大板检验报告

Inspection Report of Rapid Test Uncut Sheet

送检日期 Inspection date：2024.02.01 报告日期 Report date：2024.02.01

产品名称 Product name	梅毒螺旋体(TP)抗体检测大板（胶体金法）——卡型 Treponema Pallidum（TP）Antibody Rapid Test Uncut Sheet（Colloidal Gold）——cassette		
批　　号 Batch No.	2024013101	货号 Catalog No.	FAR-119
生产日期 Production date	2024.01.31	有效期至 Valid until	2026.01.30
生产批量 Production batch	1595 张	规　格 Specification	300*60mm
检验依据 Inspection standards	梅毒螺旋体（TP）抗体检测大板（胶体金法）质量标准 Quality standard for Treponema Pallidum antibody rapid test uncut sheet (Colloidal Gold)		

序号 NO.	检验项目 Test Items	标准规定 Quality Standard	检验数据 Inspection Data	结论 Results
1	外观 Exterior	大板外观完好、无污渍、无褶皱，各组分粘贴整齐，粘贴顺序正确和牢固。 The appearance of the uncut sheet is intact, no stains, no wrinkles, the components are glued neatly, and the order of sticking is correct and firm.	☑符合 Conformity □不符合 Nonconformity	☑合格 Qualified □不合格 Unqualified
2	物理检查 Physical inspection	大板长 300mm±3、宽 60mm±0.6 试纸条液体移动速度不低于 10mm/min。 Length 300mm±3, width 60mm±0.6, the liquid moving speed of the test strip is not less than 10mm/min.	☑符合 Conformity □不符合 Nonconformity	☑合格 Qualified □不合格 Unqualified
3	最低 检出限 The minimum limit of detection	用 3 份检出限参考品（L1、L2、L3）进行检测，每份重复检测 3 次。L1 检测结果应为阳性，L2 检测结果应为阴性或阳性，L3 检测结果应为阴性。 The minimum detection limit reference substance (L1、L2、L3) of Hepatitis C virus were tested 3 times each, the L1 test results should all be positive, the L2 test results should be negative or positive, and the L3 test results should all be negative.	☑符合 Conformity □不符合 Nonconformity	☑合格 Qualified □不合格 Unqualified

4	阳性质控符合率 Positive consistency rate	用 10 份阳性参考品（P1-P10）进行检测，结果应均为阳性。 Test 10 positive reference materials (P1-P10), the results should all be positive.	符合率：10/10 Coincidence rate	☑合格 Qualified ☐不合格 Unqualified
5	阴性质控符合率 Negative consistency rate	用 20 份阴性参考品（N1-N20）进行检测，结果应均为阴性。 Test 20 negative reference materials (N1-N20), the results should all be negative.	符合率：20/20 Coincidence rate	☑合格 Qualified ☐不合格 Unqualified
6	重复性检测 Repeatability test	取同一批号的检测试剂 10 人份，检测重复性参考品（R），检测结果应一致，均为阳性，且显色均一。 Take out 10 test reagents from the same batch and test the reference materials of repeatability (R). The test result should be consistently positive, and the color rendering should be uniform as well.	符合率：10/10 Coincidence rate	☑合格 Qualified ☐不合格 Unqualified

结论：本品依企业标准质量标准及检验操作规程检验，结果 合格 。

Conclusion: This product was tested in accordance with the company's quality standards and inspection operating procedures, and the results were qualified.

质检专用章

检验人 Inspector：RD033　　检验日期 Inspection date：2024.02.01

复核人 Reviewer：GM007　　复核日期 Review date：2024.02.01

批准人 Approver：RD030　　批准日期 Approved date：2024.02.01