☐ ADMINISTRATE POLICY & PROCEDURE (APP)	☐ INSTITUTIONAL POLICY & PROCEDURE (IPP) ☐ INTERDEPARTMENTAL ☐ INTERNAL

TITLE		POLICY NUMBER/V#
Proficiency Testing		MMC – LAB – 14 (01)
INITIATED DATE	**EFFECTIVE DATE**	**REVISED DATE**
02/08/2025	**01/09/2025**	**01/08/2028**
REPLACES NUMBER		**NO. OF PAGES**
N\A		07

APPLIES TO	RESPONSIBILITY
Laboratory Department	All lab staff.

1. Policy

1.1. Proficiency programs are used as an external check on the quality control and quality assurance of the test system. Proficiency testing can be done either by participating in an external quality assurance program, or by performing the split testing method for some samples to be done & compared with national or international references. External assessment checks are being at least 2 times per year. This happens through the inter-laboratory Quality assessment program or System "IQAS" between Mayyara polyclinic Medical Complex laboratory and Al Borg laboratories Quality services.

1.2. All laboratory analyses are covered with Proficiency Testing.

1.3. Alternative Proficiency Testing is performed when appropriate

1.4. Proficiency Testing results are not shared with other laboratories.

1.5. Proficiency Testing results are evaluated and compared to the acceptable performance.

2. Purpose:

2.1. Participation in proficiency testing (PT) survey evaluates the laboratory's performance compared to its peers and/or reference laboratories & To ensure accurate and reliable patient test results, Proficiency Testing (PT) will assist to determine that methods (including supplies and equipment used in those test methods) are working as expected and that test outcomes are meeting predetermined standards

3. Definition

3.1. Proficiency Testing "PT" or "IQAS" A program in which multiple samples are periodically sent to members of a group of laboratories for analysis by accredited organization, whereby each laboratory's results are compared with those of other laboratories in the group with an assigned value and reported to the participating laboratories

4. Affected department

4.1. All lab Staff.

5. Procedures:

Proficiency testing can be done either by participating in an external quality assessment program, or by performing the split testing method for some samples to be done & compared with national or international standards reference.

5.1 General guidelines for PT sample handling include:

5.1.1 Verify acceptable shipping temperature upon receipt.
5.1.2 Inspect samples for damage, breakage, or leaking sample containers.
5.1.3 Verify the correct number of samples is received.
5.1.4 Verify the correct samples as per institution-specific order are received.
5.1.5 Ensure that all discrepancies or problems are handled as per institution specific policy and procedure and reported to the PT provider immediately, as re shipping deadlines apply for all samples.
5.1.6 Document all steps of the proficiency testing process. All steps of the PT process should be documented on a checklist for retention with all PT event documentation. This checklist may be provided by the PT provider, accreditation agency, or be institution specific.

5.2 General Requirements for Proficiency Testing

5.2.1 Laboratory staff must perform the testing in the same exact manner as patient testing is performed

5.2.2 Proficiency Testing samples are tested by the same personnel handling patient samples.

5.2.3 Testing personnel assigned to perform PT may not consult with others unless this is part of the normal testing process.

5.2.4 Proficiency testing samples may not be sent to another laboratory for analysis. In addition, results may not be discussed with staff at another testing site until results have been submitted to the PT agency.

5.2.5 All steps of proficiency testing must be documented in daily test logs.

5.2.6 All testing personnel must review the results of proficiency testing. Any corrective action taken in response to incorrect results must also be reviewed by staff.

5.2.7 Proficiency Testing records are reviewed and approved by laboratory management.

5.3 Split Testing Method:

Mayyara polyclinic laboratory will establish an in house split sample methodology for PT testing, every six months (Internal Proficiency testing) some samples covering the entire ranges for chemistry, hematology and hormones sections will be tested in comparable laboratory instruments, results for those samples will be analyzed, total errors will be calculated and compared to the allowable total errors for every test published by CLIA. Results within the acceptable total errors goals will be accepted, while out of range results will be investigated and recalibration of changing reagents and or instrument or methodology will be considered

5.3.1 Every 6 months the Quality Assurance (QA) officer of the laboratory is to:

5.3.1.1 Ensure that the instruments and methodologies to be tested are working well, calibrated, and quality control runs were performed and accepted at the time of testing.

5.3.1.2 Perform the split sample for chemistry, hematology, and hormones instruments and methodologies.

5.3.1.3 Distribute the spitted samples to the responsible technicians forever section to be analyzed.

5.3.1.4 Collect all tested results from all sections and indorse it to the laboratory director.

5.4 The laboratory director will calculate the total errors for every test:

5.4.1 For quantitative techniques: the difference will be calculated between each result, then the difference will be expressed as % which will be considered as the total error %, to be compared to the allowable total error goals.

5.4.2 For qualitative techniques, agreements for 80% of all tested results will be considered acceptable.

5.5 Corrective actions will be taken for non-acceptable results.

5.6 Results of the PT, the review comments will be shared by every staff member during the monthly staff meeting that immediately follows the receipt of the results and comments.

5.4 Requirements for Successful Participation in Proficiency Testing

5.4.1 Successful performance: an overall score of 80% or better for an individual analytic.

5.4.2 Satisfactory participation: an overall score of 80% or greater for each analyte tested.

5.4.3 Unsuccessful performance: an individual score of less than 80%

5.4.4 Unsatisfactory participation: an overall score of less than 80% for two consecutive challenges or two out three consecutive challenges. At the direction of the laboratory director, a laboratory demonstrating unsatisfactory participation may be prohibited from continuing to perform that test or group of tests.

5.4.5 Review of Proficiency Testing: All testing personnel will review and initial final proficiency testing reports. The objective is to instruct testing personnel in regard to procedures and potential sources of error, testing problems or variation in testing results.

5.4.5.1 A two level control set (high and low or positive and negative)

5.4.5.2 Lot number of the kit or reagent system.
5.4.5.3 Date of expiration of the kit or reagent system.
5.4.5.4 Results that were obtained (e.g. positive, negative or quantitative values).

NOTE: Do not use the symbols "+" and "-". Positive results must be documented as either "Positive", "Pos", or "P". Negative results must be documented as either "Negative", "Neg", or "N".

5.4.5.5 A determination of pass or failure of the QC results.
5.4.5.6 Initials site for person performing the QC test.
5.4.5.7 Corrective action section to note what was done whenever invalid QC results are obtained.

5.5 External Proficiency assessment Survey "IQAS"

The laboratory will participate in external proficiency panels/surveys, which are blind assessments of the laboratory's performance. Where possible, the laboratory will participate in a proficiency program for each test performed in the laboratory sections through contract with Al Borg Quality laboratory which send challenge specimen or proficiency testing samples which covered all laboratory tests in all sections at a timely manner 3 times / year and analyzed taking the following considerations :

5.5.1 Proficiency samples are tested in the same manner as any routine specimen submitted to the laboratory.
5.5.2 Proficiency testing samples must be processed and integrated within the normal workload.
5.5.3 Proficiency testing samples should be analyzed by laboratory personnel who routinely test patient samples (not done carefully by senior lab technician staff) and without special treatment.
5.5.4 Conduct testing within the required timeframe.
5.5.5 Communicates problems with supervisors or specialists.
5.5.6 Inter-laboratory discussion of PT results is not permitted. Then,
5.5.7 The laboratory supervisor or specialist will review the final result forms and send them to the testing laboratory in a timely manner.
5.5.8 A copy of the final results form will be kept in the External Proficiency Testing file.

5.5.9 When the survey results are returned, the laboratory specialist and director will review and sign the results. All proficiency program reports should be reviewed, signed and dated by the laboratory specialist and director as soon as possible upon receipt. The signed copy should be filed with the original results. The laboratory specialist and director must review any deficiencies cited by any proficiency program or accrediting organization in which the laboratory participates.

These deficiency reports will be filed in the proficiency test result file with the original report.

PT: As a tool for laboratory improvement:

All laboratories will occasionally have an unacceptable PT result, unacceptable proficiency testing performance may reveal an inadequacy in specimen handling or in an analytic process that is not revealed by other indicators, each unacceptable result should be thoroughly investigated to maximize the opportunity to correct a problem. Whenever possible, the laboratory should use the information gained from investigation of the unacceptable result to prevent similar problems in the future, laboratory personnel should ask: how can we change our systems so that this problem cannot occur again.

Documentation:

- ✔ The section supervisor, QA officer and director of the laboratory must regularly review the PT result. The cause (s) of any unacceptable result must be investigated.
- ✔ The conclusion and corrective action for any unacceptable result should be documented.

6. Responsibilities:

6.1. All lab Staff

7. Reference:

7.1. Steindel SJ. Gones BA. Routine outpatient laboratory test turnaround times and practice patterns, a College of American Pathologists Q-probes study. Arch. Pathol. Lab Med 2002 **Dacie and Lewis, Practical hematology-ninth edition-page 574**

7.2. International council; for standardization in hematology 1998 guidelines for organization and management of external quality assessment using proficiency testing – international journal of hematology 68:45-52

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