theranos	Standard Operating Procedure	Document Number: CL SOP-12005 Revision: F
	CLIA Laboratory	Effective Date: 12/7/2015
Reporting of Critical Values		

Author(s):

Signature: Sonia A. Cendejas	Digitally signed by Sonia A. Cendejas Date: 2015.12.04 08:43:56 -07'00'
Name: Sonia Cendejas	Title: Laboratory Manager

Reviewer(s):

Signature: Hoda Alamdar	Digitally signed by Hoda Alamdar DN: cn=Hoda Alamdar, o, ou, email=halamdar@theranos.com, c=US Date: 2015.12.04 18:09:09 -08'00'
Name: Hoda Alamdar	Title: General Supervisor
Signature: Francisco Nepacena	Digitally signed by Francisco Nepacena DN: cn=Francisco Nepacena, o=Theranos, ou=JP Lab, email=FNepacena@Theranos.com, c=US Date: 2015.12.07 12:17:11 -08'00'
Name: Francisco Nepacena	Title: Technical Supervisor
Signature: Jennifer Trick	Digitally signed by Jennifer Trick Date: 2015.12.04 08:58:23 -07'00'
Name: Jennifer Trick	Title: General Supervisor

Approver(s):

Signature: Daniel L. Young	Digitally signed by Daniel L. Young Date: 2015.12.04 07:48:32 -08'00'
Name: Daniel Young	Title: Laboratory Director
Signature: DocuSigned by: Sunil S. Dhawan M.D. 71D09B1B2F...	12/7/2015
Name: Sunil S. Dhawan, MD	Title: Laboratory Director

The Laboratory Director or designee will review this procedure at least annually including revisions.

Reviewed By:	Date:	Comments:

Reporting of Critical Values

Reporting of Critical Values

1. Purpose

1.1. The purpose of this procedure is to guide Testing Personnel on how to communicate assay critical value(s) to the appropriate medical care provider, patient/guardian and emergency contact.

2. Scope

2.1. The scope of this procedure is intended to consistently and accurately communicate valuable information to the appropriate medical care provider, patient/guardian and emergency contact with proper documentation.

3. Responsibilities

3.1. Testing Personnel are responsible for following this procedure and informing the medical care provider, parent/guardian and emergency contact of every patient for which a critical value is obtained.

4. Definitions

4.1. **Adult:** Person 18 years old or older
4.2. **Child:** Person aged 1 month to 18 years
4.3. **Patient:** Individual who received testing by Theranos. Patients may also be called for critical results in connection with Direct Testing
4.4. **Guardian:** Legal guardian of a patient who may receive results for patient if patient is unreachable.
4.5. **Newborn:** Person aged one month or less
4.6. **Emergency Contact:** Emergency contact provided by patient and who may receive results for patient if patient is unreachable.
4.7. **Critical Value** - Any test result that may require rapid clinical attention to avert significant patient morbidity or mortality.
4.8. **Medical care provider** - A physician, physician's assistant, or nurse who is directly responsible for the patient at the time the critical result is called to access the patient's protected health information
4.9. **Testing Personnel** – A healthcare professional who performs chemical, hematological, immunologic, microscopic and bacteriological diagnostic analyses on body fluids such as blood, urine, sputum, stool, cerebrospinal fluid (CSF), peritoneal fluid, pericardial fluid and synovial fluid, as well as other specimens.

5. Materials

5.1. Appendix A – Critical Values
5.2. Appendix B – Direct Testing Critical Values
5.3. Appendix C – Scenarios for Patient, Provider and Government requests for results
5.4. Appendix D – Critical Results Not Requiring Call to Medical Care Provider
5.5. CL FRM-12005-F1 Critical Value Log Sheet
5.6. CL FRM-12007-F3 Results Request Call Log

6. Timing

6.1. Critical calls to medical care providers, patient/guardian and emergency contact should be made immediately upon identification of a critical result. If the first attempt is unsuccessful, secondary and tertiary attempts should be made as appropriate.

7. Procedure

7.1. Reporting Critical Results to Medical Provider:

7.1.1. If a patient's sample exhibits any of the critical values listed in Appendix A, follow the procedure below:

7.1.2. Call the medical care provider listed on the requisition. This first call/attempt should happen immediately upon identification of a critical result, regardless of time of day

7.1.3. Tell the medical care provider the following:

7.1.3.1. The patient's name, date of birth, gender and Reference ID (this is the LIS Accession Number

7.1.3.2. The name of the test(s) and its critical value(s)

7.1.3.3. Ask the medical care provider to repeat it back to you

7.1.4. Document this event on a **Critical Value Log sheet Form (CL FRM-12005-F1)**

7.1.5. If there is no answer, leave the following scripted message:

7.1.5.1. This message is for Dr. _____. My name is _____ and I am a <insert title> for Theranos. I have an urgent message that needs your immediate attention concerning your patient and a critical value. Please call 650-461-7653 (for Arizona) 855-843-7200 (for Newark) and ask for me or the <insert title> on duty. Your reference ID is <LIS Accession Number>

7.1.6. When the medical care provider calls back, verify the provider's identity in accordance with **Authentication Matrix (see Appendix C)** and then follow step 7.1.3. Ensure that you ask for the Reference ID to quickly locate Caller the visit in return LIS.

7.1.7. Note: If the call is made towards the end of the shift and there will not be a person at Theranos Request that the Doctor return your call within one hour because there would be not be a person to answer to answer the call, leave the patient's name, Date of Birth, gender and the critical value. his/her call until the following day

7.1.8. If an answering service answers your phone call, communicate the following scripted message:

7.1.8.1. My name is _____ and I am a <insert title> for Theranos. Please have the "on call "doctor" paged. I have an urgent message that needs his/her immediate attention concerning a patient and a critical value. Please call 650-461-7653 (for Arizona) 855-843-7200 (for Newark) and ask for me or the <insert title> on duty. Your reference ID is <LIS Accession Number>

7.1.9. When the medical care provider calls back, verify the provider's identity in accordance with the **Authentication Matrix (see Appendix C)** and then follow step 7.1.3. Ensure that you ask for the Reference ID to quickly locate the visit in LIS.

7.1.10. Note: If the call is made towards the end of the shift and there will not be a person at Theranos to answer the return call, leave the patient's name, Date of Birth, gender and the critical value. Request that the Doctor return your call within one hour because there would not be a person to answer his/her call until the following day.

7.1.11. See Appendix D for critical results and associated ICD-9 codes that do not require a call to the medical care provider

7.1.12. If critical result cannot be given to the medical care provider on the first attempt, log the attempt into the log and release the result through the LIS

7.1.13. Review log for necessary secondary and tertiary calls and make the appropriate calls and log appropriately until 3 attempts for every critical result have been completed

7.2. Reporting Critical Results to Patient for Direct Testing:

7.2.1. If a patient's sample exhibits any of the critical values listed in Appendix B, follow the procedure below:

7.2.2. Call the patient/guardian listed on the requisition. This first call/attempt should happen immediately upon identification of a critical result, regardless of time of day

7.2.3. Tell the patient/guardian the following:

7.2.3.1. The patient's name, date of birth, gender and Reference ID (this is the LIS Accession Number)

7.2.3.2. The name of the test(s) and its critical value(s)

7.2.3.3. Ask the patient/guardian to repeat it back to you

7.2.3.4. Please contact your healthcare provider regarding these results and obtaining appropriate medical care. If your healthcare provider is not available please seek immediate medical attention. **Do not provide any interpretative information.**

7.2.4. Document this event on the **Critical Value Log sheet Form (CL FRM-12005-F1)**

7.2.5. If there is no answer, leave the following scripted message:

7.2.5.1. This message is for _____. My name is _____ and I am a <insert title> for Theranos. I have an urgent message that needs your immediate attention concerning a critical value for a test that was performed by our laboratory. Please call 650-461-7653 (for Arizona) 855-843-7200 (for Newark) and ask for me or the <insert title> on duty. Your reference ID is <LIS Accession Number>

7.2.6. When the patient/guardian calls back, verify the patient/guardian's identity in accordance with the **Authentication Matrix (see Appendix C)** and then follow step 7.2.3. Ensure that you ask for the Reference ID to quickly locate the visit in LIS

7.2.7. Note: If the call is made towards the end of the shift and there will not be a person at Theranos to answer the return call, leave the patient's name, Date of Birth, gender and the fact that a critical value has been obtained for a lab result from the patient's visit. Request that the patient return your call back immediately.

7.2.8. If critical result cannot be given to the patient on the first attempt, log the attempt into the **Critical Value Log sheet Form (CL FRM-12005-F1)** and release the result through the LIS

7.2.9. Review log for necessary secondary and tertiary calls and make the appropriate calls and log appropriately until 3 attempts for every critical result have been completed

7.2.10. If a patient/guardian does not answer on the first attempt then we contact the Emergency Contact using the following script:

7.2.10.1. Hello, My name is _____ and I am a <insert title> for Theranos. We are trying to reach <patient> regarding a critical result for a test that was performed by our laboratory. Can you assist us in reaching this individual?

7.2.11. If you need to leave a message, utilize the following script:

7.2.11.1. This message is for _____. My name is _____ and I am a <insert title> for Theranos. I have an urgent message that needs your immediate attention concerning a critical value for <patient> for a test that was performed by our laboratory. We are calling you because you are listed as <patient> Emergency Contact. Please call 650-461-7653 (for Arizona) 855-843-7200 (for Newark) and ask for me or the <insert title> on duty. Please also contact <patient> and inform them of the need to contact our laboratory immediately at this number. Your reference ID is <LIS Accession Number>

7.2.12. When the Emergency Contact calls back, verify the Emergency Contact's identity in accordance with the **Authentication Matrix (see Appendix C)** and then follow step 7.2.3. Ensure that you ask for the Reference ID to quickly locate the visit in LIS

7.2.13. Second Attempt to Emergency Contact will use the following process:

7.2.14. Tell the Emergency Contact the following:

7.2.14.1. The patient's name, date of birth, gender and Reference ID (LIS Accession Number)

7.2.14.2. The fact that a critical value has been obtained for a result on the patient's visit

7.2.14.3. Ask the Emergency Contact to repeat it back to you

7.2.14.4. Please contact <patient> and have <patient> contact his/her healthcare provider regarding these results and obtaining appropriate medical care. If <patient>'s healthcare provider is not available, please advise <patient> to seek immediate medical attention. **Do not provide any interpretative information.**

7.2.15. Document this event on the **Critical Value Log sheet Form (CL FRM-12005-F1)**

7.2.16. If you need to leave a message, utilize the following script:

7.2.16.1. This message is for _____. My name is _____ and I am a <insert title> for Theranos. I have an urgent message that needs your immediate attention concerning a critical value for <patient>. We are calling you because you are listed as <patient> Emergency Contact. Please call 650-461-7653 (for Arizona) 855-843-7200 (for Newark) and ask for me or the <insert title> on duty. Please also contact <patient> and inform them of the need to contact our laboratory immediately at this number. Your reference ID is <LIS Accession Number>

7.3. Releasing Partial CBC Results for HGB and HCT (rest are pending slide review):

7.3.1. CBC results are imported

7.3.2. One or both of HGB and/or HCT are critical AND there is a need to perform a slide review

7.3.3. Team calls critical for HGB and/or HCT

7.3.4. Team wishes to report HGB and HCT because neither will be changed based on slide review

7.3.5. When there is a pending Action on CBC, the **team cannot Approve All**. However, the **team can Approve Checked or edit and release any individual result on the visit**

7.4. Calling Slide Review Results:

7.4.1. When a Slide Review is needed to confirm results, the Newark team will confirm/modify the results based on slide review. The Newark team will then call any critical results that have been confirmed and/or modified. See above instructions for calling critical results to medical care provider and/or patient

7.5. No Diagnosis Code:

7.5.1. If no diagnosis code is written on the order, you must call on any critical results (see appendix D for Critical Results Not Requiring Call to Medical Care Provider

7.6. Requests for Results

7.6.1. Laboratory may be contacted or results to be send by patient, provider and/or government agency. Results can be obtained through the Customer Service Department or the Laboratory Personnel (see Appendix C for call scenarios)

7.6.2. Authenticate caller using 3 elements in accordance with **Authentication Matrix (see Appendix C)**

7.6.3. After the caller has been authenticated, release requested information

7.6.3.1. If the caller cannot be authenticated, notify the caller that results cannot be released at this time and escalate the issue to a supervisor immediately

7.6.4. Document all calls and any actions taken on **CL FRM-12007-F3 Inbound Outbound Call Log**

8. Revision History

REVISION HISTORY			
Revision Level	**Effective Date**	**Initiator**	**DCO Number**
A	4/1/2014	L. Gee	CL DCO-00007
B	5/2/2014	L. Gee	CL DCO-00012
C	8/1/2014	L. Gee	CL DCO-00029
D	10/7/2015	S. Cendejas	CL DCO-00103
E	09/19/2015	L Gee	CL DCO-00100
F	12/2/2015	S. Cendejas	CL DCO-00109
Section Number	**Description and Justification of Changes**		
All	Adding in timing of critical result calls, handling of hemoglobin and hematocrit results, directions for direct testing and critical calls to patients, and responsibility for critical calls confirmed/modified by slide review.		
All	Added section 7.6 for Authentication of Callers. Added Appendixes A, B & C for SOP references		
Rev. E	Removed crystals in Urinalysis section		
Rev. F	Update definitions, materials, and procedure. Adding in direct testing critical results		

Appendix A

CHEMISTRY

Test	Units	Age	Lower Limit	Upper Limit
Albumin	g/dL	Children	1.7	6.8
Bicarbonate (CO2)	mmol/L	Any age	10	40
Bilirubin, total	mg/dL	< 1 year	-	15
Urea Nitrogen, Serum or plasma	mg/dL	Adult	-	80
Urea Nitrogen, Serum or plasma	mg/dL	Children	-	55
Calcium	mg/dL	Adult	6	13
Calcium	mg/dL	Children	6.5	12.7
Chloride	mEq/L	Any age	80	120
Creatinine	mg/dL	Adult	-	5
Creatinine	mg/dL	Children	-	3.8
Glucose	mg/dL	Newborn	40	200
Glucose	mg/dL	Children	46	445
Glucose	mg/dL	Adult	40	450
Iron	ug/dL	Any age	-	500
Magnesium	ug/dL	Any age	1	4.7
Phosphorus	mg/dL	Any age	1	9
Potassium	mEq/L	Newborn	2.8	6.2
Potassium	mEq/L	Adult	2.8	6.2
Protein, total	g/dL	Children	3.4	9.5
Sodium	mEq/L	Any age	120	160
Troponin	ng/mL	Any age	-	1.0

COAGULATION

Test	Units	Age	Lower Limit	Upper Limit
aPTT	sec	Any age	-	100
Fibrinogen	mg/dL	Any age	100	800
INR	-	Any age	-	> 5
PT	sec	Any age	-	45

HEMATOLOGY

Test	Units	Age	Lower Limit	Upper Limit
ANC	K/μL	Any age	0.5	-
Hct (PCV)	%	Any age	21.0	65.0
Hgb	g/dL	Any age	7.0	-
Plt	K/μL	Any age	10	-
Plt	K/μL	Any age	100 if 2+ microangiopathic changes	
WBC	K/μL	Any age (outpatient)	0.5	50.0
Manual Differential	% - -	Any age	- • Smear consistent with aplastic anemia	• Blasts >0 (1st time or relapse) • Depranocytes (sickle cells) present (1st time or relapse) • Intracellular organisms present

URINALYSIS

Test	Units	Age	Upper Limit
Glucose	mg/dL	Any age	500
Ketones	mg/dL	Any age	80

Appendix B

Direct Testing Critical Values

GENERAL IMMUNOLOGY

Test	Age	Result
Chlamydia, DNA, Qualitative	Any age	Positive
Gonorrhea, DNA, Qualitative	Any age	Positive
HbsAg	Any age	Reactive
HCV Antibody Screen	Any age	Reactive
HIV 1 Antibody Screen w/ reflex to IHC-1/HIV-2 Antibody Differentiation	Any age	Reactive
HIV 2 Antibody Screen w/ reflex to IHC-1/HIV-2 Antibody Differentiation	Any age	Reactive
HIV-1/HIV-2 Antibody Differentiation	Any age	Reactive
Treponema pallidum Ab	Any age	Reactive

CHEMISTRY

Test	Units	Age	Lower Limit	Upper Limit
Albumin	g/dL	Children	1.7	6.8
Bicarbonate (CO2)	mmol/L	Any age	10	40
Bilirubin, total	mg/dL	< 1 year	-	15
Urea Nitrogen, Serum or plasma	mg/dL	Adult	-	80
Urea Nitrogen, Serum or plasma	mg/dL	Children	-	55
Calcium	mg/dL	Adult	6	13
Calcium	mg/dL	Children	6.5	12.7
Chloride	mEq/L	Any age	80	120
Creatinine	mg/dL	Adult	-	5
Creatinine	mg/dL	Children	-	3.8
Glucose	mg/dL	Newborn	40	200
Glucose	mg/dL	Children	46	445
Glucose	mg/dL	Adult	40	450
Iron	ug/dL	Any age	-	500
Magnesium	ug/dL	Any age	1	4.7
Phosphorus	mg/dL	Any age	1	9
Potassium	mEq/L	Newborn	2.8	6.2
Potassium	mEq/L	Adult	2.8	6.2
Protein, total	g/dL	Children	3.4	9.5

Sodium	mEq/L	Any age	120	160
Troponin	Ng/mL	Any age	-	1.0

COAGULATION

Test	Units	Age	Lower Limit	Upper Limit
aPTT	sec	Any age	-	100
Fibrinogen	mg/dL	Any age	100	800
INR	-	Any age	-	> 5
PT	sec	Any age	-	45

HEMATOLOGY

Test	Units	Age	Lower Limit	Upper Limit
ANC	K/μL	Any age	0.5	-
Hct (PCV)	%	Any age	21.0	65.0
Hgb	g/dL	Any age	7.0	-
Plt	K/μL	Any age	10	-
Plt	K/μL	Any age	100 if 2+ microangiopathic changes	
WBC	K/μL	Any age (outpatient)	0.5	50.0
Manual Differential	% - -	Any age	- • Smear consistent with aplastic anemia	• Blasts >0 (1st time or relapse) • Depranocytes (sickle cells) present (1st time or relapse) • Intracellular organisms present

URINALYSIS

Test	Units	Age	Upper Limit
Glucose	mg/dL	Any age	500
Ketones	mg/dL	Any age	80
Micro	-	Any age	Pathological crystals (e.g., Urate, Cys, Leu, Tyr)

Appendix C

HIPAA Caller Authentication Matrix – Customer Service Department

MUST authenticate (3) or more data elements before releasing PHI

Authentication Data Elements	Provider/Practice	Patient	Parent / Guardian	Emergency Contact	Healthcare Plans/Government Agencies
Patient Name	x	x	x	x	x
Patient DoB	x	x			x
Patient Address		x			x
Contact Name			x	x	
Relationship to Patient			x	x	
Accession Number / Sample ID (SID)					
Provider / Practice Name	x				
Provider / Practice Phone Number	x				

Appendix D

Critical Results Not Requiring Call to Medical Care Provider		
ICD-9 Code	**Test**	**ICD-9 Long Description**
V42.23, V42.33, V58.61	PT and INR	
268.9	Vitamin D	Unspecified Vitamin D Deficiency (toxic/critical Vitamin D results)
244.9	TSH, Free T4, T3	Unspecified hypothyroidism
786	CO2/Bicarbs	Hyperventialtion for CO2/Bicarbs
276	K	Hyperkalemia for Potassium (also we can include hypo as well). Also with electrolytes.
585	BUN, eGFR Crea	Kidney dse. For BUN, eGFR and Crea (mostly for CMP's)
204, 205, 208	CBC	Leukemia's for CBC's
287	PLT	Thomrocytopenia/purpura for PLT
791	Ketones	Elevated Urine ketones