


Schedule

Issue date: 19 March 2025
Valid Until: -



NO: SAMM 1149

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| LABORATORY LOCATION: (PERMANENT LABORATORY)  | Jabatan Patologi, Level 3, Hospital Tunku Azizah Level 3, Hospital Tunku Azizah, Jalan Raja Muda Abdul Aziz, 50300 WP Kuala Lumpur. , 50300, WILAYAH PERSEKUTUAN KUALA LUMPUR MALAYSIA |
| ACCREDITED SINCE : | 19 MARCH 2025 |
| FIELD(S) OF MEDICAL TESTING : | MOLECULAR GENETICS |

The standard used for assessment of this laboratory is MS ISO 15189:2022 (ISO 15189:2022, IDT).

A medical laboratory's fulfilment of the requirements of ISO 15189 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results. The management system requirements in ISO 15189 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001. (See Joint IAF-ILAC-ISO Communiqué, November 2021)

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| CENTRAL LOCATION | Jabatan Patologi, Level 3, Hospital Tunku Azizah Level 3, Hospital Tunku Azizah, Jalan Raja Muda Abdul Aziz, 50300 WP Kuala Lumpur. , 50300, Wilayah Persekutuan Kuala Lumpur |
| FIELD(S) OF MEDICAL TESTING : | MOLECULAR GENETICS, |

SCOPE OF MEDICAL TESTING : MOLECULAR GENETICS

| Specimen Tested | Type of Test/ Properties Measured/ | Test Methods, Specifications/ Equipment/Techniques Used |
|-----------------|--|--|
| Cancer Genetics | None | None |
| Tissue | Epidermal Growth Factor | Real-time Polymerase Chain |
| | Receptor (EGFR) Mutation test | Reaction (PCR) as documented in |
| | None | HTA/PAT/GEN/MG/TPM-07 |
| | None | DNA Extraction and Quantification for |
| | None | Formalin-Fixed Paraffin- Embedded |
| | None | Tissue (FFPET) as documented in |
| | None | HTA/PAT/GEN/MG/TPM-08 |
| | Routine Preparation of | Manual documented in Histopathology as |
| | Histology Sections | Procedures Manual HISTO 007 to (GPQD/HI/SOP- |
| | Embedding Cutting | 023) |
| | Staining | nan |
| | Tissue Processing | Auto Instrument as documented in Histopathology |
| | Tissue Processing | Procedures Manual HISTO |
| | Tissue Processing | -Thermo Scientific Excelsior AS (2) |
| | Tissue Processing | (GPQD/HI/SOP-050) and microwave |
| | Tissue Processing | hybrid tissue processor (2) (GPQD/HI/SOP-063) |
| | Staining of Slides | Manual documented in Histopathology, as |
| | #NAME? | Procedures Manual: (GPQD/HI/SOP-021), |
| | #NAME? | Shandon Varistain® Gemini ES Autostainer(1 |
| | #NAME? | (GPQD/HI/SOP-56/V1) and |
| #NAME? | Prisma HISTO (1) (GPQD/HI/SOP-024 & | |

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| Gomori's Methenamine | GPQD/HI/SOP-208) |
| Silver | HISTO (GPQD/HI/SOP-024 & |
| - Per's Prussian | GPQD/HI/SOP-209) |
| - Gordon & Sweet's | HISTO (GPQD/HI/SOP-024 & |
| - Masson's Trichrome | GPQD/HI/SOP-034) |
| - Masson's Trichrome | (HISTO GPQD/HI/SOP-024 & GPQD/HI/SOP-30) |
| - Masson's Trichrome | (HISTO GPQD/HI/SOP-024 & GPQD/HI/SOP-25) |
| - Masson's Trichrome | (HISTO GPQD/HI/SOP-024 & GPQD/HI/SOP-53) |
| Grossing procedure | Manual as documented in: |
| Embedding | GPQD/HI/SO-16, GPQD/HI/SOP-15 |
| Processing | GPQD/HI/SOP-19 |
| Section cutting | GPQD/IPH/Lab operation/SOP-2 |
| Staining of sections | GPQD/HI/SOP-20 |
| Ziehl-Neelsen Stain | GPQD/HI/SOP-21 |
| Technique | GPQD/HI/SOP-28 |
| Reporting Procedure | GPQD/HI/SOP-22 |
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| Direct Smear AFB | None |

NOTE :

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