

心肌多项标志物检测用质控品

货号: CQ3259

包装: 3x1x2 ml

批号: 602366(4646CK-4648CK)

效期: 2025-12

产品描述

本品为心肌多项标志物检测用质控品，又称三水平心肌质控品，适用于体外诊断中临床生化或免疫检测系统的心肌标志物检测的质量控制。

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。

该质控品采用人基质血清,对所有捐献者的血清均进行了 HIV(HIV1、HIV2)抗体、肝炎 B 表面抗原(HbsAg)和肝炎 C 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。

然而,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

复溶后,建议 2~8℃冷藏保存。如果原瓶保存并且未被污染,2~8℃可保存 5 天, -20℃冷冻可保存 28 天,只能冻融 1 次,肌钙蛋白 I 于-20℃冷冻保存可稳定 14 天。每次取出所需用量,用后剩余的样品不可以返回原瓶。

未开瓶,2~8℃可保存至效期末。

使用说明

该三水平心肌质控品为冻干品。

1. 小心打开瓶盖,用 2 ml 的蒸馏水在 20℃~25℃的条件下复溶,盖好瓶盖,静置 30 分钟,轻轻旋转,确保所有干粉充分溶解。不要震荡,避免产生气泡;
2. 参考各个仪器的质控说明;
3. 冷冻保存未使用的材料。再次使用前,确保材料混合均匀。

包装规格

三水平心肌质控品

浓度水平	水平 1	水平 2	水平 3
包装规格	1 x 2 ml	1 x 2 ml	1 x 2 ml

需要自备的材料

移液管,蒸馏水

赋值

每一批质控血清都要送到大量的外部实验室,然后将结果与朗道实验室内部得到的结果用相同的统计分析进行赋值。在实验室建立起自己的靶值和 SD 范围前,质控范围值用来协助实验室进行质量控制。

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。

三水平心肌质控 水平 1

Cat. No. CQ3259 Lot. No. 4646CK Size 1 x 2ml Expiry 2025-12-28

Range					
Analyte	unit	Target	low	high	methods
肌酸激酶(CK)	U/l	107	88	126	Vitros 37°C
	U/l	82	67	97	CK-NAC (IFCC) 37°C
	U/l	51	42	60	CK-NAC (IFCC) 30°C
	U/l	35	28	42	CK-NAC (IFCC) 25°C
肌酸激酶同工酶 (质量)	ng/ml = µg/l	4.69	3.28	6.10	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.02	2.81	5.23	Abbott Architect / Alinity
同型半胱氨酸	µmol/l	12.4	9.92	14.9	Abbott Architect
	µmol/l	17.2	13.8	20.6	Roche Cobas 6000/8000
	µmol/l	16.2	13.0	19.4	Enzymatic
肌红蛋白	ng/ml = µg/l	48.1	33.7	62.5	Abbott Architect
肌钙蛋白 I	ng/ml = µg/l	0.272	0.218	0.326	Ortho Vitros ECi
	ng/l = pg/ml	272	218	326	
	ng/ml = µg/l	0.281	0.225	0.337	Abbott Architect
	ng/l = pg/ml	281	225	337	
	ng/ml = µg/l	0.304	0.243	0.365	Abbott i STAT
	ng/l = pg/ml	304	243	365	
	ng/ml = µg/l	0.102	0.082	0.122	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	102	82.0	122	
	ng/ml = µg/l	0.277	0.222	0.332	Abbott Architect STAT hs
	ng/l = pg/ml	277	222	332	
	ng/ml = µg/l	0.212	0.170	0.254	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	212	170	254	
	ng/ml = µg/l	0.237	0.190	0.284	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	237	190	284	
	ng/ml = µg/l	0.081	0.065	0.097	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	81.0	65.0	97.0	
肌钙蛋白 T	ng/ml = µg/l	0.093	0.074	0.112	Beckman Dxl Hs
	ng/l = pg/ml	93.0	74.0	112	
	ng/ml = µg/l	0.016	0.011	0.021	Roche Cobas Troponin T HS
	ng/l = pg/ml	16.0	11.0	21.0	
	ng/ml = µg/l	0.016	0.011	0.021	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	16.0	11.0	21.0	
	ng/ml = µg/l	0.016	0.011	0.021	Roche Cobas e801 TnT hs
	ng/l = pg/ml	16.0	11.0	21.0	

三水平心肌质控 水平2

Cat. No. CQ3259		Lot. No. 4647CK		Size 1 x 2ml Expiry 2025-12-28	
Range					
Analyte	unit	Target	low	high	methods
肌酸激酶(CK)	U/l	306	251	361	Vitros 37°C
	U/l	224	184	264	CK-NAC (IFCC) 37°C
	U/l	140	115	165	CK-NAC (IFCC) 30°C
	U/l	95	78	112	CK-NAC (IFCC) 25°C
肌酸激酶同工酶（活性）	U/l	19.3	15.4	23.2	Immunoinhibition substrate start 37°C
	U/l	11.2	8.95	13.5	Immunoinhibition substrate start 30°C
	U/l	6.85	5.47	8.23	Immunoinhibition substrate start 25°C
	U/l	16.7	13.4	20.0	Immunoinhibition serum start 37°C
	U/l	9.71	7.79	11.6	Immunoinhibition serum start 30°C
	U/l	5.93	4.76	7.10	Immunoinhibition serum start 25°C
	U/l	20.0	16.0	24.0	Immunoinhibition (IFCC) 37°C
	U/l	11.6	9.30	13.9	Immunoinhibition (IFCC) 30°C
肌酸激酶同工酶（质量）	U/l	7.10	5.68	8.52	Immunoinhibition (IFCC) 25°C
	ng/ml = µg/l	16.1	11.3	20.9	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	15.8	11.1	20.5	Abbott Architect / Alinity
	同型半胱氨酸	µmol/l	19.6	15.7	23.5
µmol/l		31.9	25.5	38.3	Roche Cobas 6000/8000
µmol/l		22.9	18.3	27.5	Enzymatic
肌红蛋白		ng/ml = µg/l	155	109	202
肌钙蛋白 I	ng/ml = µg/l	13.0	10.4	15.6	Ortho Vitros ECi
	ng/l = pg/ml	13000	10400	15600	
	ng/ml = µg/l	2.55	2.04	3.06	Abbott Architect
	ng/l = pg/ml	2550	2040	3060	
	ng/ml = µg/l	10.2	8.16	12.2	Abbott i STAT
	ng/l = pg/ml	10200	8160	12200	
	ng/ml = µg/l	1.16	0.928	1.39	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1160	928	1392	
	ng/ml = µg/l	2.45	1.96	2.94	Abbott Architect STAT hs
	ng/l = pg/ml	2450	1960	2940	
	ng/ml = µg/l	11.7	9.36	14.0	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	11700	9360	14000	
	ng/ml = µg/l	6.89	5.51	8.27	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	6890	5510	8270	
	ng/ml = µg/l	2.48	1.98	2.98	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	2480	1980	2980	
肌钙蛋白 I	ng/ml = µg/l	2.57	2.06	3.08	Beckman Dxl Hs
	ng/l = pg/ml	2570	2060	3080	
	ng/ml = µg/l	0.244	0.171	0.317	Roche Cobas h232
	ng/l = pg/ml	244	171	317	
	ng/ml = µg/l	0.331	0.232	0.430	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	331	232	430	
	ng/ml = µg/l	0.411	0.288	0.534	Roche Cobas e801 TnT hs
	ng/l = pg/ml	411	288	534	

三水平心肌质控 水平3

Cat. No. CQ3259 Lot. No. 4648CK Size 1 x 2ml Expiry 2025-12-28

Range					
Analyte	unit	Target	low	high	methods
肌酸激酶(CK)	U/l	870	713	1027	Vitros 37°C
	U/l	661	542	780	CK-NAC (IFCC) 37°C
	U/l	414	339	489	CK-NAC (IFCC) 30°C
	U/l	281	230	332	CK-NAC (IFCC) 25°C
肌酸激酶同工酶 (活性)	U/l	104	83.2	125	Immunoinhibition substrate start 37°C
	U/l	60.4	48.4	72.4	Immunoinhibition substrate start 30°C
	U/l	36.9	29.5	44.3	Immunoinhibition substrate start 25°C
	U/l	102	81.6	122	Immunoinhibition serum start 37°C
	U/l	59.3	47.4	71.2	Immunoinhibition serum start 30°C
	U/l	36.2	29.0	43.4	Immunoinhibition serum start 25°C
	U/l	108	86.4	130	Immunoinhibition (IFCC) 37°C
	U/l	62.8	50.2	75.4	Immunoinhibition (IFCC) 30°C
	U/l	38.3	30.7	45.9	Immunoinhibition (IFCC) 25°C
肌酸激酶同工酶 (质量)	ng/ml = µg/l	108	75.6	140	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	113	79.1	147	Abbott Architect / Alinity
同型半胱氨酸	µmol/l	39.4	31.5	47.3	Abbott Architect
	µmol/l	67.6	54.1	81.1	Roche Cobas 6000/8000
	µmol/l	40.3	32.2	48.4	Enzymatic
肌红蛋白	ng/ml = µg/l	270	189	351	Abbott Architect
肌钙蛋白 I	ng/ml = µg/l	51.1	40.9	61.3	Ortho Vitros ECi
	ng/l = pg/ml	51100	40900	61300	
	ng/ml = µg/l	46.9	37.5	56.3	Tosoh Series
	ng/l = pg/ml	46900	37500	56300	
	ng/ml = µg/l	44.0	35.2	52.8	Abbott i STAT
	ng/l = pg/ml	44000	35200	52800	
	ng/ml = µg/l	3.14	2.51	3.77	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	3140	2510	3770	
	ng/ml = µg/l	7.93	6.34	9.52	Abbott Architect STAT hs
	ng/l = pg/ml	7930	6340	9520	
	ng/ml = µg/l	23.0	18.4	27.6	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	23000	18400	27600	
	ng/ml = µg/l	12.8	10.2	15.4	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	12800	10200	15400	
肌钙蛋白 T	ng/ml = µg/l	13.0	10.4	15.6	Beckman Dxl Hs
	ng/l = pg/ml	13000	10400	15600	
	ng/ml = µg/l	0.992	0.694	1.290	Roche Cobas Troponin T HS
	ng/l = pg/ml	992	694	1290	
	ng/ml = µg/l	0.592	0.414	0.770	Roche Cobas h232
	ng/l = pg/ml	592	414	770	
	ng/ml = µg/l	0.977	0.684	1.270	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	977	684	1270	
	ng/ml = µg/l	1.230	0.861	1.600	Roche Cobas e801 TnT hs
	ng/l = pg/ml	1230	861	1599	