

糖化血红蛋白 (HbA_{1c}) 质控品

货号: HA5072

包装: 2x2x0.5 ml

批号: 2341HA & 2343HA

效期: 2025-04-28

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_{1c}) 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 _{1c} 质控 1)	水平 2 (HbA _{1c} 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 进行下载。

水平1

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	5.09	4.07 - 6.11
Abbott Architect c / Alinity c (IFCC)	mmol/mol	32.1	25.7 - 38.5
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	38.5	30.8 - 46.2
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	6.27	5.02 - 7.52
Agappe Mispa i3 (IFCC)	mmol/mol	45.0	36.0 - 54.0
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.0	29.6 - 44.4
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Beckman AU Instruments (IFCC)	mmol/mol	39.2	31.4 - 47.0
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Beckman DxC600/DxC800 (IFCC)	mmol/mol	38.8	31.0 - 46.6
BioHermes Hb A1c (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
BioHermes Hb A1c (IFCC)	mmol/mol	38.6	30.9 - 46.3
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Biorad D-10 (IFCC)	mmol/mol	39.2	31.4 - 47.0
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Biorad D-100 (IFCC)	mmol/mol	39.1	31.3 - 46.9
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.2	31.4 - 47.0
Centronic HbA1c (DCCT/NGSP)	%HbA1c	6.02	4.82 - 7.22
Centronic HbA1c (IFCC)	mmol/mol	42.3	33.8 - 50.8
Clover A1c (DCCT/NGSP)	%HbA1c	6.11	4.89 - 7.33
Clover A1c (IFCC)	mmol/mol	43.3	34.6 - 52.0
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.76	5.41 - 8.11
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	50.4	40.3 - 60.5
Erba XL Series (DCCT/NGSP)	%HbA1c	5.97	4.78 - 7.16
Erba XL Series (IFCC)	mmol/mol	41.7	33.4 - 50.0
Labnovation LD-500 (DCCT/NGSP)	%HbA1c	6.02	4.82 - 7.22
Labnovation LD-500 (IFCC)	mmol/mol	42.3	33.8 - 50.8
Menarini HB Next (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Menarini HB Next (IFCC)	mmol/mol	37.0	29.6 - 44.4
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	5.50	4.40 - 6.60
Mindray BS200/300/400/800 (IFCC)	mmol/mol	36.6	29.3 - 43.9
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Mindray H50/ H50P (IFCC)	mmol/mol	38.5	30.8 - 46.2
Nycocard Reader (DCCT/NGSP)	%HbA1c	6.96	5.57 - 8.35
Nycocard Reader (IFCC)	mmol/mol	52.6	42.1 - 63.1
Ortho Vitros A1c I (Enzymatic) (DCCT/NGSP)	%HbA1c	6.40	5.12 - 7.68
Ortho Vitros A1c I (Enzymatic) (IFCC)	mmol/mol	46.4	37.1 - 55.7
Ortho Vitros d%A1c (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Ortho Vitros d%A1c (IFCC)	mmol/mol	38.5	30.8 - 46.2
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	5.14	4.11 - 6.17
Randox Rx HbA1c (IFCC)	mmol/mol	32.7	26.2 - 39.2
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	5.43	4.34 - 6.52
Randox Rx HbA1c II (IFCC)	mmol/mol	35.8	28.6 - 43.0
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
Roche Cobas 4000/c311 (IFCC)	mmol/mol	38.6	30.9 - 46.3
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.71	4.57 - 6.85
Roche Cobas 6000/8000 (IFCC)	mmol/mol	38.9	31.1 - 46.7
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Roche Cobas c303/c503 (IFCC)	mmol/mol	40.1	32.1 - 48.1
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.83	4.66 - 7.00
Roche Cobas c513 (IFCC)	mmol/mol	40.2	32.2 - 48.2
Roche Integra (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Roche Integra (IFCC)	mmol/mol	39.0	31.2 - 46.8
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	40.1	32.1 - 48.1
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.7	29.4 - 44.0
Shenzhen Lifotronic HbA1c (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Shenzhen Lifotronic HbA1c (IFCC)	mmol/mol	39.1	31.3 - 46.9
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	4.94	3.95 - 5.93
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	30.5	24.4 - 36.6
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	5.05	4.04 - 6.06
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	31.7	25.4 - 38.0
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.97	4.78 - 7.16
Siemens DCA2000/Vantage (IFCC)	mmol/mol	41.7	33.4 - 50.0

Method	Units	Target	Range
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Siemens/Dade Dimension (IFCC)	mmol/mol	40.3	32.2 - 48.4
TOSOH G8 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.72	5.26 - 6.12
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	39.0	35.9 - 42.1
TOSOH GX Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.67	5.22 - 6.07
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	38.5	35.4 - 41.6
TOSOH G11 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.70	5.24 - 6.10
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	38.8	35.7 - 41.9
Trinity Biotech Premier Hb9210 (DCCT / NGSP)	%HbA1c	6.26	5.88 - 6.64
Trinity Biotech Premier Hb9210 (IFCC)	mmol/mol	44.9	40.8 - 49.0
uWondfo Finicare Meter (DCCT/NGSP)	%HbA1c	6.27	5.02 - 7.52
Wondfo Finicare Meter (IFCC)	mmol/mol	45.0	36.0 - 44.0

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	14.2	11.4 - 17.0
Randox RX Series	g/dl	14.5	11.6 - 17.4
Roche Cobas 6000/8000	g/dl	15.7	12.6 - 18.8

水平2

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.7	8.55 - 12.9
Abbott Architect c / Alinity c (IFCC)	mmol/mol	93.4	74.7 - 112
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	12.0	9.58 - 14.4
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	108	86.4 - 130
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	13.0	10.4 - 15.6
Agappe Mispa i3 (IFCC)	mmol/mol	119	95.2 - 143
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	11.0	8.82 - 13.2
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	96.7	77.4 - 116
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	11.7	9.34 - 14.1
Beckman AU Instruments (IFCC)	mmol/mol	104	83.2 - 125
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	11.7	9.33 - 14.1
Beckman DxC600/DxC800 (IFCC)	mmol/mol	104	83.2 - 125
BioHermes Hb A1c (DCCT/NGSP)	%HbA1c	11.5	9.18 - 13.8
BioHermes Hb A1c (IFCC)	mmol/mol	102	81.6 - 122
Biorad D-10 (DCCT/NGSP)	%HbA1c	11.7	9.32 - 14.1
Biorad D-10 (IFCC)	mmol/mol	104	83.2 - 125
Biorad D-100 (DCCT/NGSP)	%HbA1c	11.6	9.27 - 13.9
Biorad D-100 (IFCC)	mmol/mol	103	82.4 - 124
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	11.5	9.17 - 13.8
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	102	81.6 - 122
Centronic HbA1c (DCCT/NGSP)	%HbA1c	11.6	9.30 - 13.9
Centronic HbA1c (IFCC)	mmol/mol	103	82.4 - 124
Clover A1c (DCCT/NGSP)	%HbA1c	11.0	8.79 - 13.2
Clover A1c (IFCC)	mmol/mol	96.7	77.4 - 116
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.9	9.49 - 14.3
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	107	85.6 - 128
Erba XL Series (DCCT/NGSP)	%HbA1c	11.1	8.85 - 13.4
Erba XL Series (IFCC)	mmol/mol	97.8	78.2 - 117
Labnovation LD-500 (DCCT/NGSP)	%HbA1c	10.5	8.37 - 12.6
Labnovation LD-500 (IFCC)	mmol/mol	91.3	73.0 - 110
Menarini HB Next (DCCT/NGSP)	%HbA1c	10.7	8.53 - 12.9
Menarini HB Next (IFCC)	mmol/mol	93.4	74.7 - 112
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	11.7	9.32 - 14.1
Mindray BS200/300/400/800 (IFCC)	mmol/mol	104	83.2 - 125
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	11.4	9.10 - 13.7
Mindray H50/ H50P (IFCC)	mmol/mol	101	80.8 - 121
Nycocard Reader (DCCT/NGSP)	%HbA1c	10.5	8.39 - 12.6
Nycocard Reader (IFCC)	mmol/mol	91.3	73.0 - 110
Ortho Vitros A1C1 (Enzymatic) (DCCT/NGSP)	%HbA1c	12.3	9.84 - 14.8
Ortho Vitros A1C1 (Enzymatic) (IFCC)	mmol/mol	111	88.8 - 133
Ortho Vitros d%A1c (DCCT/NGSP)	%HbA1c	11.7	9.35 - 14.1
Ortho Vitros d%A1c (IFCC)	mmol/mol	104	83.2 - 125
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	15.7	12.6 - 18.8
Randox Rx HbA1c IFCC	mmol/mol	148	118 - 178
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Randox Rx HbA1c II (IFCC)	mmol/mol	105	84.0 - 126
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.6	9.32 - 13.9
Roche Cobas 4000/c311 (IFCC)	mmol/mol	103	82.4 - 124
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	11.5	9.19 - 13.8
Roche Cobas 6000/8000 (IFCC)	mmol/mol	102	81.6 - 122
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	11.7	9.39 - 14.0
Roche Cobas c303/c503 (IFCC)	mmol/mol	104	83.2 - 125
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	11.6	9.30 - 13.9
Roche Cobas c513 (IFCC)	mmol/mol	103	82.4 - 124
Roche Integra (DCCT/NGSP)	%HbA1c	11.8	9.42 - 14.2
Roche Integra (IFCC)	mmol/mol	105	84.0 - 126
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	12.0	9.58 - 14.4
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	108	86.4 - 130
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	11.1	8.90 - 13.3
Sebia Capillarys / Minicap (IFCC)	mmol/mol	97.8	78.2 - 117
Shenzhen Lifotronic HbA1c (DCCT/NGSP)	%HbA1c	11.4	9.09 - 13.7
Shenzhen Lifotronic HbA1c (IFCC)	mmol/mol	101	80.8 - 121
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	10.8	8.60 - 13.0
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	10.8	8.60 - 13.0
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	12.2	9.76 - 14.6
Siemens DCA2000/Vantage (IFCC)	mmol/mol	110	88.0 - 132

Method	Units	Target	Range
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	11.5	9.22 - 13.8
Siemens/Dade Dimension (IFCC)	mmol/mol	102	81.6 - 122
TOSOH G8 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.5	10.5 - 12.3
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	102	93.5 - 110
TOSOH GX Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.4	10.5 - 12.2
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	101	93.0 - 109
TOSOH G11 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.3	10.4 - 12.1
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	100	92.0 - 108
Trinity Biotech Premier Hb9210 (DCCT / NGSP)	%HbA1c	11.5	10.8 - 12.2
Trinity Biotech Premier Hb9210 (IFCC)	mmol/mol	102	94.9 - 110
Wondfo Finecare Meter (DCCT/NGSP)	%HbA1c	11.5	9.21 - 13.8
Wondfo Finecare Meter (IFCC)	mmol/mol	102	81.6 - 122

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	13.4	10.7 - 16.1
Randox RX Series	g/dl	14.5	11.6 - 17.4
Roche Cobas 6000/8000	g/dl	15.3	12.2 - 18.4

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