

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

(Certificate No: L1461-240924)

This is to certify that

## The Clinical Laboratory of Chinese Foundation of Health The Neonatal Screening Center

5F, No.55, Dong-Xing Rd., Taipei City 11070, Taiwan (R.O.C.)

## is accredited in respect of laboratory

Accreditation Criteria : ISO 15189: 2022

Accreditation Number : 1461

Originally Accredited: January 27, 2006

Effective Period: October 16, 2024 to October 15, 2027

Accredited Scope : Medical Field, see described in the Appendix



Yi-Ling Chen

Yi-Ling Chen President, Taiwan Accreditation Foundation September 24, 2024

Certificate No: L1461-240924

Accreditation Number : 1461

Laboratory Head: KAO, Shu-Min

HJ0101 Amino acid assay of congenital disease

Blood spot

Standard Operational Procedure for MS/MS-Amino acid (SOP-0101)

► HJ0104 Enzyme examination for congenital disease

Blood spot

Standard Operational Procedure for G6PD activity: enzyme activity Fluorometric analysis (SOP-0103)

Standard Operational Procedure for Biotinidase (SOP-0107)

Standard Operational Procedure for DMD (SOP-0113)

► HJ0106 Molecular biological examination of congenital disease

Blood spot

Standard Operational Procedure for Citrullinemia type II genotyping (SOP-0109)

HJ0106 Molecular biological examination of congenital disease

Blood spot

Standard Operational Procedure for Metabolic disorders of fatty acid-Next generation sequencing (SOP-0110)

Testing target: CPT1A, CPT2, SLC25A20, ETFDH, ETFA, ETFB, ACADVL

Reference database: ClinVar: https://www.ncbi.nlm.nih.gov/clinvar/

The Human Gene Mutation Database (HGMD): https://www.hgmd.cf.ac.uk/ac/index.php

HJ0107 Metabolic disorders of fatty acid and organic acid in neonatal screening

Blood spot

Standard Operational Procedure for MS/MS- fatty acid and organic acid (SOP-0102)

Standard Operational Procedure for MMA/MCA (SOP-0108)

► HJ0108 Hormone examination for congenital disease

Blood spot

Standard Operational Procedure for Thyroid Stimulating Hormone (TSH): Time-resolved FIA (SOP-0105)

Standard Operational Procedure for Congenital Adrenal hyperplasia — 17α-OH-progesterone: Time-resolved FIA (SOP-0106)

► HJ0109 Sugar examination for congenital disease

Blood spot

Standard Operational Procedure for Galactosemia-Galactose: Fluorometric enzymatic assay (SOP-0104)

(Null below)

