

## 糖化血红蛋白 (HbA<sub>1c</sub>) 质控品

货号: HA5072

包装: 2x2x0.5 ml

批号: 2261HA & 2264HA

效期: 2024-02-28

### 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。

- 小心打开瓶盖;
- 准确量取 0.5 ml 的蒸馏水加入;
- 盖好瓶盖, 转动试剂瓶若干次, 室温下静置 15 分钟;
- 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。

水平1

方法学	单位	靶值	范围
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	5.33	4.26 - 6.40
Abbott Architect c / Alinity c (IFCC)	mmol/mol	34.8	27.8 - 41.8
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	5.86	4.69 - 7.03
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	40.5	32.4 - 48.6
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	6.52	5.22 - 7.82
Agappe Mispa i3 (IFCC)	mmol/mol	47.8	38.2 - 57.4
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	6.75	5.40 - 8.10
Arkray PocketChem A1c (IFCC)	mmol/mol	50.3	40.2 - 60.4
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.62	4.50 - 6.74
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.9	30.3 - 45.5
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.81	4.65 - 6.97
Beckman AU Instruments (IFCC)	mmol/mol	40.0	32.0 - 48.0
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.56	4.45 - 6.67
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	37.3	29.8 - 44.8
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.77	4.62 - 6.92
Biorad D-10 (IFCC)	mmol/mol	39.6	31.7 - 47.5
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.78	4.62 - 6.94
Biorad D-100 (IFCC)	mmol/mol	39.7	31.8 - 47.6
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.5	31.6 - 47.4
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA1c	5.89	4.71 - 7.07
Boditech Med Inc i-CHROMA (IFCC)	mmol/mol	40.9	32.7 - 49.1
Centronic HbA1c (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Centronic HbA1c (IFCC)	mmol/mol	39.5	31.6 - 47.4
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Ceragem Labona Check (IFCC)	mmol/mol	37.6	30.1 - 45.1
Clover A1c (DCCT/NGSP)	%HbA1c	6.36	5.09 - 7.63
Clover A1c (IFCC)	mmol/mol	46.0	36.8 - 55.2
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	7.07	5.66 - 8.48
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	53.8	43.0 - 64.6
Erba XL Series (DCCT/NGSP)	%HbA1c	6.15	4.92 - 7.38
Erba XL Series (IFCC)	mmol/mol	43.7	35.0 - 52.4
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	5.64	4.51 - 6.77
Mindray BS200/300/400/800 (IFCC)	mmol/mol	38.1	30.5 - 45.7
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Mindray H50/ H50P (IFCC)	mmol/mol	39.1	31.3 - 46.9
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HbA1c	6.99	5.59 - 8.39
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	52.9	42.3 - 63.5
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	39.1	31.3 - 46.9
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Randox Rx HbA1c (IFCC)	mmol/mol	40.1	32.1 - 48.1
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	5.27	4.22 - 6.32
Randox Rx HbA1c II (IFCC)	mmol/mol	34.1	27.3 - 40.9
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.64	4.51 - 6.77
Roche Cobas 4000/c311 (IFCC)	mmol/mol	38.1	30.5 - 45.7
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.69	4.55 - 6.83
Roche Cobas 6000/8000 (IFCC)	mmol/mol	38.7	31.0 - 46.4
Roche Cobas c503 (DCCT/NGSP)	%HbA1c	5.81	4.65 - 6.97
Roche Cobas c503 (IFCC)	mmol/mol	40.0	32.0 - 48.0
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.80	4.64 - 6.96
Roche Cobas c513 (IFCC)	mmol/mol	39.9	31.9 - 47.9
Roche Integra (DCCT/NGSP)	%HbA1c	5.77	4.62 - 6.92
Roche Integra (IFCC)	mmol/mol	39.6	31.7 - 47.5
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	39.1	31.3 - 46.9

水平1

Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Sebia Capillarys / Minicap (IFCC)	mmol/mol	37.6	30.1 - 45.1
Siemens Advia CH A1c_E (DCCT/NGSP)	%HbA1c	5.26	4.21 - 6.31
Siemens Advia CH A1c_E (IFCC)	mmol/mol	34.0	27.2 - 40.8
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	5.45	4.36 - 6.54
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	36.1	28.9 - 43.3
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.97	4.78 - 7.16
Siemens DCA2000/Vantage (IFCC)	mmol/mol	41.7	33.4 - 50.0
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.86	4.69 - 7.03
Siemens/Dade Dimension (IFCC)	mmol/mol	40.5	32.4 - 48.6

<u>总血红蛋白</u>	<u>单位</u>	<u>靶值</u>	<u>范围</u>
Beckman AU Instruments	g/dl	14.25	11.40 - 17.10
Randox Rx Series	g/dl	14.19	11.35 - 17.03
Roche Cobas 4000/c311	g/dl	13.46	10.77 - 16.15
Roche Cobas 6000/8000	g/dl	15.66	12.53 - 18.79

水平2

方法学	单位	靶值	范围
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Abbott Architect c / Alinity c (IFCC)	mmol/mol	93.4	74.7 - 112
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	101	80.9 - 121
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	12.7	10.2 - 15.2
Agappe Mispa i3 (IFCC)	mmol/mol	115	92.2 - 138
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Arkray PocketChem A1c (IFCC)	mmol/mol	101	80.9 - 121
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	93.4	74.7 - 112
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Beckman AU Instruments (IFCC)	mmol/mol	97.8	78.2 - 117
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	100	80.0 - 120
Biorad D-10 (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Biorad D-10 (IFCC)	mmol/mol	98.9	79.1 - 119
Biorad D-100 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Biorad D-100 (IFCC)	mmol/mol	96.7	77.4 - 116
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	96.7	77.4 - 116
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Boditech Med Inc i-CHROMA (IFCC)	mmol/mol	90.2	72.2 - 108
Centronic HbA1c (DCCT/NGSP)	%HbA1c	10.2	8.16 - 12.2
Centronic HbA1c (IFCC)	mmol/mol	88.0	70.4 - 106
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	9.90	7.92 - 11.9
Ceragem Labona Check (IFCC)	mmol/mol	84.7	67.8 - 102
Clover A1c (DCCT/NGSP)	%HbA1c	10.3	8.24 - 12.4
Clover A1c (IFCC)	mmol/mol	89.1	71.3 - 107
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	100	80.0 - 120
Erba XL Series (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Erba XL Series (IFCC)	mmol/mol	98.9	79.1 - 119
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Mindray BS200/300/400/800 (IFCC)	mmol/mol	96.7	77.4 - 116
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Mindray H50/ H50P (IFCC)	mmol/mol	97.8	78.2 - 117
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	103	82.6 - 124
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	97.8	78.2 - 117
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	12.6	10.1 - 15.1
Randox Rx HbA1c (IFCC)	mmol/mol	114	91.4 - 137
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Randox Rx HbA1c II (IFCC)	mmol/mol	92.4	73.9 - 111
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Cobas 4000/c311 (IFCC)	mmol/mol	97.8	78.2 - 117
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Roche Cobas 6000/8000 (IFCC)	mmol/mol	96.7	77.4 - 116
Roche Cobas c503 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Roche Cobas c503 (IFCC)	mmol/mol	96.7	77.4 - 116
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Cobas c513 (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Integra (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Integra (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	97.8	78.2 - 117

水平2

Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Sebia Capillarys / Minicap (IFCC)	mmol/mol	93.4	74.7 - 112
Siemens Advia CH A1c_E (DCCT/NGSP)	%HbA1c	10.5	8.40 - 12.6
Siemens Advia CH A1c_E (IFCC)	mmol/mol	91.3	73.0 - 110
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	93.4	74.7 - 112
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Siemens DCA2000/Vantage (IFCC)	mmol/mol	101	80.9 - 121
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Siemens/Dade Dimension (IFCC)	mmol/mol	95.6	76.5 - 115

总血红蛋白	单位	靶值	范围
Beckman AU Instruments	g/dl	14.10	11.28 - 16.92
Randox Rx Series	g/dl	13.70	10.96 - 16.44
Roche Cobas 4000/c311	g/dl	13.70	10.96 - 16.44
Roche Cobas 6000/8000	g/dl	15.00	12.00 - 18.00

EC REP

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