	Standard Operating Procedure	Document Number: CL SOP-13002
	CLIA Laboratory	Revision: A Effective Date: 06/09/2011
Complaint Investigation and Communication		

CONTROLLED DOCUMENT

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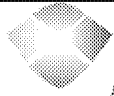
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Standard Operating Procedure

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Revision: A


CLIA Laboratory

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Complaint Investigation and Communication

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1 PURPOSE

1.1 This Standard Operating Procedure (SOP) describes the protocol for complaint investigation and communication

2 SCOPE

2.1 This document advises the Laboratory director, Client Solutions and Laboratory Personnel at Theranos on the protocol for complaint investigation and communication.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Not applicable

4 RESPONSIBILITIES

4.1 It is the responsibility of Client Services to document all complaints and report them to the Laboratory director

4.2 It is the responsibility of the laboratory director to undertake complaint investigation and take corrective action as required

4.3 It is the responsibility of Laboratory director to ensure Laboratory personnel are trained if required as part of corrective action

5 PROCEDURE

5.1 The laboratory will consider all complaints about lab conduct with the utmost seriousness.

5.2 All complaints are logged in on form CL FRM-13002-F1 Complaint Investigation and Communication Logsheet. Particulars are documented on form CL FRM-13002-F2 Complaint Report Form and then reported to the Laboratory Director. The Complaint Report Form record includes:

5.2.1 Reference ID number (consecutive)

5.2.2 Identification of the client (name, provider or client name, address, phone, fax, email)

5.2.3 Identification of the patient/specimen concerned

5.2.4 Complaint category classification

5.2.4.1 (Delayed) turn-around-time

5.2.4.2 Problem with communication or responsiveness

5.2.4.3 Transcription error

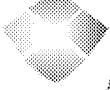
5.2.4.4 Result error

5.2.4.5 Safety

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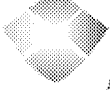
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- 5.2.4.6 Administrative
- 5.2.4.7 Incorrect invoicing
- 5.2.4.8 Business practices
- 5.2.4.9 Reportable (to a regulatory agency)
- 5.2.4.10 Other (specify)
- 5.2.5 Brief narrative description of the complaint
- 5.2.6 Response to the complaint
- 5.2.7 Lab Director investigation summary
- 5.2.8 Action taken
 - 5.2.8.1 Resolution with client
 - 5.2.8.2 Reference to corrective and preventative action taken (if any)



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- 5.3 When indicated, the lab director will conduct an investigation into the complaint, seek a resolution and determine how the issue may be prevented in the future. These will also be documented on CL FRM-13002-F2 (see section 5.2).
- 5.4 The lab must documenting problems arising as a result of a breakdown in communication. Corrective actions must be taken to both resolve the problem and minimize future communication breakdowns.
- 5.5 When required personnel should be trained and a competency assessment performed after training.

6 RECORDS

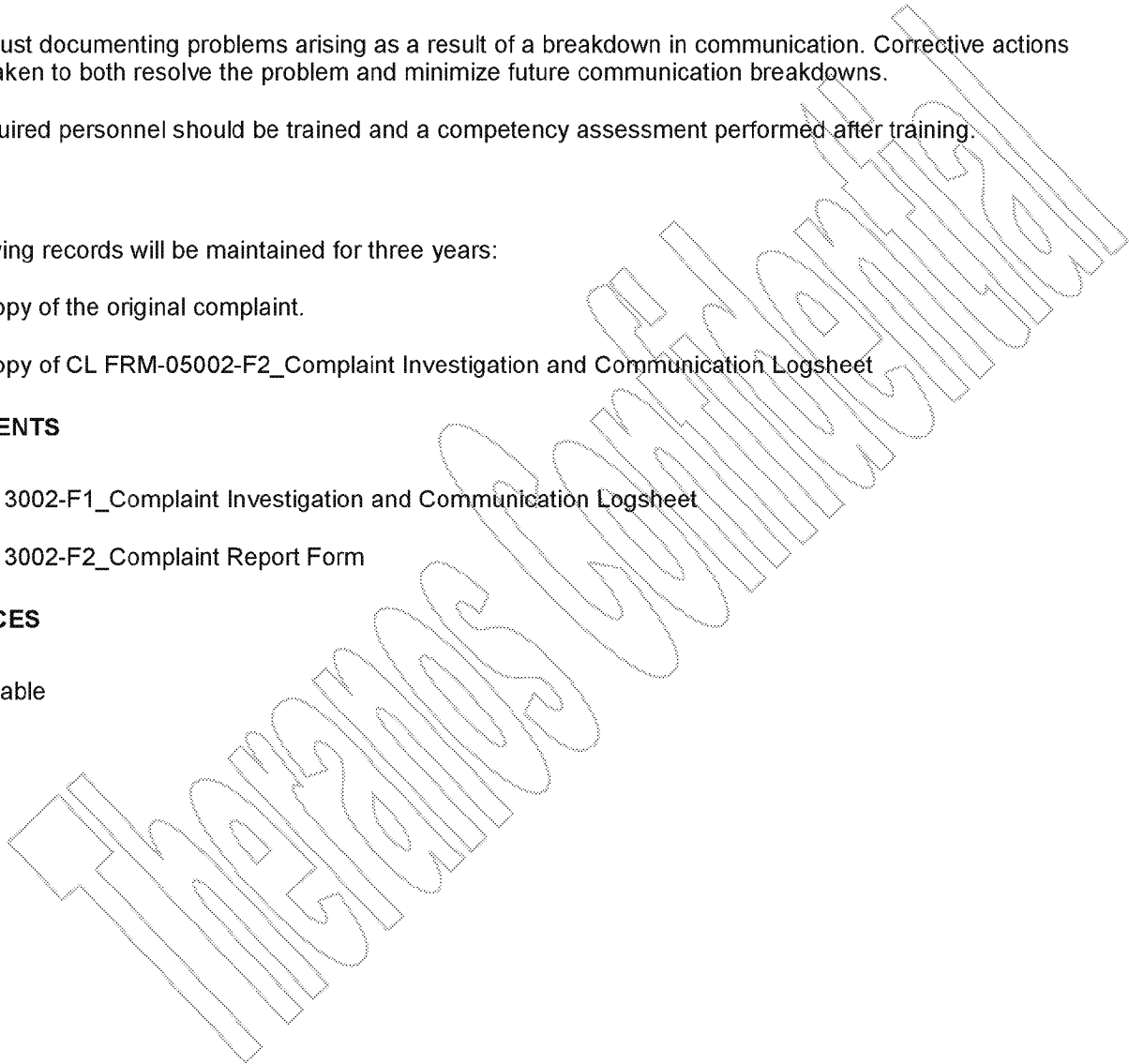
- 6.1 The following records will be maintained for three years:
 - 6.1.1 Copy of the original complaint.
 - 6.1.2 Copy of CL FRM-05002-F2_Complaint Investigation and Communication Logsheet

7 ATTACHMENTS

- 7.1 CL FRM-13002-F1_Complaint Investigation and Communication Logsheet
- 7.2 CL FRM-13002-F2_Complaint Report Form

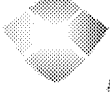
8 REFERENCES

- 8.1 Not applicable



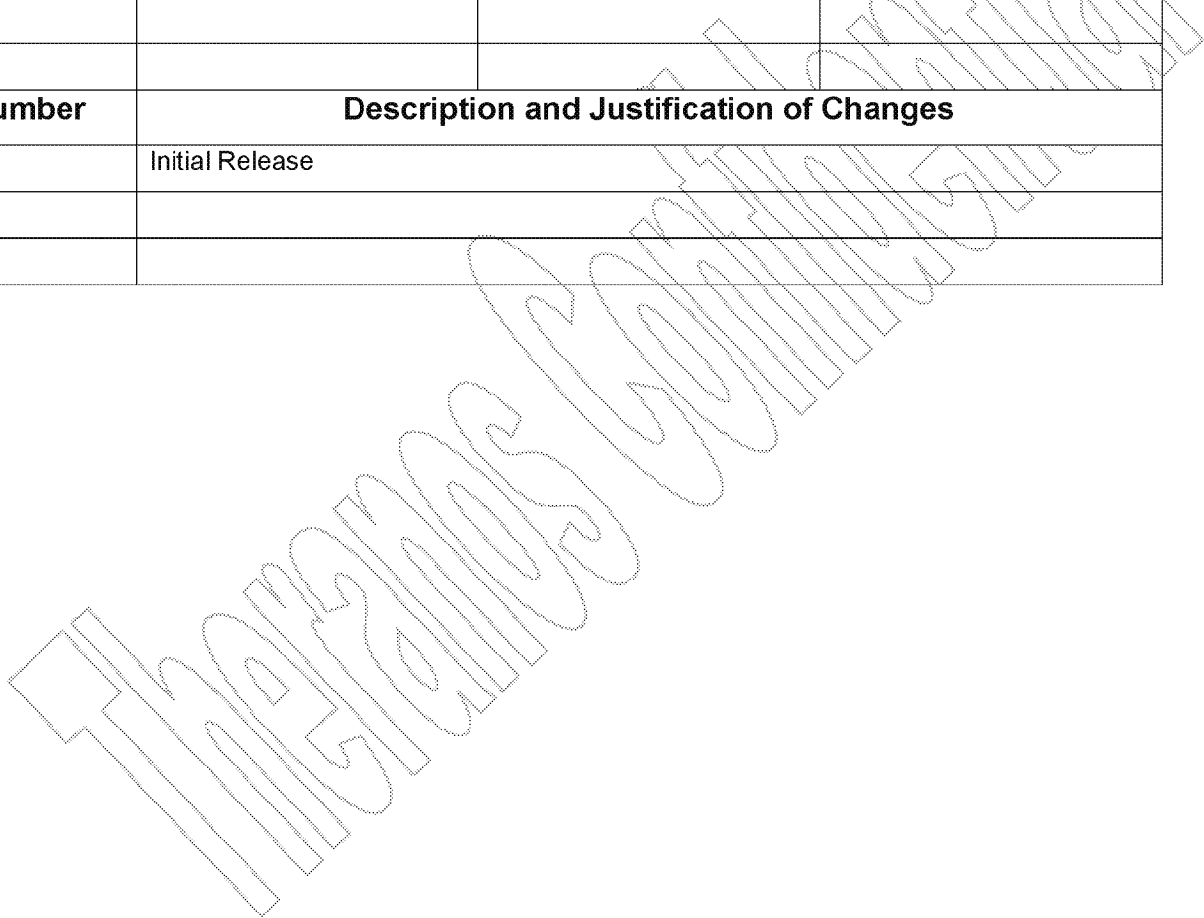
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9 REVISION HISTORY

REVISION HISTORY			
Revision Level	Effective Date	Initiator	ECO Number
A	06/09/2011	A. Gelb	CL ECO-00012
Section Number	Description and Justification of Changes		
ALL	Initial Release		



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