財團法人全國認證基金會
Taiwan Accreditation Foundation

認 證 證 書

(證書編號：L3062-231023)

茲證明

欣奕醫事檢驗所

欣奕醫事檢驗所

新北市永和區中山路一段 172 號 8 樓

為本會認證之實驗室

認 證 依 據：ISO 15189：2012
認 證 編 號：3062
初次認證日期：一百零四年七月十日
認證有效期間：一百一十年七月十日至一百一十三年七月九日止
認 證 範 圍：醫學領域，如續頁

掃描確認真偽

董事長

連錦漳

中華民國一一二年十月二十三日

認證編號　：3062
實驗室主管：古琪茗

◤ HE0409　特異過敏原免疫試驗
血清
BIOIC 過敏原晶片檢查標準操作手冊 (SOP-HE0409)
測試場地: 1.234017 新北市永和區中山路一段 168 號 11 樓

◤ HF0702　HCV 病毒負荷量檢查
血清, 血漿
HCV 病毒負荷量檢查標準操作手冊 (SOP-HF0702)

◤ HF0703　HBV 病毒負荷量檢查
血清, 血漿
HBV 病毒負荷量檢查標準操作手冊 (SOP-HF0703)

◤ HF0732　C 型肝炎病毒基因分型檢測
血清, 血漿
HCV 病毒分型檢查標準操作手冊 (SOP-HF0799-01)

◤ HJ0106　X 染色體脆折症基因檢測
血液
X 染色體脆折症基因檢測標準操作手冊 (SOP-HJ0106-02)
檢測標的: *FMR1* 基因
測試場地: 1.234017 新北市永和區中山路一段 168 號 11 樓

◤ HJ0106　亨丁頓舞蹈症基因檢測
血液
亨丁舞蹈症基因檢測標準操作手冊 (SOP-HJ0106-03)
檢測標的: *HTT* 基因
測試場地: 1.234017 新北市永和區中山路一段 168 號 11 樓

◤ HJ0106　脊髓性肌肉萎縮症基因檢測
血液
脊髓性肌肉萎縮症基因檢測標準操作手冊 (SOP-HJ0106-01)
檢測標的: *SMN1* 基因, *SMN2* 基因
測試場地: 1.234017 新北市永和區中山路一段 168 號 11 樓

◤ HJ0199　葉酸代謝基因檢測
血液
MTHFR 基因檢測標準操作手冊 (SOP-HJ0199-01)
檢測標的: *MTHFR* 基因
測試場地: 1.234017 新北市永和區中山路一段 168 號 11 樓

◤HJ0199　非侵入性胎兒染色體基因檢測

血液

NIFTY 非侵入性胎兒染色體基因檢測標準操作手冊 (SOP-HJ0199)

檢測標的: 人類 22 對染色體

(1) 雙胞胎 NIFTY (3 項)

21 號染色體三體症, 18 號染色體三體症, 13 號染色體三體症

(2) 單胞胎 NIFTY (7 項)

21 號染色體三體症, 18 號染色體三體症, 13 號染色體三體症, 透納氏症 (XO), 三染色體 X 症候群 (XXX), 柯林菲特氏症 (XXY), XYY 症候群 (XYY)

(3) 單胞胎 NIFTY (39 項)

21 號染色體三體症, 18 號染色體三體症, 13 號染色體三體症, 9 號染色體三體症, 16 號染色體三體症, 22 號染色體三體症, 透納氏症 (XO), 三染色體 X 症候群 (XXX), 柯林菲特氏症 (XXY), XYY 症候群 (XYY), 1p36 缺失症候群, 2q33.1 缺失症候群, 貓哭症候群, Langer-Giedion 症候群, 狄喬治症候群第 2 型, 雅各布森症候群, 天使症候群, 普瑞德威利症候群, 16p12.2-p11.2 缺失症候群, Smith-Magenis 症候群, 18q 缺失症候群, 狄喬治症候群第 1 型, 其他染色體微缺失/重複 (大於 10 Mb), 其他 16 對常染色體非整倍體

(4) 單胞胎 NIFTY (111 項)

21 號染色體三體症, 18 號染色體三體症, 13 號染色體三體症, 9 號染色體三體症, 16 號染色體三體症, 22 號染色體三體症, 透納氏症 (XO), 三染色體 X 症候群 (XXX), 柯林菲特氏症 (XXY), XYY 症候群 (XYY), 1p36 缺失症候群, 2q33.1 缺失症候群, 貓哭症候群, Langer-Giedion 症候群, 狄喬治症候群第 2 型, 雅各布森症候群, 天使症候群, 普瑞德威利症候群, 16p12.2-p11.2 缺失症候群, Smith-Magenis 症候群, 18q 缺失症候群, 狄喬治症候群第 1 型, 其他 16 對常染色體非整倍體, 1p31 重複症候群, 1p32-p31 缺失症候群, 1q41-42 缺失症候群, 2p12-p11.2 缺失症候群, 2p16.1-p15 缺失症候群, 裂手裂足症第 5 型, 2q31.1 重複症候群, 2q35 重複症候群, 前腦發育畸形症第 6 型, 3pter-p25 缺失症候群, 3q13.31 缺失症候群, Dandy-Walker 症候群, 3q29 缺失症候群, 3q29 重複症候群, Wolf-Hirschhorn 症候群, 4q21 缺失症候群, 4q32.1-q32.2 三重複症候群, 5q12 缺失症候群, 5q14.3 缺失症候群, 6pter-p24 缺失症候群, 6q11-q14 缺失症候群, 6q24-q25 缺失症候群, CHDM 症, 7q 缺失症候群, 7q11.23 缺失症候群, 7q11.23 重複症候群, 8p23.1 缺失症候群, 8p23.1 重複症候群, 8q12.1-q21.2 缺失症候群, 8q22.1 缺失症候群, 8q22.1 重複症候群, 9p 缺失症候群, 10q22.3-q23.2 缺失症候群, 10q26 缺失症候群, Potocki-Shaffer 症候群, WAGR 症候群, WAGRO 症候群, 12q14 微缺失症候群, 13q14 缺失症候群, 14q11-q22 缺失症候群, Frias 症候群, 15q11-q13 重複症候群, 15q14 缺失症候群, 15q25 缺失症候群, 先天性橫膈膜疝氣, 15q26-qter 缺失症候群, Levy-Shanske 症候群, 16p 缺失症候群, 16p13.3 缺失症候群, 16p12.2-p11.2 重複症候群, 16q22 缺失症候群, Potocki-Lupski 症候群, Yuan-Harel-Lupski 症候群, 17p13.3 缺失症候群, 17p13.3 重複症候群, 17q12 缺失症候群, 17q12 重複症候群, 17q21.31 重複症候群, 17q23.1-q23.2 缺失症候群, 18p 缺失症候群, 19q13.11 缺失症候群, 前腦發育畸形症第 1 型, 貓眼症候群, 22q11.2 缺失症候群, 22q11.2 重複症候群, Xp21 缺失症候群, Xp11.23-p11.22 重複症候群, Xp11.3 缺失症候群, Xq21 缺失症候群, Xq22.3 端粒缺失症候群, Xq27.3-q28 重複症候群, Xq28 缺失症候群, 其他染色體微缺失/重複 (大於 5 Mb)

(以下空白)

財團法人全國認證基金會
Taiwan Accreditation Foundation

Certificate of Accreditation

(Certificate No：L3062-231023)

This is to certify that

NEWCL Biomedical Laboratory
NEWCL Biomedical Laboratory
8F., No.172, Sec.1, zhongshan Rd., Yonghe Dist., New Taipei City 234, Taiwan (R.O.C.)

is accredited in respect of laboratory

Accreditation Criteria	：	ISO 15189：2012
Accreditation Number	：	3062
Originally Accredited	：	July 10, 2015
Effective Period	：	July 10, 2021 to July 09, 2024
Accredited Scope	：	Medical Field, see described in the Appendix

Scan to verify

Ching-Chang Lien

Ching-Chang Lien
President, Taiwan Accreditation Foundation
October 23, 2023

The Appendix forms an integral part of this Certificate, which shall be invalid when use without the Appendix

Accreditation Number : 3062

Laboratory Head : KU, Chi-Ming

◤ HE0409 Specific allergen test
Serum
BIOIC Allergy examination (SOP-HE0409)
Testing Site: 1.11F., No.168, Sec. 1, Zhongshan Rd., Yonghe Dist., New Taipei City 234017, Taiwan (R.O.C.)

◤ HF0702 HCV viral load examination
Serum, Plasma
HCV viral load examination (SOP-HF0702)

◤ HF0703 HBV viral load examination
Serum, Plasma
HBV viral load examination (SOP-HF0703)

◤ HF0732 Hepatitis C virus (HCV) genotyping test
Serum, Plasma
HCV Genotype examination (SOP-HF0799-01)

◤ HJ0106 Fragile X Syndrome Genetic Testing-FMR1 Gene
Blood
Standard Operation Procedure for Fragile X Syndrome Genetic Testing-FMR1 Gene (SOP-HJ0106-02)
Testing target: *FMR1* gene
Testing Site: 1.11F., No.168, Sec. 1, Zhongshan Rd., Yonghe Dist., New Taipei City 234017, Taiwan (R.O.C.)

◤ HJ0106 Huntington's Disease Genetic Testing
Blood
Standard Operation Procedure for Huntington's Disease Genetic Testing-HTT Gene (SOP-HJ0106-03)
Testing target: *HTT* gene
Testing Site: 1.11F., No.168, Sec. 1, Zhongshan Rd., Yonghe Dist., New Taipei City 234017, Taiwan (R.O.C.)

◤ HJ0106 Spinal Muscular Atrophy Genetic Testing-SMN Gene
Blood
Standard Operation Procedure for Spinal Muscular Atrophy Genetic Testing-SMN Gene (SOP-HJ0106-01)
Testing target: *SMN1* gene, *SMN2* gene
Testing Site: 1.11F., No.168, Sec. 1, Zhongshan Rd., Yonghe Dist., New Taipei City 234017, Taiwan (R.O.C.)

◤ HJ0199 Folate Metabolism Genetic Testing-MTHFR Gene
Blood
Standard Operation Procedure for Folate Metabolism Genetic Testing-MTHFR Gene (SOP-HJ0199-01)
Testing target: *MTHFR* gene
Testing Site: 1.11F., No.168, Sec. 1, Zhongshan Rd., Yonghe Dist., New Taipei City 234017, Taiwan (R.O.C.)

◤ HJ0199 Non-Invasive-Fetal-Trisomy Test (NIFTY)
Blood
Standard Operation Procedure for Non-Invasive-Fetal-Trisomy Test (NIFTY) (SOP-HJ0199)
Testing target: The 22 pairs of chromosomes in human
(1) Twins NIFTY (3 Items)
Trisomy 21, Trisomy 18, Trisomy 13
(2) Single Birth NIFTY (7 Items)
Trisomy 21, Trisomy 18, Trisomy 13, Monosomy X, Trisomy X (XXX) , XXY Syndrome (XXY) , XYY Syndrome (XYY)
(3) Single Birth NIFTY (39 Items)
Trisomy 21, Trisomy 18, Trisomy 13, Trisomy 9, Trisomy 16, Trisomy 22, Monosomy X, Trisomy X, XXY Syndrome, XYY Syndrome, Chromosome 1p36 deletion syndrome, Chromosome 2q33.1 deletion syndrome, Cri-du-chat syndrome, Langer-Giedion syndrome, DiGeorge syndrome complex 2, Jacobsen syndrome, Angelman syndrome, Prader-Will syndrome, Chromosome 16p12.2-p11.2 deletionsyndrome, Smith-Magenis syndrome, Chromosome 18q deletion syndrome, DiGeorge syndrome complex 1, Other duplication/deletion syndromes (≧ 10 Mb) , Other autosomal Trisomies
(4) Single Birth NIFTY (111 Items)
Trisomy 21, Trisomy 18, Trisomy 13, Trisomy 9, Trisomy 16, Trisomy 22, Monosomy X, Trisomy X, XXY Syndrome, XYY Syndrome, Chromosome 1p36 deletion syndrome, Chromosome 2q33.1 deletion syndrome, Cri-du-chat syndrome, Langer-Giedion syndrome, DiGeorge syndrome complex 2, Jacobsen syndrome, Angelman syndrome, Prader-Will syndrome, Chromosome 16p12.2-p11.2 deletionsyndrome, Smith-Magenis syndrome, Chromosome 18q deletion syndrome, DiGeorge syndrome complex 1, Other autosomal Trisomies, Chromosome 1p31 duplication syndrome, Chromosome 1p32-p31 deletion syndrome, Chromosome 1q41-q42 deletion syndrome, Chromosome 2p12-p11.2 deletion syndrome, Chromosome 2p16.1-p15 deletion syndrome, Split-hand/foot malformation 5, Chromosome 2q31.1 duplication syndrome, Chromosome 2q35 duplication syndrome, Holoprosencephaly 6, Chromosome 3pter-p25 deletion syndrome, Chromosome 3q13.31 deletion syndrome, Dandy-Walker syndrome, Chromosome 3q29 deletion syndrome, Chromosome 3q29 duplication syndrome, Wolf-Hirschhorn syndrome, Chromosome 4q21 deletion syndrome, Chromosome 4q32.1-q32.2 triplication syndrome, Chromosome 5q12 deletion syndrome, Chromosome 5q14.3 deletion syndrome, Chromosome 6pter-p24 deletion syndrome, Chromosome 6q11-q14 deletion syndrome, Chromosome 6q24-q25 deletion syndrome, CHDM (Chordoma) , Chromosome 7q deletion, Chromosome 7q11.23 deletion syndrome, Chromosome 7q11.23 duplication syndrome, Chromosome 8p23.1 deletion syndrome, Chromosome 8p23.1 duplication syndrome, Chromosome 8q12.1-q21.2 deletion syndrome, Chromosome 8q22.1 deletion syndrome, Chromosome 8q22.1 duplication syndrome, Chromosome 9p deletion syndrome, Chromosome 10q22.3-q23.2 deletion syndrome, Chromosome 10q26 deletion syndrome, Potocki-Shaffer syndrome, WAGR syndrome, WAGRO syndrome, Chromosome 12q14 microdeletion syndrome, Chromosome 13q14 deletion syndrome, Chromosome 14q11-q22 deletion syndrome, Frias syndrome, Chromosome 15q11-q13 duplication syndrome, Chromosome 15q14 deletion syndrome, Chromosome 15q25 deletion syndrome, HCD (Congenital diaphragmatic hernia) , Chromosome 15q26-qter deletion syndrome, Levy-Shanske syndrome, Chromosome 16p deletion syndrome, Chromosome 16p13.3 deletion syndrome, Chromosome 16p12.2-p11.2 microduplication syndrome, Chromosome 16q22 deletion syndrome, Potocki-Lupski syndrome, Yuan-Harel-Lupski syndrome, Chromosome 17p13.3 deletion syndrome, Chromosome 17p13.3 duplication syndrome, Chromosome 17q12 deletion syndrome, , Chromosome 17q12 duplication syndrome, Chromosome 17q21.31 duplication syndrome, Chromosome 17q23.1-q23.2 deletion syndrome, Chromosome 18p deletion syndrome, Chromosome 19q13.11 deletion syndrome
Holoprosencephaly 1, Cat-Eye syndrome, Chromosome 22q11.2 deletion syndrome, Chromosome 22q11.2 duplication syndrome, Chromosome Xp21 deletion syndrome, Chromosome Xp11.23-p11.22 duplication syndrome, Chromosome Xp11.3 deletion syndrome, Chromosome Xq21 deletion syndrome, Chromosome Xq22.3 telomeric deletion syndrome, Chromosome Xq27.3-q28 duplication syndrome, Chromosome Xq28 deletion syndrome, Other duplication/deletion syndromes (≧5 Mb)

(Null below)