BIOGENIX

POLICY PROCEDURE FOR REPORTING OF LABORATORY — RESULTS

	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	MS. PREETY RAHEJA	QUALITY MANAGER		30/06/2020
Reviewed by	DR. JULIET TEDDY	DEPUTY DIRECTOR		01/07/2020
Approved by	DR. SALLY ABDULLA IBRAHIM	LABORATORY DIRECTOR		01/07/2020

1. TABLE OF CONTENT

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4. POLICY STATEMENT

The result releasing is done following this policy and procedure. All the patient reports should be validated by the pathologists before they are being released to treating physicians for clinical decision making. As this will help in the prevention of analytical as well as clerical errors that may have the potential to adversely affect patient outcome if not filtered

5. PURPOSE

To describe the process of appropriately reporting laboratory test results. This procedure ensures that the result reporting process is performed adequately and with appropriate quality control and quality assurance in a manner that reduces errors or misreporting of results. The procedure is as per clause No. 5.8 of ISO 15189:2012 Medical laboratories – Requirements for Quality and Competence.

6. SCOPE

6.1 The procedures to be followed for reporting of all results after completion of analysis.

6.2 The contents of laboratory reports

6.3 Target Audience: BIOGENIX Laboratory technologists, coordinators, and admin staff.

7. DEFINITIONS:

7.1 Patient result validation is a vital final stage of laboratory quality assurance and is usually the responsibility of all laboratory staff. It is a set of procedures undertaken by the staff of the lab for continuously assessing laboratory work and emergent results, in order to decide whether they are reliable enough to be released.

8. ACRONYMS

8.1 STAT – Latin word “statim” means immediately
8.2 LIMS – Laboratory Information Management System

9. RESPONSIBILITIES

9.1 Laboratory Director: It is the responsibility of the laboratory director to formulate and materialize the prompt, effective and convenient report delivery procedure and system.

9.2 Laboratory Technical and clerical Staff. Laboratory technologists and coordinators should review the results coming out from machines, validate them on LIMS, correct released report errors (if any), get final approval from the pathologists, and document amendment in the report.

10. PROCEDURE

10.1 REPORTING OF RESULTS:

10.1.1 The result of all the examination is reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

10.1.2 All reports will be available in the LIMS after being confirmed by the technologist and validated by the pathologists. No results will be received by patients or a co-patient from the laboratory. If the patient requires hardcopy of particular lab results, it will be issued to the requesting facility contact point who in turn can hand over the report.

10.1.3 Laboratory reports will be generated by lab coordinator after the results are confirmed by the responsible technologist, who performed the analysis.

10.1.4 All the reports will be reviewed. Manual test results and reports transmitted by the LIMS are validated by the pathologists.

10.2 REPORT ATTRIBUTES:

10.2.1 There is a comment regarding required sample type (naso-pharyngeal, throat swabs, EDTA or serum) for each test, and sample quality (required container) in case it affects the results.

10.2.2 Patient preparation requirements for each test that are not met are also mentioned in the report.

10.2.3 If from a request some tests done and some rejected it is also mentioned in the report the reason of rejection (wrong vial, leakage, hemolysed sample, sample Quantity not sufficient. Etc.)

10.2.4 If any sample not received, the remark about the missing sample also is there in the report, in case report is released before receiving the pending sample.

10.2.5 Interpretive comments on results, where applicable, which help the physician in making necessary decision regarding patient health status.

10.3 Testing Report Contents:

10.3.1 Patient name, age, gender and patient Identification number (Emirates Id), sample number on each page of the report;

10.3.2 Name of the requesting of medical Centre;

10.3.3 Type of Sample;

10.3.4 Date and time of registration into the LIS;

10.3.5 Collection Time;

10.3.6 Date and time of verifying;

10.3.7 Name of the person who verified the report.

10.3.8 There are computerized signatures of the pathologist on the verified reports

10.3.9 Methodology of the test done;

10.3.10 Interpretation where required;

10.3.11 Wherever required comment regarding sample quality, sample suitability, etc.

10.3.12 Page number on each page of the report.

11. CROSS REFERENCE

11.1 ISO 15189:2012 Medical laboratories – Requirements for Quality and Competence.

11.2 Emirates International Accreditation Centre Accreditation Requirements for Medical Laboratory Testing (EIAC)

12. RELEVANT DOCUMENTS & RECORDS