Ministry of Health

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Directorate/Institution	Diagnostic Laboratories Services at Directorate General of Specialized Medical Care (DGSMC) at Ministry of Health (MOH)
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Acknowledgment

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Acronyms:

IRLS	Electronic Incident Reporting and Learning System.
LIS	Laboratory information system

1. Purpose

This document describes the procedure for amended reports (revised reports) with significant modifications to a previously released report and made available for clinical decision. They can be monitored as a key performance indicator in clinical laboratories. Amendments are usually given greater emphasis, as this may affect patient care, and must be accompanied by additional notification to the clinicians.

2. Scope

This document is applicable for all medical laboratories under MOH and other collaborative governmental and non-governmental health institutions.

3. Definitions

3.1 Amended report: is defined as changes to information that occur after release of an original report. This includes instances where "significant" information in the original report is deemed to be incorrect (an error) and which is identified at a time later than issuing of the original report. Such incorrect information may relate to significant alteration of diagnosis and management.

4. Procedure

4.1. Background:

- Amendment of reports can include but not limited to the following:
  - Results entered in the wrong field.
  - Transposed numbers or decimal misplaced.
  - Missing information of the report.
  - Result values have been entered and accepted, but do not belong to this patient.
  - Result is wrong.
  - Quality control did not pass and result was reported.
- The following list are not considered to be classified as an amended report:
  - Corrected minor typing errors or spelling mistakes.
  - Final report after provisionally released reports.
  - Any supplementary report.

4.2. Procedural steps:

4.2.1. Once needed, the amendment of report can be done by any laboratory staff.

4.2.2. In the event that an error (technical/clerical) is made, or misidentification of a specimen is discovered, and patient results have been reported, corrective action must be taken immediately under the direction of the microbiologist or senior staff.

4.2.3. This action includes:

- Confirmation that an error was made,
- Identification of all specimens involved
- Generation of corrected results for all tests affected.
- The notification of the ordering clinician must be immediate.

4.2.4. The results change and notification to the clinician should be documented.

4.2.5. Steps of amendment in LIS:

- Recall the result.
- Select amended report from the drop box.
- Enter the reason of amendment.
- Enter the correct result.
- Add the following comments: clearly state “This is an amended report, please disregard previous report on this specimen number”
- Release the corrected result.

4.2.6. Notification of Corrected Results:

- Clinician must be notified immediately when changes in reported results may affect patient treatment.
- Any result that is corrected and has gone from a normal value to an abnormal value or has gone from an abnormal value to normal value must be called to the concerned clinician immediately.
- Information about the error will be given in detail to the caring physician. This includes correct patient, correct report.
- For the proper communication pathway, refer to critical results notification S.O.P. to communicate the amendment.

4.2.7. Documentation of notification must be put into the lab remarks. This documentation must include: reason for amendment, who was notified, time and

date of notification, read back verification. In case of notification failure, document it and inform the microbiologist or the senior supervisor.

4.2.8. Determine if other specimen(s) were also affected. Take appropriate action with all specimens and values that are found to be involved.

4.2.9. In circumstances where the results have been made for clinical decision making prior to amendment, nonconformance should be raised to detail the adverse incident with an indication of the action taken to reduce the possibility of recurrence.

4.2.10. All amended reports should be audited regularly to calculate the amended report rates and also for classifications of reasons for amendment. (Note that the new and the old results can be traced in the LIS).

4.2.11. The information could potentially be used to improve error detection and reduce the number of amended reports. Preventative actions should be initiated as required.

5. Responsibilities

5.1. Responsible staff:

- To ensure the adherence to amendment procedure and critical result communication procedure.
- To ensure the proper training and education for lab staff.
- To facilitate the alternative channels once needed

5.2. Quality manager /officer

- To follow up the implementation of the procedure
- To monitor regularly communication of amended results
- To raise non-conformance with corrective action once needed.
- To monitor the amendment rate regularly.
- To investigate and ensure the proper closure of the IRLS reports.

5.3. All lab staff:

- To adhere to the amendment procedure.
- To record communication and release amended results immediately as recommended
- To report communication failures or incident.

6. Document History and Version Control

Version	Description	Review Date
1	Initial Release	May 2026

7. References

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
Cancellation and Correction of Records and Results	The University of Toledo Medical Centre	1/04/2021	
Management of post analytical processes in the clinical laboratory according to ISO 15189:2012 Standard requirements: considerations on the review, reporting and release of results	M Liboria López Yeste, Silvia Izquierdo Álvarez ,Antonia R. Pons Mas	January11, 2021	
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Amended Reports	Shanequa Bradley	19-Dec-2016	
Supplementary and Amended Reports – Anatomical Pathology	The Royal College of Pathologists of Australia	Mach 2014	