



*Early **CAN**cer Detection in the **LivEr** of Filipinos with Chronic Hepatitis B using
AI-driven Integration of Clinical and Genomic Biomarkers
(CANDLE Study)*

Background

The Philippine Council of Health Research and Development under the Department of Science and Technology has approved the program entitled **Early CANcer Detection in the LivEr of Filipinos with Chronic Hepatitis B Using AI-Driven Integration of Clinical and Genomic Biomarkers (CANDLE Study)**.

The CANDLE Study consists of two projects. Project 1 aims to establish a clinical and genomic profile of Filipino population for early detection of liver cancer. This will be implemented by the University of the Philippines Manila. Meanwhile, the general objective of Project 2 is to utilize the recent progress in omics research and leverage on AI capabilities to develop the Computational Omic Analysis Tool (COAT), an AI-driven computational tool that can ingest massive genomic data, ultrasound images, serum biomarkers and other clinical information. This will be conducted in the University of the Philippines Los Banos. The duration of the program is 5 years.

TERMS OF REFERENCE

Laboratory tests and services for the Project 1 entitled 'Establishing a Clinical and Genomic Profile of Filipinos for Early Detection of Liver Cancer':

- I. **Scope of work:** Blood extraction, DNA extraction, ultrasound imaging, transport of DNA to the Philippine Genome Center, and laboratory services - baseline liver function test, viral load testing, serum testing (single contract).
- II. **Tests to be performed per participant:**

A. Baseline Visit Package 1 (for Hep B Positive)

- HBsAg
- HBeAg
- AntiHBe
- AntiHBc Total
- AntiHBs
- HBV DNA (IU/L)
- AntiHCV
- AntiHAV IgG
- FBS
- Total Cholesterol (Lipid Profile)
- LDL (Lipid Profile)
- HDL (Lipid Profile)
- VLDL (Lipid Profile)
- Triglycerides (Lipid Profile)
- Creatinine
- Albumin (g/L)
- Serum Sodium
- Serum Total bilirubin (mg/dl)
- ALT (U/L)
- AST (U/L)
- Alkaline Phosphatase
- INR
- Haemoglobin (g/L) (CBC dc pc)
- White cell count



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Platelet count
LIVERFAST
AFP
AFP L3
PIVKA II/DCP
Upper Abdomen Ultrasound
HBV Genotype (DONE ONLY ONCE AT STUDY ENTRY FOR HBV +)
DNA Extraction from Whole Blood (DONE ONLY ONCE AT STUDY ENTRY)

B. Baseline Visit Package 2 (for Hep B Negative)

HBsAg
AntiHBc Total
AntiHBs
AntiHCV
FBS
Total Cholesterol (Lipid Profile)
LDL (Lipid Profile)
HDL (Lipid Profile)
VLDL (Lipid Profile)
Triglycerides (Lipid Profile)
Creatinine
Albumin (g/L)
Serum Sodium
Serum Total bilirubin (mg/dl)
ALT (U/L)
AST (U/L)
Alkaline Phosphatase
INR
Haemoglobin (g/L) (CBC dc pc)
White cell count
Platelet count
LIVERFAST
AFP
AFP L3
PIVKA II/DCP
Upper Abdomen Ultrasound
DNA Extraction from Whole Blood (DONE ONLY ONCE AT STUDY ENTRY)

C. Control (Hep B Positive) Followup Package (every 6 or 12 months)

HBeAg (YEARLY ONLY)
Anti-HBe (YEARLY ONLY)
HBsAg (YEARLY ONLY)
AntiHBs (YEARLY ONLY)
HBV DNA
Sodium
Creatinine
Albumin (g/L)
Serum Total bilirubin (mg/d)
ALT (U/L)
AST (U/L)
Alkaline Phosphatase
INR
Haemoglobin (g/L) (CBC DC PC)



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White cell count
Platelet count
AFP
PIVKA II
AFP L3
LIVERFAST (YEARLY ONLY)
Upper Abdomen Ultrasound

D. Patient (Hep B Negative) Followup Package (Every 6 months except LiverFAST)

Creatinine
Albumin (g/L)
Serum Total bilirubin (mg/d)
ALT (U/L)
AST (U/L)
Alkaline Phosphatase
INR
Haemoglobin (g/L) (CBC Dc PC)
White cell count
Platelet count
AFP
PIVKA II
AFP L3
LIVERFAST (Yearly ONLY)
Liver Ultrasound

III. **Service:** Willing to do blood extraction, perform the laboratory services and ultrasound imaging on endorsed participants by the study; Willing to do DNA Extraction from whole blood; Willing to transport the extracted DNA to the Philippine Genome Center

IV. **Criteria for evaluation of proposal:**

- A. Duly registered and DOH licensed medical laboratory
- B. With standardization of laboratory tests across multiple branches in the Philippines wherein tests are performed using the same method and instruments
- C. Has a centralized server for all the branches and will be able to upload the results to the web application of CANDLE Study weekly

Format of Data

1. Laboratory results: Excel file, and online access will be provided to Authorized Coordinators
2. Genotyping results: PDF
3. Serum Biomarkers: PDF
4. Ultrasound image: JPEG file
5. Ultrasound results : Excel file
6. Naming convention for Ultrasound: <patient id>_<date>.jpeg

V. **Contract duration:** 1 Year – 100 individuals (baseline and follow-up)

VI. **Price:** For Year 1 – the total price for the baseline tests of the 100 participants must be within Php 9,999,998

VII. **Basis for the approved budget:** Based on the quotation of a laboratory that can provide ALL the tests listed above



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VIII. **Payment terms:** Issuance of statement of account every 15 days (15th and 30th of the month) payable through check within 60 days

APPROVED:

Beatrice J. Tjangco 6 Aug 2019
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