肉眼可见 (日光灯下距离 30 厘米) 的小黑点属于不合格产品。Products with substances similar to oils and fats belong to unqualified products; Black spot: the product has the naked eye visible small black spot (fluorescent lamp distance 30cm) belongs to unqualified product.	所有产品均无污染 All specifications are free of contamination	合格 Qualified



内陷 Invagination	产品有任何肉眼可见（日光灯下距离 30 厘米）的内陷均属于不合格品。Product has the naked eye visible invagination (fluorescent lamp distance 30cm) belongs to unqualified product.	所有产品均无内陷 All specifications are free of invagination	合格 Qualified
性能 Performance	按照规定抽取部分做应用测试，能满足实验需求。 According to the regulations, the part is extracted for application test, which can meet the needs of the experiment.	所有产品均合格 All the products are qualified	合格 Qualified
无菌检验 Sterile test	《中华人民共和国药典》2020 版直接接种法：检测样品均为阴性。 Direct inoculation method in <i>The Pharmacopoeia of the People's Republic of China</i> edition 2020: all the tested samples were negative.	红色 Red	合格 Qualified
RNA 酶检验 RNA enzyme test	荧光定量分析法：检测样品均为阴性。Fluorescence quantitative analysis: all the samples tested were negative.	阴性 Negative	合格 Qualified
DNA 酶检验 DNA enzyme test	荧光定量分析法：检测样品均为阴性。Fluorescence quantitative analysis: all the samples tested were negative.	阴性 Negative	合格 Qualified
内毒素检验 Endotoxin test	《中华人民共和国药典》2020 版小于 0.1EU/mL：检测样品均阴性。Pharmacopoeia of the People's Republic of China 2020 version less than 0.1EU/mL: All the tested samples were negative.	阴性 Negative	合格 Qualified
<p>检验结果： 根据产品检验参考标准中检验项目进行检验，所有检验项目均符合要求，因此此批产品检验合格，可入库发货。</p> <p>Test result: According to the inspection items in the product inspection reference standard, all inspection items meet the requirements. Therefore, this batch of products can be stored and delivered.</p> <div style="text-align: center;">               签发日期: 2021 年 10 月 16 日              Issuing date: 2021.10.16         </div>			

检验：王滴、桂良凤      审核：李子庆      批准：刘小影      表单编号：SWE-QA-SMP-006-03

Inspected by: Wang Di, Gui Liangfeng      Checked by: Li Ziqing      Approved by: Liu Xiaoying      No: SWE-QA-SMP-006-03