

## 糖化血红蛋白 (HbA<sub>1c</sub>) 质控品

货号: HA5072

包装: 2x2x0.5 ml

批号: 455040 (1978HA & 1981HA)

效期: 2020-11-28

### 产品描述

本质控品适用于临床化学体外诊断系统检测糖化血红蛋白 (HbA<sub>1c</sub>) 的质量控制。朗道供应两个水平: 低浓度水平 (水平 1) 和正常浓度水平 (水平 2)。

### 安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸。按照实验室常规预防措施对试剂进行处理。

警告: 本品为潜在的生物危险物质。

该质控品采用人血, 对所有捐献者的血液均进行了人类免疫缺陷病毒 HIV (HIV1、HIV2) 抗体、乙型肝炎表面抗原 (HbsAg) 和丙型肝炎病毒 (HCV) 抗体的测试, 发现均呈阴性。所采用的方法均经 FDA 认证。

但既然没有一种方法能够完全保证其没有传染物质, 因此该质控品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

### 保存和稳定性

未开瓶, 2~8°C 可保存至效期末。

复溶后, 2~8°C 保存可稳定 1 个月。稳定性数据基于免疫比浊法方法学实验数据的统计。注意: 复溶后不要冷冻。

### 使用说明

该糖化血红蛋白质控品为冻干品。

1. 小心打开瓶盖;
2. 准确量取 0.5 ml 的蒸馏水加入;
3. 盖好瓶盖, 转动试剂瓶若干次, 室温下静置 15 分钟;
4. 15 分钟后, 旋转和翻转试剂瓶, 继续复溶, 直到所有的冻干材料已溶解及溶液已混合均匀为止。

注意: 按照所使用试剂盒的说明书, 应将质控品按照与病人样本相同的方式处理。如果使用朗道试剂盒分析糖化血红蛋白和总血红蛋白, 须进行预处理: 将 10 µL 质控液与 400 µL 血红蛋白变性试剂混合作 1:41 稀释。

### 提供的材料

浓度水平	水平 1 (HbA <sub>1c</sub> 质控 1)	水平 2 (HbA <sub>1c</sub> 质控 2)
包装规格	2 x 0.5 ml	2 x 0.5 ml

### 需要自备的材料

移液管, 蒸馏水

**赋值:** 每一批质控血液都要送到大量的外部实验室, 通过对这些实验室返回的结果统计而赋值。

**注:** 详细赋值信息请以原版英文说明书为准, 原版说明书请在英国朗道公司官网 [www.randox.com](http://www.randox.com) 进行下载。

## LEVEL I

方法学	Units	Target	Range
Abbott Architect c systems (DCCT / NGSP)	%HbA <sub>1c</sub>	5.41	4.33 – 6.49
Abbott Architect c systems (IFCC)	mmol/mol	35.6	28.5 – 42.7
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA <sub>1c</sub>	6.47	5.18 – 7.76
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	47.2	37.8 – 56.6
Abbott Architect i systems (DCCT / NGSP)	%HbA <sub>1c</sub>	6.95	5.56 – 8.34
Abbott Architect i systems (IFCC)	mmol/mol	52.5	42.0 – 63.0
Arkray Menarini HA8121/40/60/80 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.69	4.55 – 6.83
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	38.7	31.0 – 46.4
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.85	4.68 – 7.02
Beckman AU400/480/600/640/2700/5400 (IFCC)	mmol/mol	40.4	32.3 – 48.5
Beckman DxC600/DxC800 (DCCT / NGSP)	%HbA <sub>1c</sub>	6.07	4.86 – 7.28
Beckman DxC600/DxC800 (IFCC)	mmol/mol	42.8	34.2 – 51.4
Bioanalytic Diagnostic HbA <sub>1c</sub> (DCCT / NGSP)	%HbA <sub>1c</sub>	5.83	4.66 – 7.00
Bioanalytic Diagnostic HbA <sub>1c</sub> (IFCC)	mmol/mol	40.2	32.2 – 48.2
Biorad D-10 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.70	4.56 – 6.84
Biorad D-10 (IFCC)	mmol/mol	38.8	31.0 – 46.6
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA <sub>1c</sub>	5.81	4.65 – 6.97
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	40.0	32.0 – 48.0
EKF Quotient Quo-Lab A1c Test (DCCT / NGSP)	%HbA <sub>1c</sub>	6.72	5.38 – 8.06
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	49.9	39.9 – 59.9
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA <sub>1c</sub>	6.20	4.96 – 7.44
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	44.3	35.4 – 53.2
Mindray BS200/300/400 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.80	4.64 – 6.96
Mindray BS200/300/400 (IFCC)	mmol/mol	39.9	31.9 – 47.9
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA <sub>1c</sub>	5.72	4.58 – 6.86
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	39.0	31.2 – 46.8
Randox Rx Series (DCCT / NGSP)	%HbA <sub>1c</sub>	5.95	4.76 – 7.14
Randox Rx Series (IFCC)	mmol/mol	41.5	33.2 – 49.8
Roche Cobas 4000/c311 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.59	4.47 – 6.71
Roche Cobas 4000/c311 (IFCC)	mmol/mol	37.6	30.1 – 45.1
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.62	4.50 – 6.74
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.9	30.3 – 45.5
Roche Integra (DCCT / NGSP)	%HbA <sub>1c</sub>	5.73	4.58 – 6.88
Roche Integra (IFCC)	mmol/mol	39.1	31.3 – 46.9
Roche Modular P/Cobas c111 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.80	4.64 – 6.96
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	39.9	31.9 – 47.9
Sebia Capillarys / Minicap (DCCT / NGSP)	%HbA <sub>1c</sub>	5.56	4.45 – 6.67
Sebia Capillarys / Minicap (IFCC)	mmol/mol	37.3	29.8 – 44.8
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.93	4.74 – 7.12
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	41.3	33.0 – 49.6
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA <sub>1c</sub>	6.35	5.08 – 7.62
Siemens DCA2000/Vantage (IFCC)	mmol/mol	45.9	36.7 – 55.1
Siemens/Dade Dimension (DCCT / NGSP)	%HbA <sub>1c</sub>	5.93	4.74 – 7.12
Siemens/Dade Dimension (IFCC)	mmol/mol	41.3	33.0 – 49.6
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA <sub>1c</sub>	5.74	4.59 – 6.89
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	39.2	31.4 – 47.0

## LEVEL 1 (continued)

方法学	Units	Target	Range
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA <sub>1c</sub>	6.32	5.06 – 7.58
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	45.6	36.5 – 54.7
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA <sub>1c</sub>	7.73	6.18 – 9.28
Trinity Biotech Tri-stat (IFCC)	mmol/mol	61.0	48.8 – 73.2
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA <sub>1c</sub>	6.35	5.08 – 7.62
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	45.9	36.7 – 55.1

Total Haemoglobin		Target	Range
Randox Rx Series	g/dl	13.1	10.5 – 15.7

## LEVEL 2

方法学	Units	Target	Range
Abbott Architect c systems (DCCT / NGSP)	%HbA <sub>1c</sub>	10.8	8.64 – 13.0
Abbott Architect c systems (IFCC)	mmol/mol	94.5	75.6 – 113
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA <sub>1c</sub>	12.5	10.0 – 15.0
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	113	90.4 – 136
Abbott Architect i systems (DCCT / NGSP)	%HbA <sub>1c</sub>	13.2	10.6 – 15.8
Abbott Architect i systems (IFCC)	mmol/mol	121	96.8 – 145
Arkray Menarini HA8121/40/60/80 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.1	8.88 – 13.3
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	97.8	78.2 – 117
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Beckman AU400/480/600/640/2700/5400 (IFCC)	mmol/mol	100	80.0 – 120
Beckman DxC600/DxC800 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Beckman DxC600/DxC800 (IFCC)	mmol/mol	102	81.6 – 122
Bioanalytic Diagnostic HbA <sub>1c</sub> (DCCT / NGSP)	%HbA <sub>1c</sub>	12.8	10.2 – 15.4
Bioanalytic Diagnostic HbA <sub>1c</sub> (IFCC)	mmol/mol	116	92.8 – 139
Biorad D-10 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.2	8.96 – 13.4
Biorad D-10 (IFCC)	mmol/mol	98.9	79.1 – 119
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA <sub>1c</sub>	11.2	8.96 – 13.4
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	98.9	79.1 – 119
EKF Quotient Quo-Lab A <sub>1c</sub> Test (DCCT / NGSP)	%HbA <sub>1c</sub>	11.8	9.44 – 14.2
EKF Quotient Quo-Lab A <sub>1c</sub> Test (IFCC)	mmol/mol	105	84.0 – 126
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	100	80 – 120
Mindray BS200/300/400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Mindray BS200/300/400 (IFCC)	mmol/mol	101	80.8 – 121
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	101	80.8 – 121
Randox Rx Series (DCCT / NGSP)	%HbA <sub>1c</sub>	12.5	10.0 – 15.0
Randox Rx Series (IFCC)	mmol/mol	113	90.4 – 136
Roche Cobas 4000/c31 I (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Roche Cobas 4000/c31 I (IFCC)	mmol/mol	102	81.6 – 122

**LEVEL 2 (continued)**

方法学	Units	Target	Range
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Roche Cobas 6000/8000 (IFCC)	mmol/mol	101	80.8 – 121
Roche Integra (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Roche Integra (IFCC)	mmol/mol	101	80.8 – 121
Roche Modular P/Cobas c111 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	100	80.0 – 120
Sebia Capillarys / Minicap (DCCT / NGSP)	%HbA <sub>1c</sub>	10.9	8.72 – 13.1
Sebia Capillarys / Minicap (IFCC)	mmol/mol	95.6	76.5 – 115
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.0	8.80 – 13.2
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	96.7	77.4 – 116
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA <sub>1c</sub>	12.2	9.76 – 14.6
Siemens DCA2000/Vantage (IFCC)	mmol/mol	110	88.0 – 132
Siemens/Dade Dimension (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Siemens/Dade Dimension (IFCC)	mmol/mol	102	81.6 – 122
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA <sub>1c</sub>	11.0	8.80 – 13.2
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	96.7	77.4 – 116
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.1	8.88 – 13.3
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	97.8	78.2 – 117
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA <sub>1c</sub>	12.1	9.68 – 14.5
Trinity Biotech Tri-stat (IFCC)	mmol/mol	109	87.2 – 131
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.1	8.88 – 13.3
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	97.8	78.2 – 117

Total Haemoglobin		Target	Range
Randox Rx Series	g/dl	12.6	10.1 – 15.1

26 Mar '18 ne