KINGDOM OF SAUDI ARABIA

Ministry Of Health

General directorate of Health Affairs AL-Baha

Mayyara General Medical Complex

المملكة العربية السعودية
وزارة الصحة
المديرية العامة للشئون الصحية بمنطقة الباحة
مجمع ميارا الطبي العام

☐ ADMINISTRATE POLICY & PROCEDURE (APP)		☐ INSTITUTIONAL POLICY & PROCEDURE (IPP) ☐ INTERDEPARTMENTAL ☐ INTERNAL
TITLE		**POLICY NUMBER/V#**
New Test Policy		**MMC – LAB – 19 (01)**
INITIATED DATE	**EFFECTIVE DATE**	**REVISED DATE**
02/08/2025	**01/09/2025**	**01/08/2028**
REPLACES NUMBER		**NO. OF PAGES**
N\A		**03**
APPLIES TO		**RESPONSIBILITY**
Laboratory Department		**All Lab Staff**

1.0 Policy:

4.1 It is the responsibility of the requesting staff to:

4.1.1 Collect the data indicating the need for the designated service...

4.1.2 Log all the new service data in a logbook according to the appropriate dates

4.1.3 Submit the data to the quality officer

4.2 It is the responsibility of the Quality Officer to:

4.2.1 Ensure the timely and accurate processing of the data.

4.2.2 Study the cost-effectiveness and complexity of the service.

4.2.3 Refer the study file to the administrative director.

2.0 Purpose:

To establish policy and procedures relevant to the processing of the newly requested service.

3.0 Procedure:

5.1 The following information must be verified while processing the new requested service

5.1.1 Cost-effectiveness study is reviewed by the financial office and approved.

5.1.2 A copy of the study is reviewed by the supervisor and approved.

5.1.3. Budget is reviewed and is available and complete.

5.1.4. New service educational needs are made available.
5.1.5. general considerations.

- laboratory space available;
- service/support of vendors;
- possibility of batching work;
- pre analytical variables;
- performance (sensitivity and specificity);
- Food and Drug Administration (FDA) approval/clearance;
- reagents needed/waste produced; and
- physical requirements, such as temperature, humidity, and lighting availability
- After concluding the initial research, a timeline is generated by the laboratory to follow for communicating the laboratory's goals to product vendors.

5.2 Interacting with Vendors

5.2.1 Vendors are essential for implementing a new test that uses a particular product so these laboratories can be visited during heavy testing times, which can yield beneficial information.

5.2.2 Using the information from each vendor will lead to the decision process.

5.3 Special requirements to be considered in case of introducing new test:

5.3.1 Knowledge of personnel performing test;
5.3.2 training and experience of personnel performing tests;
5.3.3 reagent and material preparation;
5.3.4 characteristics of operational steps;
5.3.5 calibration, quality control (QC), and proficiency testing materials;
5.3.6 test system troubleshooting; and
5.3.7 Interpretation and judgment.

5.4 Approval by the executive committee meeting

5.5New service monitoring by the quality officer The laboratory must monitor, assess, and correct problems when necessary through ugh use of written procedures and policies. This documentation includes the technical procedure, QC log, and quality-assessment manual for the test and reporting to the LAB director and reported to the executive committee meeting for corrective actions.

4.0 Distribution:

N/A

5.0 Approval:

APPROVALS & REVIEWS: 8			
Prepared By	**Title**	**Date**	**Signature**
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