RANDOX

糖化血红蛋白(HbA1c)质控品

货号: HA5072　　包装: 2x2x0.5 ml

批号: 2158HA & 2161HA　　效期: 2023-01

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℃可保存至效期末。

复溶后，2～8℃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。

LEVEL 1

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	5.53	4.42 - 6.64
Abbott Architect c / Alinity c (IFCC)	mmol/mol	36.9	29.5 - 44.3
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	5.99	4.79 - 7.19
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	42.0	33.6 - 50.4
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	6.25	5.00 - 7.50
Arkray PocketChem A1c (IFCC)	mmol/mol	44.8	35.8 - 53.8
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	38.8	31.0 - 46.6
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Beckman AU Instruments (IFCC)	mmol/mol	39.5	31.6 - 47.4
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.79	4.63 - 6.95
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	39.8	31.8 - 47.8
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.80	4.64 - 6.96
Biorad D-10 (IFCC)	mmol/mol	39.9	31.9 - 47.9
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.77	4.62 - 6.92
Biorad D-100 (IFCC)	mmol/mol	39.6	31.7 - 47.5
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.86	4.69 - 7.03
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	40.5	32.4 - 48.6
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	5.85	4.68 - 7.02
Ceragem Labona Check (IFCC)	mmol/mol	40.4	32.3 - 48.5
Clover A1c (DCCT/NGSP)	%HbA1c	6.32	5.06 - 7.58
Clover A1c (IFCC)	mmol/mol	45.6	36.5 - 54.7
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.47	5.18 - 7.76
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	47.2	37.8 - 56.6
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 (DCCT/NGSP)	%HbA1c	6.06	4.85 - 7.27
Mindray BS200/300/400 (IFCC)	mmol/mol	42.7	34.2 - 51.2
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	39.0	31.2 - 46.8
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	6.17	4.94 - 7.40
Randox Rx HbA1c (IFCC)	mmol/mol	43.9	35.1 - 52.7
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.60	4.48 - 6.72
Roche Cobas 4000/c311 (IFCC)	mmol/mol	37.7	30.2 - 45.2
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Roche Cobas 6000/8000 (IFCC)	mmol/mol	38.5	30.8 - 46.2
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	5.73	4.58 - 6.88
Roche Integra (IFCC)	mmol/mol	39.1	31.3 - 46.9
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.93	4.74 - 7.12
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	41.3	33.0 - 49.6
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.7	29.4 - 44.0
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	5.77	4.62 - 6.92
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	39.6	31.7 - 47.5
Siemens Atellica CH (DCCT/NGSP)	%HbA1c	5.83	4.66 - 7.00
Siemens Atellica CH (IFCC)	mmol/mol	40.2	32.2 - 48.2
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.93	4.74 - 7.12
Siemens DCA2000/Vantage (IFCC)	mmol/mol	41.3	33.0 - 49.6
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.96	4.77 - 7.15
Siemens/Dade Dimension (IFCC)	mmol/mol	41.6	33.3 - 49.9

Total Haemoglobin	Units	Target	Range
Abbott Architect c	g/dl	4.61	3.69 - 5.53
Beckman AU Instruments	g/dl	11.3	9.04 - 13.6
Randox RX Series	g/dl	12.4	9.92 - 14.9
Roche Cobas 4000/c311	g/dl	12.3	9.84 - 14.8
Roche Cobas 6000/8000	g/dl	12.9	10.3 - 15.5

LEVEL 2

Method	Units	Target	Range
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	11.5	9.20 - 13.8
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	102	81.6 - 122
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Arkray PocketChem A1c (IFCC)	mmol/mol	97.8	78.2 - 117
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	10.9	8.72 - 13.1
Beckman AU Instruments (IFCC)	mmol/mol	95.6	76.5 - 115
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	92.4	73.9 - 111
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	7.77	6.22 - 9.32
Ceragem Labona Check (IFCC)	mmol/mol	61.4	49.1 - 73.7
Clover A1c (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Clover A1c (IFCC)	mmol/mol	90.2	72.2 - 108
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	10.7	8.56 - 12.8
Erba XL Series (IFCC)	mmol/mol	93.4	74.7 - 112
Mindray BS200/300/400 (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Mindray BS200/300/400 (IFCC)	mmol/mol	100	80.0 - 120
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	93.4	74.7 - 112
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	12.2	9.76 - 14.6
Randox Rx HbA1c (IFCC)	mmol/mol	110	88.0 - 132
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 c513 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Cobas c513 (IFCC)	mmol/mol	97.8	78.2 - 117
Roche Integra (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Roche Integra (IFCC)	mmol/mol	96.7	77.4 - 116
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	94.5	75.6 - 113
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Sebia Capillarys / Minicap (IFCC)	mmol/mol	92.4	73.9 - 111
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	90.2	72.2 - 108
Siemens Atellica CH (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Siemens Atellica CH (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	80.8 - 121
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Siemens/Dade Dimension (IFCC)	mmol/mol	94.5	75.6 - 113

Total Haemoglobin	Units	Target	Range
Abbott Architect c	g/dl	4.89	3.91 - 5.87
Beckman AU Instruments	g/dl	11.9	9.52 - 14.3
Randox RX Series	g/dl	12.9	10.3 - 15.5
Roche Cobas 4000/c311	g/dl	12.6	10.1 - 15.1
Roche Cobas 6000/8000	g/dl	13.5	10.8 - 16.2