



REGISTRATION NO. 04717Q10000277

## **CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES**

This is to certify that the quality management system of

**Caretium Medical Instruments Co., Limited.**

Registered Address: Beishan Industrial Park 7<sup>th</sup> Floor Building 1, Beishan Road, Yantian,  
Shenzhen, China Postcode: 518083

Manufacturing Address: Beishan Industrial Park 7<sup>th</sup> Floor Building 1, Beishan Road,  
Yantian, Shenzhen, China ; Future plaza, Building A, 10<sup>th</sup> Floor, Unit 1002,  
Nanshan, Shenzhen, P.R.China; Beishan Industrial Park 4<sup>th</sup> Floor Building 1,  
No.146, Beishan Road, Yantian, Shenzhen, China

Has been assessed and conformed to the following standard(s)

**YY/T 0287-2017 idt ISO 13485:2016**

The certificate is valid for the following scope:

The Design, Development, Production and Service of Full Auto-Biochem Analyzer,  
Semi-auto Biochemistry Analyzer, Automatic Electrolyte Analyzer, Electrolyte Analyzer,  
Automatic Biochemistry Analyzer, Microplate Washer, Microplate Reader, Automated  
Erythrocyte Sedimentation Rate Analyzer, Fully Automatic Blood Cell Counter, Automatic  
Glycated Hemoglobin Analyzer, Semi-auto Coagulation Analyzer, Reagent for Electrolyte  
Analyzer(Ion Selective Electrode Method), Lysing Agent, Diluent , Reagent for Automatic  
Glycated Hemoglobin Analyzer, Reference Electrode Filling Solution (Ion Selective  
Electrode Method), Ion Electrode Filling Solution (Ion Selective Electrode Method).

The Design and Development of In Vitro Diagnostic Reagent (See the Attached).

Date of issue: August 04, 2017

Date of expiry: July 17, 2020

General Manager:

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**Attached:**

- 1、Alanine Aminotransferase Reagent (Alanine substrate method) (Single reagent: 10ml×4; 30ml×5; 45ml×4; 50ml×6; 75ml×4; Double reagent: R1: 80ml×2, R2: 20ml×4, R1: 80ml×1, R2: 20ml×2, R1: 60ml×2, R2: 30ml×2, R1: 40ml×2, R2: 10ml×4, R1: 40ml×1, R2: 10ml×2);
- 2、Aspartate Aminotransferase Reagent (Aspartate substrate method) (Single reagent: 10ml×4; 30ml×5; 45ml×4; 50ml×6; 75ml×4; Double reagent: R1: 80ml×2, R2: 20ml×4, R1: 80ml×1, R2: 20ml×2, R1: 60ml×2, R2: 30ml×2, R1: 40ml×2, R2: 10ml×4, R1: 40ml×1, R2: 10ml×2);
- 3、CRP Reagents (immunoturbidimetry) (R1: 20ml×2, R2: 10ml×1, R1: 30ml×2, R2: 15ml×1, R1: 40ml×2, R2: 10ml×2, R1: 60ml×2, R2: 30ml×1, R1: 80ml×2, R2: 40ml×1, R1: 80ml×4, R2: 80ml×1);
- 4、γ-glutamyltransferase Reagents (GCANA substrate method) (Single reagent: 10ml×4; 30ml×5; 45ml×4; 50ml×6; 75ml×4; 90ml×4; Double reagent: R1: 80ml×2, R2: 16ml×2; R1: 50ml×4, R2: 20ml×2; R1: 50ml×2, R2: 20ml×1; R1: 40ml×2, R2: 16ml×1; R1: 30ml×2, R2: 12ml×1; R1: 80ml×2, R2: 32ml×1; R1: 50ml×3, R2: 30ml×1; R1: 50ml×3, R2: 15ml×2; R1: 40ml×5, R2: 20ml×2; R1: 40ml×5, R2: 10ml×4);
- 5、Uric Acid reagent kit (uricase method) (Single reagent: 20ml×5; 10ml×3; 45ml×2; 50ml×2; 50ml×5; 50ml×6; 65ml×2; 60ml×4; 75ml×4; 90ml×4; 100ml×2; Double reagent: R1: 80ml×4, R2: 40ml×2; R1: 80ml×2, R2: 20ml×2; R1: 80ml×2, R2: 40ml×1; R1: 60ml×4, R2: 30ml×2; R1: 60ml×3, R2: 15ml×3; R1: 50ml×4, R2: 25ml×2; R1: 50ml×2, R2: 25ml×1; R1: 40ml×2, R2: 20ml×1; R1: 40ml×4, R2: 10ml×4; R1: 40ml×5, R2: 10ml×5; R1: 20ml×2, R2: 10ml×1);
- 6、Urea reagent kit (Urease glutamate dehydrogenase) (Single reagent: 20ml×5; 10ml×3; 45ml×2; 50ml×2; 50ml×5; 50ml×6; 65ml×2; 60ml×4; 75ml×4; 90ml×4; 100ml×2; Double reagent: R1: 80ml×4, R2: 40ml×2; R1: 80ml×2, R2: 20ml×2; R1: 80ml×2, R2: 40ml×1; R1: 60ml×4, R2: 30ml×2; R1: 60ml×3, R2: 15ml×3; R1: 50ml×4, R2: 25ml×2; R1: 50ml×2, R2: 25ml×1; R1: 40ml×2, R2: 20ml×1; R1: 40ml×4, R2: 10ml×4; R1: 40ml×5, R2: 10ml×5; R1: 20ml×2, R2: 10ml×1);
- 7、Enzymatic Creatinine<sub>2</sub> Reagents (ammonia iminohydrolase) (R1: 75ml×3, R2: 75ml×1; R1: 75ml×2, R2: 25ml×2; R1: 60ml×4, R2: 40ml×2; R1: 60ml×3, R2: 20ml×3; R1: 60ml×3, R2: 60ml×1; R1: 60ml×2, R2: 20ml×2; R1: 60ml×1, R2: 20ml×1; R1: 45ml×3, R2: 15ml×3; R1: 45ml×4, R2: 30ml×2; R1: 45ml×2, R2: 30ml×1; R1: 30ml×3, R2: 30ml×1; R1: 10ml×3, R2: 10ml×1);
- 8、Triglycerid reagent kit (GPOPAP method) (Single reagent: 100ml×2; 60ml×4; 65ml×2; 50ml×2; 45ml×2; 90ml×4; 75ml×4; 50ml×6; 10ml×3; 20ml×5; Double reagent: R1: 80ml×3, R2: 20ml×2; R1: 60ml×4, R2: 40ml×1; R1: 60ml×3, R2: 15ml×2; R1: 50ml×6, R2: 25ml×2; R1: 20ml×3, R2: 10ml×1);
- 9、T-CHO reagent kit (CHODPAP method) (Single reagent: 100ml×2; 60ml×4; 65ml×2; 50ml×2; 45ml×2; 90ml×4; 75ml×4; 50ml×6; 10ml×3; 20ml×5; Double reagent: R1: 80ml×2, R2: 40ml×2; R1: 60ml×4, R2: 60ml×2; R1: 60ml×3, R2: 30ml×3; R1: 50ml×4, R2: 50ml×2; R1: 10ml×3, R2: 15ml×1);
- 10、Microalbumin reagent kit (immunoturbidimetry) (R1: 15ml×2, R2: 12ml×1; R1: 20ml×2, R2: 16ml×1; R1: 40ml×2, R2: 32ml×1; R1: 60ml×1, R2: 24ml×1; R1: 60ml×2, R2: 48ml×2; R1: 80ml×2, R2: 64ml×1);

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11. HDL cholesterol reagent kit (direct method surfactant removal method) (R1: 75ml×1, R2: 25ml×1; R1: 60ml×4, R2: 40ml×2; R1: 60ml×3, R2: 20ml×3; R1: 60ml×2, R2: 20ml×2; R1: 60ml×1, R2: 20ml×1; R1: 50ml×3, R2: 50ml×1; R1: 45ml×3, R2: 15ml×3; R1: 10ml×3, R2: 10ml×1; R1: 30ml×3, R2: 30ml×1);
12. LDL cholesterol reagent kit (direct method Hydrogen peroxide removal method) (R1: 75ml×1, R2: 25ml×1; R1: 60ml×4, R2: 40ml×2; R1: 60ml×3, R2: 20ml×3; R1: 60ml×2, R2: 20ml×2; R1: 60ml×1, R2: 20ml×1; R1: 50ml×3, R2: 50ml×1; R1: 45ml×3, R2: 15ml×3; R1: 10ml×3, R2: 10ml×1; R1: 30ml×3, R2: 30ml×1);
13. APOA1 surveis reagent kit (immunoturbidimetry) (10ml×3; 20ml×5; 45ml×6; 60ml×4; 75ml×4; 90ml×4);
14. APOB surveis reagent kit (immunoturbidimetry) (10ml×3; 20ml×5; 45ml×6; 60ml×4; 75ml×4; 90ml×4);
15. α-HBDH Multi-Purpose Liquid Reagent (α-ketobutyric acid substrate method) (R1: 80ml×4, R2: 40ml×2; R1: 80ml×2, R2: 20ml×2; R1: 60ml×3, R2: 15ml×3; R1: 60ml×4, R2: 30ml×2; R1: 60ml×2, R2: 30ml×1; R1: 60ml×2, R2: 15ml×2; R1: 50ml×4, R2: 25ml×2; R1: 40ml×5, R2: 10ml×5; R1: 40ml×2, R2: 10ml×2; R1: 20ml×2, R2: 10ml×1);
16. Creatine kinase assay kit (immunosuppression) (R1: 80ml×4, R2: 40ml×2; R1: 80ml×2, R2: 20ml×2; R1: 60ml×3, R2: 15ml×3; R1: 60ml×4, R2: 30ml×2; R1: 60ml×2, R2: 30ml×1; R1: 60ml×2, R2: 15ml×2; R1: 50ml×4, R2: 25ml×2; R1: 40ml×5, R2: 10ml×5; R1: 40ml×2, R2: 10ml×2; R1: 30ml×4, R2: 30ml×1; R1: 20ml×4, R2: 20ml×1; R1: 20ml×2, R2: 10ml×1);
17. α-Amylase Assay Kit (EPS substrate method) (Single reagent: 20ml×5; 75ml×4; 30ml×5; 50ml×6; 60ml×2; 10ml×3; Double reagent: R1: 80ml×5, R2: 40ml×2; R1: 80ml×2, R2: 16ml×2; R1: 60ml×3, R2: 12ml×3; R1: 60ml×2, R2: 24ml×1; R1: 60ml×2, R2: 12ml×2; R1: 40ml×5, R2: 8ml×5; R1: 50ml×2, R2: 10ml×2; R1: 30ml×5, R2: 30ml×1; R1: 20ml×5, R2: 20ml×1; R1: 25ml×1, R2: 5ml×1);
18. Alkaline Phosphatase Detection Kit (NPP substrate AMP buffer) (Single reagent: 90ml×4; 75ml×4; 60ml×4; 50ml×6; 50ml×5; 50ml×4; 50ml×2; 45ml×2; 30ml×5; 10ml×4; 20ml×2 Double reagent: R1: 80ml×4, R2: 40ml×2; R1: 80ml×2, R2: 20ml×2; R1: 60ml×3, R2: 15ml×3; R1: 60ml×4, R2: 30ml×2; R1: 60ml×2, R2: 15ml×2; R1: 60ml×2, R2: 30ml×1; R1: 50ml×4, R2: 25ml×2; R1: 40ml×5, R2: 10ml×5; R1: 40ml×4, R2: 10ml×4; R1: 40ml×2, R2: 10ml×2; R1: 20ml×2, R2: 10ml×1);
19. Glucose assay kit (hexokinase method) (10ml×3; 20ml×5; 45ml×6; 60ml×4; 75ml×4; 90ml×4);
20. Homocysteine Kit (Enzymatic cycling assay) (R1: 20ml×2, R2: 10ml×1; R1: 37ml×2, R2: 10ml×2; R1: 74ml×1, R2: 20ml×1; R1: 74ml×2, R2: 20ml×2; R1: 74ml×4, R2: 20ml×4);
21. CSF Test Kit (Pyrogallol red colorimetric method) (10ml×3; 40ml×2; 60ml×2; 60ml×4; 80ml×2; 80ml×4);
22. C3 Multi-Purpose Liquid Reagent (immunoturbidimetry) (R1: 20ml×2, R2: 20ml×1; R1: 15ml×2, R2: 15ml×1; R1: 45ml×2, R2: 45ml×1; R1: 60ml×1, R2: 30ml×1; R1: 60ml×2, R2: 60ml×1; R1: 80ml×2, R2: 80ml×1);
23. C4 Multi-Purpose Liquid Reagent (immunoturbidimetry) (R1: 15ml×2, R2: 12ml×1; R1: 20ml×2, R2: 16ml×1; R1: 40ml×2, R2: 32ml×1; R1: 60ml×1, R2: 24ml×1; R1: 60ml×2, R2: 48ml×1; R1: 80ml×2, R2: 64ml×1);

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24. Ig A Reagent kit (immunoturbidimetry) (R1: 15ml×2, R2: 15ml×1; R1: 30ml×2, R2: 30ml×1; R1: 45ml×2, R2: 45ml×1; R1: 60ml×1, R2: 30ml×1; R1: 60ml×2, R2: 60ml×1; R1: 80ml×2, R2: 80ml×1);
25. Ig G Reagent kit (immunoturbidimetry) (R1: 15ml×2, R2: 15ml×1; R1: 30ml×2, R2: 30ml×1; R1: 45ml×2, R2: 45ml×1; R1: 60ml×1, R2: 30ml×1; R1: 60ml×2, R2: 60ml×1; R1: 80ml×2, R2: 80ml×1);
26. Ig M Reagent kit (immunoturbidimetry) (R1: 20ml×1, R2: 5ml×1; R1: 20ml×2, R2: 10ml×1; R1: 40ml×1, R2: 10ml×1; R1: 60ml×2, R2: 30ml×1; R1: 80ml×2, R2: 40ml×1; R1: 80ml×4, R2: 80ml×1);
27. PreAlb (immunoturbidimetry) (R1: 20ml×1, R2: 8ml×1; R1: 15ml×2, R2: 12ml×1; R1: 40ml×2, R2: 32ml×1; R1: 60ml×1, R2: 24ml×1; R1: 60ml×2, R2: 48ml×1; R1: 80ml×2, R2: 64ml×1);
28. Iron reagent kit (ferrous benzoxazines method) (R1: 25ml×1, R2: 5ml×1; R1: 50ml×1, R2: 10ml×1; R1: 50ml×2, R2: 20ml×1; R1: 60ml×2, R2: 24ml×1; R1: 80ml×2, R2: 32ml×1; R1: 20ml×4, R2: 8ml×1);
29. Phosphorus Assay Kit (phosphomolybdate method) (Single reagent: 30ml×2; 40ml×2; 60ml×2; 60ml×4; 80ml×2; 10ml×4; Double reagent: R1: 50ml×4, R2: 50ml×2; R1: 30ml×4, R2: 30ml×2; R1: 10ml×4, R2: 10ml×2; R1: 60ml×4, R2: 60ml×2; R1: 40ml×4, R2: 40ml×2; R1: 80ml×4, R2: 80ml×2);
30. Adenosine deaminase Test Kit (peroxidase method) (R1: 20ml×3, R2: 20ml×1; R1: 10ml×3, R2: 10ml×1; R1: 45ml×3, R2: 15ml×3; R1: 45ml×4, R2: 30ml×2; R1: 60ml×3, R2: 60ml×1; R1: 80ml×3, R2: 80ml×1);
31. Direct Bilirubin (DBIL) Reagent (vanadate oxidation method) (R1: 20ml×2, R2: 10ml×1; R1: 40ml×5, R2: 10ml×5; R1: 60ml×2, R2: 15ml×2; R1: 60ml×4, R2: 30ml×2; R1: 30ml×4, R2: 30ml×1; R1: 50ml×4, R2: 25ml×2; R1: 60ml×3, R2: 15ml×3; R1: 80ml×2, R2: 20ml×2);
32. Total Bilirubin (TBIL) Reagent (vanadate oxidation method) (R1: 20ml×2, R2: 10ml×1; R1: 40ml×5, R2: 10ml×5; R1: 60ml×2, R2: 15ml×2; R1: 60ml×4, R2: 30ml×2; R1: 30ml×4, R2: 30ml×1; R1: 50ml×4, R2: 25ml×2; R1: 60ml×3, R2: 15ml×3; R1: 80ml×2, R2: 20ml×2);
33. Total Bile Acid Assay Kit (cycling enzymatic method) (R1: 20ml×3, R2: 20ml×1; R1: 10ml×3, R2: 10ml×1; R1: 50ml×3, R2: 50ml×1; R1: 60ml×3, R2: 60ml×1; R1: 75ml×3, R2: 75ml×1);
34. CK (Phosphoric acid substrate method) (R1: 20ml×2, R2: 10ml×1; R1: 40ml×4, R2: 10ml×1; R1: 50ml×4, R2: 25ml×2; R1: 60ml×4, R2: 30ml×2; R1: 80ml×2, R2: 20ml×2);
35. ChE Kit (Butyl thiocholine substrate method) (R1: 40ml×2, R2: 10ml×2; R1: 80ml×2, R2: 20ml×2; R1: 60ml×2, R2: 15ml×2);
36. Calcium reagent kit (OCPC method) (R1: 50ml×2, R2: 50ml×2; R1: 30ml×3, R2: 30ml×3; R1: 10ml×5, R2: 10ml×5; R1: 40ml×2, R2: 40ml×2; R1: 20ml×3, R2: 20ml×3);
37. LDH Assay Kit (lactate substrate method) (R1: 50ml×3, R2: 50ml×1; R1: 30ml×3, R2: 30ml×1; R1: 20ml×3, R2: 20ml×1; R1: 10ml×6, R2: 10ml×2; R1: 60ml×3, R2: 60ml×1; R1: 80ml×3, R2: 80ml×1);
38. TP Assay Kit (biuret method) (100ml×4; 50ml×6; 20ml×6; 80ml×4; 30ml×6; 10ml×10)
39. ALB Mensuration Reagent Kit (BCG method) (100ml×4; 50ml×6; 20ml×6; 80ml×4; 30ml×6; 10ml×10)

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