



America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Overall Scope Statement: Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System, Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer

Facility(ies): **Zybio Inc.**
 Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Production and Distribution of Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzers, Nucleic Acid Isolation Systems, Hematology Analyzers, Chemiluminescence Immunoassay Analyzers; Design and Development Nucleic Acid Isolation Reagent, Nucleic Acid Detection Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

Page 2 of 3
 Date of Issue: 2022-02-03

Michael Ogunleye

(Michael Ogunleye)
 Manager, US Certification Body,
 Medical and Health Services

[Handwritten signature and stamp]



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



CERTIFICATE

No. QS5 001708 0003 Rev. 03

Facility(ies): **Zybio Inc.**
Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Production and Distribution of
Clinical Chemistry, Immunochromatography Diagnostic Kit,
Nucleic Acid Isolation Reagent, Hematology Analysis Reagent,
Chemiluminescence Reagent, Nucleic Acid Detection Kit,
Microbial Sample Treatment Kit, Disposable Virus Sampling
Tube, Pathological Reagent Kit, Urine Test Strip

Facility(ies): **Zybio Inc.**
Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of
Jianqiao Industrial Park, Dadukou District, 400082 Chongqing,
PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Production and Distribution of Nucleic Acid Isolation Reagent

Facility(ies): **Zybio Inc.**
Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue, Dadukou
District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

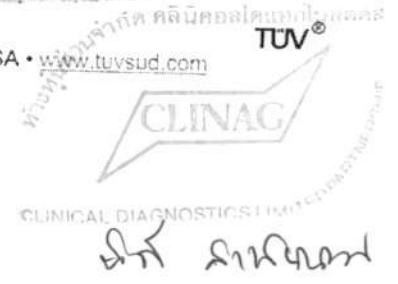
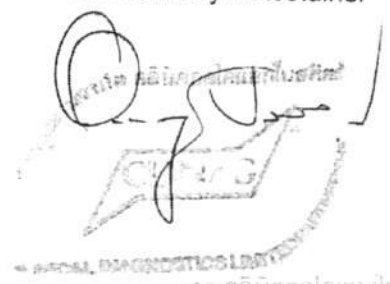
Facility Scopes: Production and Distribution of Disposable Virus Sampling Tube

Facility(ies): **Zybio Inc.**
Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C
of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Production and Distribution of Pathological Reagent,
Chemiluminescence Reagent, Microbial Sample Treatment Kit,
Mass Spectrometry System, Immunohistochemistry Autostainer

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Date of Issue: 2022-02-03

Michael Ogunleye
(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

Certificate

No. Q5 001708 0001 Rev. 04

Holder of Certificate: **Zybio Inc.**
Floor 1 to Floor 5, Building 30
No. 6 of Taikang Road
Block C of Jianqiao Industrial Park
Dadukou District
400082 Chongqing
PEOPLE'S REPUBLIC OF CHINA

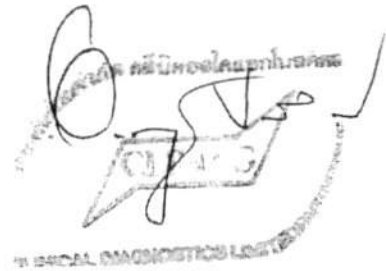
Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System, Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer

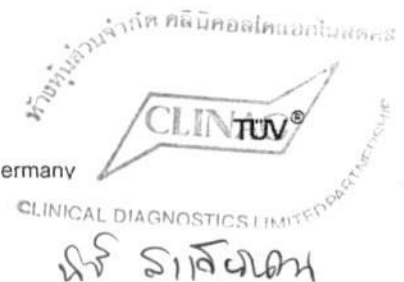
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 001708 0001 Rev. 04

Report No.: SH21101401 / SH21101401-CN
Valid from: 2022-02-25
Valid until: 2025-02-24



Date, 2022-02-24

Christoph Dicks
Head of Certification/Notified Body



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q5 001708 0001 Rev. 04

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C
of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Blood
Culture System, Urine Analyzer, Immune Quantitative Analyzer,
Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation
Systems, Hematology Analyzer, Chemiluminescence
Immunoassay Analyzer

Design and Development of Nucleic Acid Isolation Reagent,
Nucleic Acid Detection Kit, Mass Spectrometry System,
Immunohistochemistry Autostainer

Zybio Inc.
Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Clinical
Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit,
Nucleic Acid Isolation Reagent, Hematology Analysis Reagent,
Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial
Sample Treatment Kit, Disposable Virus Sampling Tube, Blood
Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip

Zybio Inc.
Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of
Jianqiao Industrial Park, Dadukou District, 400082 Chongqing,
PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Nucleic Acid Isolation Reagent

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT

Certificate

No. Q5 001708 0001 Rev. 04

Facility(ies):

Zybio Inc.
Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue,
Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC
OF CHINA

Production and Distribution of Disposable Virus Sampling Tube

Zybio Inc.
Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C
of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Pathological Reagent,
Chemiluminescence Reagent, Microbial Sample Treatment Kit,
Mass Spectrometry System, Immunohistochemistry Autostainer

ฉส สหกรณ์

Letter of Authorization

We, **Zybio Inc.** (Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082) hereby authorize **Clinical Diagnostics Limited Partnership** (126 soi Jaransanitwong 67 Bangplad Bangkok Thailand 10700) as our **distributor** to distribute and market **Mass Spectrometry System (EXS2600)** to Thailand.

The term of the Authorization Letter will commence as of the Effective Date from **Jan 1st, 2023 to 31st Dec., 2025**) and shall continue for a period of 3 years.


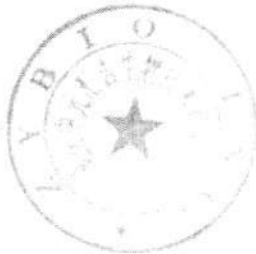
Zybio Inc. shall not be responsible for any liabilities arising from or in connection with the covenants or agreements entered into by and between the Distributor and any other person and/or body corporate.

Name: Same Cai

Title: Director

Date: 2023-09-17

Zybio Inc.



คลินิกวินิจฉัย ศูนย์เทคโนโลยีทางการแพทย์

CLINICAL DIAGNOSTICS LIMITED PARTNERSHIP
ณัฐพร นิมิตต์



Krungthai
กรุงเทพ

รหัสอ้างอิง (000021)0517/871214

วันที่ 17 พฤษภาคม 2564

ธนาคารขอรับรองว่า หจก.คลินิกคอลไดแอกโนสติกส์
โดย นายอุกฤษฏ์ ขวรวิญญานันท์
เป็นลูกค้าของธนาคาร มีบัญชีเงินฝาก รายละเอียด ดังนี้ :-

ตำแหน่ง กรรมการผู้จัดการ

รับรองบัญชีเงินฝาก ณ วันที่ : 17 พฤษภาคม 2564

เวลา : 11:18 น.

ประเภทบัญชี

บัญชีเลขที่

วันที่เปิดบัญชี

ชื่อบัญชี

กระแสรายวัน

021-6-02788-8

27 พฤศจิกายน 2563

คลินิกคอลไดแอกโนสติกส์

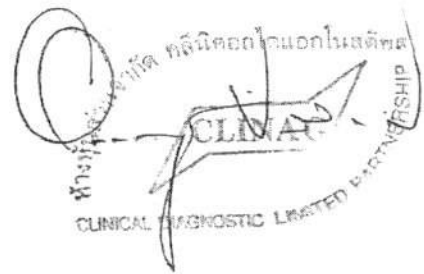
สาขาสะพานขาว

หมายเหตุ :

- กรณีนำฝากเป็นเช็ค ได้ระบุธนาคาร 21241

- โอนเงินแล้ว รบกวนผู้จัดการโอนเงินกลับที่

*** E-mail: clinag123@gmail.com



จึงเรียนมาเพื่อ โปรดให้ความอนุเคราะห์

ขอแสดงความนับถือ

บพจ. ธนาคารกรุงไทย



(นางรุ่งรวัชนี โชติพรหม) B. 20814

ผู้มีอำนาจลงนาม

ธนาคารขอสงวนสิทธิ์ในการรับรองเฉพาะข้อมูลต่อบุคคลตามที่ปรากฏในหนังสือฉบับนี้เท่านั้น

สาขาสะพานขาว

Tel. 022825007 ต่อ 106



รฟ นาฬิกาน