

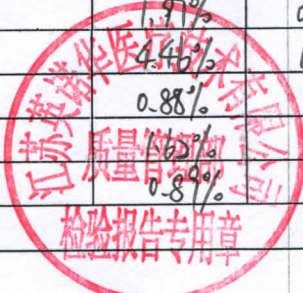
临床生化校准血清出厂检验报告

检验依据: 医疗器械产品技术要求编号: 苏械注准 20172401340

检验日期: 2021.12.08 血清批号: 2211009N

| 检验项目 | 要求 | 结果 | 判定 |
|-------|--|------|----|
| 试剂外观 | 淡黄或黄色冻干粉, 加水复溶后为淡黄色半透明液体, 无悬浮物和沉淀物。 | 符合要求 | ✓ |
| 生物安全性 | 质控物的 HBsAg、HIV-1/HIV-2 抗体、HCV 抗体、梅毒病毒检测应为阴性。 | 均为阴性 | ✓ |

| 项目 | | 准确度 | 瓶内 CV | 瓶间 CV | 判定 |
|----------------|---------|----------------------|-------|-------|----|
| 要求 | 检测试剂批号 | 测量结果与校准品靶值 偏差≤10% | CV≤5% | CV≤8% | |
| ALT/GPT | 2211008 | 2.9% | 4.34% | 7.3% | ✓ |
| GOT/AST | 2211013 | 6.0% | 1.33% | 0% | ✓ |
| AKP/ALP | 2210825 | 1.4% | 0.59% | 1.7% | ✓ |
| γ-GT/GGT | 2210726 | 5.0% | 4.08% | 4.6% | ✓ |
| α-HBDH | 2210517 | 4.4% | 2.57% | 1.3% | ✓ |
| LDH | 2210927 | 2.1% | 1.44% | 0.9% | ✓ |
| CK | 2210928 | 2.9% | 4.54% | 4.5% | ✓ |
| α-AMY | 2210722 | 3.1% | 1.73% | 1.6% | ✓ |
| TP | 2210827 | 2.2% | 0.80% | 0.3% | ✓ |
| ALB | 2210903 | 1.0% | 0.78% | 0.7% | ✓ |
| Crea (苦味酸法) | 2211012 | 7.3% | 4.79% | 4.5% | ✓ |
| GLU(GOD-PAP 法) | 2210910 | 7.1% | 4.41% | 0.7% | ✓ |
| UA | 2210713 | 1.3% | 2.96% | 1.9% | ✓ |
| Urea | 2210923 | 6.6% | 3.58% | 1.5% | ✓ |
| TG | 2211015 | 4.0% | 4.33% | 0.5% | ✓ |
| CHO | 2210823 | 1.7% | 3.51% | 2.5% | ✓ |
| TBA | 2210813 | 5.6% | 1.70% | 0.4% | ✓ |
| TB (重氮法) | 2210922 | 7.7% | 0.98% | 0.6% | ✓ |
| TB (钼酸盐法) | 2210924 | 7.1% | 0.83% | 0.2% | ✓ |
| DB (重氮法) | 2210916 | 7.4% | 2.19% | 0.8% | ✓ |
| DB (钼酸盐法) | 2210723 | 1.9% | 2.66% | 1.2% | ✓ |
| Ca (偶氮肿III法) | 2210708 | 4.8% | 1.91% | 0.3% | ✓ |
| P | 2210906 | 2.0% | 4.46% | 1.2% | ✓ |
| Cl (硫氰酸汞法) | 2210701 | 4.2% | 0.88% | 1.6% | ✓ |
| K | 2210514 | 4.68% | 0.89% | 0.5% | ✓ |
| Na | 2210514 | 7.27% | 0.89% | 0.5% | ✓ |
| 本批次检验结论 | 合格 | | | | |



检验人: 张峰

复核人: 梁华星

批准人: 李成