BIOGENIX

RELEASE OF LABORATORY RESULTS

POLICY & PROCEDURE

	NAME	DESIGNATION	SIGNATURE	DATE
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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

Reporting, delivery of patient testing results, and correcting results after reporting policy will be implemented as per the following procedures.

5. PURPOSE

5.1 To describe the process of appropriately releasing laboratory test results. This procedure documents who is authorized to release laboratory test results, who may receive them, and the means of delivering patient results to secure results from unauthorized usage.

5.2 The procedure is as per clause No. 5.9 of ISO 15189:2012 Medical laboratories – Requirements for Quality and Competence.

6. SCOPE

6.1 The procedures to be followed for releasing of all results after completion of analysis to requesting healthcare facilities.

6.2 Scope of this policy covers all the patient reports generated in the lab for all in-house tests and documenting correction of released reports.

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

7. DEFINITIONS: N/A

8. ACRONYMS

8.1 STAT – Latin word “statim” means immediately

8.2 Patient ID No – Patient Identification Number

9. RESPONSIBILITIES

9.1 Laboratory Director: It is the responsibility of the laboratory director/ Pathologists to formulate effective and report release method which reflects correct test results and ensures confidentiality of patient data and protects them from unauthorized usage.

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, get final approval from the pathologists, and document amendment in the report.

10. PROCEDURE

10.1 REPORTING AND DELIVERY 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 laboratory coordinators 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.

10.1.5 Reporting by telephone: Only Critical values and STAT requests will be reported to the requesting physician or the contact person for the requesting facility.

10.1.6 A consolidated patient results reports will be sent to the requesting medical facility via email. or via by uploading them into the shared online website for samples received from SEHA facilities.

10.2 FOLLOWING IS THE PROPOSED VALIDATION CYCLE FOR MANUAL TESTS DONE IN THE LAB:

10.2.1 Validation of manual (non-automated) tests is through addition of the approval yes sign to the master result sheet after the result being checked independently by two suitably qualified members of the staff.

10.2.2 Identification of the received specimens and accessioning is done after sample inactivation. Then samples are taken up for processing. Worksheets are initially made ready either by scanning patient barcodes or fixing patient ID label over existing barcodes if not properly identified.

10.2.3 Tests are processed and the results are entered in the worksheets.

10.2.4 Completed worksheets for tests are signed by adding the name of the technologist who is doing the test.

10.2.5 Pathologists confirm the manual test results by adding the yes sign in the master-result worksheet or validating the results in the LIMS to release reports.

10.2.6 All the manual reports need to be signed by the typist who is sending the reports to clients.

10.3 FOLLOWING IS THE PROPOSED VALIDATION CYCLE OF AUTOMATED TEST RESULTS IN THE LAB:

10.3.1 Identification of the specimens and accessioning are done using barcode immediately after inactivating them.

10.3.2 Samples are processed after scanning the barcode containing patient identification details and the test ordered.

10.3.3 Samples are processed and all the data falling within the set limit in the analyzer are transferred to the LIMS directly. Results falling out of the limits are collected in a separate folder for the technologist's review and confirmation. Tests requiring repeat analysis are performed and the results are confirmed if they are satisfactory.

10.3.4 Technologist who performed the tests access the LIMS using his unique ID and password to run the tests and review all the results. It helps to track the person who performed a particular analysis.

10.3.5 Delta check is done using the programmed parameters in the LIMS. All the flags are checked (for positive, negative, borderline as well as invalid results) and errors and discrepancies are corrected.

10.3.6 Final validation of the results transmitted into the LIS and manual test results entered by the typists is done by the pathologists and corrective actions are taken if required.

10.3.7 Patient results are released LIS with the electronic signature of the pathologist who validated the reports. The reports can be printed in the final format by the admin staff and authorized report releasing clerk if requested by the client otherwise results are sent my email to the requesting facilities.

10.4 CORRECTING RESULTS AFTER REPORTING:

10.4.1 Incase laboratory released reports need to be corrected during daily working hours, the contact person for the requesting facility or the requesting physician should be notified immediately.

10.4.2 After daily working hours, either the requesting physician if available or the contact person for the requesting facility.

10.4.3 In all situations, if an erroneous report is issued, The corrected report will state previous reported results as well as the corrected results in both the hard copy as well as the soft copy of the report in the LIMS. The audit trail for the person who amended the report has to be possible.

10.4.4 The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report.

10.4.5 The revised report shows the time and date of the change and the name of the person responsible for the change.

10.4.6 The corrected report should be released only after being reviewed and approved by the laboratory director

10.5 REFERENCE RANGE, COMMENTS, AND INTERPRETATIONS:

10.5.1 All reports will show the reference range for the analysis requested.

10.5.2 Technical staff should not give any medical advice regarding the results, in case that a patient or a co-patient comes to the laboratory asking for medical advice or interpretation of the results.

10.5.3 The Head of Section can offer comments and or interpretation for the results obtained and should consult the requesting physician to discuss the results of the patient.

10.6 RETRIEVAL OF LABORATORY RESULTS:

10.6.1 Inquiries regarding missing results should be made to the laboratory admin staff through lab email address

10.6.2 Check first that the specimen was actually collected and delivered to the laboratory in the barcode sample accession.

10.6.3 Check if it is a STAT or a routine test. Only STAT/urgent tests have a maximum of 10 hours turnaround time. Routine tests are turned out as they are finished depending on the test.

10.6.4 Check the lab record number, the test requested, data and time of collection.

10.6.5 A report will be generated for the missed manual results after tracing the attached worksheet from the stored request forms.

10.7 REPORTING LOGIC:

First step: Blank/Positive control should pass following criteria!!! Blank control (VIC＞32，FAM＞38) while Positive control (VIC＜32，FAM＜32) *If VIC of Blank control fails in quality control, perform whole plate sample RE-extraction; *If FAM of Blank control fails in quality control, perform RE-extraction for sample with positive results; *If Positive control fails in quality control, perform whole plate sample RE-extraction. *If VIC of whole plate appear style of “Horse Tail(VIC curve raised at same PCR cycle but separate from each other widely at 40 cycle (fig. 1), which may cause the false negative results)”, perform whole plate sample RE-extraction
For each test specimen, VIC must present “S” curve with VIC Ct value ≤32; When Ct value at VIC channel are higher than 32, or with no Ct value at VIC, re-extraction is required.

Interpretation on positive, grey zone and negative (Ct at FAM)	Action on 1st test result	No. of reference result	Action after re-test
No "S" curve and No Ct value at FAM: Negative	Negative report	1	N/A
"S" curve and FAM Ct≤35: High positive	Positive report	1	N/A
"S" curve and 35<FAM Ct≤38: Weak positive	RE	2	If "S" curve and FAM Ct≤38 in RE results, release **Positive** report.
		2	If negative RE result, **Presumptive Positive.**
		2	If "S" curve and FAM Ct>38 in RE results, **Presumptive Positive**
"S" curve and FAM CT>38: Grey zone	RE	2	If no Ct at FAM for RE result, release **Negative** report.
		2	If "S" curve and FAM Ct≤38 in RE results, release **Positive** report.
		2	If "S" curve and FAM Ct>38 in RE results, **Presumptive Positive.**
No "S" curve but with Ct value at FAM: Re-extraction	RE	2	If result remains as 1st test, perform Re-collection

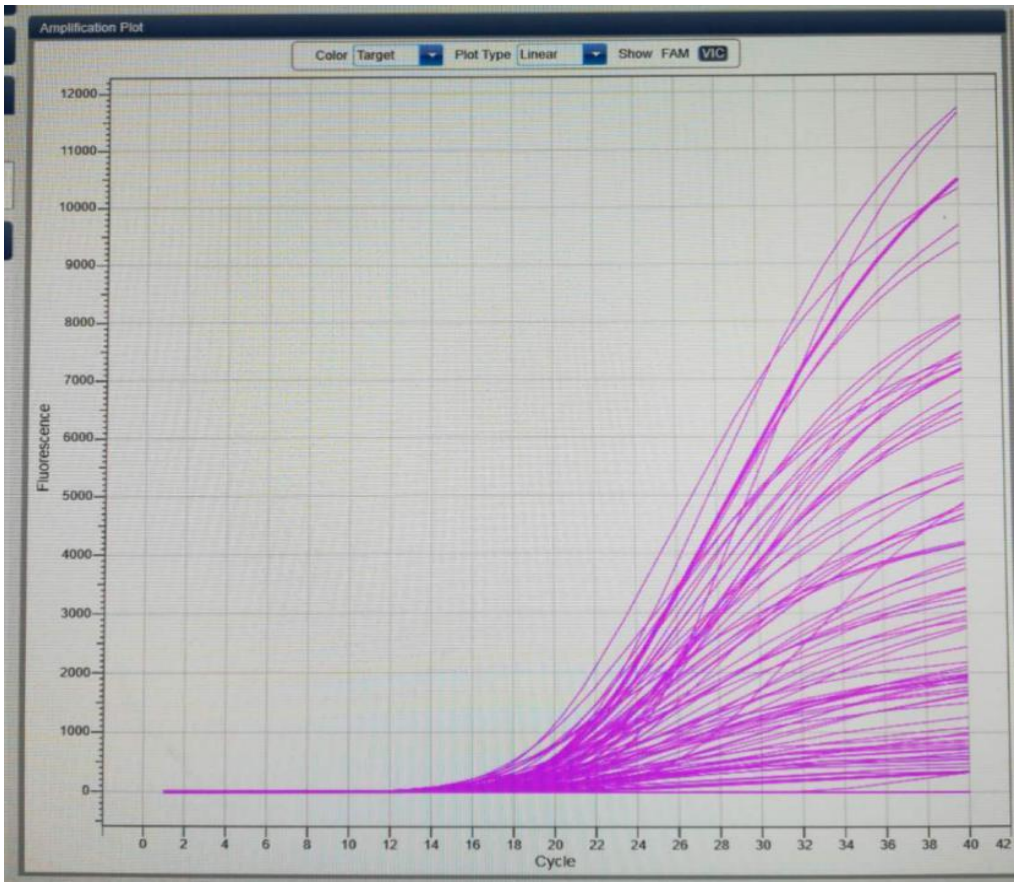

Fig.1 Horse tail of VIC curve of whole plate

11. CROSS REFERENCE

11.1 Laboratory reporting policy, West Tennessee Healthcare Integrated Laboratory Physician's Laboratory Handbook, Policy # 3030 (PLH3030-03). http://www.gomcl.com/PLHDOCS/PLH303.pdf

11.2 Client response center reporting procedures, Department of Pathology, Dartmouth-Hitchcock Medical Center.
http://labhandbook.hitchcock.org/reporting.html

12. RELEVANT DOCUMENTS & RECORDS

12.1 N/A