

## Certificate of Analysis

|                                      |                                                                                                                                                                                                                            |                           |                                                                                                                                                                                        |                                |                   |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------|
| 产品名称<br>Product Name                 | 总胆汁酸检测试剂盒 (循环酶法)<br>Total Bile Acid (TBA) Test Kit (Enzymatic Cycling)                                                                                                                                                     |                           |                                                                                                                                                                                        | 物料编码<br>Material Code          | 71317             |
| 批号<br>Lot No.                        | 60330017H                                                                                                                                                                                                                  | 包装规格<br>Package           | R1:48ml×2 R2:16ml<br>×2                                                                                                                                                                | 生产日期<br>Manufacture Date       | 2026.4.9          |
| 组装批量<br>Lot Size                     | R1:48ml×2 R2:16ml×<br>2                                                                                                                                                                                                    | 销售区域<br>Market Area       | 中国/China                                                                                                                                                                               | 效期<br>Expiry Date              | 2027.4.8          |
| 取样量<br>Sample Amount                 | 1盒                                                                                                                                                                                                                         | 送检日期<br>Sampling Date     | 2026.4.9                                                                                                                                                                               | 检验日期<br>Analysis Date          | 2026.4.9          |
| 检验依据<br>Inspection Basis             | 产品检验规程/ Inspection procedures                                                                                                                                                                                              |                           |                                                                                                                                                                                        |                                |                   |
| 检验项目 Test<br>Items                   | 检验标准 Quality Standard                                                                                                                                                                                                      |                           | 检验结果 Result                                                                                                                                                                            |                                | 评价<br>Comment     |
| 外观和性状<br>Appearance<br>and Character | 试剂盒组分齐全完整; 标签、标识清晰完整<br>Reagent componets are complete. Labels are<br>clear and correct.<br>R1为无色或淡黄色澄清液体<br>R1 is colorless or light yellow clear liquid<br>R2为无色或淡黄色澄清液体<br>R2 is colorless or light yellow clear liquid |                           | 试剂盒组分齐全完整; 标签、标识清晰完整<br>Reagent componets are complete. Labels<br>are clear and correct.<br>R1为淡黄色澄清液体<br>R1 is light yellow clear liquid<br>R2为无色澄清液体<br>R2 is colorless clear liquid |                                | 符合标准<br>Qualified |
| 净含量<br>Volume                        | R1:48ml×2 R2:16ml×2<br>R1:48ml×2 R2:16ml×2                                                                                                                                                                                 |                           | R1 48.3ml R2 16.2ml                                                                                                                                                                    |                                | 符合标准<br>Qualified |
| 试剂空白<br>Reagent blank                | 试剂空白吸光度≤0.8, (405nm, 1cm optical<br>path)<br>Reagent blank absorbances≤0.8, (405nm, 1cm optical<br>path)                                                                                                                   |                           | 0.3065                                                                                                                                                                                 |                                | 符合标准<br>Qualified |
|                                      | 试剂空白吸光度变化率 (ΔA/min) 应≤0.04<br>Change rate of blank absorbance of reagent(ΔA/min)≤<br>0.04                                                                                                                                  |                           | 0.001995                                                                                                                                                                               |                                | 符合标准<br>Qualified |
| 准确度<br>Accuracy                      | 质控结果是否在靶值范围之内<br>whether the quality control results are within the<br>target range                                                                                                                                        |                           | Yes                                                                                                                                                                                    |                                | 符合标准<br>Qualified |
| 线性范围<br>Linear Range                 | 线性范围: 0~150 μmol/L内, r 不小于0.990<br>range: 0~150μmol/L, r≥0.990                                                                                                                                                             |                           | 0.9995                                                                                                                                                                                 |                                | 符合标准<br>Qualified |
| 重复性<br>Reproducibility               | 重复性CV不大于5%<br>repeatability CV≤5%                                                                                                                                                                                          |                           | 0.95%                                                                                                                                                                                  |                                | 符合标准<br>Qualified |
| 结论<br>Conclusion                     | 合格/Pass                                                                                                                                                                                                                    |                           |                                                                                                                                                                                        |                                |                   |
| 备注 Remarks                           |                                                                                                                                                                                                                            |                           |                                                                                                                                                                                        |                                |                   |
| 检验 QC                                | Chen Hong                                                                                                                                                                                                                  | 复核 Checked<br>By          | Wang Ruyan                                                                                                                                                                             | 批准<br>Approve<br>d By          | Wang Helian       |
| 签名/日期<br>Signature /<br>Date         | 2026.4.9                                                                                                                                                                                                                   | 签名/日期<br>Signature / Date | 2026.4.9                                                                                                                                                                               | 签名/日期<br>Signature<br>e / Date | 2026.4.9          |

