

检验报告
Certificate of Analysis

No. COA20250412071

产品名称 Product Name	生化复合定值质控品 ClinChem Multi Control(level 2)	REF	N/A
批号 Lot No.	059425004	型号 Model of the Reagent	N/A
物料编码 Material Code	105-009120-00	包装规格 Package Size	6×5 mL
生产日期 Manufacture Date	N/A	有效期 Expiry date	2027-03-31
标准依据 Standard basis	产品检验规范 Specification for Product Inspection		

检测项目 Subjects	接受标准 Accept criteria	检测结果 Results	结果判定 Conclusion
1、外观性状 Appearance			
包装检验 Package	分装瓶为棕色硬质玻璃瓶，盖有橡胶瓶内塞和塑料外盖；盒贴、瓶贴、标签标识、说明书应完整、清晰。橡胶瓶内塞与玻璃配合后应无泄漏；塑料外盖应无明显划痕、崩缺。 The bottle should be a brown hard glass bottle with a rubber inner plug and a plastic outer lid; the packet sticker, bottle sticker, label identification, and instructions should be complete and clear. Make sure there is no leakage after the rubber inner plug fit the bottle, and there is no obvious scratches or damages to the plastic outer lid.	分装瓶为棕色硬质玻璃瓶，盖有橡胶瓶内塞和塑料外盖；盒贴、瓶贴、标签标识、说明书完整、清晰。橡胶瓶内塞与玻璃配合后无泄漏；塑料外盖无明显划痕、崩缺。 The bottle were a brown hard glass bottle with a rubber inner plug and a plastic outer lid; the packet sticker, bottle sticker, label identification, and instructions were complete and clear. Make sure there is no leakage after the rubber inner plug fit the bottle, and there is no obvious scratches or damages to the plastic outer lid.	符合/Pass
颜色性状 Apparent properties	复溶前应为黄色冻干粉末，复溶后应为清澈黄色液体，无沉淀、悬浮物和絮状物； Original:Yellow powder, Reconstituted: Clear and yellow liquid without precipitate, suspension and floccule	复溶前为黄色冻干粉末，复溶后为清澈黄色液体，无沉淀、悬浮物和絮状物； Original:Yellow powder, Reconstituted:Clear and yellow liquid without precipitate, suspension and floccule	符合/Pass
2、装量 Volume			



装量 Volume	每瓶质控品（含瓶重）均应不少于13g。 The weight of each bottle of control (including boottle weight) should be not less than 13g.	15 g	符合/Pass
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3、性能 Performance

参考值及参考范围 Reference and reference range	ALB II：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 47.2(40.0~54.4)g/L Testing results of Quality control should be within target range.	ALB II:测试结果1: 47.90; 测试结果2: 47.69; 测试结果3: 47.68	符合/Pass
	ALBn：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 48.6(41.4~55.8)g/L Testing results of Quality control should be within target range.	ALBn:测试结果1: 48.82; 测试结果2: 48.83; 测试结果3: 48.85	
	ALP：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 231(195~267)U/L Testing results of Quality control should be within target range.	ALP:测试结果1: 219.17; 测试结果2: 219.98; 测试结果3: 218.66	
	ALT：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 137(116~158)U/L Testing results of Quality control should be within target range.	ALT:测试结果1: 135.91; 测试结果2: 135.42; 测试结果3: 134.97	
	ALTn：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 142(121~163)U/L Testing results of Quality control should be within target range.	ALTn:测试结果1: 142.37; 测试结果2: 142.18; 测试结果3: 142.10	
	ApoA1：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 1.71(1.32~2.10)g/L Testing results of Quality control should be within target range.	ApoA1:测试结果1: 1.68; 测试结果2: 1.67; 测试结果3: 1.66	
	ApoB：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 0.762(0.591~0.933)g/L Testing results of Quality control should be within target range.	ApoB:测试结果1: 0.82; 测试结果2: 0.80; 测试结果3: 0.81	
	ASO II：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 285(186~384)IU/mL Testing results of Quality control should be within target range.	ASO II:测试结果1: 272.56; 测试结果2: 273.39; 测试结果3: 273.45	
	AST：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 150(126~174)U/L Testing results of Quality control should be within target range.	AST:测试结果1: 150.01; 测试结果2: 151.84; 测试结果3: 151.33	

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ASTn: 质控品测定结果应在给定的参考范围内。
靶值范围/target range: 153(129~177)U/L

Testing results of Quality control should be within target range.

C3: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 1.44(1.14~1.74)g/L

Testing results of Quality control should be within target range.

C4: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 0.267(0.213~0.321)g/L

Testing results of Quality control should be within target range.

Ca: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 3.31(2.92~3.70)mmol/L

Testing results of Quality control should be within target range.

CHE: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 9128(7292~10964)U/L

Testing results of Quality control should be within target range.

CK: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 260(221~299)U/L

Testing results of Quality control should be within target range.

CK-MB: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 109(85~133)U/L

Testing results of Quality control should be within target range.

Cl-: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 110(98~122)mmol/L

Testing results of Quality control should be within target range.

CREA (SOX): 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 371(314~428) $\mu\text{mol/L}$

Testing results of Quality control should be within target range.

CRP: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 54.6(38.1~71.1)mg/L

Testing results of Quality control should be within target range.

D-Bil (DSA) II: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 45.1(34.9~55.3) $\mu\text{mol/L}$

Testing results of Quality control should be within target range.

ASTn:测试结果1: 153.49; 测试结果2: 153.11; 测试结果3: 153.03

C3:测试结果1: 1.42; 测试结果2: 1.43; 测试结果3: 1.43

C4:测试结果1: 0.27; 测试结果2: 0.26; 测试结果3: 0.27

Ca:测试结果1: 3.24; 测试结果2: 3.29; 测试结果3: 3.26

CHE:测试结果1: 9015.48; 测试结果2: 8940.68; 测试结果3: 8853.01

CK:测试结果1: 256.80; 测试结果2: 257.24; 测试结果3: 257.78

CK-MB:测试结果1: 108.75; 测试结果2: 108.17; 测试结果3: 107.22

Cl-:测试结果1: 110.17; 测试结果2: 110.74; 测试结果3: 110.69

CREA (SOX):测试结果1: 363.53; 测试结果2: 363.69; 测试结果3: 363.54

CRP:测试结果1: 57.77; 测试结果2: 57.45; 测试结果3: 57.53

D-Bil II (DSA):测试结果1: 45.12; 测试结果2: 44.95; 测试结果3: 44.94

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D-Bil (VOX): 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 31.1(24.2~38.0) $\mu\text{mol/L}$ Testing results of Quality control should be within target range.	D-Bil (VOX): 测试结果1: 31.99; 测试结果2: 31.86; 测试结果3: 31.83
DBILn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 30.1(23.2~37.0) $\mu\text{mol/L}$ Testing results of Quality control should be within target range.	DBILn: 测试结果1: 30.07; 测试结果2: 30.07; 测试结果3: 29.93
Fe: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 43.3(34.6~52.0) $\mu\text{mol/L}$ Testing results of Quality control should be within target range.	Fe: 测试结果1: 43.27; 测试结果2: 43.10; 测试结果3: 43.10
FER: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 177(150~204) ng/mL Testing results of Quality control should be within target range.	FER: 测试结果1: 178.10; 测试结果2: 177.16; 测试结果3: 176.59
Glu (GOD): 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 13.5(11.4~15.6) mmol/L Testing results of Quality control should be within target range.	Glu (GOD): 测试结果1: 13.71; 测试结果2: 13.70; 测试结果3: 13.73
Glu (HK): 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 13.6(11.5~15.7) mmol/L Testing results of Quality control should be within target range.	Glu (HK): 测试结果1: 14.20; 测试结果2: 14.18; 测试结果3: 14.03
GLUn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 13.6(11.5~15.7) mmol/L Testing results of Quality control should be within target range.	GLUn: 测试结果1: 13.89; 测试结果2: 13.84; 测试结果3: 13.81
HDL-C: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 1.46(1.13~1.79) mmol/L Testing results of Quality control should be within target range.	HDL-C: 测试结果1: 1.47; 测试结果2: 1.47; 测试结果3: 1.48
HS-CRP: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 53.8(37.6~70.0) mg/L Testing results of Quality control should be within target range.	HS-CRP: 测试结果1: 52.32; 测试结果2: 52.35; 测试结果3: 52.27
IgA: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 2.58(2.01~3.15) g/L Testing results of Quality control should be within target range.	IgA: 测试结果1: 2.65; 测试结果2: 2.63; 测试结果3: 2.65
IgG: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 11.8(9.1~14.5) g/L Testing results of Quality control should be within target range.	IgG: 测试结果1: 11.92; 测试结果2: 11.87; 测试结果3: 12.01

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IgM: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 1.04(0.80~1.28)g/L

Testing results of Quality control should be within target range.

IgM:测试结果1: 1.05; 测试结果2: 1.06; 测试结果3: 1.05

K+: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 6.12(5.52~6.72)mmol/L

Testing results of Quality control should be within target range.

K+:测试结果1: 6.13; 测试结果2: 6.14; 测试结果3: 6.14

LDH: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 297(252~342)U/L

Testing results of Quality control should be within target range.

LDH:测试结果1: 289.54; 测试结果2: 288.49; 测试结果3: 286.73

LDL-C: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 2.68(2.08~3.28)mmol/L

Testing results of Quality control should be within target range.

LDL-C:测试结果1: 2.79; 测试结果2: 2.79; 测试结果3: 2.79

LIP: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 107(86~128)U/L

Testing results of Quality control should be within target range.

LIP:测试结果1: 105.69; 测试结果2: 106.16; 测试结果3: 106.06

Mg II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 1.42(1.24~1.60)mmol/L

Testing results of Quality control should be within target range.

Mg II:测试结果1: 1.41; 测试结果2: 1.41; 测试结果3: 1.41

Na+: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 138(123~153)mmol/L

Testing results of Quality control should be within target range.

Na+:测试结果1: 138.06; 测试结果2: 138.16; 测试结果3: 138.36

P II: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 2.90(2.45~3.35)g/L

Testing results of Quality control should be within target range.

P II:测试结果1: 2.85; 测试结果2: 2.88; 测试结果3: 2.89

P: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 2.93(2.48~3.38)mmol/L

Testing results of Quality control should be within target range.

P:测试结果1: 2.96; 测试结果2: 2.95; 测试结果3: 2.95

PA: 质控品测定结果应在给定的参考范围内。

靶值范围/target range: 270(210~330)mg/L

Testing results of Quality control should be within target range.

PA:测试结果1: 261.70; 测试结果2: 261.62; 测试结果3: 261.88

T-Bil (DSA) II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 75.0(58.2~91.8)μmol/L

Testing results of Quality control should be within target range.

T-Bil II (DSA):测试结果1: 73.63; 测试结果2: 74.10; 测试结果3: 74.05

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T-Bil (VOX): 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 63.8 (49.4~78.2) $\mu\text{mol/L}$	T-Bil (VOX): 测试结果1: 68.25; 测试结果2: 68.16; 测试结果3: 68.42
Testing results of Quality control should be within target range.	
TBILn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 63.7(49.3~78.1) $\mu\text{mol/L}$	TBILn: 测试结果1: 67.97; 测试结果2: 67.77; 测试结果3: 67.90
Testing results of Quality control should be within target range.	
TC: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 4.37(3.77~4.97) mmol/L	TC: 测试结果1: 4.36; 测试结果2: 4.33; 测试结果3: 4.39
Testing results of Quality control should be within target range.	
TG: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 2.43(2.10~2.76) mmol/L	TG: 测试结果1: 2.34; 测试结果2: 2.34; 测试结果3: 2.35
Testing results of Quality control should be within target range.	
TP II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 79.4(67.4~91.4) g/L	TP II: 测试结果1: 76.86; 测试结果2: 77.02; 测试结果3: 77.73
Testing results of Quality control should be within target range.	
TP: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 81.7(69.4~94.0) mmol/L	TP: 测试结果1: 81.39; 测试结果2: 81.10; 测试结果3: 81.70
Testing results of Quality control should be within target range.	
TPn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 79.5(67.5~91.5) g/L	TPn: 测试结果1: 79.63; 测试结果2: 79.37; 测试结果3: 79.15
Testing results of Quality control should be within target range.	
TRF: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 3.09(2.64~3.54) g/L	TRF: 测试结果1: 3.10; 测试结果2: 3.09; 测试结果3: 3.10
Testing results of Quality control should be within target range.	
UA: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 637(550~724) $\mu\text{mol/L}$	UA: 测试结果1: 630.34; 测试结果2: 627.84; 测试结果3: 628.95
Testing results of Quality control should be within target range.	
UAn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 630(546~714) $\mu\text{mol/L}$	UAn: 测试结果1: 641.19; 测试结果2: 640.98; 测试结果3: 640.35
Testing results of Quality control should be within target range.	
UIBC: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 30.6(24.3~36.9) $\mu\text{mol/L}$	UIBC: 测试结果1: 32.31; 测试结果2: 32.18; 测试结果3: 34.66
Testing results of Quality control should be within target range.	

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UREA: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 21.2(17.9~24.5)mmol/L

Testing results of Quality control should be within target range.

UREA:测试结果1: 20.89; 测试结果2: 20.73; 测试结果3: 20.73

UREAn: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 21.1(17.8~24.4)mmol/L

Testing results of Quality control should be within target range.

UREAn:测试结果1: 21.33; 测试结果2: 21.16; 测试结果3: 21.10

α -AMY: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 204(174~234)U/L

Testing results of Quality control should be within target range.

α -AMY:测试结果1: 202.18; 测试结果2: 200.59; 测试结果3: 200.94

α -HBDH: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 329(281~377)U/L

Testing results of Quality control should be within target range.

α -HBDH:测试结果1: 327.42; 测试结果2: 328.04; 测试结果3: 330.55

γ -GT: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 199(169~229)U/L

Testing results of Quality control should be within target range.

γ -GT:测试结果1: 194.67; 测试结果2: 194.04; 测试结果3: 194.67

ALB II: 瓶内SD/ SD within<2.00g/L或瓶内CV%/ CV% within<2.2%

ALB II:SD:0.23 CV:0.49%

ALBn: 瓶内SD/ SD within<2.00g/L或瓶内CV%/ CV% within<2.2%

ALBn:SD:0.13 CV:0.27%

ALP: 瓶内SD/ SD within<3.20U/L或瓶内CV%/ CV% within<4.0%

ALP:SD:0.57 CV:0.26%

瓶内均一性
Inter-vial
homogeneity

符合/Pass

ALT: 瓶内SD/ SD within<3.20U/L或瓶内CV%/ CV% within<4.0%

ALT:SD:0.63 CV:0.47%

ALTn: 瓶内SD/ SD within<3.20U/L或瓶内CV%/ CV% within<4.0%

ALTn:SD:0.81 CV:0.57%

ApoA1: 瓶内SD/ SD within<0.05g/L或瓶内CV%/ CV% within<5.0%

ApoA1:SD:0.01 CV:0.44%

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ApoB: 瓶内SD/ SD within<0.05g/L或瓶内C
V%/ CV% within<5.0% ApoB:SD:0.01 CV:1.79%

ASO II: 瓶内SD/ SD within≤8.00IU/mL或
瓶内CV%/ CV% within≤6.0% ASO II:SD:0.50 CV:0.18%

AST: 瓶内SD/ SD within<3.20U/L或瓶内C
V%/ CV% within<4.0% AST:SD:0.81 CV:0.54%

ASTn: 瓶内SD/ SD within<3.20U/L或瓶内C
V%/ CV% within<4.0% ASTn:SD:0.35 CV:0.23%

C3: 瓶内SD/ SD within<0.032g/L或瓶内C
V%/ CV% within<4.5% C3:SD:0.01 CV:0.61%

C4: 瓶内SD/ SD within<0.02g/L或瓶内CV%/
CV% within<4.5% C4:SD:0.00 CV:0.91%

Ca: 瓶内SD/ SD within<0.06mmol/L或瓶内
CV%/ CV% within<2.5% Ca:SD:0.03 CV:0.98%

CHE: 瓶内SD/ SD within≤51.50U/L或瓶内
CV%/ CV% within<3.0% CHE:SD:34.21 CV:0.38%

CK: 瓶内SD/ SD within<6.00U/L或瓶内CV%/
CV% within<4.0% CK:SD:0.86 CV:0.33%

CK-MB: 瓶内SD/ SD within<3.00U/L或瓶内
CV%/ CV% within<2.0% CK-MB:SD:1.72 CV:1.59%

Cl-: 瓶内SD/ SD within<1.59mmol/L或瓶内
CV%/ CV% within<1.5% Cl-:SD:0.25 CV:0.23%

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CREA (SOX): 瓶内SD/ SD within $<10.00\mu$
mol/L或瓶内CV%/ CV% within $<3.5\%$ CREA (SOX):SD:1.12 CV:0.31%

CRP: 瓶内SD/ SD within $<0.50\text{mg/L}$ 或瓶内C
V%/ CV% within $<5.0\%$ CRP:SD:0.38 CV:0.65%

D-Bil (DSA) II: 瓶内SD/ SD within <4.00
 $\mu\text{mol/L}$ 或瓶内CV%/ CV% within $<5.0\%$ D-Bil II (DSA) :SD:0.13 CV:
0.28%

D-Bil (VOX): 瓶内SD/ SD within $<4.00\mu$
mol/L或瓶内CV%/ CV% within $<5.0\%$ D-Bil (VOX):SD:0.10 CV:0.32%

DBILn: 瓶内SD/ SD within $<4.00\mu\text{mol/L}$ 或
瓶内CV%/ CV% within $<5.0\%$ DBILn:SD:0.12 CV:0.42%

Fe: 瓶内SD/ SD within $\leq 0.80\mu\text{mol/L}$ 或瓶内
CV%/ CV% within $<3.0\%$ Fe:SD:0.12 CV:0.28%

FER: 瓶内SD/ SD within $\leq 2.10\text{ng/mL}$ 或瓶内
CV%/ CV% within $\leq 7.0\%$ FER:SD:1.20 CV:0.68%

Glu (GOD): 瓶内SD/ SD within $<0.11\text{mmol/}$
L或瓶内CV%/ CV% within $<2.0\%$ Glu (GOD) :SD:0.04 CV:0.26%

Glu (HK): 瓶内SD/ SD within $<0.11\text{mmol/L}$
或瓶内CV%/ CV% within $<2.0\%$ Glu (HK) :SD:0.08 CV:0.53%

GLUn: 瓶内SD/ SD within $<0.11\text{mmol/L}$ 或瓶
内CV%/ CV% within $<2.0\%$ GLUn:SD:0.04 CV:0.32%

HDL-C: 瓶内SD/ SD within $<0.10\text{mmol/L}$ 或瓶
内CV%/ CV% within $<5.0\%$ HDL-C:SD:0.01 CV:0.87%

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HS-CRP: 瓶内SD/ SD within \leq 0.50mg/L或瓶
内CV%/ CV% within \leq 5.0%

HS-CRP:SD:0.24 CV:0.46%

IgA: 瓶内SD/ SD within $<$ 0.05g/L或瓶内C
V%/ CV% within $<$ 5.0%

IgA:SD:0.01 CV:0.34%

IgG: 瓶内SD/ SD within $<$ 0.20g/L或瓶内C
V%/ CV% within $<$ 5.0%

IgG:SD:0.11 CV:0.94%

IgM: 瓶内SD/ SD within $<$ 0.05g/L或瓶内C
V%/ CV% within $<$ 5.0%

IgM:SD:0.00 CV:0.44%

K+: 瓶内SD/ SD within $<$ 0.08mmol/L或瓶内
CV%/ CV% within $<$ 1.5%

K+:SD:0.02 CV:0.25%

LDH: 瓶内SD/ SD within $<$ 5.80U/L或瓶内C
V%/ CV% within $<$ 4.0%

LDH:SD:0.78 CV:0.27%

LDL-C: 瓶内SD/ SD within $<$ 0.10mmol/L或瓶
内CV%/ CV% within $<$ 5.0%

LDL-C:SD:0.01 CV:0.27%

LIP: 瓶内SD/ SD within \leq 2.00U/L或瓶内C
V%/ CV% within $<$ 5.0%

LIP:SD:0.41 CV:0.38%

Mg II: 瓶内SD/ SD within $<$ 0.05mmol/L或瓶
内CV%/ CV% within $<$ 3.0%

Mg II:SD:0.01 CV:0.86%

Na+: 瓶内SD/ SD within $<$ 1.46mmol/L或瓶内
CV%/ CV% within $<$ 1.0%

Na+:SD:0.27 CV:0.19%

P II: 瓶内SD/ SD within $<$ 0.06mmol/L或瓶
内CV%/ CV% within $<$ 2.5%

P II:SD:0.01 CV:0.38%

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P: 瓶内SD/ SD within<0.06mmol/L或瓶内C
V%/ CV% within<2.5%

P:SD:0.01 CV:0.27%

PA: 瓶内SD/ SD within<3.00mg/L或瓶内C
V%/ CV% within<4.5%

PA:SD:1.03 CV:0.40%

T-Bil (DSA) II: 瓶内SD/ SD within<4.00
 μ mol/L或瓶内CV%/ CV% within<5.0%

T-Bil II (DSA) :SD:0.21 CV:
0.28%

T-Bil (VOX): 瓶内SD/ SD within<4.00 μ
mol/L或瓶内CV%/ CV% within<5.0%

T-Bil (VOX):SD:0.21 CV:0.31%

TBILn: 瓶内SD/ SD within<4.00 μ mol/L或
瓶内CV%/ CV% within<5.0%

TBILn:SD:0.11 CV:0.16%

TC: 瓶内SD/ SD within<0.13mmol/L或瓶内
CV%/ CV% within<3.0%

TC:SD:0.02 CV:0.44%

TG: 瓶内SD/ SD within<0.07mmol/L或瓶内
CV%/ CV% within<3.0%

TG:SD:0.00 CV:0.14%

TP II: 瓶内SD/ SD within<2.00g/L或瓶内
CV%/ CV% within<2.2%

TP II:SD:0.22 CV:0.28%

TP: 瓶内SD/ SD within<2.00g/L或瓶内CV%/
CV% within<2.2%

TP:SD:0.29 CV:0.36%

TPn: 瓶内SD/ SD within<2.00g/L或瓶内C
V%/ CV% within<2.2%

TPn:SD:0.24 CV:0.31%

TRF: 瓶内SD/ SD within<0.02g/L或瓶内C
V%/ CV% within \leq 5.0%

TRF:SD:0.01 CV:0.35%

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UA：瓶内SD/ SD within<13.00 μmol/L或瓶内CV%/ CV% within<3.0% UA:SD:1.92 CV:0.31%

UAn：瓶内SD/ SD within<13.00 μmol/L或瓶内CV%/ CV% within<3.0% UAn:SD:1.22 CV:0.19%

UIBC：瓶内SD/ SD within<0.65 μmol/L或瓶内CV%/ CV% within≤5.0% UIBC:SD:1.36 CV:4.04%

UREA：瓶内SD/ SD within<0.6mmol/L或瓶内CV%/ CV% within<3.0% UREA:SD:0.13 CV:0.65%

UREAn：瓶内SD/ SD within<0.6mmol/L或瓶内CV%/ CV% within<3.0% UREAn:SD:0.19 CV:0.92%

α-AMY：瓶内SD/ SD within<3.20U/L或瓶内CV%/ CV% within<4.0% α-AMY:SD:0.61 CV:0.30%

α-HBDH：瓶内SD/ SD within<6.00U/L或瓶内CV%/ CV% within<4.0% α-HBDH:SD:1.18 CV:0.36%

γ-GT：瓶内SD/ SD within<3.20U/L或瓶内CV%/ CV% within<4.0% γ-GT:SD:0.47 CV:0.24%

生物安全性
Biosafety

HBsAg、HIV抗体、HCV抗体、梅毒螺旋体TP抗体检测应为阴性。
HBsAg , HIV antibody, HCV antibody, and TP antibody testing results of the control should be negative.

阴性/negative
符合/Pass

结论
Summary

合格/PASS

备注
Remarks



检验：
Analysis
日期：
Date

徐江明Xu
Jiangming
2025-04-12

Xu Jiangming

批准（检验工程师）：
Approved by(Quality Engineer)
日期：
Date

黄小凤Huang
Xiaofeng
2025-04-12

Huang Xiaofeng

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