



生物智造，助力卓越  
Each molecule promises accuracy

## 检验报告 Certificate of Analysis

记录编号: R-QC-SMP-0013-03 版本号: 00

品名 Product Name	糖化白蛋白 (GA) 检测试剂盒 (GA-D) Glycated albumin assay kit (GA-D)		
批号 Batch Number	HH20220701	货号 Catalog Number	HOEM1008-02
生产日期 Production Date	2022.07.01	有效期至 Expiry Date	2023.06.30
储存条件 Storage Condition	2-8°C		
检验项目 Test Items	标准 Specification	结果 Result	
外观 Appearance	R1 为无色至淡黄色澄清液体, R2 为黄色澄清液体 R1 is colorless to light yellow clear liquid, R2 is yellow clear liquid	合格 PASS	
试剂空白吸光度 Reagent blank absorbance	试剂空白吸光度应 $\leq 0.1$ Reagent blank absorbance $\leq 0.1$	合格 PASS	
准确度 Accuracy	检测高中低值质控品各三次, 相对靶值偏差 $\leq \pm 10\%$ Test high, middle and low control each three times, Relative deviation $\leq \pm 10\%$	合格 PASS	
重复性 Repeat-ability	测定同一质控 10 次, $CV \leq 5\%$ Test one control 10 times, $CV \leq 5\%$	合格 PASS	
批间差 Lot-to-lot variation	连续三批相对极差 $R \leq 10\%$ Range of three lots $R \leq 10\%$	合格 PASS	
分析灵敏度 Analytical sensitivity	样本浓度为 1.000 g/dL 时, 吸光度差值 $\geq 0.0536$ When the sample concentration is 1.000g/dl, absorbance is greater than 0.0536	合格 PASS	
稳定性 Stability	2-8°C 条件密闭避光储存, 可稳定 1 年 (加速模拟实验) Stored unopened at 2-8°C and protected from light, stable 1 year (accelerated simulating test)	合格 PASS	
结论: Conclusion:			

检验人/日期:  2022.07.25  
Analyzed by/Date:

复核人/日期:  2022.07.25  
Reviewed by/Date:

批准人/日期:  2022.07.25  
Approved by/Date: