

BẢN TIÊU CHUẨN MÀ CHỦ SỞ HỮU CÔNG BỐ ÁP DỤNG
Tài liệu đã được ký và đóng dấu xác nhận

Hà Nội, ngày 11 tháng 07 năm 2022

Người đại diện hợp pháp của cơ sở



GIÁM ĐỐC

Nguyễn Hồng Thái



迪瑞医疗科技股份有限公司

DIRUI Industrial Co., Ltd

出厂检验报告单

CERTIFICATE OF ANALYSIS



产品名称：白蛋白测定试剂盒（溴甲酚绿法）

Product Name: Albumin Reagent Kit

生产批号：20210123

生产日期：20210123

失效日期：20220722

检验日期：20210125

Production Lot No.:

Date of Manufacture:

Expiry Date:

Test Date:

序号 No.	检验项目 Test Item	标准规定 Criteria	检验结果 Test Result
1	外观 Appearance	试剂 R 应为黄绿色澄清液体，可含有少量不影响测值的不溶性物质 R is yellow green clear liquid and can contain a small amount of insoluble particles which cannot affect the test.	合格 Qualified
2	净含量 Net Volume	不少于标示值 No less than labeled value.	合格 Qualified
3	试剂空白吸光度 Reagent Blank Absorbance Value	试剂空白吸光度 A 应在 0.100~0.200 之间 Reagent Blank Absorbance Value A should be within 0.100 to 0.200.	0.1730
4	分析灵敏度 Analytical Sensitivity	试剂测试 40g/L 被测物时，吸光度差值 $\Delta A > 0.2$ When testing the sample of 40g/L, absorbance Value $\Delta A > 0.2$	0.658
5	线性区间 Linear Range	测试血清样本，试剂线性在 2.0~60.0g/L 区间内，线性相关系数 $ r \geq 0.9900$ When the sample is serum, within [2.0, 60.0] g/L, $ r \geq 0.9900$	R=0.9994
		[2.0, 20.0] g/L 区间内，线性绝对偏差应在 ± 2.4 g/L 范围内 Within [2.0, 20.0] g/L, linear absolute deviation should be within ± 2.4 g/L	-0.79; -0.40; -0.08; 0.79
		(20.0, 60.0] g/L 区间内，线性相对偏差应不超过 $\pm 10\%$ Within (20.0, 60.0] g/L, linear relative deviation should be within $\pm 10\%$	3.64%; -1.13%
6	准确度 Accuracy	相对偏差应在 $\pm 6.0\%$ 范围内。 Relative deviation should be within $\pm 6.0\%$.	1.15%

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7	包装 Package	瓶签、盒标、说明书完整，试剂瓶与装量配套，包装材料文字清晰。 The bottle label, box label, and instructions should be complete; the reagent bottle matches the filling volume; words on package are clear.	合格 Qualified
结论： 符合标准，准许出厂 Conclusion: The criteria are met; the product is permitted to leave the factory.			

检验人：
Tested by:

孙立媛

复核人：
Checked by:

张洪强

批准放行人：
Approved by:

王峰

