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Test Result Reporting		

CONTROLLED DOCUMENT

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Test Result Reporting

Test Result Reporting

1 PURPOSE

1.1 This Standard Operating Procedure (SOP) defines guidelines for the reporting of test results.

2 SCOPE

2.1 This document advises the CLIA Laboratory personnel at Theranos on the protocol for test result reporting.

3 DENITITIONS AND ABBREVIATIONS

3.1 Corrected Report: Corrected reports are issued when major test information present after issuing the original report is changed.

3.2 CAPA: Corrective and Preventative Action.

3.3 CLS: Clinical Laboratory Scientist

3.4 Amended Report: Amended reports are issued when minor transcription, patient identification, specimen site, or other related reporting errors are found. A corrected report differs from an amended report because test information, such as assay results, remain unchanged.

3.5 Final Report: A final report is a completed report that includes the final test results and which is a permanent part of the medical record.

3.6 Preliminary Report: A preliminary report is used when there is a delay in producing the final report. It could be delayed for a number of reasons, such as the need for repeat, confirmatory or referral testing.

4 RESPONSIBILITIES

4.1 It is the responsibility of the authorized personnel in CLIA laboratory at Theranos to follow the procedures outlined in this SOP.

5 PROCEDURE

5.1 Test results will be reported to the appropriate healthcare provider in a timely, accurate, reliable and confidential manner.

5.2 The results generated from the Vital diagnostic Eon 100 Instrument will be entered into the appropriate forms (CL FRM-12001-F1, CL FRM-12001-F2, CL FRM-12001-F3, CL FRM-12001-F4) or printed and attached to form CL FRM-12001-F5 for the analytes ordered on the requisition form.

5.2.1 The results will be verified by the licensed Testing Personnel, the Clinical Consultant or the Laboratory Director

5.3 Preliminary and Final Reports

5.3.1 Reporting is currently by manual entry by the method in section 5.3.2 or 5.3.3

5.3.2 The appropriate test report form CL FRM-12001-F1 (preliminary results as appropriate to the assay(s)) or CL-FRM-12001-F2 (final results) will be completed by the Testing Personnel. Alternatively, a Laboratory Report Coversheet CL FRM-12001-F5 may be filled out and sent along

with the instrument printout. The minimum required information is as follows:

5.3.2.1 Name and address of the laboratory location at which the test was performed and the name of the director

5.3.2.2 Patient name and other unique identifier

5.3.2.3 Specimen type

5.3.2.4 Date and time of specimen collection

5.3.2.5 Date and time of testing as indicated by time of verification

5.3.2.6 Test performed and test result and units of measurement, as applicable. This is included in the validation protocols and/or SOPs for the analytes tested.

5.3.2.7 Reference range, as appropriate. This is included in the validation protocols for the analytes tested or in the case of kits may be provided by the kit manufacturer.

5.3.2.8 Condition and disposition of specimens not meeting the laboratory's criteria for acceptability.

5.3.2.9 Appropriate descriptive information for specimens deemed less than optimal.

5.3.2.10 The information will be verified by Testing Personnel or the General Supervisor prior to release.

5.3.2.11 The results will be sent by the method(s) requested (i.e., phone, fax, or mail).

5.4 Amended Reports

5.4.1 Upon discovering an error that requires amendment (i.e., transcription, patient identification, specimen site, or other related reporting errors), the staff member will refer the matter to Testing Personnel or General Supervisor who will fill out form CL FRM-12001-F3 and release the results.

5.4.2 The Clinical Consultant or Laboratory Director will contact the healthcare provider to inform them that an amended report has been issued.

5.5 Corrected Reports

5.5.1 Upon discovering an error that requires correction (i.e., change in a test result), the staff member will refer the matter to Testing Personnel or General Supervisor who will fill out form CL FRM-12001-F4 and release the results.

5.5.1.1 The Testing Personnel, General Supervisor, Clinical Consultant or Laboratory Director, as appropriate, will investigate the cause per CL SOP-00008.

5.5.2 The Clinical Consultant or Laboratory Director will contact the healthcare provider to inform them that a corrected report has been issued.

5.6 Critical Values

5.6.1 Critical Values are found in attachment CL FRM -12001-A1.

5.6.2 Follow SOP CL SOP-7005 Repeat Testing as appropriate.

5.6.3 Licensed Testing Personnel are to attempt to contact the Emergency Contact as soon as possible (within 15-30 minutes) of the result being finalized. This process will be documented on the Specimen Processing Form CL FRM-05003-F2.

5.6.3.1 A call is strongly preferred. Ask the client contact for their full name and title or position. Ask them to correctly spell the patient's full name, read back the test results and any read back any other information provided.

5.6.3.2 If a fax is requested, append the fax confirmation report showing successful transmission to the Specimen Processing Form.

5.6.4 The Clinical Consultant or Laboratory Director will also be notified by Testing Personnel so that they can follow-up with the Emergency Contact as warranted.

5.7 Confidentiality

5.7.1 The laboratory will ensure patient confidentiality through those parts of the testing process that are under the laboratory's control following receipt in the laboratory adhering to HIPAA guidelines.

5.7.2 Results or transcripts of laboratory tests or examinations will be released only to authorized healthcare provider(s).

6 RECORDS

6.1 The specimen requisition, original report or an exact duplicate of each test report, including preliminary, final, corrected and amended reports, will be retained for a minimum of three (3) years after the date of reporting.

7 ATTACHMENTS

7.1 CL FRM-12001-F1 Preliminary Report

7.2 CL FRM-12001-F2 Final Report

7.3 CL FRM-12001-F3 Amended Report

7.4 CL FRM-12001-F4 Corrected Report

7.5 CL FRM-12001-F5 Laboratory Report Coversheet

7.6 CL FRM-12001-A1 Critical Values.

8 REFERENCES

Clinical Laboratory Improvement Amendments of 1988

CL SOP-00008 Corrective and Preventative Action

CL SOP-7005 Repeat Testing

9 REVISION HISTORY

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**ECO Number**
A	06/09/2011	A. Gelb	CL ECO-00011
B	06/13/2001	A. Gelb	CL ECO-00016
Section Number	**Description and Justification of Changes**		
5.3 and 7; 5.6	Added reference to Laboratory Report Coversheet; Added Critical Values		