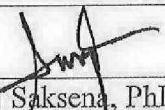
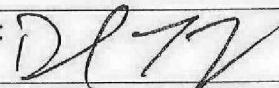


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	CLIA Laboratory	Effective Date: 01/01/2014
<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		


**Author(s):**

Signature: 	Date: 7/2/2015
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**Reviewer(s)**

Signature: 	Date: 7/2/2015
Name: Daniel Young, PhD	Title: Vice President

**Approver(s):**

Signature: 	Date: 9/18/15
Name: Sunil Dhawan, MD	Title: Laboratory Director

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<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		

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	CLIA Laboratory	Effective Date: 01/01/2014
<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		

**1 Purpose**

- 1.1 The purpose of this proposal is to devise an alternative assessment protocol (AAP) for laboratory-developed tests on the EDISON 3.5 immunoassay instrument.
- 1.2 Guideline: For non-CMS-regulated tests or those which lack FDA clearance, commercial or external PT programs may not be available for certain analytes. In such instances, an AAP will be used to ensure accuracy of the ongoing test system performance.

**2 Scope**

- 2.1 The alternative assessment protocol (AAP) applies to all laboratory developed tests on the EDISON 3.5 instrument, and will be conducted every 6 months.

**3 Responsibilities**

- 3.1 It is the responsibility of the technical supervisor (TS) to ensure that the alternative assessment procedure (AAP) is conducted every 6 months for all analytes.
- 3.2 Laboratory Testing Personnel are responsible for the following:
  - 3.2.1 Receiving and processing the proficiency testing samples from in-house patient collections.
  - 3.2.2 Reporting the results to the TS or designee for evaluation
  - 3.2.3 Completing applicable fields on CL FRM-00006-F1 *Proficiency Testing Evaluation*
- 3.3 The Laboratory Technical Supervisor is responsible for the following:
  - 3.3.1 Making sure that proficiency testing samples are identified and prepared for the Laboratory
  - 3.3.2 Evaluating proficiency testing sample results

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	<b>CLIA Laboratory</b>	<small>Effective Date: 01/01/2014</small>
<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		

3.3.3 Completing applicable fields on CL FRM-00006-F1 *Proficiency Testing Evaluation*

3.4 The Laboratory Director is responsible for the following:

3.4.1 Reviewing and approving each PT testing event documentation.

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	CLIA Laboratory	Effective Date: 01/01/2014
<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		

#### 4 Procedure

- 4.1 Obtain 5 venous clinical samples from an in-house collection.
- 4.2 Obtain also, 5 matching fingerstick (capillary) specimens.
- 4.3 At least 10mL of LiHep anticoagulated blood should be collected for the venous clinical specimens.
- 4.4 Run the predicate Siemens Immulite or Siemens ADVIA Centaur XP and Theranos LDT methods in parallel for each patient sample.
- 4.5 Calculate the bias of the Theranos LDT test as follows:  $\text{bias} = \frac{\text{Theranos value} - \text{Immulite or Centaur value}}{\text{Immulite value or Centaur value}}$

#### 5 Acceptance criteria

- 5.1 The bias should not exceed the total allowable error stated in CLIA '88 Proficiency Testing Limits (Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2008, 493.927 through 493.937).
- 5.2 If an analyte fails  $>20\%$  ( $\geq 1$  out of 5) of the patient clinical samples, then the proficiency will be deemed to have failed the proficiency event.
- 5.3 If an analyte fails on a proficiency event, corrective actions will be implemented, according to CL-QOP-00006
- 5.4 If an analyte fails two consecutive proficiency events, testing will be discontinued for that analyte, until such time as the assay is corrected, and passes AAP PT re-testing.
  - 5.4.1 The latter event will be documented and signed off by the laboratory director
  - 5.4.2 Resumption of testing will only occur upon documentation and approval by the laboratory director.

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<b>Proficiency testing for Theranos Lab-Developed Tests (Immunoassays)</b>		

## 6 RECORDS

6.1 All PT records will be retained for a minimum of 3 years

## 7 REFERENCES

- 7.1 42 CFR Part 493 Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests
- 7.2 42 CFR Part 493.1236, Standard: Evaluation of proficiency testing performance
- 7.3 42 CFR Part 493.1445, Standard: Laboratory Director Responsibilities
- 7.4 CLSI Guideline GP27
- 7.5 CLSI Guideline GP 29

## 8 REVISION HISTORY

REVISION HISTORY			
Revision Level	Effective Date	Initiator	DCO Number
A	11/26/2013	A. Rosendorff	DCO-000126
B	01/01/2014	S. Saksena	DCO-00093
Section Number	Description and Justification of Changes		
All	A: initial release		
B	Update to current practice		

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Alternative Assessment Program

CL FRM-00022-F3

Revision A

Effective

6/15/2015

AAP Program: Testing Date: 08/18/2014	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Thyroxine, Free (ng/dL)						100%
Thyroxine, Free Predicate	1.42	0.81	1.17	1.33	1.02	
Thyroxine, Free Theranos	1.19	0.80	1.26	1.12	1.02	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
Predicate Value) / Analyte Predicate Value (%)	-16%	-2%	8%	-16%	0%	

AAP Program: Testing Date: 08/17/2014	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
PSA, Total (ng/mL)						100%
PSA, Total Predicate	2.81	0.61	0.89	0.46	3.32	
PSA, Total Theranos	2.36	0.61	0.96	0.42	2.71	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
Predicate Value) / Analyte Predicate Value (%)	-16%	0%	8%	-9%	-18%	

AAP Program: Testing Date: 08/04/2014	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Thyroid Stimulating Hormone (uIU/mL)						100%
Thyroid Stimulating Hormone Predicate	0.84	2.52	2.02	1.21	1.65	
Thyroid Stimulating Hormone Theranos	0.87	2.74	2.37	1.35	1.48	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
Predicate Value) / Analyte Predicate Value (%)	4%	9%	17%	12%	-10%	

AAP Program: Testing Date: 08/04/2014	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Vitamin D (ng/mL)						100%
Vitamin D Predicate	29.6	56.5	22.5	42.3	10.8	
Vitamin D Theranos	32.1	46.0	26.8	42.9	11.3	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	8%	-19%	19%	1%	5%	

Data Entered By: Suraj Saxena Date: 11/14/15  
 Verify By: Gurbir Sidhu Date: 11/14/15  
 Laboratory Director: Sunil Dhawan, MD Date: 11/15/15

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Alternative Assessment Program

CL FRM-00022-F3

Revision A

Effective 6/15/2015

AAP Program: Testing Date: <u>10/21/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Estradiol (pg/mL)						100%
Estradiol Predicate	<20	<20	44.6	200.0	<20	
Estradiol Theranos	<LLOQ	<LLOQ	49.5	178.3	<LLOQ	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	N/A	N/A	11	-11	N/A	

AAP Program: Testing Date: <u>10/22/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Thyroxine, Free (ng/dL)						100%
Thyroxine, Free Predicate	3.69	6.84	6.4	1.16	4.39	
Thyroxine, Free Theranos	3.33	5.96	5.86	1.32	4.19	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-10	-13	-9	14	-5	

AAP Program: Testing Date: <u>10/22/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Human Chorionic Gonadotropin (mIU/mL)						100%
Human Chorionic Gonadotropin Predicate	259	<1	<1	<1	<1	
Human Chorionic Gonadotropin Theranos	223.3	<LLOQ	<LLOQ	<LLOQ	<LLOQ	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-14	N/A	N/A	N/A	N/A	

AAP Program: Testing Date: <u>10/20/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Prolactin (ng/mL)						100%
Prolactin Predicate	124.50	72.10	10.13	210.50	35.74	
Prolactin Theranos	129.41	68.98	9.20	176.95	34.50	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	4	-4	-9	-16	-3	

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AAP Program: Testing Date: <u>10/03/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Sex Hormone Binding Globulin (nmol/L)						100%
Sex Hormone Binding Globulin Predicate	41.5	25.7	40.2	42.0	17.0	
Sex Hormone Binding Globulin Theranos	39.5	24.7	42.4	49.2	17.9	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-5	-4	5	17	5	

AAP Program: Testing Date: <u>10/02/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
PSA, Total (ng/mL)						100%
PSA, Total Predicate	1.07	0.59	0.72	0.46	0.66	
PSA, Total Theranos	0.93	0.54	0.62	0.42	0.68	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-13	-8	-13	-9	3	

AAP Program: Testing Date: <u>11/11/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Thyroid Stimulating Hormone (uIU/mL)						100%
Thyroid Stimulating Hormone Predicate	2.73	0.89	0.88	1.96	1.46	
Thyroid Stimulating Hormone Theranos	2.32	0.81	0.74	2.15	1.48	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-15	-9	-16	9	1	

AAP Program: Testing Date: <u>10/20/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Testosterone (ng/dL)						100%
Testosterone Predicate	991.0	284.0	1098.0	63.4	315.0	
Testosterone Theranos	973.1	250.7	981.5	62.9	282.3	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-2	-12	-11	-1	-10	

AAP Program: Testing Date: <u>11/20/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Triiodothyronine (ng/dL)						100%
Triiodothyronine Predicate	107	98	83	97	125	
Triiodothyronine Theranos	107	110	87	81	121	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	0	12	5	-16	-3	

AAP Program: Testing Date: <u>10/20/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Thyroxine, Total (ug/dL)						100%
Thyroxine, Total Predicate	4.70	5.34	7.20	6.88	8.17	
Thyroxine, Total Theranos	4.28	5.87	6.49	8.16	9.75	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	-9	10	-10	19	19	

AAP Program: Testing Date: <u>10/21/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Vitamin B12 (pg/mL)						100%
Vitamin B12 Predicate	341.0	565.0	465.0	418.0	491.0	
Vitamin B12 Theranos	348.9	499.6	543.5	410.0	513.0	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	2	-12	17	-2	4	

AAP Program: Testing Date: <u>11/4/2014</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Vitamin D (ng/mL)						100%
Vitamin D Predicate	35.5	11.1	30.1	20.8	12.8	
Vitamin D Theranos	39.8	11	32.8	24.9	14.2	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value (%)	12	-1	9	20	11	

Data Entered By: <u>Suraj Saxena</u>	Date: <u>11-16-15</u>
Verify By: <u>Gubbia Siddhu</u>	Date: <u>11-16-15</u>
Laboratory Director: _____	Date: _____

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Alternative Assessment Program

CL FRM-00022-F3

Revision A

Effective 6/15/2015

AAP Program: Testing Date: <u>03/13/2015</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
Sex Hormone Binding Globulin (nmol/L)						100%
Sex Hormone Binding Globulin Predicate	26.7	57.7	27.6	48.8	21.5	
Sex Hormone Binding Globulin Theranos	26.3	68.1	25.9	51.7	22.5	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value	-1	18	-6	6	5	

AAP Program: Testing Date: <u>03/05/2015</u>	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Score
PSA, Total (ng/mL)						100%
PSA, Total Predicate	1.12	0.60	0.57	0.74	0.82	
PSA, Total Theranos	1.11	0.54	0.64	0.62	0.93	
TAE	± 20%	± 20%	± 20%	± 20%	± 20%	
100 x (Analyte Theranos Value - Analyte Predicate Value) / Analyte Predicate Value	-1	-1	-11	12	-16	

Data Entered By: <u>SURAJ SAKSENA</u>	Date: <u>11/15/15</u>
Verify By: <u>GUARIA SIDHU</u>	Date: <u>11/15/15</u>
Laboratory Director: <u>[Signature]</u>	Date: <u>11/15/15</u>

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5/9/2014

Summary of Predicate Controls Analyzed in April 2014

	# of Controls	2SD	3SD	% 2SD	% 3SD
CBC	2879	0	0	0.0	0.0
Chemistry	2370	11	4	0.5	0.2
DCA	249	0	0	0.0	0.0
Immulite	1382	10	15	0.7	1.1
DiaSorin	180	0	0	0.0	0.0
Iris	1328	0	0	0.0	0.0
Total	8388	21	19	0.3	0.2

April Predicate Assays and levels with 10x above the mean

	Level	Adjustments Dates		Level	Adjustments Dates
RBC	2 and 3	4/8	Estradiol	1,2 and 3	4/16
Mean Corpuscular Volume	1, 2 and 3		Folic Acid	2 and 3	4/9
Red Cell Distribution Width	1, 2 and 3	4/9	T3	2 and 3	4/11, 4/27
Platelet	1, 2 and 3	4/9	HCG	1 and 2	4/1, 4/17
Hematocrit	2	4/20	HDL	1	4/26
Mean Platelet Volume	2 and 3	4/8	LDL	1,2 and 3	4/9,23,26
Plateletcrit (%)	3		Lipase	1 and 2	4/3,16,30
Platelet Distribution Width	3		Phosphorous	3	4/1,7,15,22
Monocytes, Absolute	2		Progesterone	2	4/11, 4/26
Basophils, Absolute	1 and 2	4/8	Protein	1 and 3	4/26
Chloride	1,2 and 3	4/1,7,16,22,28	Thyroxine	1	4/10, 4/26
Urea Nitrogen	1 and 3	4/23,29	TIBC	2 and 3	4/8
Albumin	3	4/13	Total PSA	1	4/9, 4/24
Amylase	1 and 2	4/5,10,16,24	Triglycerides	1,2 and 3	4/27,4/30
DHEA-S	1	4/3, 4/18	TSH	1	4/11, 4/25



April Predicate Assays and Levels with >3SD above the mean

	Level	Times		Level	Times
Immunoglobulin A	1	1	Ferritin	1	1
Immunoglobulin G	1	1	Vitamin B	2	1
Albumin	2	1	Progesterone	1	1
Thyroglobulin Autoantibodies	2	2	H. pylori	3	3

April Predicate Assays and Levels with >3SD below the mean

	Level	Times		Level	Times
Thyroxine, Total	1	1	Rubella IgG	1 and 3	2
TT3	2	1	Cortisol	2	2
Vitamin B	3	1	TSH	1	1

Prepared By: \_\_\_\_\_

Langly Gee

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Adam Rosendorff

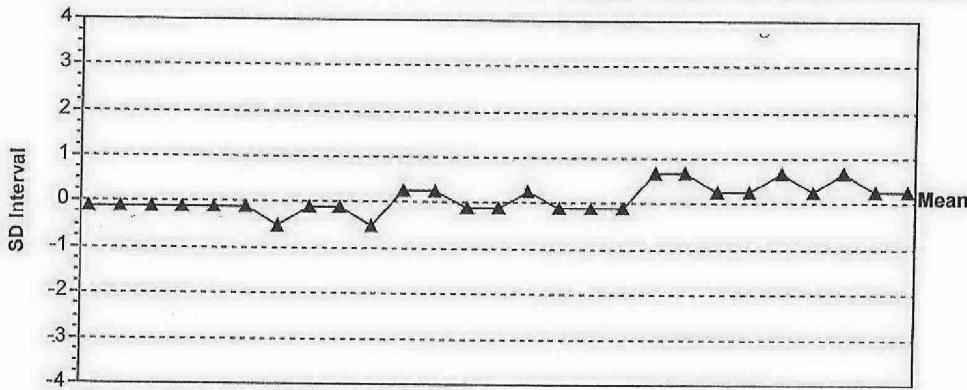
Date: \_\_\_\_\_



Advia 1800 #1

Test: Albumin (g/dL)

Control .MULTIQUAL 1 Advia Level 1



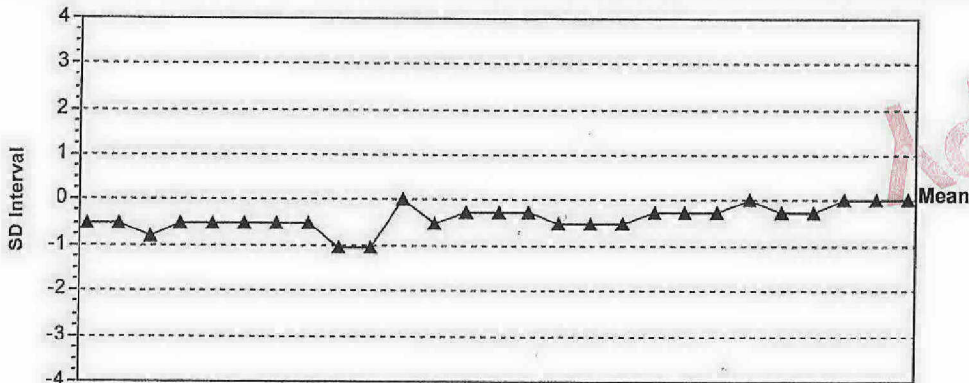
Lot #: 45661

Expires: 8/31/2015

Date/Time	Result	Mean	2SD	Tech	Flag	Comments
4/1/14 12:30	2.50	2.53	0.50	BRB		
4/2/14 11:35	2.50	2.53	0.50	DR		
4/3/14 14:37	2.50	2.53	0.50	DR		
4/4/14 14:15	2.50	2.53	0.50	BRB		
4/5/14 13:51	2.50	2.53	0.50	ET		
4/6/14 17:20	2.50	2.53	0.50	HA		
4/7/14 14:44	2.40	2.53	0.50	DBR		
4/8/14 15:00	2.50	2.53	0.50	DBR	10 on side of mc	
4/9/14 14:59	2.50	2.53	0.50	DBR	10 on side of mc	
4/10/14 14:00	2.40	2.53	0.50	DBR	10 on side of mc	
4/13/14 14:59	2.60	2.53	0.50	DBR		
4/14/14 08:07	2.60	2.53	0.50	EC		
4/15/14 13:51	2.50	2.53	0.50	EC		
4/16/14 13:13	2.50	2.53	0.50	ET		
4/17/14 10:33	2.60	2.53	0.50	BB		
4/18/14 14:48	2.50	2.53	0.50	BRB		
4/19/14 15:40	2.50	2.53	0.50	BRB		
4/21/14 12:21	2.50	2.53	0.50	ET		
4/22/14 16:24	2.70	2.53	0.50	DBR		
4/23/14 13:13	2.70	2.53	0.50	BRB		
4/24/14 14:40	2.60	2.53	0.50	DRB		
4/25/14 10:51	2.60	2.53	0.50	DR		
4/26/14 15:03	2.70	2.53	0.50	DBR		
4/27/14 10:19	2.60	2.53	0.50	MJM		
4/28/14 12:08	2.70	2.53	0.50	DBR		
4/29/14 12:59	2.60	2.53	0.50	DBR		
4/30/14 11:27	2.60	2.53	0.50	DBR		

Advia Level 1      Calculated Mean: 2.55      2SD: 0.17      %CV: 3.3      n: 27      Reviewed By: *ms/2/14*

Control .MULTIQUAL 2 Advia Level 2



Lot #: 45662

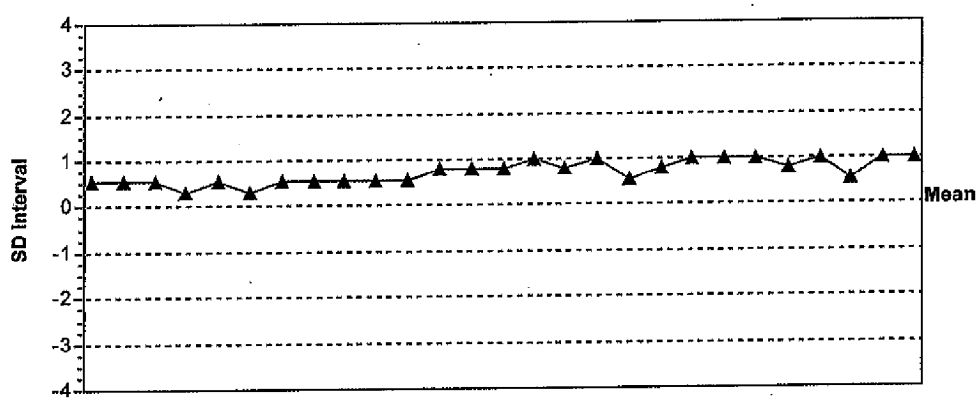
Expires: 8/31/2015

Test: Albumin (g/dL)

Date/Time	Result	Mean	2SD	Tech	Flag	Comments
4/1/14 12:30	3.60	3.80	0.76	BRB	10	on side of mc
4/2/14 11:35	3.60	3.80	0.76	DR	10	on side of mc
4/3/14 14:37	3.50	3.80	0.76	DR	10	on side of mc
4/4/14 14:15	3.60	3.80	0.76	BRB	10	on side of mc
4/5/14 13:51	3.60	3.80	0.76	ET	10	on side of mc
4/6/14 17:20	3.60	3.80	0.76	HA	10	on side of mc
4/7/14 14:44	3.60	3.80	0.76	DBR	10	on side of mc
4/8/14 15:00	3.60	3.80	0.76	DBR	10	on side of mc
4/9/14 14:59	3.40	3.80	0.76	DBR	10	on side of mc
4/10/14 14:00	3.40	3.80	0.76	DBR	10	on side of mc
4/13/14 15:00	3.80	3.80	0.76	DBR		
4/14/14 08:08	3.60	3.80	0.76	EC		
4/15/14 13:52	3.70	3.80	0.76	EC		
4/16/14 13:19	3.70	3.80	0.76	ET		
4/17/14 10:33	3.70	3.80	0.76	BB		
4/18/14 14:49	3.60	3.80	0.76	BRB		
4/19/14 15:40	3.60	3.80	0.76	BRB		
4/21/14 12:22	3.60	3.80	0.76	ET		
4/22/14 16:25	3.70	3.80	0.76	DBR		
4/23/14 13:13	3.70	3.80	0.76	BRB		
4/24/14 14:40	3.70	3.80	0.76	DRB	10	on side of mc
4/25/14 10:51	3.80	3.80	0.76	DR		
4/26/14 15:03	3.70	3.80	0.76	DBR		
4/27/14 10:21	3.70	3.80	0.76	MJM		
4/28/14 12:08	3.80	3.80	0.76	DBR		
4/29/14 12:59	3.80	3.80	0.76	DBR		
4/30/14 11:27	3.80	3.80	0.76	DBR		

Advia Level 2      Calculated Mean: 3.65      2SD: 0.22      %CV: 3.0      n: 27      Reviewed By: 25/2/14

Control .MULTIQUAL 3      Advia Level 3



Lot #: 45663      Expires: 8/31/2015

Date/Time	Result	Mean	2SD	Tech	Flag	Comments
4/1/14 12:30	4.30	4.08	0.82	BRB	10	on side of mc
4/2/14 11:35	4.30	4.08	0.82	DR	10	on side of mc
4/3/14 14:37	4.30	4.08	0.82	DR	10	on side of mc
4/4/14 14:15	4.20	4.08	0.82	BRB	10	on side of mc
4/5/14 13:51	4.30	4.08	0.82	ET	10	on side of mc
4/6/14 17:20	4.20	4.08	0.82	HA	10	on side of mc
4/7/14 14:44	4.30	4.08	0.82	DBR	10	on side of mc
4/8/14 15:00	4.30	4.08	0.82	DBR	10	on side of mc
4/9/14 15:02	4.30	4.08	0.82	DBR	10	on side of mc
4/10/14 14:00	4.30	4.08	0.82	DBR	10	on side of mc
4/13/14 15:00	4.30	4.08	0.82	DBR	10	on side of mc
4/14/14 08:08	4.40	4.08	0.82	EC	10	on side of mc
4/15/14 13:54	4.40	4.08	0.82	EC	10	on side of mc
4/16/14 13:19	4.40	4.08	0.82	ET	10	on side of mc
4/17/14 10:34	4.50	4.08	0.82	BB	10	on side of mc
4/18/14 14:50	4.40	4.08	0.82	BRB	10	on side of mc
4/19/14 15:40	4.50	4.08	0.82	BRB	10	on side of mc
4/21/14 12:23	4.30	4.08	0.82	ET	10	on side of mc
4/22/14 16:25	4.40	4.08	0.82	DBR	10	on side of mc
4/23/14 13:14	4.50	4.08	0.82	BRB	10	on side of mc
4/24/14 14:40	4.50	4.08	0.82	DRB	10	on side of mc
4/25/14 10:51	4.50	4.08	0.82	DR	10	on side of mc
4/26/14 15:03	4.40	4.08	0.82	DBR	10	on side of mc
4/27/14 10:22	4.50	4.08	0.82	MJM	10	on side of mc
4/28/14 12:08	4.30	4.08	0.82	DBR	10	on side of mc
4/29/14 14:03	4.50	4.08	0.82	DBR	10	on side of mc
4/30/14 11:27	4.50	4.08	0.82	DBR	10	on side of mc

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10/13/2014

SEPTEMBER PREDICATE CONTROLS ANALYZED

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Predicate	# of Controls	2SD	3SD	% 2SD	% 3SD
BCS	83	0	0	0.0	0.0
CBC	198	0	0	0.0	0.0
Centaur1*	1566	20	2	1.3	0.1
Centaur2*	92	9	3	9.8	3.3
Chemistry	1349	5	1	0.4	0.1
DCA	0	0	0	0.0	0.0
DiaSorin	806	22	0	0.6	0.0
Drew3	1440	0	0	0.0	0.0
ESR	4	0	0	0.0	0.0
Immulinite**	1668	22	9	1.3	0.5
Iris	1392	0	0	0.0	0.0
Lead	0	0	0	0.0	0.0
m2000	97	0	0	0.0	0.0
RPR	18	0	0	0.0	0.0
TANGO / 3-Cell	90	7	0	7.8	0.0
TANGO / ABO	134	1	0	0.7	0.0
Totals	8937	86	15	1.0	0.2

Centaur*	Times	Immulinite**	Times
Homocysteine	6	Testosterone*	6
Insulin	5	DHEA-S	3
TSTO	4	Progesterone	3
Troponin	3	TT3	3
IgE	3		

September Predicate Assays and Levels with 10x above the mean

PRL	1 and 3	
DHEA-S	2 and 3	Changed to Centaur
IgE	1	Changed to Centaur
Progesterone	3	Changed to Centaur
SHBG*	1 and 2	
tPSA*	1, 2 and 3	
Thyroxine, Free*	3	

\*Swapna plans to switch to Centaur after move  
 Red: Centaur

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September Predicate Assays and Levels with 10x below the mean

eE2	1,2 and 3	
fT3	1	
PRGE	2 and 3	
Cortisol*	1 and 3	
Estradiol	1	Changed to Centaur
fPSA*	1, 2 and 3	
iPTH*	1 and 2	
TT4*	2	

\*Swapna plan to switch to Centaur after move

September Predicate Assays and Levels with >2SD above the mean

Ferritin	2	C-Peptide	3
Folate	1	DHEA-S	2 and 3
Homocysteine	1 and 2	Progesterone	1
Insulin	2	Testosterone	1, 2 and 3
Troponin	1,2 and 3	Thyroglobulin	3
Chloride	1	TT3	1

September Predicate Assays and Levels with >2SD below the mean

BNP	2 and 3	Estradiol	1
eE2	1 and 2	Estriol, Uncon.	3
fT3	1	fPSA	1, 2 and 3
PRGE	1	HbA1c	1, 2 and 3
Tup	2	iPTH	1 and 2
Cortisol	1 and 3	TT4	2

September Predicate Assays and Levels with >3SD above the mean

Ferritin	2	Thyroglobulin	1 and 3
Homocysteine	1	TT3	1
Progesterone	1	TUp	1,2 and 3
Testosterone	1	Chloride	1

2

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September Predicate Assays and Levels with >3SD below the mean

CPSA	1	TBG	1
TSTO	1 and 2		

Prepared By: *Langly Gee*  
Langly Gee  
Date: 10/16/2014

Reviewed By: *Adam Rosendorff*  
Adam Rosendorff  
Date: 10/16/2014



device_name	Test.Name	total_warnings	total_10_x	total_R_4s
ADVIA_1_SR	ALB	55	55	0
ADVIA_1_SR	ALPAMP	48	48	0
ADVIA_1_SR	ALT	29	27	0
ADVIA_1_SR	AST	10	10	0
ADVIA_1_SR	CA_2	66	66	0
ADVIA_1_SR	CKNAC	18	18	0
ADVIA_1_SR	CI	2	2	0
ADVIA_1_SR	CO2_L	2	2	0
ADVIA_1_SR	D LDL	22	21	0
ADVIA_1_SR	DBIL_2	30	30	0
ADVIA_1_SR	D-HDL	66	66	0
ADVIA_1_SR	ECRE_2	19	19	0
ADVIA_1_SR	GLUH_3	66	66	0
ADVIA_1_SR	K	15	15	0
ADVIA_1_SR	Na	1	1	0
ADVIA_1_SR	TBIL_2	13	13	0
ADVIA_1_SR	UN	32	32	0
ADVIA_1_SR	IRON_2	11	11	0
ADVIA_1_SR	MG	1	1	0
ADVIA_1_SR	TIBC	6	6	0

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2/7/2015

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JANUARY THERANOS CONTROLS ANALYZED

Theranos	# of Controls	25D	3SD	% 25D	% 3SD
CBC	1276	28	22	2.2	1.7
Advia*	5778	134	70	2.3	1.2
Edison**	2522	181	266	7.2	10.5
Total	9576	343	358	3.6	3.7

Advia\*

Lithium	30	Me	12
TIBC	22	ALP	11
hsCRP	19	Phos	11
LDL	18	GGT	10
LAC	12		



EDISON\*\*

Assay	QCs Analyzed	Low Level Pass	High Level Pass	2SD Low Level	3SD Low Level	2SD High Level	3SD High Level	%2SD	%3SD	Readers
FT4	208	70	72	17	22	10	17	13.0	18.8	6
HCG	103	48	52	0	1	0	2	0.0	2.9	5
SHBG	129	41	49	4	13	6	16	7.8	22.5	7
tPSA	206	94	95	3	5	6	3	4.4	3.9	6
TSH	583	258	262	12	18	16	17	4.8	6.0	23
TST	245	105	101	10	8	12	9	9.0	6.9	15
TT3	124	47	42	3	12	8	12	8.9	19.4	6
TT4	94	47	34	4	2	2	5	6.4	7.4	6
VB12	478	189	176	29	36	27	21	11.7	11.9	12
VD	352	149	144	5	22	7	25	3.4	13.4	18
Totals	2522	1048	1027	87	139	94	127	7.2	10.5	104

January Theranos Assays and Levels with 10x above the mean

TIBC 1 and 2

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January Theranos Assays and Levels with >2SD above the mean

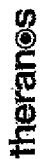
BUN	1	TRIG	1	Creat	1
GGT	1	Albumin	1 and 2	GGT	1
LDL	1, 2 and 3	ALT	1	hsCRP	1 and 2
Lipase	1	Amylase	1	IgA	3
Lithium	3	AST	1	Lithium	2
Mg	1	BUN	1, 2 and 3	TIBC	2 and 3
Phos	1 and 2	CA	2 and 3	TIBC	3
TIBC	3	Chol	1		

Black - Advia 2  
 Red - Advia 3

January Theranos Assays and Levels with >2SD below the mean

ALP	1	UA	1	Lithium	1, 2 and 3
ALT	1	ALP	1	Mg	1
AST	1	CA	2 and 3	Sal	1
CK	1	CK	1	TIBC	1
HDL	1, 2 and 3	CO2	1	UA	1
Phos	2	GGT	1		
TIBC	3	LAC	1, 2 and 3		





January Theranos Assays and Levels with >3SD above the mean

Albumin	1	D Bil	1	TIBC	1
ALP	1	GGT	1 and 3	Tprotein	1
ALT	1	Glucose	1	TRIG	1
Amylase	1	HDL	1	UA	1
AST	1	Iron	1	Albumin	3
BUN	1	K	1	CO2	3
CA	1	LDLP	1	Creat	1
Chol	1	Lipase	2	Fer	1 and 2
CK	1	Mg	1 and 2	GGT	1
Cl	1	Na	1	hsCRP	1 and 2
CO2	1	Phos	1	Lithium	1, 2 and 3
Crea	1	TBIL	1		

January Theranos Assays and Levels with > 3SD below the mean

Cl	2 and 3	Lithium	1	APO A1	1, 2 and 3
GGT	1	Na	2	Lipase	1
K	2	TIBC	1 and 2	Lithium	1

January Theranos Assays and Levels with 2.2SD above the mean

AST	1	TRIG	1	Lithium	2
LDL	1 and 2	hsCRP	2	TIBC	2 and 3
TIBC	3				

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January Theranos Assays and Levels with 2 STD below the mean

HDL	3	ALP	1	Lithium	2
Phos	2	LAC	1, 2 and 3		

Prepared By: Ruby Goo  
Langly Gee

Date: 2/11/15

Reviewed By: Crash

Date: 2/12/15

*[Handwritten signature]*  
*9/19/15*

2/7/2015

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JANUARY THERANOS CONTROLS ANALYZED

Theranos	# of Controls	2SD	3SD	% 2SD	% 3SD
CBC	1276	28	22	2.2	1.7
Advia*	5778	134	70	2.3	1.2
Edison**	2522	181	266	7.2	10.5
Total	9576	343	358	3.6	3.7

Advia\*

Lithium	30	Mg	12
TIBC	22	ALP	11
hsCRP	19	Phos	11
LDL	18	GGT	10
LAC	12		

EDISON™

Assay	QCs Analyzed	Low Level		High Level		2SD		3SD		2SD		3SD		%2SD	%3SD	Readers
		Pass	Fail	Pass	Fail	Low Level	High Level	Low Level	High Level	High Level	High Level					
FT4	208	70	72	17	22	10	17	13.0	18.8	6						6
HCG	103	48	52	0	1	0	2	0.0	2.9	5						5
SHBG	129	41	49	4	13	6	16	7.8	22.5	7						7
tPSA	206	94	95	3	5	6	3	4.4	3.9	6						6
TSH	583	258	262	12	18	16	17	4.8	6.0	23						23
TST	245	105	101	10	8	12	9	9.0	6.9	15						15
TT3	124	47	42	3	12	8	12	8.9	19.4	6						6
TT4	94	47	34	4	2	2	5	6.4	7.4	6						6
VR12	478	189	176	29	36	27	21	11.7	11.9	12						12
VD	352	149	144	5	22	7	25	3.4	13.4	18						18
Totals	2522	1048	1027	87	139	94	127	7.2	10.5	104						104

January Theranos Assays and Levels with 10x above the mean

TIBC 1 and 2

theranos

January Theranos Assays and Levels with >2SD above the mean

BUN	1		TRIG	1	Creat	1
GGT	1		Albumin	1 and 2	GGT	1
LDL	1, 2 and 3		ALT	1	hsCRP	1 and 2
Lipase	1		Amylase	1	IgA	3
Lithium	3		AST	1	Lithium	2
Mg	1		BUN	1, 2 and 3	TIBC	2 and 3
Phos	1 and 2		CA	2 and 3	TIBC	3
TIBC	3		Chol	1		

Black- Advia 2  
 Red - Advia 3



January Theranos Assays and Levels with >2SD below the mean

ALP	1	UA	1	Lithium	1, 2 and 3
ALT	1	ALP	1	Mg	1
AST	1	CA	2 and 3	Sal	1
CK	1	CK	1	TIBC	1
HDL	1, 2 and 3	CO2	1	UA	1
Phos	2	GGT	1		
TIBC	3	LAC	1, 2 and 3		





January Theranos Assays and Levels with >3SD above the mean

Albumin	1	D Bil	1	TIBC	1
ALP	1	GGT	1 and 3	Tprotein	1
ALT	1	Glucose	1	TRIG	1
Amylase	1	HDL	1	UA	1
AST	1	Iron	1	Albumin	3
BUN	1	K	1	CO2	3
CA	1	LDLP	1	Creat	1
Chol	1	Lipase	2	Fer	1 and 2
CK	1	Mg	1 and 2	GGT	1
Cl	1	Na	1	hsCRP	1 and 2
CO2	1	Phos	1	Lithium	1, 2 and 3
Crea	1	TBIL	1		

January Theranos Assays and Levels with > 3SD below the mean

Cl	2 and 3	Lithium	1	APO A1	1, 2 and 3
GGT	1	Na	2	Lipase	1
K	2	TIBC	1 and 2	Lithium	1

January Theranos Assays and Levels with 2 2SD above the mean

AST	1	TRIG	1	Lithium	2
LDL	1 and 2	hsCRP	2	TIBC	2 and 3
TIBC	3				

theranos

January Theranos Assays and Levels with 2 2SD below the mean

HDL	3	ALP	1	Lithium	2
Phos	2	LAC	1, 2 and 3		

Prepared By: Rhylan  
 Langly Gee  
 Date: 2/11/15

Reviewed By: Geehan  
 Date: 2/12/15

*[Handwritten signature]*  
 9/19/15

Theranos Internal Only

## ORF Investigation Monthly Summary - April 2014

device_name	Test.Name	total_warnings	total_10_x	total_R_4s
ADVIA_1_SR	ALB	44	44	0
ADVIA_1_SR	ALPAMP	44	44	0
ADVIA_1_SR	ALT	56	56	0
ADVIA_1_SR	AST	20	20	0
ADVIA_1_SR	CA_2	82	82	0
ADVIA_1_SR	CHOL_2	19	19	0
ADVIA_1_SR	CKNAC	54	54	0
ADVIA_1_SR	Cl	93	93	0
ADVIA_1_SR	CO2_L	21	20	0
ADVIA_1_SR	D LDL	53	53	0
ADVIA_1_SR	DBIL_2	64	64	0
ADVIA_1_SR	D-HDL	84	84	0
ADVIA_1_SR	ECRE_2	16	16	0
ADVIA_1_SR	GLUH_3	84	84	0
ADVIA_1_SR	K	28	28	0
ADVIA_1_SR	Na	4	4	0
ADVIA_1_SR	TBIL_2	77	77	0
ADVIA_1_SR	TP	22	22	0
ADVIA_1_SR	Trig	66	66	0
ADVIA_1_SR	UN	16	16	0
ADVIA_1_SR	AMYLAS	10	10	0
ADVIA_1_SR	GGT	1	1	0
ADVIA_1_SR	IRON_2	42	42	0
ADVIA_1_SR	LIP	11	11	0
ADVIA_1_SR	MG	27	25	0
ADVIA_1_SR	TIBC	35	35	0
ADVIA_1_SR	UA	14	14	0
ADVIA_1_SR	LITH	3	2	0
ADVIA_1_SR	LDLP	27	27	0

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Theranos Internal Only

## ORF Investigation Monthly Summary - September 2014

device_name	Test.Name	total_warnings	total_10_x	total_R_4s
ADVIA_1_SR	ALB	49	49	0
ADVIA_1_SR	ALPAMP	21	21	0
ADVIA_1_SR	ALT	41	39	0
ADVIA_1_SR	AST	23	23	0
ADVIA_1_SR	CA_2	19	19	0
ADVIA_1_SR	CHOL_2	10	10	0
ADVIA_1_SR	CKNAC	50	50	0
ADVIA_1_SR	CI	59	59	0
ADVIA_1_SR	CO2_L	15	15	0
ADVIA_1_SR	D LDL	57	54	0
ADVIA_1_SR	DBIL_2	55	55	0
ADVIA_1_SR	D-HDL	16	15	0
ADVIA_1_SR	ECRE_2	32	31	0
ADVIA_1_SR	GLUH_3	58	58	0
ADVIA_1_SR	K	13	12	0
ADVIA_1_SR	Na	1	0	0
ADVIA_1_SR	TBIL_2	60	60	0
ADVIA_1_SR	Trig	32	32	0
ADVIA_1_SR	UN	39	39	0
ADVIA_1_SR	GGT	1	1	0
ADVIA_1_SR	IP	6	6	0
ADVIA_1_SR	IRON_2	8	8	0
ADVIA_1_SR	MG	3	3	0
ADVIA_1_SR	TIBC	22	22	0
ADVIA_1_SR	UA	12	12	0
ADVIA_1_SR	LDLP	9	9	0

COPY