



PROTECTHEALTH

HOSPITAL SERVICES OUTSOURCING PROGRAMME (HSOP)

NEW SERVICES 2026

5 February 2026

Presentation Outline

Company Background

Project Background

Request for Proposal

Q & A



ABOUT PROTECTHEALTH

ProtectHealth Corporation Sdn. Bhd. (ProtectHealth) was incorporated on 19 December 2016 as a wholly-owned subsidiary of ProtectHealth Malaysia (PHM), established under the Ministry of Health, Malaysia (MOH).

As a not-for-profit company, we coordinate, administer and manage initiatives related to financing healthcare services as mandated by MOH.

ProtectHealth Malaysia & ProtectHealth Corporation were established with:



Hospital Services Outsourcing

The Hospital Service Outsourcing Program (HSOP) is an initiative of the Ministry of Health Malaysia (KKM) to improve the accessibility and quality of healthcare. From July 2024, ProtectHealth as an HSOP implementer will outsource patients from KKM hospitals to private healthcare facilities.

perubatan MADANI

ProtectHealth has been appointed as the healthcare scheme administrator for Skim Perubatan MADANI on 5 May 2023. The pilot programme as announced by YAB Prime Minister during the Budget 2023, will initially be for 10 districts.

PeKa B40

On 15th April 2019, as per our Strategic Purchaser mandate, we carry our role as the healthcare scheme administrator for Skim Peduli Kesihatan untuk Kumpulan B40 (PeKa B40) as mandated by the Government.

ESP SPIKPA

Starting from 12th November 2020, we have been appointed as the Electronic Services Provider operator for Skim Perlindungan Insurans Kesihatan Pekerja Asing (SPIKPA).

VAKSIN COVID-19

Given our experience and capabilities in discharging Strategic Purchasing role, on 8 March 2021, ProtectHealth has been appointed by the Ministry of Health as the implementer of Private Medical Practitioners' and Healthcare NGOs' participation in the National COVID-19 Immunisation Programme.

ABOUT PROTECTHEALTH

The Company is established to serve a strong social purpose, namely:

1

to be a **leader in introducing innovative health financing mechanisms** in order to improve access and enhance the value and effectiveness of health care for the people in Malaysia;

3

to implement an equitable, effective and efficient source of funding to **supplement the public funding for health care** such that strong health services for the community can be sustained; and

2

to **create a healthy and strong competitive market to any health financing agency** by operating as an efficient organization that can serve as a benchmark to local companies of similar function;

4

to expand **accessibility to quality healthcare services** by enhancing the utilisation of the public-private ecosystem.



SHAREHOLDER STRUCTURE

**Government Owned Company
(GOC) under Ministry of Health
(MOH)**



**ProtectHealth Malaysia (PHM)
Company Limited by Guarantee
(8th Dec 2016)**

Board of Directors of PHM

100% shares owned by PHM
*PHM as a member of
ProtectHealth by "Corporate
Representative" appointed by
BOD of PHM*

**ProtectHealth Corporation Sdn. Bhd.
(Company Limited by Shares & Not-for-
profit) (19th Dec 2016)**

Board of Directors ProtectHealth



BOARD OF DIRECTORS & KEY LEADERSHIP

Board of Directors



Datuk Dr. Mahathar Abd Wahab
Chairman of the Board
Director-General of MOH



Dato' Sri Zahrul Hakim bin Abdullah
Deputy Secretary-General
of MOH



Pn Noor Alifah Norzam
Director
MOF Representative



En. Nurhisham Hussein
Non-Independent Director
Senior Director, Economy
& Finance, Prime Minister's
Office



Pn Roshidah Abdullah
Independent Director
Chartered Accountant
Formerly CFO of Sumatec



En. Johari Abdul Muid
Independent Director
Former MD of RHB and
EPF Deputy CEO



Professor Elil Renganathan
Independent Director

Key Leadership



Wan Mohd Hazwan Wan Mohd Najib
Chief Executive Officer



Dr. Gan Saw Chien
Head, Strategic Purchasing



Dr. Muhammed Anis Abd Wahab
Head, Quality Assurance



Wan Mazuki Wan Hassan
Head, Operations



Lokman Hakim Hashim
Head, Finance & Account



Mohd Farrish bin Khalid
CeIO, Certified Integrity
Officer



Azhar Samsudin
Head, Human Resources &
Administration



Amir Bedin
Head,
Digital Technologies



Norbaidzuri Mohd Yusoff
Head, Corporate
Communications



Dr. Muhammad Fairuz Abdullah
Head, Health Advocacy



Marini Jamlus
Head, Internal Audit



Syazwani Syaheerah Slamet
Head, Legal



Ain Azierah Azman
Company Secretary





PROTECTHEALTH

HOSPITAL SERVICES OUTSOURCING PROGRAMME (HSOP)

PROJECT BACKGROUND

Outsourcing in Ministry of Health, Malaysia

Started as early as the 1990s where the privatization policy was introduced and the Ministry of Health was asked to implement the outsourcing initiative as a pilot project.



Facility engineering
maintenance
services



Bio-medical
engineering
maintenance services



Catering services

Need to outsource clinical services, in view of:



High number of pending cases at public hospitals



Constraints on human resources, equipment and facilities



Potentially save government resources



The latest technology that is more efficient in private hospitals

When COVID-19 pandemic hit, services of non COVID-19 were interrupted...

- Clinic appointment for stable cases were extended
- Elective procedures were postponed

50,000 case backlog at govt hospitals

By MOHAMED BASYIR and TEOH PEI YING - January 26, 2022 @ 9:00am



Private hospitals to help clear govt backlog of 50,000 cases

FMT Reporters - January 17, 2022 8:57 AM

758 Shares

f 714

22

21



Turning Crisis Into Opportunity

Result...

Year	Total Cases			Expenditure, RM
	Surgical	Imaging/ Radiology	Overall	
2020	1,383	674	2,057	11.6 million
2021	11,684	9,088	20,772	174.8 million
2022	5,843	20,632	26,475	48.7 million

Issues & challenges



→ Leverage on ProtectHealth's experience in Strategic

ABOUT PROTECTHEALTH

Hospital Services Outsourcing

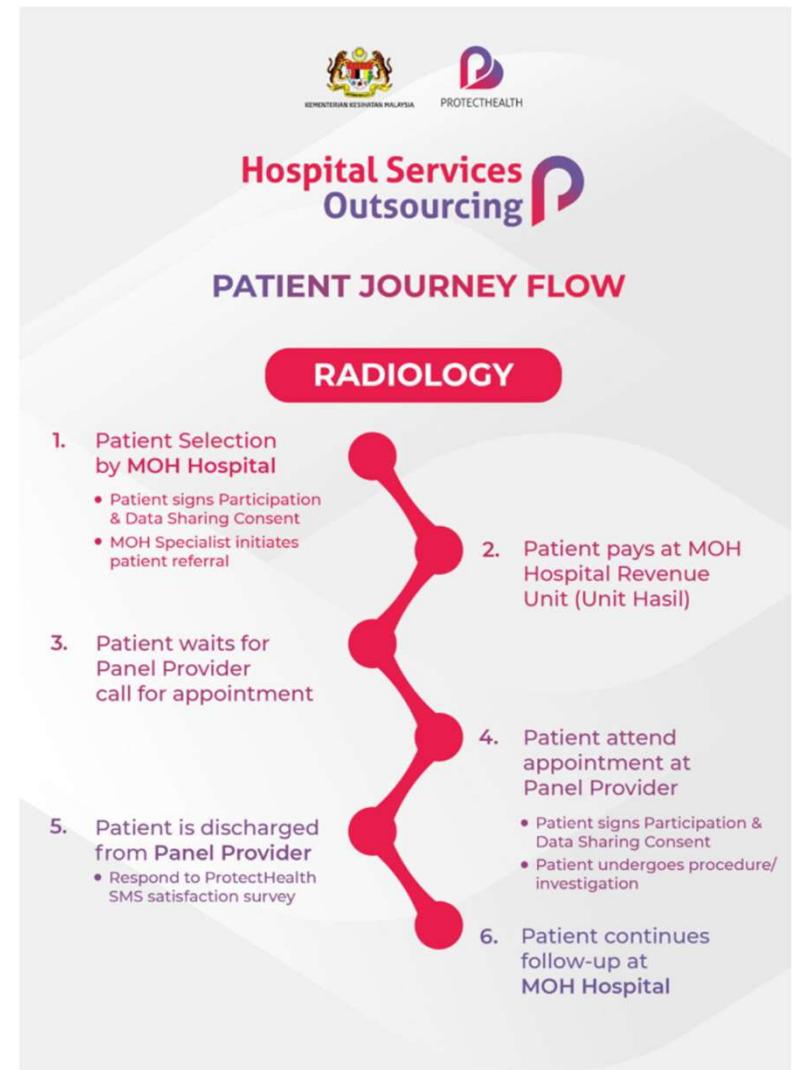
The Hospital Services Outsourcing Programme (HSOP) is an initiative by the Ministry of Health Malaysia (MOH) to improve healthcare accessibility and quality.

Starting from **18 July 2024**, HSOP will outsource patients from MOH hospitals to private healthcare facilities (referred to as Panel Providers).

This program aims to reduce patient congestion, shorten waiting times, and enhance healthcare service quality.



PROTECTHEALTH



Your Health, Our Mission

BACKGROUND

Objectives of HSOP

Reduced Waiting Time (of elective cases) - **90%**

Decongestion (of wards/emergency departments) - **5%**

Others (ad hoc outsourcing) - **5%**

HSOP Benefit Packages

1. Cardiothoracic

2. Cardiology

3. Nephrology

4. Radiology

5. General Surgery

6. Urology

7. Radiotherapy &
Oncology

8. Ophthalmology

9. General Paediatric

10. Nuclear Medicine

11. Paediatric
Cardiothoracic

12.
Hepatogastroentrology

13. Internal Medicine



MAIN OUTSOURCING PROCESS

PRICE SETTING via RFP & COSTING

Request for Proposals (RFP) from Private Hospitals

Analysis Proposed Prices & Specifications & **Compare with MOH (& Private) Costing**

Pre-determine Prices & Spec.

DIGITALISED OUTSOURCING PROCESS

Qualified providers inform maximum capacity (Digitalised Market-Place)

Pre qualify & contract with interested private hospitals

Engage with Private Hospitals

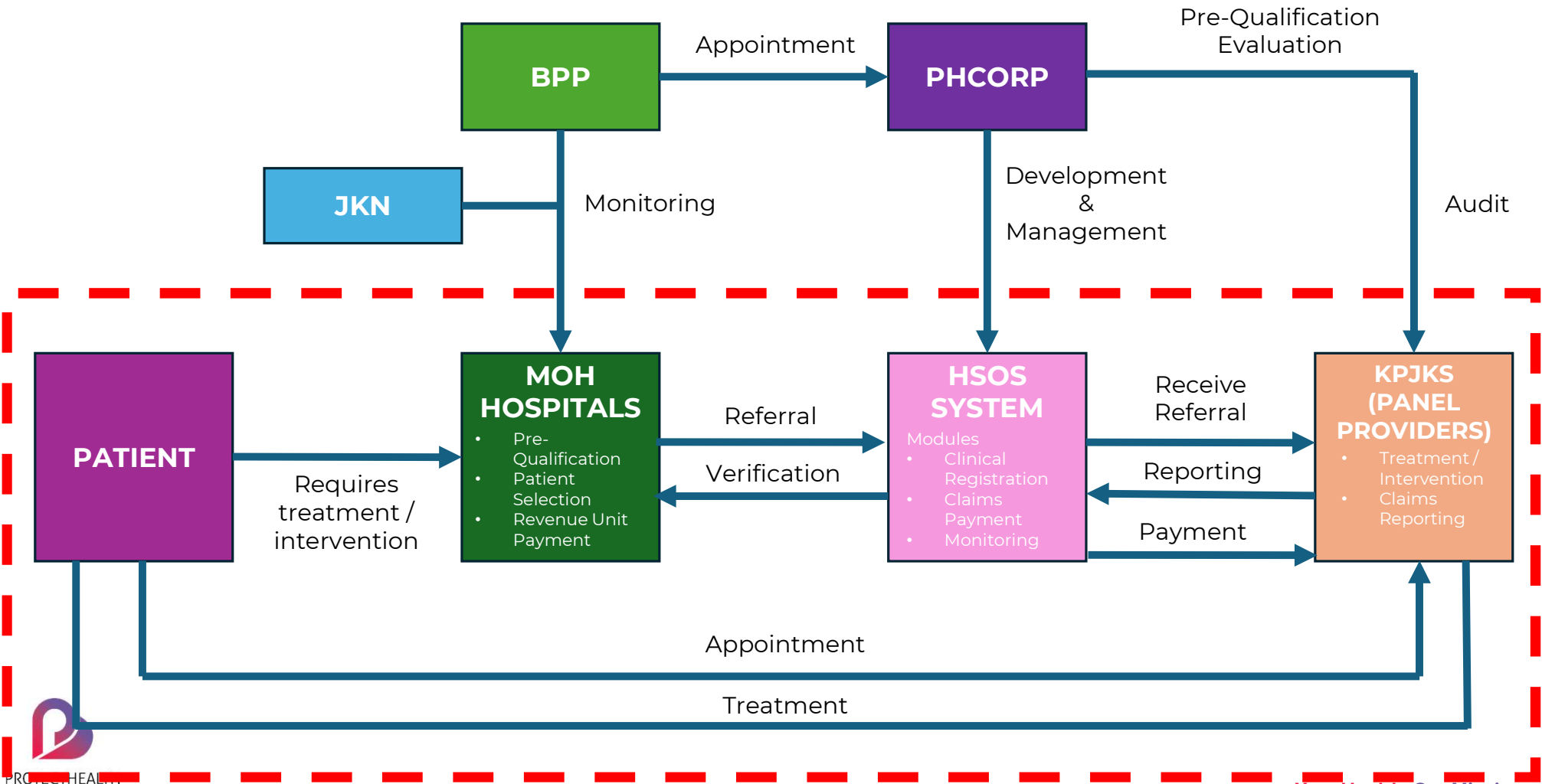
Zoning:
Optimise competition (multiple private hospitals) & **patient accessibility** (not too far)

Allocation:
Allocate equally to qualified & within zone private hospitals (not exceeding max cap)

Start Service
- MOH Specialist identify patients and refer
- Private Hosp arrange appointment, provide services & claim



RELATIONSHIP DIAGRAM FOR HSOP



HSOP 2026 IMPLEMENTATION PLAN

Information

Patient Referral Window: 9 Months



January 2026

- Implementation of HSOP 2026 for Cardiology & Cardiothoracic, pilot for HSIS



February 2026

- Implementation of 9 Services & New Pricing

9 EXISTING SERVICES

1. Cardiology
2. Cardiothoracic
3. Nephrology
4. Radiology
5. General Surgery
6. Urology
7. Ophthalmology
8. Nuclear Medicine
9. Radiotherapy



March 2026

- Implementation for 3 New Services

3 NEW SERVICES

1. Bone-Mineral Densitometry
2. Transient Elastography
3. Paediatric Cardiothoracic



July 2026

- Tentative Implementation of 3 New Services

NEW BENEFIT PACKAGES

1. Immunology Transplant
2. Audiology
3. Mammogram



October 2026

- Last patient referral







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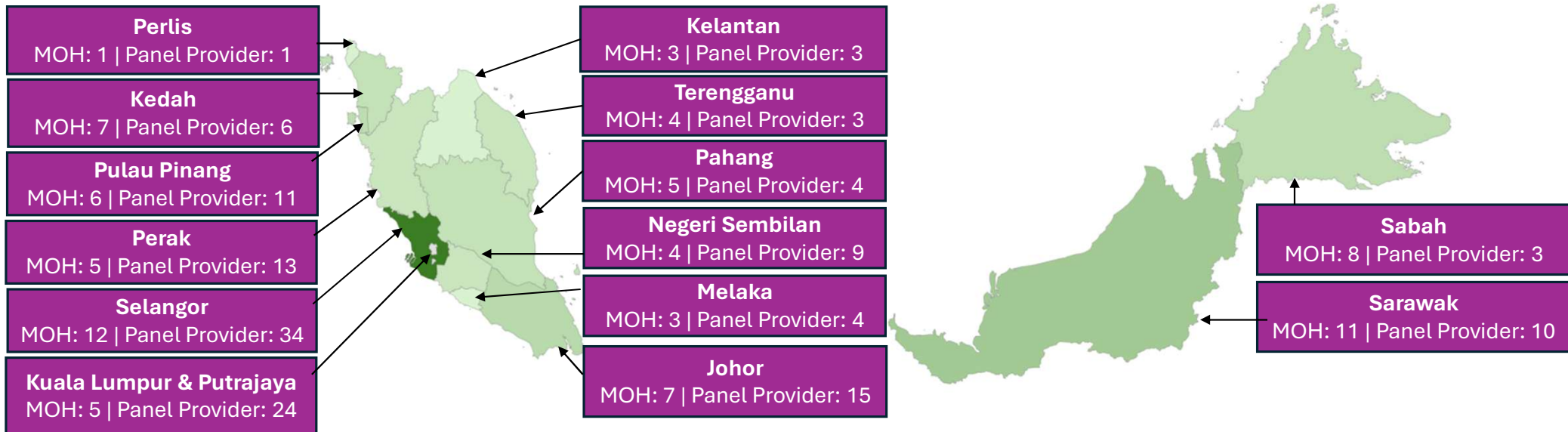
Data as of 31 December 2025

Your Health, Our Mission

HSOP 2026: MOH Facilities and Private Hospitals

Information

MOH FACILITIES (81)	PANEL PROVIDERS (140)		
81	125	13	2
MOH Hospital 	Private Hospitals 	Ambulatory Care Centre 	Hospital Pengajar Universiti 



HSOP MAPPING: MOH FACILITIES VS PANEL PROVIDERS

Notes:

1. HPU including USAINS Healthcare & Hospital Pengajar Universiti Sultan Zainal Abidin (HOSZA)
2. Private Wing University Hospital including UKM Specialist Centre (UKMSC) and UiTM Private Specialist Centre (UiTMPS)

HSOP 2026 NEW SERVICES

NO.	SERVICES (3)	SUB-SERVICES (6)	ORDERABLES (10)
1.	Immunology Transplant	a) Routine Cases (Living Donors)	Routine Cases (Living Donors) – 5 Tests
		b) Cadaveric Donor Cases (After Office Hours / Emergency / Urgent)	<ul style="list-style-type: none"> i. Cadaveric Donor Cases – 3 Tests, 1 Donor : 4 Patients ii. Cadaveric Donor Cases – 3 Tests, 1 Donor : 5 Patients iii. Cadaveric Donor Cases – 3 Tests, 1 Donor : 6 Patients
		c) Waiting List Cadaveric Kidney	Waiting List Cadaveric Kidney – 3 Tests
2.	Radiology	Diagnostic Mammogram	Mammogram of both breasts (and extra views if required) with ultrasound breasts & axilla
			Single breast mammogram (and extra views if required) with Ultrasound breast & axilla, with US of contra lateral chest wall & axilla
3.	Audiology	a) Basic Electrophysiologic Hearing Test	Basic - Natural Sleep Bilateral Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR)
		b) Complex Electrophysiologic Hearing Test	<ul style="list-style-type: none"> i. Complex - Natural Sleep ABR & ASSR ii. Complex - Sedation ABR & ASSR





PROTECTHEALTH

HOSPITAL SERVICES OUTSOURCING PROGRAMME

(HSOP)

**REQUEST FOR PROPOSAL
(RFP)**



INTRODUCTION



Objective: A Request for Proposal (RFP) is a document that outlines the requirements and specifications for a project.



Purpose: Facilitates a structured procurement process by inviting vendors to submit proposals for fulfilling a specific need.

RFP COMPONENTS

1. Introduction
&
Background

2. Scope of Work

3. Requirement

4. Pricing

5. Provider
Information

6. Submission
Guidelines

7. Terms & Conditions



IMPORTANCE OF RFP IN PROCUREMENT



Ensures a fair and competitive bidding process.



Enables objective evaluation and market analysis of vendor proposals.



Mitigates risks by defining project expectations clearly.



Enhances transparency and accountability in procurement.



PRICING

The Private Provider is expected to offer the procedural cost as a **bundled package**. In this context, a **bundle fee** entails that the price incorporates all associated services.

It is not based on individual fees for each service; instead, **a fixed fee is paid upon completion of the procedure, irrespective of any variations that may occur during the course of treatment.**

A bundled package provides a comprehensive and transparent pricing model, simplifying the billing process by encompassing all necessary services under a single, predetermined cost and **allow the private provider to optimise the necessary services providing to patients in order to deliver quality health care services with good efficiency.**

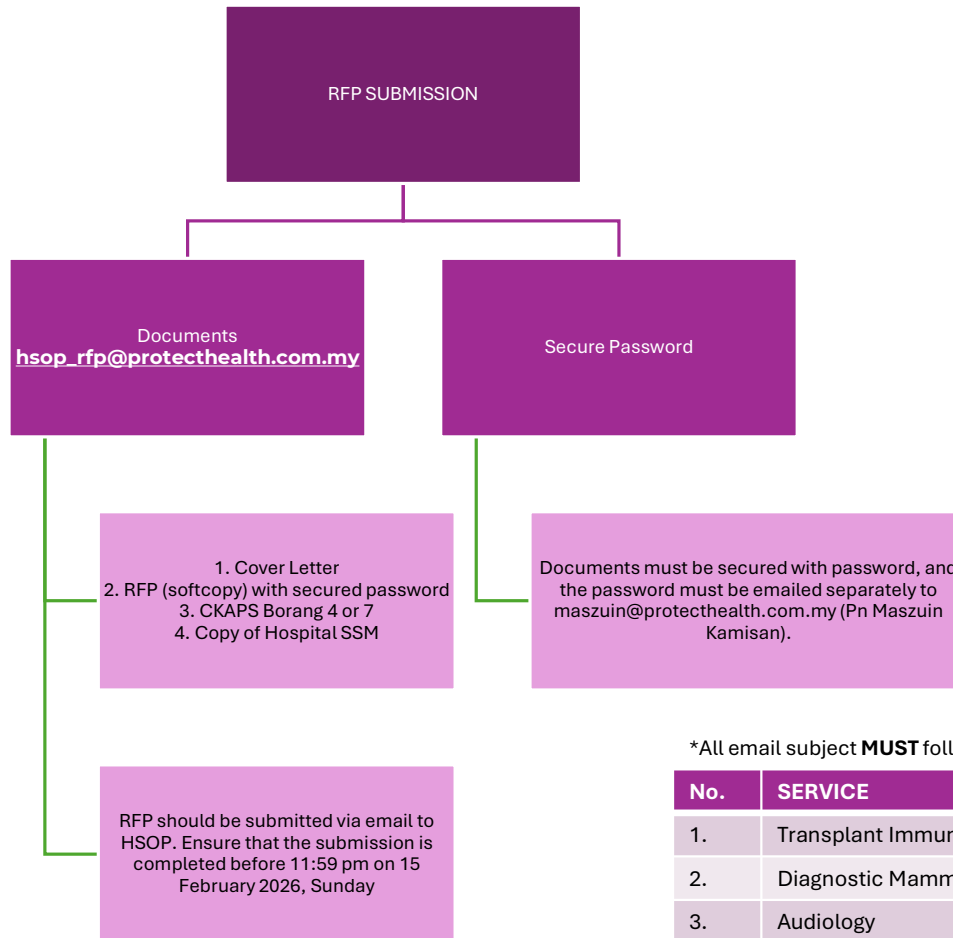


SUBMISSION GUIDELINES

- The proposal should be organized in a clear and logical manner, with each section clearly labeled. The Provider should also ensure that the proposal is complete and addresses all the requirements in the RFP.
- It should include all the necessary information as outlined in the RFP, including details below.
- **Submission Check-list**
 - Please make sure your submission is complete and all documents listed below are submitted as **electronic copy** to hsop_rfp@protecthealth.com.my with secured password.
 - Submission consists of the following:
 - 1. Request for Proposal (RFP)**
 - 2. Company Profile**
 - 3. Other supporting documents**
 - Any response received after this date may be considered non-responsive, and ProtectHealth would not be obligated to engage your organization any further in our RFP process.
 - All responses and supporting documentation shall become the property of ProtectHealth Corporation and will not be returned.



SUBMISSION GUIDELINES



*All email subject **MUST** follow the format below

No.	SERVICE	EMAIL SUBJECT
1.	Transplant Immunology	HSOP 2026 RFP Submission (Transplant Immunology)
2.	Diagnostic Mammography	HSOP 2026 RFP Submission (Diagnostic Mammography)
3.	Audiology	HSOP 2026 RFP Submission (Audiology)



DOCUMENTATION & VIDEO

The RFP documents are accessible for download starting 3 February 2026 through the ProtectHealth website.

Additionally, the video recording and presentation materials from Open Day 1 will be provided for your reference.



Hospital Services Outsourcing Programme (HSOP)			
Request for Proposal (RFP)	Engagement with ProtectHealth	Issuance of Documents	Deadline for Submission
1. IMMUNOLOGY TRANSPLANT 2. MAMMOGRAPPHY 3. AUDIOLOGY	Open Day 1 Date : 5/2/2026 (10 am – 12pm) Link : https://zoom.us/webinar/register/WN_Mnz7dl_7Se2qLbM8pZO2xw	3 February 2026 – 13 February 2026 Active : RFP IMMUNOLOGY TRANSPLANT 03022026 RFP MAMMOGRAPPHY 03022026 RFP AUDIOLOGY 03022026	15 February 2026
	Open Day 2 Date : 11/02/2026 (10 am -12pm) Link : https://zoom.us/webinar/register/WN_XrICLayISNW3xhjDzjhyAA		



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PROPOSAL ON IMMUNOLOGY TRANSPLANT

BACKGROUND: IMMUNOLOGY TRANSPLANT

- Focuses on the immune system's response to transplanted organs or tissues, aiming to prevent rejection by matching donor and recipient HLA types. It involves tests like HLA typing, crossmatching, and antibody screening to ensure compatibility and monitor post-transplant reactions
- The service consists of **three (3) sub-services**, each with defined orderables based on clinical urgency and donor type.

No.	Sub Services	Orderable	Type of Test	Testing Packages	No. of Tests / Reports	Total of Tests / Reports
1.	Living Donors for Kidney	Routine Cases - 5 Tests, 1 donor & 1 patient	<ol style="list-style-type: none"> 1. High Resolution - HLA Typing (Human Leucocyte Antigen) 2. HLA crossmatch based on Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch based on Flowcytometry 4. HLA Antibody Identification (PRA kit) 5. HLA Antibody Single Antigen 	<ol style="list-style-type: none"> 1. Donor & Patient 2. Donor & Patient 3. Donor & Patient 4. Patient 5. Patient 	<ol style="list-style-type: none"> 2 1 1 1 1 	6
2.	Cadaveric Donor Cases for Kidney	Cadaveric Donor Cases – 3 Tests, 1 Donor & 4 Patients	<ol style="list-style-type: none"> 1. Human Leucocyte Antigen (HLA) Typing 2. HLA crossmatch based on Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch based on Flowcytometry 	<ol style="list-style-type: none"> 1. Donor 2. Donor & 4 Patient 3. Donor & 4 Patient 	<ol style="list-style-type: none"> 1 4 4 	9
3		Cadaveric Donor Cases – 3 Tests, 1 Donor & 5 Patients	<ol style="list-style-type: none"> 1. Human Leucocyte Antigen (HLA) Typing 2. HLA crossmatch based on Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch based on Flowcytometry 	<ol style="list-style-type: none"> 1. Donor 2. Donor & 5 Patient 3. Donor & 5 Patient 	<ol style="list-style-type: none"> 1 5 5 	11
4.		Cadaveric Donor Cases – 3 Tests, 1 Donor & 6 Patients	<ol style="list-style-type: none"> 1. Human Leucocyte Antigen (HLA) Typing 2. HLA crossmatch based on Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch based on Flowcytometry 	<ol style="list-style-type: none"> 1. Donor 2. Donor & 6 Patient 3. Donor & 6 Patient 	<ol style="list-style-type: none"> 1 6 6 	13
5.	Waiting List Patients for Cadaveric Transplant for Kidney	Waiting List Cadaveric Kidney - 3 Tests, 1 Patient	<ol style="list-style-type: none"> 1. High Resolution - Human Leucocyte Antigen (HLA) Typing 2. HLA Antibody Identification (PRA kit) 3. HLA Antibody Single Antigen 	<ol style="list-style-type: none"> 1.Patient 2.Patient 3.Patient 	<ol style="list-style-type: none"> 1 1 1 	3



1. Scope of Work: Living Donors for Kidney

General Information

No.	Scope of Work	Description																																										
1.	Service Name	Immunology Transplant																																										
2.	Detailed Description	<p>Immunology Transplant Services for cases from living donors (routine cases) for Kidney To conduct Immunology Transplant testing, the following tests are included:</p> <ol style="list-style-type: none"> 1. High Resolution- Human Leucocyte Antigen (HLA) Typing 2. HLA crossmatch via Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch via Flow Cytometry 4. HLA Antibody Screening (PRA kit) 5. HLA Single Antigen Antibody 																																										
3.	Organ	Kidney																																										
4.	Sub-service	Living Donors for Kidney																																										
5.	Orderable	Routine Cases - 5 Tests, 1 donor & 1 patient																																										
6.	Packages	<table border="1"> <thead> <tr> <th>No.</th> <th>Test</th> <th>Testing Package</th> <th>Number of Donor & Patient Ratio</th> <th>Kidney</th> <th>No. of Test</th> <th>No. of Report</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>High Resolution - HLA Typing (Human Leucocyte Antigen)</td> <td>Donor & Patient</td> <td>1:1</td> <td>✓</td> <td>2</td> <td>2</td> </tr> <tr> <td>2.</td> <td>HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)</td> <td>Donor & Patient</td> <td>1:1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>3.</td> <td>HLA crossmatch based on Flowcytometry</td> <td>Donor & Patient</td> <td>1:1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>4.</td> <td>HLA Antibody Identification (PRA kit)</td> <td>Patient</td> <td>1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>5.</td> <td>HLA Antibody Single Antigen</td> <td>Patient</td> <td>1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	No.	Test	Testing Package	Number of Donor & Patient Ratio	Kidney	No. of Test	No. of Report	1.	High Resolution - HLA Typing (Human Leucocyte Antigen)	Donor & Patient	1:1	✓	2	2	2.	HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)	Donor & Patient	1:1	✓	1	1	3.	HLA crossmatch based on Flowcytometry	Donor & Patient	1:1	✓	1	1	4.	HLA Antibody Identification (PRA kit)	Patient	1	✓	1	1	5.	HLA Antibody Single Antigen	Patient	1	✓	1	1
No.	Test	Testing Package	Number of Donor & Patient Ratio	Kidney	No. of Test	No. of Report																																						
1.	High Resolution - HLA Typing (Human Leucocyte Antigen)	Donor & Patient	1:1	✓	2	2																																						
2.	HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)	Donor & Patient	1:1	✓	1	1																																						
3.	HLA crossmatch based on Flowcytometry	Donor & Patient	1:1	✓	1	1																																						
4.	HLA Antibody Identification (PRA kit)	Patient	1	✓	1	1																																						
5.	HLA Antibody Single Antigen	Patient	1	✓	1	1																																						



1. Scope of Work: Living Donors for Kidney

General Information

No.	Scope of Work	Description
7.	Patient Selection (Donor)/Eligibility for the Service	<ol style="list-style-type: none">1. Malaysian2. Selection from MOH Hospital based on the Handbook of Kidney Replacement Therapy (KRT) Guidelines (latest version) by Ministry of Health, Malaysia
8.	Patient Selection (Recipient) / Eligibility for the Service	<ol style="list-style-type: none">1. Malaysian2. Selection from MOH Hospital based on the Handbook of Kidney Replacement Therapy (KRT) Guidelines (latest version) by Ministry of Health, Malaysia
9.	Potential Patient Volume	Living Transplant : 20 pairs (donor + patient)



1. Scope of Work: Living Donors for Kidney

Sample

No.	Scope	Description
1.	Sample requirements	<p>Samples will be collected in MOH hospitals (Nephrology Department)</p> <p>A. Immunology Transplant Services for cases from living donors (routine cases)</p> <ol style="list-style-type: none"> 1. High- Resolution- Human Leucocyte Antigen (HLA) Typing - whole blood in EDTA tube for both donor & patient 2. HLA crossmatch via Complement Dependent Cytotoxicity (CDC) - Recipient's blood in plain tube & donor's blood in sodium heparin tube (18 mL) or any relevant anti-coagulant tube eg. Acid Citrate Dextrose (ACD) tube 3. HLA crossmatch via Flow Cytometry - Recipient's blood in plain tube & donor's blood in sodium heparin tube 4. HLA Antibody Screening (PRA kit) - Recipient's blood in plain tube 5. HLA Single Antigen Antibody - Recipient's blood in plain tube <p>B. Acceptance Criteria For Sample</p> <p>All samples sent to the panel provider SHALL be accompanied by an appropriate request form. All sample tubes SHALL be correctly labelled with the following MANDATORY IDENTIFIERS:</p> <ol style="list-style-type: none"> 1) Name 2) Identification number (IC) 3) MANDATORY IDENTIFIERS of patient and/or donor shall tally between request form and sample <p>C. Important Information On Sample Tube:</p> <ol style="list-style-type: none"> 1) Please ensure MANDATORY IDENTIFIERS used on the request form and all sample tubes are tally 2) Please write using LEGIBLE CAPITAL LETTERS to label the sample tube 3) All details must be checked carefully to ensure they are correct. Incorrectly labelled or insufficient information on sample tubes will result in testing being delayed or the testing request being rejected, and the patient or donor having to be re-bled.



1. Scope of Work: Living Donors for Kidney

Sample

No.	Scope	Description
1.	Sample requirements (cont.)	<p>D. Rejection Criteria</p> <p>It is the requesting centre's responsibility to ensure correct and sufficient information is used when requesting service from the panel provider. Incorrectly labelled or insufficient information on the sample tube will result in testing being delayed or the testing request being rejected, and the patient or donor having to be re-bled.</p> <p>Following are the rejection criteria for the panel provider. (*) Indicates MANDATORY IDENTIFIERS (the sample may be rejected if these fields are not completed)</p> <p>Request Form Related Issue</p> <ol style="list-style-type: none"> 1) (*) MANDATORY IDENTIFIERS of patient and/or donor shall tally between request form and sample 2) (*) No identification or incomplete identification details (Name) 3) (*) No identification or incomplete identification details (IC no / Passport no) 4) No requester details (signature and stamp) 5) Test request is not stated 6) Wrong request form sent 7) Incomplete request form; leaking tube;
2.	Samples Transportation	<ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. All samples should be transported in room temperature (without ice). 3. The MOH hospitals need to arrange the samples transportation to the panel provider.



1. Scope of Work: Living Donors for Kidney

Procedures

No.	Scope	Description
1.	Pre Examination	<p>A. MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. Patient identified by the nephrologist. 2. Patient has fulfilled eligibility criteria and provided consent for outsourced immunology transplant testing. 3. Information regarding immunology testing must be communicated to both donor and patient. 4. Donor and patient sample registration must be completed in the Hospital Services Outsourcing System (HSOS). 5. MOH required to refer on the sample collection and transportation guidelines by the Panel Provider. 6. All samples must be transported at room temperature (without ice) during office hours and within 24 hours. 7. MOH hospitals are responsible for arranging sample transportation to the panel provider. 8. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary. <p>B. Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. Communication between the PIC at the referring and receiving hospitals must be established when necessary. 3. The panel provider must acknowledge receipt of the sample in the HSOS. 4. The panel provider must document testing progress in the HSOS (sample received, test report completion). 5. Each test must be completed within seven (7) days.



1. Scope of Work: Living Donors for Kidney

Procedures

No.	Scope	Description
2.	Examination	<p>A. Testing and Quality Assurance Requirements</p> <ol style="list-style-type: none"> 1. All sample testing must be conducted in accordance with the documented test procedures established by the panel provider. 2. Testing must comply with the quality standards referenced in MS ISO 15189. 3. Tests shall be performed by competent laboratory staff, and all reports must be validated by authorized personnel. 4. The panel provider is required to participate in an External Quality Assurance Program (EQAP) for all tests offered. 5. If a test cannot be performed in full as specified, the panel provider must provide justification in the Hospital Services Outsourcing System (HSOS) and include the explanation in the report. 6. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.
3.	Post Examination	<p>A. Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. The verified test report must be uploaded to the HSOS within 24 hours of test completion. 2. A new sample may be required if repeat testing is necessary; communication with the MOH referring hospital must be established in such cases. <p>B. MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. The MOH referring hospital must review the test report and validate it in the HSOS. 2. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.



1. Technical Requirements: Living Donors for Kidney

Equipment

No.	Equipment	Specifications
1.	High Resolution Frequency HLA Typing	<p>HLA typing for living donor transplant.</p> <p>High-resolution HLA typing using NGS (Next Generation Sequencing) method or SSO-PCR (Sequence Specific Oligonucleotide-Polymerase Chain reaction).</p> <ol style="list-style-type: none"> The system shall be capable of performing high-resolution (two-field or higher) HLA typing with the following minimum requirements: <ul style="list-style-type: none"> Support 6 to 11 HLA loci, including but not limited to: <ol style="list-style-type: none"> Class I: HLA-A, HLA-B, HLA-C. Class II: HLA-DRB1, HLA-DQB1, HLA-DPB1. Optional / extended loci: HLA-DRB3/4/5, DQA1, DPA1. The software shall have the latest HLA allele library according to IMGT database. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
2.	HLA Antibody Test Equipment	<ol style="list-style-type: none"> The HLA antibody test kit using fluoroanalyzer equipment (Luminex) shall analyze and identify the fluorescent intensity on each microbead and then assign HLA antibody respectively. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
3.	Flowcytometer for Flowcytometry HLA Crossmatch	<ol style="list-style-type: none"> The equipment shall assess the compatibility of prospective solid organ transplant (e.g. kidney transplant) patients and donors utilizing the flowcytometer crossmatch method. The system shall be to detect the presence of immunoglobulin (IgG) on the surface of lymphocytes. The system shall be equipped with at least 2 lasers, which is capable to detect at least 6 colours. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
4.	Flourescence Microscope for CDC Crossmatch	<ol style="list-style-type: none"> The equipment shall assess the compatibility of prospective solid organ transplant (e.g. kidney transplant) patients and donors utilizing the microscope crossmatch method. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
5.	Reagents	<ol style="list-style-type: none"> All reagents as specify for the test. The reagents shall be registered by MDA.



Acronym

HLA-A: Human Leukocyte Antigen A
 HLA-B: Human Leukocyte Antigen B
 HLA-C: Human Leukocyte Antigen C

HLA-DRB1: Human Leukocyte Antigen DR Beta 1
 HLA-DQB1: Human Leukocyte Antigen DQ Beta 1
 HLA-DPB1: Human Leukocyte Antigen DP Beta 1
 HLA-DRB3/4/5: Human Leukocyte Antigen DR Beta 3/4/5

DQA1 (HLA-DQA1): Human Leukocyte Antigen DQ Alpha 1
 DPA1 (HLA-DPA1): Human Leukocyte Antigen DP Alpha 1
 IMGT: International ImMunoGeneTics Information System

1. Technical Requirements: Living Donors for Kidney

Staffing

No.	Staff	Requirements
1.	Certified Pathologist or Transfusion Specialist trained in Transplant Immunology	Registered under NSR and MMC, up-to-date APC.
2.	Trained and certified Medical Laboratory Technician	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.
3.	Trained and certified Scientific Officer/ Laboratory Scientist	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.

Facilities - The facility shall be a hospital equipped with medical laboratory services, with the medical laboratory required to comply with the relevant laboratory standards

No.	Facilities	Requirements
1.	Hospital with medical laboratory	A. Certified by CKAPS
2.	Medical laboratory	1. Accreditation ISO 15189:2022 (Medical laboratories - Requirements for quality and competence) (Mandatory) 2. Without accreditation (IQA/EQA)* (Mandatory) 3. Other Accreditation, please specify (Optional)

Reporting

No.	Reporting	Requirements
1.	Test Report	1. Test reporting format must follow ISO15189 Medical Laboratory Requirement for Quality Competence. 2. Test report need to be available in the HSOS within 24 hours after verification.



Acronym

SAMM: Skim Akreditasi Makmal Malaysia

IQA: Internal Quality Assurance

EQA: External Quality Assessment

2. Scope of Work: Cadaveric Donor Cases for Kidney

General Information

No.	Scope of Work	Description																					
1.	Service Name	Immunology Transplant																					
2.	Detailed Description	<p>Immunology Transplant Services for cadaveric donor cases for kidney (after office hours)</p> <p>To conduct Immunology Transplant testing, the following tests are included:</p> <ol style="list-style-type: none"> 1. Urgent Human Leucocyte Antigen (HLA) Typing 2. HLA crossmatch via Complement Dependent Cytotoxicity (CDC) 3. HLA crossmatch via Flow Cytometry 																					
3.	Organ	Kidney																					
4.	Sub-service	Cadaveric Donor Cases for Kidney																					
5.	Orderable	<ol style="list-style-type: none"> 1. Cadaveric Donor Cases – 3 Tests, 1 Donor & 4 Patients 2. Cadaveric Donor Cases – 3 Tests, 1 Donor & 5 Patients 3. Cadaveric Donor Cases – 3 Tests, 1 Donor & 6 Patients 																					
6.	Packages	<table border="1"> <tbody> <tr> <td>1.</td> <td>Human Leucocyte Antigen (HLA) Typing</td> <td>Donor</td> <td>1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>2.</td> <td>HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)</td> <td>Donor & Patient</td> <td>1:4 1:5 1:6</td> <td>✓</td> <td>4 5 6</td> <td>4 5 6</td> </tr> <tr> <td>3.</td> <td>HLA crossmatch based on Flowcytometry</td> <td>Donor & Patient</td> <td>1:4 1:5 1:6</td> <td>✓</td> <td>4 5 6</td> <td>4 5 6</td> </tr> </tbody> </table>	1.	Human Leucocyte Antigen (HLA) Typing	Donor	1	✓	1	1	2.	HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)	Donor & Patient	1:4 1:5 1:6	✓	4 5 6	4 5 6	3.	HLA crossmatch based on Flowcytometry	Donor & Patient	1:4 1:5 1:6	✓	4 5 6	4 5 6
1.	Human Leucocyte Antigen (HLA) Typing	Donor	1	✓	1	1																	
2.	HLA crossmatch based on Complement Dependent Cytotoxicity (CDC)	Donor & Patient	1:4 1:5 1:6	✓	4 5 6	4 5 6																	
3.	HLA crossmatch based on Flowcytometry	Donor & Patient	1:4 1:5 1:6	✓	4 5 6	4 5 6																	



2. Scope of Work: Cadaveric Donor Cases for Kidney

General Information

No.	Scope of Work	Description
7.	Patient Selection (Donor)/Eligibility for the Service	<ol style="list-style-type: none">1. Malaysian2. Selection from MOH Hospital based on the Handbook of Kidney Replacement Therapy (KRT) Guidelines (latest version) by Ministry of Health, Malaysia
8.	Patient Selection (Recipient) / Eligibility for the Service	<ol style="list-style-type: none">1. Malaysian2. Selection from MOH Hospital based on the Handbook of Kidney Replacement Therapy (KRT) Guidelines (latest version) by Ministry of Health, Malaysia
9.	Potential Patient Volume	<p>A total of 10 cadaveric transplant cases is targeted for 3 months. For each cadaveric donor case, a total of 4, 5, or 6 potential patients shall be tested against one donor. For every cadaveric donor, patient matching and testing will involve a maximum of six (6) potential patients. Therefore the potential patient volume for 1 case is as follows :</p> <ol style="list-style-type: none">1. At a ratio of 1 donor to 4 patients,OR2. At a ratio of 1 donor to 5 patients, OR3. At a ratio of 1 donor to 6 patients.



2. Scope of Work: Cadaveric Donor Cases for Kidney

Sample

No.	Scope	Description
1.	Sample requirements	<p>A. Recipient and donor samples will be courier by MOH hospitals. Immunology Transplant Services for cadaveric donor cases (after office hours). 1. Urgent Human Leucocyte Antigen (HLA) Typing - whole blood in EDTA tube for both donor. 2. HLA crossmatch via Complement Dependent Cytotoxicity (CDC) - Recipient's blood in plain tube & donor's blood in sodium heparin tube or any relevant anti-coagulant tube eg. Acid Citrate Dextrose (ACD) tube. 3. HLA crossmatch via Flow Cytometry - Recipient's blood in plain tube (6 mL) & donor's blood in sodium heparin tube.</p> <p>B. Acceptance Criteria For Sample All samples sent to the panel provider SHALL be accompanied by an appropriate request form. All sample tubes SHALL be correctly labelled with the following MANDATORY IDENTIFIERS: 1. Name. 2. Identification number (IC). 3. MANDATORY IDENTIFIERS of patient and/or donor shall tally between request form and sample.</p> <p>C. Important Information on Sample Tube: 1. Please ensure MANDATORY IDENTIFIERS used on the request form and all sample tubes are tally. 2. Please write using LEGIBLE CAPITAL LETTERS to label the sample tube. 3. All details must be checked carefully to ensure they are correct. Incorrectly labelled or insufficient information on sample tubes will result in testing being delayed or the testing request being rejected</p>



2. Scope of Work: Cadaveric Donor Cases for Kidney

Sample

No.	Scope	Description
1.	Sample requirements (cont.)	<p>D. Rejection Criteria</p> <p>It is the requesting centre's responsibility to ensure correct and sufficient information is used when requesting service from the panel provider. Incorrectly labelled or insufficient information on the sample tube will result in testing being delayed or the testing request being rejected.</p> <p>Following are the rejection criteria for the panel provider. (*) Indicates MANDATORY IDENTIFIERS (the sample may be rejected if these fields are not completed).</p> <p>Request Form Related Issue.</p> <ol style="list-style-type: none"> 1. (*) MANDATORY IDENTIFIERS of patient and/or donor shall tally between request form and sample. 2. (*) No identification or incomplete identification details (Name). 3. (*) No identification or incomplete identification details (IC no). 4. No requester details (signature and stamp). 5. Test request is not stated 6. Wrong request form sent 7. Incomplete request form 8. Leaking tube
2.	Samples Transportation	<ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. All samples should be transported in room temperature (without ice). 3. The MOH hospitals need to arrange the samples transportation to the panel provider.



2. Scope of Work: Cadaveric Donor Cases for Kidney

Procedures

No.	Scope	Description
1.	Pre Examination	<p>A. MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. Patients identified by the nephrologist. 2. Patients have fulfilled eligibility criteria and provided consents for outsourced immunology transplant testing. 3. Information regarding immunology testing must be communicated to patients. 4. Donor and patients sample registration must be completed in the Hospital Services Outsourcing System (HSOS). 5. MOH required to refer on the sample collection and transportation guidelines by the Panel Provider. 6. All samples must be transported at room temperature (without ice) immediately to the panel provider. 7. MOH hospitals are responsible for arranging sample transportation to the panel provider. 8. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary. <p>B. Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. Communication between the PIC at the referring and receiving hospitals must be established when necessary. 3. The panel provider must acknowledge receipt of the sample in the HSOS. 4. The panel provider must document testing progress in the HSOS (sample received, test report completion). 5. Each test must be completed immediately.



2. Scope of Work: Cadaveric Donor Cases for Kidney

Procedures

No.	Scope	Description
2.	Examination	<p>Testing and Quality Assurance Requirements</p> <ol style="list-style-type: none"> 1. All sample testing must be conducted in accordance with the documented test procedures established by the panel provider. 2. Testing must comply with the quality standards referenced in MS ISO 15189. 3. Tests shall be performed by competent laboratory staff, and all reports must be validated by authorized personnel. 4. The panel provider is required to participate in an External Quality Assurance Program (EQAP) for all tests offered. 5. If a test cannot be performed in full as specified, the panel provider must provide justification in the Hospital Services Outsourcing System (HSOS) and include the explanation in the report. 6. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.
3.	Post Examination	<p>Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. Preliminary report shall be conveyed verbally to referring hospital immediately after completion of test 2. The verified test report must be uploaded to the HSOS within 24 hours of test completion. 3. A new sample may be required if repeat testing is necessary; communication with the MOH referring hospital must be established in such cases. <p>MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. The MOH referring hospital must review the test report and validate it in the HSOS. 2. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.



2. Technical Requirements: Cadaveric Donor Cases for Kidney

Equipment

No.	Equipment	Specifications
1.	Urgent HLA Typing	<p>HLA typing for cadaveric donor transplant.</p> <p>Urgent HLA typing using molecular method.</p> <ol style="list-style-type: none"> The system shall be capable of performing HLA typing with the following minimum requirements: <ul style="list-style-type: none"> Support 6 to 11 HLA loci, including but not limited to: <ol style="list-style-type: none"> Class I: HLA-A, HLA-B, HLA-C. Class II: HLA-DRB1, HLA-DQB1, HLA-DPB1. Optional / extended loci: HLA-DRB3/4/5, DQA1, DPA1. The software shall have the latest HLA allele library according to IMGT database. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
2.	HLA Crossmatch: Flowcytometry System	<ol style="list-style-type: none"> The equipment shall assess the compatibility of prospective solid organ transplant (e.g. kidney transplant) patients and donors utilizing the flowcytometer crossmatch method. The system shall be to detect the presence of immunoglobulin (IgG) on the surface of lymphocytes. The system shall be equipped with at least 2 lasers, which is capable to detect at least 6 colours. The equipment shall be maintained according to plan preventive maintenance and registered by MDA
3.	Flourescence Microscope For CDC Crossmatch	<ol style="list-style-type: none"> The equipment shall assess the compatibility of prospective solid organ transplant (e.g. kidney transplant) patients and donors utilizing the microscope crossmatch method. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.
4.	Reagents	<ol style="list-style-type: none"> All reagents as specify for the test The reagents shall be registered by MDA.



Acronym

HLA-A: Human Leukocyte Antigen A
 HLA-B: Human Leukocyte Antigen B
 HLA-C: Human Leukocyte Antigen C

HLA-DRB1: Human Leukocyte Antigen DR Beta 1
 HLA-DQB1: Human Leukocyte Antigen DQ Beta 1
 HLA-DPB1: Human Leukocyte Antigen DP Beta 1
 HLA-DRB3/4/5: Human Leukocyte Antigen DR Beta 3/4/5

DQA1 (HLA-DQA1): Human Leukocyte Antigen DQ Alpha 1
 DPA1 (HLA-DPA1): Human Leukocyte Antigen DP Alpha 1
 IMGT: International ImMunoGeneTics Information System

2. Technical Requirements: Cadaveric Donor Cases for Kidney

Staffing

No.	Staff	Requirements
1.	Certified Pathologist or Transfusion Specialist trained in Transplant Immunology	Registered under NSR and MMC, up-to-date APC.
2.	Trained and certified Medical Laboratory Technician	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.
3.	Trained and certified Scientific Officer/ Laboratory Scientist	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.

FACILITIES - The facility shall be a hospital equipped with medical laboratory services, with the medical laboratory required to comply with the relevant laboratory standards

No.	Facilities	Requirements
1.	Hospital with medical laboratory	A. Certified by CKAPS
2.	Medical laboratory	1. Accreditation ISO 15189:2022 (Medical laboratories - Requirements for quality and competence) (Mandatory) 2. Without accreditation (IQA/EQA)* (Mandatory) 3. Other Accreditation, please specify (Optional)

Reporting

No.	Reporting	Requirements
1.	Test Report	1. Test reporting format must follow ISO15189 Medical Laboratory Requirement for Quality Competence. 2. Test report need to be available in the HSOS within 24 hours after verification.



3. Scope of Work: Waiting List Patients for Cadaveric Transplant for Kidney

General Information

No.	Scope of Work	Description																					
1.	Service Name	Immunology Transplant																					
2.	Detailed Description	Immunology Transplant Services for Waiting List Patients for Cadaveric Transplant for Kidney To conduct Immunology Transplant testing, the following tests are included: 1. High resolution Human Leucocyte Antigen (HLA) Typing 2. HLA Antibody Screening (PRA kit) 3. HLA Single Antigen Antibody																					
3.	Organ	Kidney																					
4.	Sub-service	Waiting List Patients for Cadaveric Transplant for Kidney																					
5.	Orderable	Waiting List Cadaveric Kidney - 3 Tests, 1 Patient																					
6.	Packages	<table border="1"> <tbody> <tr> <td>1.</td> <td>High Resolution - Human Leucocyte Antigen (HLA) Typing</td> <td>Patient</td> <td>0:1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>2.</td> <td>HLA Antibody Identification (PRA kit)</td> <td>Patient</td> <td>0:1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> <tr> <td>3.</td> <td>HLA Antibody Single Antigen</td> <td>Patient</td> <td>0:1</td> <td>✓</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	1.	High Resolution - Human Leucocyte Antigen (HLA) Typing	Patient	0:1	✓	1	1	2.	HLA Antibody Identification (PRA kit)	Patient	0:1	✓	1	1	3.	HLA Antibody Single Antigen	Patient	0:1	✓	1	1
1.	High Resolution - Human Leucocyte Antigen (HLA) Typing	Patient	0:1	✓	1	1																	
2.	HLA Antibody Identification (PRA kit)	Patient	0:1	✓	1	1																	
3.	HLA Antibody Single Antigen	Patient	0:1	✓	1	1																	
7.	Patient Selection(Waiting list) /Eligibility for the Service	1. Malaysian 2. Selection from MOH Hospital based on the Handbook of Kidney Replacement Therapy (KRT) Guidelines (latest version) by Ministry of Health, Malaysia																					
8.	Potential Patient Volume	Waiting List : 100																					



3. Scope of Work: Waiting List Patients for Cadaveric Transplant for Kidney

Sample

No.	Scope	Description
1.	Sample requirements	<p>A. Samples will be courier by MOH hospitals (Nephrology Department) Immunology Transplant Services for Waiting List Patients for cadaveric transplant. 1. High- Resolution- Human Leucocyte Antigen (HLA) Typing - whole blood in EDTA tube for patient. 2. HLA Antibody Screening (PRA kit) - Patient's blood in plain tube. 3. HLA Single Antigen Antibody - Patient's blood in plain tube.</p> <p>B. Acceptance Criteria For Sample All samples sent to the panel provider SHALL be accompanied by an appropriate request form. All sample tubes SHALL be correctly labelled with the following MANDATORY IDENTIFIERS: 1. Name 2. Identification number (IC) 3. MANDATORY IDENTIFIERS of patient shall tally between request form and sample</p> <p>C. Important Information on Sample Tube: 1. Please ensure MANDATORY IDENTIFIERS used on the request form and all sample tubes are tally 2. Please write using LEGIBLE CAPITAL LETTERS to label the sample tube 3. All details must be checked carefully to ensure they are correct Incorrectly labelled or insufficient information on sample tubes will result in testing being delayed or the testing request being rejected, and the patient having to be re-bled.</p>



3. Scope of Work: Waiting List Patients for Cadaveric Transplant for Kidney

Sample

No.	Scope	Description
1.	Sample requirements (cont.)	<p>D. Rejection Criteria</p> <p>It is the requesting centre's responsibility to ensure correct and sufficient information is used when requesting service from the panel provider. Incorrectly labelled or insufficient information on the sample tube will result in testing being delayed or the testing request being rejected, and the patient having to be re-bled.</p> <p>Following are the rejection criteria for the panel provider. (*) Indicates MANDATORY IDENTIFIERS (the sample may be rejected if these fields are not completed)</p> <p>Request Form Related Issue</p> <ol style="list-style-type: none"> 1. (*) MANDATORY IDENTIFIERS of patient shall tally between request form and sample 2. (*) No identification or incomplete identification details (Name) 3. (*) No identification or incomplete identification details (IC no / Passport no) 4. No requester details (signature and stamp) 5. Test request is not stated 6. Wrong request form sent 7. Incomplete request form 8. Leaking tube
2.	Samples Transportation	<ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. All samples should be transported in room temperature (without ice). 3. The MOH hospitals need to arrange the samples transportation to the panel provider.



3. Scope of Work: Waiting List Patients for Cadaveric Transplant for Kidney

Procedures

No.	Scope	Description
1.	Pre Examination	<p>A. MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. Patients identified by the nephrologist. 2. Patients have fulfilled eligibility criteria and provided consents for outsourced immunology transplant testing. 3. Information regarding immunology testing must be communicated to patients. 4. Donor and patients sample registration must be completed in the Hospital Services Outsourcing System (HSOS). 5. MOH required to refer on the sample collection and transportation guidelines by the Panel Provider. 6. All samples must be transported at room temperature (without ice) immediately to the panel provider. 7. MOH hospitals are responsible for arranging sample transportation to the panel provider. 8. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary. <p>B. Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. Panel Provider require to share the sample collection and transportation guidelines to the MOH. 2. Communication between the PIC at the referring and receiving hospitals must be established when necessary. 3. The panel provider must acknowledge receipt of the sample in the HSOS. 4. The panel provider must document testing progress in the HSOS (sample received, test report completion). 5. Each test must be completed immediately.



3. Scope of Work: Waiting List Patients for Cadaveric Transplant for Kidney

Procedures

No.	Scope	Description
2	Examination	<p>Testing and Quality Assurance Requirements</p> <ol style="list-style-type: none"> 1. All sample testing must be conducted in accordance with the documented test procedures established by the panel provider. 2. Testing must comply with the quality standards referenced in MS ISO 15189. 3. Tests shall be performed by competent laboratory staff, and all reports must be validated by authorized personnel. 4. The panel provider is required to participate in an External Quality Assurance Program (EQAP) for all tests offered. 5. If a test cannot be performed in full as specified, the panel provider must provide justification in the Hospital Services Outsourcing System (HSOS) and include the explanation in the report. 6. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.
3.	Post Examination	<p>Panel Provider Receiving Hospital</p> <ol style="list-style-type: none"> 1. Preliminary report shall be conveyed verbally to referring hospital immediately after completion of test 2. The verified test report must be uploaded to the HSOS within 24 hours of test completion. 3. A new sample may be required if repeat testing is necessary; communication with the MOH referring hospital must be established in such cases. <p>MOH Referring Hospital</p> <ol style="list-style-type: none"> 1. The MOH referring hospital must review the test report and validate it in the HSOS. 2. Communication between the Person-in-Charge (PIC) at the referring and receiving hospitals must be established when necessary.



3. Technical Requirements - Waiting List Patients for Cadaveric Transplant for Kidney

Equipment

No.	Equipment	Specifications
1.	High Resolution Frequency HLA Typing	<p>HLA typing for Waiting List Patients for cadaveric transplant. High-resolution HLA typing using NGS (Next Generation Sequencing) method or SSO-PCR (Sequence Specific Oligonucleotide-Polymerase Chain reaction).</p> <p>1. The system shall be capable of performing high-resolution (two-field or higher) HLA typing with the following minimum requirements: Support 6 to 11 HLA loci, including but not limited to:</p> <ul style="list-style-type: none"> a. Class I: HLA-A, HLA-B, HLA-C. b. Class II: HLA-DRB1, HLA-DQB1, HLA-DPB1. c. Optional / extended loci: HLA-DRB3/4/5, DQA1, DPA1. <p>2. The software shall have the latest HLA allele library according to IMGT database.</p> <p>3. The equipment shall be maintained according to plan preventive maintenance and registered by MDA.</p>
2.	HLA Antibody Test Equipment	<p>1. The HLA antibody test kit using fluoroanalyzer equipment (Luminex) shall analyze and identify the fluorescent intensity on each microbead and then assign HLA antibody respectively.</p> <p>2. The equipment shall be maintained according to plan preventive maintenance and registered by MDA</p>
3.	Reagents	<p>1. All reagents as specify for the test.</p> <p>2. The reagents shall be registered by MDA.</p>



Acronym

HLA-A: Human Leukocyte Antigen A
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 HLA-C: Human Leukocyte Antigen C

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 HLA-DPB1: Human Leukocyte Antigen DP Beta 1
 HLA-DRB3/4/5: Human Leukocyte Antigen DR Beta 3/4/5

DQA1 (HLA-DQA1): Human Leukocyte Antigen DQ Alpha 1
 DPA1 (HLA-DPA1): Human Leukocyte Antigen DP Alpha 1
 IMGT: International ImMunoGeneTics Information System

3. Technical Requirements - Waiting List Patients for Cadaveric Transplant for Kidney

Staffing

No.	Staff	Requirements
1.	Certified Pathologist or Transfusion Specialist trained in Transplant Immunology	Registered under NSR and MMC, up-to-date APC.
2.	Trained and certified Medical Laboratory Technician	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.
3.	Trained and certified Scientific Officer/ Laboratory Scientist	Supporting letter from Pathologist or Transfusion Specialist trained in Transplant Immunology.

Facilities - The facility shall be a hospital equipped with medical laboratory services, with the medical laboratory required to comply with the relevant laboratory standards

No.	Facilities	Requirements
1.	Hospital with medical laboratory	A. Certified by CKAPS
2.	Medical laboratory	1. Accreditation ISO 15189:2022 (Medical laboratories - Requirements for quality and competence) (Mandatory) 2. Without accreditation (IQA/EQA)* (Mandatory) 3. Other Accreditation, please specify (Optional)

Reporting

No.	Reporting	Requirements
1.	Test Report	1. Test reporting format must follow ISO15189 Medical Laboratory Requirement for Quality Competence. 2. Test report need to be available in the HSOS within 24 hours after verification.



Acronym

SAMM: Skim Akreditasi Makmal Malaysia

IQA: Internal Quality Assurance

EQA: External Quality Assessment



PROTECTHEALTH

PROPOSAL ON DIAGNOSTIC MAMMOGRAPHY

4. Background: Radiology

General Information

NO.	SCOPE OF WORK	DESCRIPTION
1	Service	Radiology
2	Sub-Services	Diagnostic Mammogram With Ultrasound Breasts & Axilla
3	Detailed Description	Diagnostic Mammogram with Ultrasound Breasts & Axilla for 1.Mammogram of both breasts(and extra views if required) with ultrasound breasts & axilla 2.Single breast mammogram(and extra views if required) with US breast & axilla,with US of contra lateral chest wall & axilla.
4	Orderable	1.Mammogram of both breasts(and extra views if required) with ultrasound breasts & axilla 2.Single breast mammogram(and extra views if required) with US breast & axilla,with US of contra lateral chest wall & axilla.



4. Scope of Work: Radiology

Patient Selection

NO.	SCOPE OF WORK	DESCRIPTION
1	Patient Selection/ Eligibility for the Service	<p>Inclusion</p> <ol style="list-style-type: none"> 1. All outpatients and stable elective cases 2. Malaysian Citizens 3. Patient's willingness to attend private/university hospital 4. Female ONLY 5. Stable 6. Age 40-73 7. Mobile and able to stand. Ambulating independently or with minimal assistance e.g. using walking stick/frame or minimal use of wheelchair for long distance mobility. 8. For cases of Diagnostic mammogram, high risk patient for breast cancer and surveillance. 9. Bilateral mastectomy and pregnant patient is excluded. <p>Exclusion</p> <p>If ANY one of the above general requirements and inclusion criteria is not fulfilled, the patient will be EXCLUDED from the outsourcing programme.</p> <ol style="list-style-type: none"> 1. Non-Malaysian. 2. Foreigner or Refugees. 3. Permanent/Temporary residents with Red or Green IC Holder. 4. Pregnant or Suspected pregnancy 5. Post breast reconstruction /augmentation / implant / filler injection etc. 6. Post bilateral mastectomy. 7. Male patients.
2	Potential Patient Volume	3000(for 3 months in 2026)



4. Scope of Work: Radiology

Procedures

NO.	SCOPE OF WORK	DESCRIPTION
1	Pre Procedure Care	<p>Preprocedural protocol (for patient and panel provider):</p> <ol style="list-style-type: none">1. Do not use deodorant, talcum powder or perfume on the breast or underarms.2. You will need to undress from the waist up, so wear a two-piece outfit (blouse or a T-shirt) rather than a dress.3. Please plan to arrive at least 15 minutes prior to your scheduled appointment time.4. If you suspect you may be pregnant, do inform the radiology staff. You will need to sign a Pregnancy Declaration consent form.5. If you are lactating, please pump your breasts one hour before the procedure.
2	Post Procedure Care	<ol style="list-style-type: none">1. Following the procedure, the Panel Provider uploads the required procedure consent form, documents, reporting, and images.2. If a patient develops any emergency crisis (i.e. vasovagal attack, hypoglycaemia) in the Panel Provider, immediate care is to be provided by the Provider before transferring the patient to the referring MOH facilities.
3	Patient follow up	<ol style="list-style-type: none">1. No follow up at panel provider2. As per Ministry of Health follow up date



4. Technical Requirements - Radiology

Equipment

No.	Equipment	Specification
1	MAMMOGRAM MACHINE Full Field Digital Mammography (FFDM) or 3D/Digital Breast Tomosynthesis	<ol style="list-style-type: none"> 1. MDA certification 2. Certification of pass QC test by Class H (radiation licensing) within the last 1 year 3. Pass LPPKN mammography quality audit by Collage of Radiology Malaysia 4. Pass Quality Assurance Program (QAP) Radiology (mammogram) by Bahagian Kawalan Radiasi (BKRP) 5. Radiology equipment without MDA : <ol style="list-style-type: none"> i. If the MDA certificate expired within the past 5 years, it may still be considered. The panel provider must provide the Planned Preventive Maintenance (PPM) records for the equipment. ii. Equipment aged more than 10 years is not acceptable.



4. Technical Requirements - Radiology

Equipment

No.	Equipment	Specification
2	ULTRASOUND MACHINE Minimum requirement of Medium range Ultrasound.	Mid-range 3 probes
		Able to perform 2D
		Fully digital colour Doppler ultrasound system
		Linear array probe (small parts) : 4-15 MHz for breast, axilla and chest wall.
		Medical Device Authority (MDA) approval is mandatory or accompanied by valid documentation of Planned Preventive Maintenance (PPM) arrangements.
		Radiology equipment without MDA : i. If the MDA certificate expired within the past 5 years, it may still be considered. The panel provider must provide the PPM records for the equipment. ii. Equipment aged more than 10 years is not acceptable.
3	CD/DVD Burner	All images need to be burnt in CD using DICOM format.



4. Technical Requirements - Radiology

Staffing Requirement

NO.	STAFFING	REQUIREMENTS
1	Radiologist	<ol style="list-style-type: none">1. The private must employ qualified and licensed radiologists.2. All radiologists must be board-certified, licensed (NSR, latest APC, and curriculum vitae with minimum 3 years experience).
2	Radiographer	<ol style="list-style-type: none">1. Trained radiographers with Certification of Mammogram training/CME attended.

Facility Requirement

NO .	FACILITY	REQUIREMENTS
1	Emergency response	Private facilities is able to handle any emergency situation i.e.vasovagal, hypoglycaemia.
2	Radiology Department	<ol style="list-style-type: none">1. The PACS should have the capacity to hold the images data for at least 2 weeks.2. The private hospital pre-existing PACS should be efficient to handle storage, retrieval, and distribution of diagnostic images and reports.3. PACS must comply with industry standards, ensuring interoperability with other healthcare systems and facilitating data exchange ie: DICOM compatibility.



4. Technical Requirements - Radiology

Reporting

NO.	REPORTING	REQUIREMENTS
1	CD/DVD	All images must be recorded onto CD/DVD in DICOM format (2 sets), and proper documentation must be maintained during dispatch. The CDs/DVDs should be made available within a maximum of seven (7) working days after the procedure.
2	Image Archiving and Storage	The private hospital is required to retain the images for a minimum of two (2) weeks to facilitate image retrieval as per local capacity.
3	Report	All reports should be submitted to the referring radiology department for compilation and imaging archiving. Two (2) hardcopy reports must be provided within seven (7) working days for both the referring radiologist and the requesting physician. It is essential to adhere to the attached reporting template for specific indications or examinations requested by the clinician.
4	Reporting Format	Title of reporting format must follow request form /orderable



4. Technical Requirements - Radiology

Reporting

NO.	REPORTING TEMPLATE	DESCRIPTION
1	MAMMOGRAM	<p>Bilateral/ Right/ Left mammogram</p> <ul style="list-style-type: none"> ✓ Breast density (Birads A, B, C or D) ✓ Dominant mass ✓ Architectural distortion ✓ Suspicious calcifications ✓ Skin, nipple and axillary nodes
2	ULTRASOUND	<p>US Breast and Axilla & US Chest Wall & Axilla</p> <p>Lesion, Location & Laterality (Distance from nipple)</p> <ul style="list-style-type: none"> ✓ Size (3 Dimensions) ✓ Echogenicity, vascularity ✓ Calcification ✓ Architectural distortion ✓ Margin/lobulation <p>Ductal Dilation</p> <p>Axillary lymph nodes : cortical thickness and size</p>
3		<p>Notes:</p> <ol style="list-style-type: none"> 1. Conclusion must include BIRADS assessment & recommendation 2. DISCLAIMER : False negative rate of mammogram is about 10-15%. Clinical correlation is recommended if there is a persistent clinical concern





PROTECTHEALTH

PROPOSAL ON AUDIOLOGY

Diagnostic Universal Neonatal Hearing Screening

BACKGROUND: AUDIOLOGY

(1) Basic Electrophysiologic Hearing Test

(A) Basic - Natural Sleep Bilateral Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR)

(2) Complex Electrophysiologic Hearing Test

(A) Complex - Natural Sleep ABR & ASSR
(B) Complex - Sedation ABR & ASSR



5. Scope of Work: Basic Electrophysiologic Hearing Test

General Information

NO.	SCOPE OF WORK	DESCRIPTION
1	Service Name	Audiology
2	Sub-Service	Basic Electrophysiologic Hearing Test
3	Orderable	Basic – Natural Sleep Bilateral Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR)
4	Detailed Description	<p>The service encompasses comprehensive diagnostic audiology assessment for Infants Who Fail Universal Neonatal Hearing Screening (UNHS) : Follow-up diagnostic testing for infants who do not pass second stage screening.</p> <p>The diagnostic evaluation includes the following procedures:</p> <p>i. Auditory Brainstem Response (ABR) Diagnostic Test The Auditory Brainstem Response (ABR) test is an objective hearing test that measures electrical activity from the auditory nerve and brainstem in response to sound. Electrodes placed on the scalp record neural responses to clicks or tone bursts delivered through earphones. ABR is used to assess hearing sensitivity and detect auditory nerve or brainstem abnormalities.</p> <p>ii. Auditory Steady State Response (ASSR) Auditory Steady-State Response (ASSR) is an objective hearing test that measures the brain’s electrical responses to continuous, modulated sound stimuli. Electrodes placed on the scalp record responses that occur at the same frequency as the stimulus, allowing frequency-specific estimation of hearing thresholds. ASSR is useful for infants and individuals who cannot provide reliable behavioral responses, especially in cases of severe to profound hearing loss.</p>



5. Scope of Work: Basic Electrophysiologic Hearing Test

General Information

NO.	SCOPE OF WORK	DESCRIPTION
5	Patient Selection/Eligibility for the Service	<p>Inclusion Criteria:</p> <p>Patient eligibility for this diagnostic assessment is determined by the following clinical indications:</p> <ol style="list-style-type: none"> 1. Patient is Malaysian with MyKID/Birth Certificate 2. Mother identification (MyKad) 3. Age: 1 - 3 months old 4. Failed the second stage neonatal hearing screening (Otoacoustic Emissions [OAE] or Automated Auditory Brainstem Response [AABR]). 5. Referral only by MOH Audiologist 6. Parents/Legal Guardian of patient must agree to be outsourced to Panel Provider hospital 7. Parents/Legal Guardian of patient to arrange own transportation to Panel Provider hospital <p>Exclusion criteria;</p> <ol style="list-style-type: none"> 1. Non-malaysian, Foreigner or Permanent Resident 2. Infants with selected identified risk factors for congenital hearing loss such as: <ol style="list-style-type: none"> a. Neonatal Encephalopathy, b. Extracorporeal Membrane Oxygenation (ECMO), c. In utero infections, such as herpes, rubella, syphilis, and toxoplasmosis, cytomegalovirus (CMV) d. Syndromes identified with atypical hearing thresholds, e. Culture-positive infections associated with sensorineural hearing loss 3. Patient with medical history of: <ol style="list-style-type: none"> a. Epilepsy b. Congenital Heart Disease
6	Potential Patient Volume	600 (capacity for 3 months)



5. Scope of Work: Basic Electrophysiologic Hearing Test

Procedures

NO.	SCOPE OF WORK	DESCRIPTION
1	Pre Procedure Care	<p><u>A. MOH Hospital</u> MOH Audiologistd needs to do:</p> <ol style="list-style-type: none"> 1. Triage and consultation before referral 2. Educate caretakers on pre and intra procedure preparation <p><u>B. Panel Provider</u> Panel provider needs to:</p> <ol style="list-style-type: none"> 1. Call Parents/Legal Guardian for appointment 2. Not proceed with test if patient is unwell and/or unable to sleep during appointment date, and need to re-schedule due to reliability of the result. Only one rescheduling is permitted, and the Panel Provider is required to inform the MOH Audiologist through the system and provide justification for the rescheduling. 3. Re-scheduling need to be done within 30 days from referring date
2	Intra Procedure Care	<ol style="list-style-type: none"> 1. Auditory Brainstem Response (ABR) testing: <ol style="list-style-type: none"> a. Test both ears b. Explain procedure and obtain informed consent c. Ensure patient is relaxed, still, or asleep d. Clean skin and place surface electrodes on scalp and mastoids/earlobes e. Deliver auditory stimuli (clicks or tone bursts) via insert earphones f. Record and average electrical responses from auditory nerve and brainstem g. Analyze ABR waveforms (Waves I-V) for latency and amplitude 2. Auditory Steady-State Response (ASSR) <ol style="list-style-type: none"> a. Test both ears b. Present continuous, amplitude- and/or frequency-modulated tones via earphones c. Record steady-state electrical responses from the auditory pathway d. Analyze responses using computerized statistical methods e. Estimate frequency-specific hearing thresholds for each ear f. Remove electrodes and monitor patient



5. Scope of Work: Basic Electrophysiologic Hearing Test

Procedures

NO.	SCOPE OF WORK	DESCRIPTION
3	Post Procedure Care	<ol style="list-style-type: none"> 1. Following the procedure, the Panel Provider uploads the required procedure consent form, documents, and reporting. 2. If a patient develops any emergency crisis (i.e. respiratory distress, hypoglycaemia) in the Panel Provider, immediate care is to be provided by the Provider before transferring the patient to the referring MOH facilities. 3. Any complication has to be handled by panel providers.
4	Patient Follow-Up	No Follow-up at Panel Provider
5	Complication	<ol style="list-style-type: none"> 1. In the event of any medical emergency, the Panel Provider must provide emergency care for stabilization, to inform via phone the MOH Audiologist (communication should be documented). 2. In an unexpected events (e.g. patient falls, choking, etc.), the Panel Provider should be responsible for patient care.
6	Notes	<ol style="list-style-type: none"> 1. The patient must have a MyKid or Birth Certificate. If the patient does not have either, the patient's citizenship shall be based on the mother's citizenship for up to 60 days from the date of birth. 2. There is a possibility that some referred cases from MOH Hospitals to the Panel Provider may involve syndromic babies, systemic illnesses, or congenital anomalies. This may happen because the baby's condition is not physically obvious at an early stage, resulting in unintentional referrals. If, during examination, the Panel Provider identifies that the baby has such conditions, they are allowed to refer the patient back to the MOH Hospital if they are not comfortable managing the case or do not wish to take on the additional risk. 3. If the patient awakens during the procedure, the referring MOH Audiologist must be informed, and the patient shall be referred back to the MOH facility. 4. The Panel Provider shall not transfer patients undergoing testing to another private hospital.



5. Technical Requirements: Basic Electrophysiologic Hearing Test

Equipment

No.	Equipment	Specifications
1	Auditory Evoked Potential Machine	<ol style="list-style-type: none"> 1. Capable to perform ABR and ASSR 2. Minimum 2-4 recording channel 3. Transducer: Insert earphones 4. Ability for patient data storage and export the result for reporting 5. Planned Preventive Maintenance (PPM) 6. MDA certificate 7. Equipment aged more than 10 years is not acceptable
2	Auditory Evoked Potential Machine with Auditory Brainstem Response (ABR) Software	<p>Type of test: Objective electrophysiological hearing test</p> <ol style="list-style-type: none"> 1. Physiological site: Auditory nerve and brainstem pathways 2. Stimulus type : Clicks / tone bursts / Chirp 3. Stimulus polarity : Rarefaction, condensation, or alternating 4. Stimulus rate: ~11–21 stimuli per second (commonly used) 5. Intensity range: Approximately 20–90 dB nHL 6. Recording electrodes: Surface electrodes placed on scalp and mastoids/earlobes 7. Waveform components: Waves I–V 8. Analysis parameters: Latency, inter-peak intervals, and amplitude 9. Test condition: Patient asleep or relaxed



5. Technical Requirements: Basic Electrophysiologic Hearing Test

Equipment

No.	Equipment	Specifications
3	Auditory Evoked Potential Machine with Auditory Steady-State Response (ASSR) Software	<p>Type of test: Objective electrophysiological hearing test</p> <ol style="list-style-type: none">1. Physiological site: Auditory nerve and brainstem/cortical generators2. Stimulus type: Continuous amplitude- and/or frequency-modulated tones3. Carrier frequencies: at least 3 Frequencies of 500 Hz, 1000 Hz, 2000 Hz, or 4000 Hz4. Modulation frequency: Typically 40–120 Hz5. Stimulus presentation: Monotic or dichotic via insert earphones6. Intensity range: Approximately 20–120 dB HL (equipment dependent)7. Recording electrodes: Surface electrodes on scalp and mastoids/earlobes8. Response characteristic: Steady-state neural response phase-locked to modulation frequency9. Analysis method: Automated statistical detection (e.g. FFT-based analysis)10. Test condition: Patient asleep or relaxed11. Clinical applications: Frequency-specific threshold estimation



5. Technical Requirements: Basic Electrophysiologic Hearing Test

Staffing Requirement

No.	Staffing	Requirements
1	Certified Audiologist	1. Updated Malaysian Allied Health Practicing Certificate (MAHPC). Have to be updated every 2 years 2. Able to operate ABR and ASSR equipment

Facility Requirement

No.	Facility	Requirements: Panel Providers may deliver services in either a Hospital or a Private Hearing Aid Centre and are required to indicate one primary service delivery setting during registration
1	Hospital	CKAPS
2	Private Hearing Aid Centre	1. SSM 2. Justification on availability of resident Audiologist (Appointment letter)
3	Test Environment	1. Quiet, sound-treated room or audiology booth to minimize electrical and acoustic noise 2. Comfortable room temperature and lighting suitable for patient relaxation or sleep 3. Adequate space for patient, audiologist, and monitoring equipment



5. Technical Requirements: Basic Electrophysiologic Hearing Test

Reporting

NO.	REPORTING	REQUIREMENTS
1	Autogenerate report from the machine	<ol style="list-style-type: none"> 1. Name, age, gender, and MyKID no 2. Date of test 3. Graph of ABR Waveform with marked Wave I, III, and V 4. Graph of ASSR / Estimated Audiogram 5. Report verification by Audiologist
2	Reporting Form	<ol style="list-style-type: none"> 1. Name, age, gender, and MyKID no 2. Date of test 3. Type of test: ABR or ASSR 4. Patient state: awake, relaxed, or asleep 5. Ear tested: right, left, or both 6. Type of stimulus: clicks / Chirp/ tone bursts (ABR), or modulated tones (ASSR) 7. Stimulus polarity 8. Waveform characteristics (ABR: Waves I–V; ASSR: response amplitude and phase coherence) 9. Results: <ol style="list-style-type: none"> a. ABR: Presence/absence of waves, absolute latencies, interpeak latencies, and estimated hearing thresholds b. ASSR: Frequency-specific thresholds (for each tested frequency) c. Degree and type of hearing loss, if present d. Reliability and limitations of the test (e.g., artifacts, patient movement) 10. Report verification by Audiologist
3	Submission	Autogenerated report of ABR and ASSR, and Reporting Form to be uploaded in HSOS system within 48 hours upon completion of tests



6. Scope of Work: Complex Electrophysiologic Hearing Test

General Information

NO.	SCOPE OF WORK	DESCRIPTION
1	Service Name	Audiology
2	Sub-Service	Complex Electrophysiologic Hearing Test
3	Orderable	(1) Complex - Natural Sleep ABR & ASSR (2) Complex - Sedation ABR & ASSR (Bilateral Auditory Brainstem Response (ABR) and Auditory Steady State Response (ASSR))
4	Detailed Description	<p>The service encompasses comprehensive diagnostic audiology assessment for Infants Who Fail Universal Neonatal Hearing Screening (UNHS) : Follow-up diagnostic testing for infants who do not pass second stage screening.</p> <p>The diagnostic evaluation includes the following procedures:</p> <p>i. Auditory Brainstem Response (ABR) Diagnostic Test The Auditory Brainstem Response (ABR) test is an objective hearing test that measures electrical activity from the auditory nerve and brainstem in response to sound. Electrodes placed on the scalp record neural responses to clicks or tone bursts delivered through earphones. ABR is used to assess hearing sensitivity and detect auditory nerve or brainstem abnormalities.</p> <p>ii. Auditory Steady State Response (ASSR) Auditory Steady-State Response (ASSR) is an objective hearing test that measures the brain's electrical responses to continuous, modulated sound stimuli. Electrodes placed on the scalp record responses that occur at the same frequency as the stimulus, allowing frequency-specific estimation of hearing thresholds. ASSR is useful for infants and individuals who cannot provide reliable behavioral responses, especially in cases of severe to profound hearing loss.</p>



6. Scope of Work: Complex Electrophysiologic Hearing Test

Patient

NO.	SCOPE OF WORK	DESCRIPTION
1	Patient Selection/Eligibility for the Service	<p>Inclusion Criteria :</p> <p>Patient eligibility for this diagnostic assessment is determined by the following clinical indications:</p> <ol style="list-style-type: none"> 1. Malaysian with MyKID 2. Age 4-12 months 3. Parents or legal guardians are required to bring the Baby Health Record Book to enable monitoring of the patient's body weight. 4. Passed AABR at any stage 5. Infants with selected identified risk factors for congenital hearing loss : <ol style="list-style-type: none"> a. Family history of hearing loss b. NICU > 5 days, c. 340 Hyperbilirubinemia (> 340μmol/L or requiring Exchange Transfusion), d. Aminoglycoside administration for more than 5 days, e. Parents concern regarding hearing, speech, language, developmental delay and or developmental regression f. Neonatal Encephalopathy g. Extracorporeal Membrane Oxygenation (ECMO), h. In utero infections, such as herpes, rubella, syphilis, and toxoplasmosis, cytomegalovirus (CMV) i. Syndromes identified with atypical hearing thresholds, j. Culture-positive infections associated with sensorineural hearing loss <p>*Refer to Guideline for Neonatal Hearing Screening (MOH/P/PAK/482.22(GU)-e) https://share.google/oMKm37JfoQsOw5t3b</p> <ol style="list-style-type: none"> 6. Referral only by MOH Audiologist 7. Parents/Legal Guardian of patient must agree to be outsourced to Panel Provider hospital 8. Parents/Legal Guardian of patient to arrange own transportation to Panel Provider hospital



RFP: Scope of Work: Complex Electrophysiologic Hearing Test

Patient

NO.	SCOPE OF WORK	DESCRIPTION
2	Patient Selection/Eligibility for the Service	Exclusion criteria: 1. Non-Malaysian, Foreigner or Permanent Resident 2. Patients with excessive weight loss (>10%) 3. Patient with medical history of: a. Epilepsy b. Congenital Heart Disease
3	Potential Patient Volume	6000 (capacity for 3 months)



6. Scope of Work: Complex Electrophysiologic Hearing Test

Procedures

NO	SCOPE OF WORK	DESCRIPTION
1	Pre Procedure Care	<p>(A) MOH Audiologist needs to do:</p> <ol style="list-style-type: none"> 1. Triage and consultation before referral 2. Educate parent or legal guardians on pre and intra procedure preparation 3. Parents or Legal Guardians are required to bring the Baby Health Record Book to enable monitoring of the patient's body weight. <p>(B) Panel Provider Panel provider needs to:</p> <ol style="list-style-type: none"> 1. Call Parents/Legal Guardian for appointment 2. Parents or Legal Guardians are required to bring the Baby Health Record Book to enable monitoring of the patient's body weight. 3. Upon pre-procedure assessment, Panel Provider needs to assess the patient's condition for either natural sleep or sedation 4. Not proceed with test if patient is unwell and/or unable to sleep during appointment date, and need to re-schedule due to reliability of the result 5. Re-scheduling need to be done within 30 days from referring date. Only one rescheduling is permitted, and the Panel Provider is required to inform the MOH Audiologist through the system and provide justification for the rescheduling. 6. Pre-Sedation Preparation <ol style="list-style-type: none"> a. Medical history review (allergies, respiratory or cardiac conditions) b. Fasting according to institutional or anesthesia guidelines c. Baseline vital signs recorded d. Informed consent obtained from parent or guardian e. Sedation administered only under medical supervision 7. Sedation Method <ol style="list-style-type: none"> a. Natural sleep is preferred for infants where possible b. If sedation is required, it must be: c. Prescribed and administered by a qualified anesthesiologist. d. Appropriate for the patient's age and health status



6. Scope of Work: Complex Electrophysiologic Hearing Test

Procedures

NO.	SCOPE OF WORK	DESCRIPTION
2	Intra Procedure	<p>A. Auditory Brainstem Response (ABR) testing (sedation or natural sleep) :</p> <ol style="list-style-type: none"> 1. Test both ears 2. Ensure patient is asleep 3. Clean skin and place surface electrodes on scalp and mastoids/earlobes 4. Deliver auditory stimuli (clicks or tone bursts) via insert earphones 5. Record and average electrical responses from auditory nerve and brainstem 6. Analyze ABR waveforms (Waves I-V) for latency and amplitude <p>B. Auditory Steady-State Response (ASSR) (sedation or natural sleep)</p> <ol style="list-style-type: none"> 1. Test both ears 2. Present continuous, amplitude- and/or frequency-modulated tones via earphones 3. Record steady-state electrical responses from the auditory pathway 4. Analyze responses using computerized statistical methods 5. Estimate frequency-specific hearing thresholds for each ear 6. Remove electrodes and monitor patient <p>For sedated patient, Panel Provider needs to do continuous monitoring:</p> <ol style="list-style-type: none"> 1. Oxygen saturation 2. Heart rate 3. Respiratory status 4. Patient positioned comfortably to maintain airway patency 5. Emergency equipment readily available 6. Keep the communication with MOH hospitals immediately if any incident raised



6. Scope of Work: Complex Electrophysiologic Hearing Test

Procedures

NO.	SCOPE OF WORK	DESCRIPTION
3	Post Procedure	<ol style="list-style-type: none"> 1. Post-Sedation Care (only for patient with sedation) <ol style="list-style-type: none"> a. Patient monitored until fully awake and vital signs are stable b. Observation for adverse effects such as respiratory depression or vomiting c. Discharge only when patient is stable and fit for discharge 2. For patients undergoing procedures with sedation, day-care admission may be required to allow post-sedation observation of the patient's condition. 3. Following the procedure (with sedation or natural sleep), the Panel Provider uploads the required procedure consent form, documents, and reporting.
4	Patient Follow-Up	No Follow-up at Panel Provider
5	Complication	<ol style="list-style-type: none"> 1. In the event of any medical emergency, the Panel Provider must provide emergency care for stabilization, to inform via phone the MOH Audiologist (communication should be documented). Arrangement to transfer back to the MOH Hospital without additional charges to the patient, MOH or ProtectHealth. This is considered as part of the bundled payment, if this services is required. 2. If patient required to be transferred to MOH Hospital, the patient shall be transferred by Panel Provider's ambulance and appropriately skilled staff. 3. In an unexpected events (e.g. patient falls, choking, etc.), the Panel Provider should be responsible for patient care.
6	Notes	<ol style="list-style-type: none"> 1. If the patient awakens during the procedure, the referring MOH Audiologist must be informed, and the patient shall be referred back to the MOH facility. 2. The Panel Provider shall not transfer patients undergoing testing to another private hospital.



6. Technical Requirements: Complex Electrophysiologic Hearing Test

Equipment

No.	Equipment	Specifications
1	Auditory Evoked Potential Machine	<ol style="list-style-type: none"> 1. Capable to perform ABR and ASSR 2. Minimum 2-4 recording channel 3. Transducer: Insert earphones 4. Ability for patient data storage and export the result for reporting 5. Planned Preventive Maintenance (PPM) 6. MDA certificate 7. Equipment aged more than 10 years is not acceptable
2	Auditory Evoked Potential Machine with Auditory Brainstem Response (ABR) Software	<p>Type of test: Objective electrophysiological hearing test</p> <ol style="list-style-type: none"> 1. Physiological site: Auditory nerve and brainstem pathways 2. Stimulus type : Clicks / tone bursts / Chirp 3. Stimulus polarity : Rarefaction, condensation, or alternating 4. Stimulus rate: ~11–21 stimuli per second (commonly used) 5. Intensity range: Approximately 20–90 dB nHL 6. Recording electrodes: Surface electrodes placed on scalp and mastoids/earlobes 7. Waveform components: Waves I–V 8. Analysis parameters: Latency, inter-peak intervals, and amplitude 9. Test condition: Patient asleep or relaxed



6. Technical Requirements: Complex Electrophysiologic Hearing Test

Equipment

No.	Equipment Requirements	Specifications
3	Auditory Evoked Potential Machine with Auditory Steady-State Response (ASSR) Software	<p>Type of test: Objective electrophysiological hearing test</p> <ol style="list-style-type: none"> 1. Physiological site: Auditory nerve and brainstem/cortical generators 2. Stimulus type: Continuous amplitude- and/or frequency-modulated tones 3. Carrier frequencies: at least 3 Frequencies of 500 Hz, 1000 Hz, 2000 Hz, or 4000 Hz 4. Modulation frequency: Typically 40–120 Hz 5. Stimulus presentation: Monotic or dichotic via insert earphones 6. Intensity range: Approximately 20–120 dB HL (equipment dependent) 7. Recording electrodes: Surface electrodes on scalp and mastoids/earlobes 8. Response characteristic: Steady-state neural response phase-locked to modulation frequency 9. Analysis method: Automated statistical detection (e.g. FFT-based analysis) 10. Test condition: Patient asleep or relaxed 11. Clinical applications: Frequency-specific threshold estimation
4	Emergency Trolley	Declare



6. Technical Requirements: Complex Electrophysiologic Hearing Test

Staffing Requirement

No.	Staffing	Requirements
1	Certified Audiologist	<ol style="list-style-type: none"> 1. Updated Malaysian Allied Health Practicing Certificate (MAHPC). Have to be updated every 2 years 2. Able to operate ABR and ASSR equipment
2	Anaesthesiologist	Updated MMC, APC and NSR for Anaesthesiologist

Facility Requirement

No.	Facility	Requirements : Panel Providers may deliver services in either a Hospital or a Private Hearing Aid Centre and are required to indicate one primary service delivery setting during registration
1	Hospital	CKAPS
2	Test Environment	<ol style="list-style-type: none"> 1. Quiet, sound-treated room or audiology booth to minimize electrical and acoustic noise 2. Comfortable room temperature and lighting suitable for patient relaxation or sleep 3. Adequate space for patient, audiologist, and monitoring equipment
3	Bassinet/ baby cot	Declare



6. Technical Requirements: Complex Electrophysiologic Hearing Test

Reporting

NO.	REPORTING TEMPLATE	DESCRIPTION
1	Autogenerate report from the machine	<ol style="list-style-type: none"> 1. Name, age, gender, and MyKID no 2. Date of test 3. Graph of ABR Waveform with marked Wave I, III, and V 4. Graph of ASSR / Estimated Audiogram 5. Report verification by Audiologist
2	Reporting Form	<ol style="list-style-type: none"> 1. Name, age, gender, and MyKID no 2. Date of test 3. Type of test: ABR or ASSR 4. Patient state: awake, relaxed, or asleep 5. Ear tested: right, left, or both 6. Type of stimulus: clicks / Chirp/ tone bursts (ABR), or modulated tones (ASSR) 7. Stimulus polarity 8. Waveform characteristics (ABR: Waves I–V; ASSR: response amplitude and phase coherence) 9. Results ; <ol style="list-style-type: none"> a. ABR: Presence/absence of waves, absolute latencies, interpeak latencies, and estimated hearing thresholds b. ASSR: Frequency-specific thresholds (for each tested frequency) c. Degree and type of hearing loss, if present d. Reliability and limitations of the test (e.g., artifacts, patient movement) 10. Report verification by Audiologist
3	Sedation Report	Full sedation report and verification by Anesthesiologist
4	Submission	Autogenerated report of ABR and ASSR, Reporting Form and Sedation Report to be uploaded in HSOS system within 48 hours upon completion of tests





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Q & A





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THANK YOU

