

心肌多项标志物检测用质控品

货号: CQ3259

包装: 3x1x2 ml

批号: 616793(4681CK-4683CK)

效期: 2026-08

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°C 冷藏保存。如果原瓶保存并且未被污染，2~8°C 可保存 5 天，-20°C 冷冻可保存 28 天，只能冻融 1 次，肌钙蛋白 I 于 -20°C 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°C 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°C~25°C 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. 4681CK

Size 1 x 2ml Expiry 2026-08-28

Analyte	unit	Target	Range		methods
			low	high	
肌酸激酶(CK)	U/l	89	73	105	CK-NAC substrate start (DGKC) 37°C
	U/l	56	46	66	CK-NAC substrate start (DGKC) 30°C
	U/l	38	31	45	CK-NAC substrate start (DGKC) 25°C
	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	3.69	2.58	4.80	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.06	2.14	3.98	Abbott Architect / Alinity
同型半胱氨酸	µmol/l	11.0	8.80	13.2	Abbott Architect
	µmol/l	15.7	12.6	18.8	Roche Cobas 6000/8000
	µmol/l	15.6	12.5	18.7	Enzymatic
肌红蛋白	ng/ml = µg/l	67.5	47.3	87.8	Abbott Architect
肌钙蛋白 I	ng/ml = µg/l	0.341	0.273	0.409	Ortho Vitros ECi
	ng/l = pg/ml	341	273	409	
	ng/ml = µg/l	0.575	0.460	0.690	Tosoh Series
	ng/l = pg/ml	575	460	690	
	ng/ml = µg/l	0.107	0.086	0.128	Abbott Architect
	ng/l = pg/ml	107	86.0	128	
	ng/ml = µg/l	0.398	0.318	0.478	Abbott i STAT
	ng/l = pg/ml	398	318	478	
	ng/ml = µg/l	0.110	0.088	0.132	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	110	88.0	132	
	ng/l = pg/ml	0.047	0.037	0.057	
	ng/ml = µg/l	0.109	0.087	0.131	Abbott Architect STAT hs
	ng/l = pg/ml	109	87.0	131	
	ng/ml = µg/l	0.244	0.195	0.293	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	244	195	293	
ng/ml = µg/l	0.170	0.136	0.204	Siemens Centaur CP/XP/XPT TNIH	
ng/l = pg/ml	170	136	204		
ng/ml = µg/l	0.056	0.045	0.067	Beckman Access 2/DxC600i Hs	
ng/l = pg/ml	56.0	45.0	67.0		
肌钙蛋白 T	ng/ml = µg/l	0.014	0.010	0.018	Roche Cobas Troponin T HS
	ng/l = pg/ml	14.2	10.0	18.4	
	ng/ml = µg/l	0.013	0.009	0.017	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	13.4	9.00	17.8	
	ng/ml = µg/l	0.015	0.010	0.019	Roche Cobas e801 TnT hs
	ng/l = pg/ml	14.6	10.0	19.2	
ng/ml = µg/l	0.014	0.010	0.018	Roche Cobas e801 TnT hs STAT	
ng/l = pg/ml	13.9	10.0	17.8		

三水平心肌质控 水平2

Cat. No. CQ3259 Lot. No. 4682CK

Size 1 x 2ml Expiry 2026-08-28

Analyte	unit	Target	Range		methods
			low	high	
肌酸激酶(CK)	U/l	224	184	264	CK-NAC substrate start (DGKC) 37°C
	U/l	140	115	165	CK-NAC substrate start (DGKC) 30°C
	U/l	95	78.0	112	CK-NAC substrate start (DGKC) 25°C
	U/l	285	234	336	Vitros 37°C
	U/l	219	180	258	CK-NAC (IFCC) 37°C
	U/l	137	113	161	CK-NAC (IFCC) 30°C
	U/l	93	77	109	CK-NAC (IFCC) 25°C
肌酸激酶同工酶 (活性)	U/l	12.7	10.2	15.2	Vitros 37°C
	U/l	19.9	15.9	23.9	Immunoinhibition substrate start 37°C
	U/l	11.6	9.24	14.0	Immunoinhibition substrate start 30°C
	U/l	7.06	5.64	8.48	Immunoinhibition substrate start 25°C
	U/l	18.1	14.5	21.7	Immunoinhibition serum start 37°C
	U/l	10.5	8.43	12.6	Immunoinhibition serum start 30°C
	U/l	6.43	5.15	7.71	Immunoinhibition serum start 25°C
	U/l	18.8	15.0	22.6	Immunoinhibition (IFCC) 37°C
	U/l	10.9	8.72	13.1	Immunoinhibition (IFCC) 30°C
肌酸激酶同工酶 (质量)	ng/ml = µg/l	16.5	11.6	21.5	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	16.7	11.7	21.7	Abbott Architect / Alinity
同型半胱氨酸	µmol/l	20.1	16.1	24.1	Abbott Architect
	µmol/l	31.0	24.8	37.2	Roche Cobas 6000/8000
	µmol/l	24.1	19.3	28.9	Enzymatic
肌红蛋白	ng/ml = µg/l	192	134	250	Abbott Architect
肌钙蛋白 I	ng/ml = µg/l	10.1	8.08	12.1	Ortho Vitros ECi
	ng/l = pg/ml	10100	8080	12120	
	ng/ml = µg/l	1.63	1.30	1.96	Abbott Architect
	ng/l = pg/ml	1630	1300	1960	
	ng/ml = µg/l	9.67	7.74	11.6	Abbott i STAT
	ng/l = pg/ml	9670	7740	11600	
	ng/ml = µg/l	0.580	0.470	0.700	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	583	466	700	
	ng/ml = µg/l	1.61	1.29	1.93	Abbott Architect STAT hs
	ng/l = pg/ml	1610	1290	1930	
	ng/ml = µg/l	8.15	6.52	9.78	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	8150	6520	9780	
	ng/ml = µg/l	4.78	3.82	5.74	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	4780	3820	5740	
	ng/ml = µg/l	1.48	1.18	1.78	Beckman Access 2/DxC600i Hs
ng/l = pg/ml	1480	1180	1780		
肌钙蛋白 T	ng/ml = µg/l	5.08	4.06	6.10	Siemens Atellica IM
	ng/l = pg/ml	5080	4060	6100	
	ng/ml = µg/l	0.340	0.238	0.442	Roche Cobas Troponin T HS
	ng/l = pg/ml	340	238	442	

三水平心肌质控 水平2

Cat. No. CQ3259 Lot. No. 4682CK

Size 1 x 2ml Expiry 2026-08-28

Analyte	unit	Target	Range		methods
			low	high	
肌钙蛋白 T	ng/ml = µg/l	0.161	0.113	0.209	Roche Cobas h232
	ng/l = pg/ml	161	113	209	
	ng/ml = µg/l	0.313	0.219	0.407	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	313	219	407	
	ng/ml = µg/l	0.339	0.237	0.441	Roche Cobas e801 TnT hs
	ng/l = pg/ml	339	237	441	
	ng/ml = µg/l	0.359	0.251	0.467	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	359	251	467	

三水平心肌质控 水平3

Cat. No. CQ3259 Lot. No. 4683CK

Size 1 x 2ml Expiry 2026-08-28

Analyte	unit	Target	Range		methods
			low	high	
肌酸激酶(CK)	U/l	744	610	878	Vitros 37°C
	U/l	566	464	668	CK-NAC (IFCC) 37°C
	U/l	354	290	418	CK-NAC (IFCC) 30°C
	U/l	241	197	285	CK-NAC (IFCC) 25°C
	U/l	586	481	691	CK-NAC substrate start (DGKC) 37°C
	U/l	367	301	433	CK-NAC substrate start (DGKC) 30°C
	U/l	249	204	294	CK-NAC substrate start (DGKC) 25°C
肌酸激酶同工酶 (活性)	U/l	89.4	71.5	107	Vitros 37°C
	U/l	94.9	75.9	114	Immunoinhibition substrate start 37°C
	U/l	55.2	44.1	66.3	Immunoinhibition substrate start 30°C
	U/l	33.7	26.9	40.5	Immunoinhibition substrate start 25°C
	U/l	99.4	79.5	119	Immunoinhibition serum start 37°C
	U/l	57.8	46.2	69.4	Immunoinhibition serum start 30°C
	U/l	35.3	28.2	42.4	Immunoinhibition serum start 25°C
	U/l	95.0	76.0	114	Immunoinhibition (IFCC) 37°C
	U/l	55.2	44.2	66.2	Immunoinhibition (IFCC) 30°C
肌酸激酶同工酶 (质量)	ng/ml = µg/l	101	70.7	131	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	104	72.8	135	Abbott Architect / Alinity
同型半胱氨酸	µmol/l	35.0	28.0	42.0	Abbott Architect
	µmol/l	57.9	46.3	69.5	Roche Cobas 6000/8000
	µmol/l	38.9	31.1	46.7	Enzymatic
肌红蛋白	ng/ml = µg/l	291	204	378	Abbott Architect
肌钙蛋白 I	ng/ml = µg/l	43.7	35.0	52.4	Ortho Vitros ECi
	ng/l = pg/ml	43700	35000	52400	
	ng/ml = µg/l	46.4	37.1	55.7	Tosoh Series
	ng/l = pg/ml	46400	37100	55700	
	ng/ml = µg/l	5.60	4.48	6.72	Abbott Architect
	ng/l = pg/ml	5600	4480	6720	
	ng/ml = µg/l	38.3	30.6	46.0	Abbott i STAT
	ng/l = pg/ml	38300	30600	46000	
	ng/ml = µg/l	1.73	1.38	2.08	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1730	1380	2080	
	ng/ml = µg/l	5.58	4.46	6.70	Abbott Architect STAT hs
	ng/l = pg/ml	5580	4460	6700	
	ng/ml = µg/l	38.2	30.6	45.8	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	38160	30600	46000	
	ng/ml = µg/l	20.6	16.5	24.7	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	20600	16500	24700	
	ng/ml = µg/l	8.47	6.78	10.2	Beckman Access 2/DxC600i Hs
ng/l = pg/ml	8470	6780	10160		
ng/ml = µg/l	21.5	17.2	25.8	Siemens Atellica IM	
ng/l = pg/ml	21500	17200	25800		

三水平心肌质控 水平3

Cat. No. CQ3259 Lot. No. 4683CK

Size 1 x 2ml Expiry 2026-08-28

Analyte	unit	Target	Range		methods
			low	high	
肌钙蛋白 T	ng/ml = µg/l	0.735	0.515	0.956	Roche Cobas Troponin T HS
	ng/l = pg/ml	735	515	955	
	ng/ml = µg/l	0.444	0.311	0.577	Roche Cobas h232
	ng/l = pg/ml	0.189	0.132	0.246	
	ng/ml = µg/l	0.730	0.511	0.949	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	730	511	949	
	ng/ml = µg/l	0.853	0.597	1.110	Roche Cobas e801 TnT hs
	ng/l = pg/ml	853	597	1109	
	ng/ml = µg/l	0.897	0.628	1.170	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	897	628	1166	