

糖化血红蛋白 (HbA_{1c}) 质控品

货号: HA5072

包装: 2x2x0.5 ml

批号: 2020HA & 2023HA

效期: 2021-03-28

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I

方法学	单位	靶值	范围
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	5.30	4.24 - 6.36
Abbott Architect c / Alinity c (IFCC)	mmol/mol	34.4	27.5 - 41.3
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	6.16	4.93 - 7.39
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	43.8	35.0 - 52.6
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	6.34	5.07 - 7.61
Agappe Mispa i3 (IFCC)	mmol/mol	45.8	36.6 - 55.0
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.6	30.1 - 45.1
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.78	4.62 - 6.94
Beckman AU Instruments (IFCC)	mmol/mol	39.7	31.8 - 47.6
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Beckman DxC600/DxC800 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.58	4.46 - 6.70
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	37.5	30.0 - 45.0
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.65	4.52 - 6.78
Biorad D-10 (IFCC)	mmol/mol	38.3	30.6 - 46.0
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Biorad D-100 (IFCC)	mmol/mol	39.0	31.2 - 46.8
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	38.8	31.0 - 46.6
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	5.90	4.72 - 7.08
Ceragem Labona Check (IFCC)	mmol/mol	41.0	32.8 - 49.2
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.50	5.20 - 7.80
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	47.5	38.0 - 57.0
Erba XL Series (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Erba XL Series (IFCC)	mmol/mol	39.5	31.6 - 47.4
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	6.00	4.80 - 7.20
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	42.1	33.7 - 50.5
Mindray BS200/300/400 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Mindray BS200/300/400 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Nycocard Reader (DCCT/NGSP)	%HbA1c	7.54	6.03 - 9.05
Nycocard Reader (IFCC)	mmol/mol	58.9	47.1 - 70.7
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT/NGSP)	%HbA1c	5.63	4.50 - 6.76
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	38.0	30.4 - 45.6
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	6.13	4.90 - 7.36
Randox Rx HbA1c (IFCC)	mmol/mol	43.5	34.8 - 52.2
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.47	4.38 - 6.56
Roche Cobas 4000/c311 (IFCC)	mmol/mol	36.3	29.0 - 43.6
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.57	4.46 - 6.68
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.4	29.9 - 44.9
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Roche Cobas c513 (IFCC)	mmol/mol	38.5	30.8 - 46.2
Roche Integra (DCCT/NGSP)	%HbA1c	5.64	4.51 - 6.77
Roche Integra (IFCC)	mmol/mol	38.1	30.5 - 45.7
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	38.8	31.0 - 46.6
SD A1c Care (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
SD A1c Care (IFCC)	mmol/mol	37.0	29.6 - 44.4

水平I (continued)

方法学	单位	靶值	范围
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.45	4.36 - 6.54
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.1	28.9 - 43.3
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	6.05	4.84 - 7.26
Siemens DCA2000/Vantage (IFCC)	mmol/mol	42.6	34.1 - 51.1
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.87	4.70 - 7.04
Siemens/Dade Dimension (IFCC)	mmol/mol	40.7	32.6 - 48.8
TOSOH HLC723/G7/G8/GX (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	38.5	30.8 - 46.2
Trin Bio CLC385/PDQ/Ultra 2 (DCCT/NGSP)	%HbA1c	6.10	4.88 - 7.32
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	43.2	34.6 - 51.8
Trinity Biotech Tri-stat (DCCT/NGSP)	%HbA1c	6.94	5.55 - 8.33
Trinity Biotech Tri-stat (IFCC)	mmol/mol	52.3	41.8 - 62.8
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA1c	6.25	5.00 - 7.50
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	44.8	35.8 - 53.8

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	12.0	9.60 - 14.4
Randox Rx Series	g/dl	12.9	10.3 - 15.5
Roche Cobas 4000/c311	g/dl	13.0	10.4 - 15.6
Roche Cobas 6000/8000	g/dl	13.7	11.0 - 16.4
Siemens ADVIA 1200/1650/1800/2400	g/dl	12.8	10.2 - 15.4

水平 2

Method	単位	靶値	範囲
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.2	8.16 - 12.2
Abbott Architect c / Alinity c (IFCC)	mmol/mol	88.0	70.4 - 106
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	105	84.0 - 126
Abbott Architect i/ Alinity i (DCCT/NGSP)	%HbA1c	13.9	11.1 - 16.7
Abbott Architect i/ Alinity i (IFCC)	mmol/mol	128	102 - 154
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	13.0	10.4 - 15.6
Agappe Mispa i3 (IFCC)	mmol/mol	119	95.2 - 143
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Arkray PocketChem A1c (IFCC)	mmol/mol	98.9	79.1 - 119
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
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Beckman DxC600/DxC800 (IFCC)	mmol/mol	101	80.8 - 121
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	12.7	10.2 - 15.2
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	115	92.0 - 138
Biorad D-10 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Biorad D-10 (IFCC)	mmol/mol	96.7	77.4 - 116
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	11.1	8.88 - 13.3
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	97.8	78.2 - 117
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	9.28	7.42 - 11.1
Ceragem Labona Check (IFCC)	mmol/mol	77.9	62.3 - 93.5
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.7	9.36 - 14.0
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	104	83.2 - 125
Erba XL Series (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Erba XL Series (IFCC)	mmol/mol	90.2	72.2 - 108
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Human HumaMeter A1c (IFCC)	mmol/mol	101	80.8 - 121
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	103	82.4 - 124
Mindray BS200/300/400 (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Mindray BS200/300/400 (IFCC)	mmol/mol	103	82.4 - 124
Nycocard Reader (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Nycocard Reader (IFCC)	mmol/mol	100	80.0 - 120
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	95.6	76.5 - 115
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Randox Rx HbA1c (IFCC)	mmol/mol	105	84.0 - 126
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Cobas 4000/c311 (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Cobas 6000/8000 (IFCC)	mmol/mol	97.8	78.2 - 117
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Roche Cobas c513 (IFCC)	mmol/mol	103	82.4 - 124

水平 2 (continued)

方法学	单位	靶值	范围
Roche Integra (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Integra (IFCC)	mmol/mol	97.8	78.2 - 117
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	96.7	77.4 - 116
SD A1c Care (DCCT/NGSP)	%HbA1c	9.53	7.62 - 11.4
SD A1c Care (IFCC)	mmol/mol	80.7	64.6 - 97.0
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Sebia Capillarys / Minicap (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	11.5	9.20 - 13.8
Siemens DCA2000/Vantage (IFCC)	mmol/mol	102	81.6 - 122
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Siemens/Dade Dimension (IFCC)	mmol/mol	97.8	78.2 - 117
TOSOH HLC723/G7/G8/GX (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	94.5	75.6 - 113
Trin Bio CLC385/PDQ/Ultra 2 (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	101	80.8 - 121
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA1c	11.0	8.8 - 13.2
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	96.7	77.4 - 116

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	11.2	8.96 - 13.4
Randox Rx Series	g/dl	13.7	11 - 16.4
Roche Cobas 4000/c311	g/dl	12.0	9.6 - 14.4
Roche Cobas 6000/8000	g/dl	13.7	11 - 16.4
Siemens ADVIA 1200/1650/1800/2400	g/dl	12.9	10.3 - 15.5

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