Message

From: Langly Gee [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=LANGLY GEE5CB]
Sent: 5/9/2014 2:39:56 AM
To: Daniel Edlin [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Daniel Edlin]; Brad Arington [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Brad Arington22b]; Adam Rosendorff [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Adam Rosendorfd92]; Mark Pandori [/O=THERANOS ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Mark Pandori16d]
Subject: RE: Updated PT /Audit Renewals since 3/18
Attachments: API Microbiology.pdf; API Hematology.pdf; New York Toxicology.pdf; CAP HIV.pdf; CAP Infectious Disease Respiratory.pdf; CAP Clinical Microscopy.pdf; CAP Infectious Disease Serology.pdf

Daniel:

See attached.

Langly

From: Daniel Edlin
Sent: Thursday, May 08, 2014 7:01 PM
To: Langly Gee; Brad Arington; Adam Rosendorff; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

Yes, thanks.

From: Langly Gee
Sent: Thursday, May 08, 2014 7:00 PM
To: Daniel Edlin; Brad Arington; Adam Rosendorff; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

Daniel:

Which reports? Surveys?

Langly

From: Daniel Edlin
Sent: Thursday, May 08, 2014 6:58 PM
To: Langly Gee; Brad Arington; Adam Rosendorff; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

Please send the latest versions of these reports in PDF.

Thanks

From: Langly Gee
Sent: Thursday, May 08, 2014 6:48 PM
To: Brad Arington; Adam Rosendorff; Daniel Edlin; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

All:

Yes, the Maryland and Florida are current valid licenses and the renewal dates are listed.

Maryland should be sending the renewal paperwork by May 19, 2014 and for Florida, I will start the paperwork in July.

Langly

From: Brad Arington
Sent: Thursday, May 08, 2014 6:44 PM
To: Langly Gee; Adam Rosendorff; Daniel Edlin; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

Just a couple of clarifications. I believe that Maryland and Florida are currently valid licenses, but are up for renewal on the dates noted by Langley. (Please confirm). And as for New Jersey, the renewal is pending obtaining a Bioanalytical Laboratory Director license with the NJ Board of Medicine and I believe that Adam is taking care of that.

Brad Arington

Theranos, Inc.

Senior Regulatory Counsel

Direct: (650) 856-7304

Cell: (650) 683-0233

This email and any attachments thereto may contain private, confidential, and privileged material for the sole use of the intended recipient. Any review, copying, or distribution of this email (or any attachments thereto) by others is strictly prohibited. If you are not the intended recipient, please contact the sender immediately and permanently delete the original and any copies of this email and any attachments thereto.

From: Langly Gee
Sent: Thursday, May 08, 2014 6:39 PM
To: Adam Rosendorff; Daniel Edlin; Mark Pandori
Cc: Brad Arington
Subject: RE: Updated PT /Audit Renewals since 3/18

All:

Here are surveys performed and scores and update to licensures since 3/18.

If you need anything else, let me know.

Langly

Date	Survey	Score
3/21/14	API Microbiology	100%
4/1/14	NY Toxicology	100%
4/3/14	CAP HIV	100%
4/11/14	CAP Infectious Disease Respiratory	100%
4/29/14	CAP Clinical Microscopy	100%
5/1/14	API Hematology	100%
5/17/14	CAP Infectious Disease Serology	100%

Licensures

Received CMS Renewal – 4/11/14

CLIA - Submission due 6/14/14

New Jersey - Pending submission (Brad)

Maryland - Pending renewal application - Due 6/30/14

Florida -Pending renewal application - Due 10/21/14

From: Adam Rosendorff
Sent: Thursday, May 08, 2014 6:15 PM
To: Daniel Edlin; Mark Pandori
Cc: Brad Arington; Langly Gee
Subject: RE: Updated PT /Audit Renewals since 3/18

Langly

Maybe show our 100% grade in Hematology?

Sent from my Windows Phone

From: Daniel Edlin
Sent: 5/8/2014 6:06 PM
To: Adam Rosendorff; Mark Pandori
Cc: Brad Arington; Langly Gee
Subject: RE: Updated PT /Audit Renewals since 3/18

Adding Brad and Langly

Do we have any updated reports or licenses since 3/18?

Thanks,

Dan

From: Adam Rosendorff
Sent: Thursday, May 08, 2014 6:04 PM
To: Daniel Edlin; Mark Pandori
Subject: RE: Updated PT /Audit Renewals since 3/18

Daniel

We are continually doing proficiency testing. Langly or Brad can fill you in on State by State applications/status.

Adam

Sent from my Windows Phone

From: Daniel Edlin
Sent: 5/8/2014 5:56 PM
To: Adam Rosendorff; Mark Pandori
Subject: Updated PT /Audit Renewals since 3/18

Hi Adam and Mark,

Have we undergone any new proficiency testing or audit renewals since 3/18/14? If so, can you please send me a copy of the reports or licenses? EAH has asked for this as part of a presentation she is compiling for tomorrow so we would need this tonight.

Thanks for your help,

Dan

American Proficiency Institute

COMPARATIVE EVALUATION

2014 Microbiology - 1st Event (Kit #1)

Customer No: 59761D
CLIA No: 05D2025714

Address: Adam Rosendorff, MD
Theranos, Inc. - CLIA Laboratory
1601 S. California Avenue
Palo Alto, CA 94304

COPIES OF THE EVALUATION HAVE BEEN SENT TO:

California Department of Health Services (CLF341367)
Office of Health Care Quality
Pennsylvania Department of Health
Rhode Island Department of Health

Gram Stain

Gram Stain**

Sample	Reported Result	Expected Result	Grade
GS-01	Gram negative organism	Gram negative organism	Acceptable
GS-02	Gram negative organism	Gram negative organism	Acceptable
GS-03	Gram positive organism	Gram positive organism	Acceptable
GS-04	Gram negative organism	Gram negative organism	Acceptable
GS-05	Gram positive organism	Gram positive organism	Acceptable

Gram Stain Morphology

Sample	Reported Result	Expected Result	Grade
GS-01	Diplococci	Diplococci	Acceptable
GS-02	Rods / Bacilli	Rods / Bacilli	Acceptable
GS-03	Cocci	Cocci	Acceptable
GS-04	Rods / Bacilli	Rods / Bacilli	Acceptable
GS-05	Rods / Bacilli	Rods / Bacilli	Acceptable

Rapid Group A Strep Antigen

Group A Strep Antigen

CLIAwaived Rapid Strep A Test

Sample	Reported Result	Expected Result	Grade
ST-01	Positive	Positive	Acceptable

Urine Culture & Colony Count

Susceptibility Testing**

MIC Testing / Amikacin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Amoxicillin / Clavulanic acid

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

Confidential THPFM0004507894

MIC Testing / Ampicillin

Sample	Reported Result	Expected Result	Grade
UR-01	Resistant	Resistant Intermediate	Acceptable

MIC Testing / Aztreonam

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Cefazolin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Cefepime

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Ceftazidime

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Ceftriaxone

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Cefuroxime

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Ciprofloxacin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Gentamicin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Imipenem

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Levofloxacin

Confidential THPFM0004507895

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Meropenem

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Nitrofurantoin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible Intermediate	Acceptable

MIC Testing / Piperacillin/Tazobactam

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

MIC Testing / Tobramycin

Sample	Reported Result	Expected Result	Grade
UR-01	Susceptible	Susceptible	Acceptable

Urine Colony Count
A Quantitative Loop w any agar

Sample	Reported Result	Expected Result	Grade
UR-01	>100,000 CFU/mL	>100,000 CFU/mL 10,000-100,000 CFU/mL	Acceptable

Urine Identification**

Sample	Reported Result	Expected Result	Grade
UR-01	Klebsiella pneumoniae	Klebsiella pneumoniae	Acceptable

Confidential THPFM0004507896

American Proficiency Institute
1159 Business Park Drive, Traverse City, MI 49686

Customer No: 59761
CLIA No: 05D2025714
Address: Adam Rosendorff, MD
Theranos, Inc. - CLIA Laboratory
1601 S. California Avenue
Palo Alto, CA 94304

Performance Summary

2014 Hematology / Coagulation - 1st Event

This is a summary of your proficiency testing performance for the last three test events. It is divided into sections according to specialty/sub-specialty. Each section shows scores and long-term performance for individual analytes.

The scores for individual analytes are defined as the ratio of acceptable responses to the number of samples tested, expressed as a percentage. Unsatisfactory performance (denoted by ✓) is indicated for any analyte with less than 80% (100% for ABO Group / D (Rh) Typing).

Unsuccessful long-term performance, where indicated, is based on unsatisfactory analyte scores for two of three test events. Analytes that are scored for CMS are designated by (**); scores for these analytes are sent to CMS.

Comments shown under 'Notes' are applicable to the current Test Event only.

CHEMISTRY

Endocrinology	2013 2nd	2013 3rd	2014 1st	Long Term	Notes (2014 1st)
HCG, Urine (Urinalysis)	100%	100%			
HCG, Urine (Urinalysis-I)			100%		

HEMATOLOGY

Hematology	2013 2nd	2013 3rd	2014 1st	Long Term	Notes (2014 1st)
Blood Cell ID (Educational)	100%		100%		
Blood Cell Identification	100%	80%	100%		
D-dimer (quan)	100%	100%	100%		
Erythrocyte Count **	100%	100%	100%		
Fibrinogen **	100%	100%	100%		
Hematocrit **	100%	100%	100%		
Hemoglobin **	100%	100%	100%		
INR	100%	100%	100%		
Leukocyte Count **	100%	100%	100%		
MCV (Hem-5D)	100%	100%	100%		
Partial Thromb. Time (APTT) **	100%	100%	100%		
Platelet Count **	100%	100%	100%		
Prothrombin Time **	100%	100%	100%		
RDW (Hem-5D)	100%	100%	100%		
Reticulocyte Count (Hem-5D)	100%	100%	100%		
Sedimentation Rate	100%	100%	100%		
White Blood Cell Differential **	100%	100%	100%		
Basophils (Hem-5D) **	100%	100%	100%		
Eosinophils (Hem-5D) **	100%	100%	100%		
Lymphocytes (Hem-5D) **	100%	100%	100%		
Monocytes (Hem-5D) **	100%	100%	100%		
Neutrophils (Hem-5D) **	100%	100%	100%		

MICROSCOPY

Microscopy	2013 2nd	2013 3rd	2014 1st	Long Term	Notes (2014 1st)
Crystals (Iris)	100%	100%	100%		
Non-Squamous Epi Cells (Iris)	100%	100%	100%		
RBC (Iris)	100%	100%	100%		
WBC (Iris)	100%	100%	100%		

URINALYSIS AND OTHER TESTS

Urinalysis and Other Tests	2013 2nd	2013 3rd	2014 1st	Long Term	Notes (2014 1st)
Bilirubin (Urinalysis)	100%	100%			
Bilirubin (Urinalysis-I)			100%		
Blood or Hemoglobin (UA)	100%	100%			
Blood or Hemoglobin (UAI)			100%		
Fecal Occult Blood	100%	100%	100%		
Glucose (Urinalysis)	100%	100%			
Glucose (Urinalysis-I)			100%		
Ketones (Urinalysis)	100%	100%			
Ketones (Urinalysis-I)			100%		
Leukocyte Esterase	100%	100%			
Leukocyte Esterase (UAI)			100%		
Nitrite	100%	100%			

Confidential THPFM0004507897

URINALYSIS AND OTHER TESTS - continued

Urinalysis and Other Tests - continued

	2013 2nd	2013 3rd	2014 1st	Long Term	Notes (2014 1st)
Nitrite (Urinalysis-I)	100%	100%	100%		
pH (Urinalysis)					
pH (Urinalysis-I)	100%	100%	100%		
Protein (Urinalysis)					
Protein (Urinalysis-I)	100%	100%	100%		
Specific Gravity					
Specific Gravity (UAI)	100%	100%	100%		
Urobilinogen					
Urobilinogen (UAI)	100%	100%	100%		

1D

Confidential THPFM0004507898

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza Albany New York 12201 - 0509

Analytical Toxicology Proficiency Testing Program

Performance Summary

Test Date: March 2014

Test Event: AT141

Laboratory PFI: 8661

Dr. Adam Rosendorff
Theranos Inc
1601 S California Ave
Palo Alto CA 94304-1111

Critique of interlaboratory performance is available at www.wadsworth.org/chemheme/chem/tox/tox.htm

STATE OF NEW YORK DEPARTMENT OF HEALTH • WADSWORTH CENTER

Analytical Toxicology Proficiency Testing Program

Theranos Inc
1601 S California Ave
Palo Alto, CA 94304-1111

March 2014
Laboratory PFI: 8661

Program Design

The Wadsworth Center shipped four specimens for routine drug testing to the Theranos Inc. The specimen drug content and concentration are as listed below.

Specimen ID	Drug Content	Concentration (ng/mL)	Specimen ID	Drug Content	Concentration (ng/mL)
SY1	Amphetamine	981	SY2	Propoxyphene	921
	Methamphetamine	1749		Norpropoxyphene	653
	Benzoylecgonine	658		Ethanol, mg/dL	125
	Cannabinoids (THCA)	93			
SY3	Morphine Total	2678	SY4	Amitriptyline	1649
	Morphine Free	1937		Nortriptyline	1426
	Codeine	1420		Phencyclidine	109
	6-MAM	29		Temazepam	1003
	Methadone	877		Doxepin	1648
	EDDP	583		Nordoxepin	1270
				Ethanol, mg/dL	49

Performance Evaluation - Initial (Screen) Test

Theranos Inc conducted an initial (screen) test for the drugs listed below using the listed analytical method(s) and cutoff concentrations. The accuracy of test findings is posted under Analytical Performance.

Drugs Tested For	Cutoff (ng/mL)	Method	Test specimens SY1	SY2	SY3	SY4	Analyte Performance
Cannabinoids	20	SIAD	TP	TN	TN	TN	PASS
PCP	25	SIAD	TN	TN	TN	TP	PASS
Opiates	300	SIAD	TN	TN	TP	TN	PASS
Methadone	300	SIAD	TN	TN	TP	TN	PASS
Ethanol	10	SIAD	TN	TP	TN	TP	PASS
Benzodiazepines	200	SIAD	TN	TN	TN	TP	PASS
Amphetamines	500	SIAD	TP	TN	TN	TN	PASS

Summary Comment

(Critique of interlaboratory performance is available at www.wadsworth.org/chemheme/chem/tox/tox.htm)

Theranos Inc initial (screen) test findings are accurate. Should you have any questions or comments, please send email to Dr. Jimmy(Shijun) Lu at tox_pt@wadsworth.org.

Performance Evaluation Codes

TN – True Negative	FN – False Negative	LT – negative, less than cutoff	PL – positive, less than cutoff
TP – True Positive	FP – False Positive	PC – positive, cross-reactant	AD – negative by adulteration

Confidential

STATE OF NEW YORK DEPARTMENT OF HEALTH • WADSWORTH CENTER

Analytical Toxicology Proficiency Testing Program - Performance History

Theranos Inc, Palo Alto, CA

PFI: 8661

Urine Screen	March 2013 Test Event				August 2013 Test Event				March 2014 Test Event				Analyte Status	
Analyte	Initial	Confirm	Quant	Bias	Initial	Confirm	Quant	Bias	Initial	Confirm	Quant	Bias	Qualitative	Quantitative
Amphetamines	PASS				PASS				PASS				Successful	
benzodiazepines	PASS				PASS				PASS				Successful	
Cannabinoids	PASS				PASS				PASS				Successful	
ethanol	PASS				PASS				PASS				Successful	
Methadone	PASS				PASS				PASS				Successful	
Opiates	PASS				PASS				PASS				Successful	
PCP	PASS				PASS				PASS				Successful	

THPFM0004507901

Laboratory PFI: 8661

Dr. Adam Rosendorff
Theranos Inc
1601 S California Ave
Palo Alto CA 94304-1111

Confidential

THPFM0004507902

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

ORIGINAL EVALUATION

HIV-A 2014 HIV Viral Load

INSTITUTION: Theranos Inc
Palo Alto CA 94304-1111

ATTENTION: Langly Gee BS

CAP NUMBER: 7540853-01 **Kit#** 1

KIT INFORMATION:

Kit ID:	Kit Mailed:	Original Evaluation:	Next Mailing Date:
26565311	2/4/2014	3/27/2014	5/27/2014

COPIED TO: CMS (05D2025714)

LEGEND: **Exception Reason Codes appearing in this evaluation:**
[28] = Response qualified with a greater than or less than sign; unable to quantitate.

Reviewed By

4/3/2014
Date

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507903

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 26565311
Kit Mailed: 2/4/2014
Original Evaluation: 3/27/2014

EVALUATION

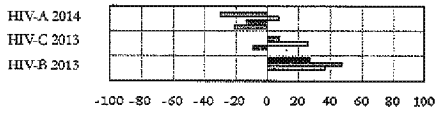
ORIGINAL

HIV-A 2014 HIV Viral Load

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
HIV Viral Load	**HV2-01**	<1.60	0.000	0.000	20				[28]
copies/mL	**HV2-02**	2.91	2.995	0.089	108	-1.0	2.72	3.27	Acceptable
ABBOTT REALTIME IVD	**HV2-03**	6.01	5.990	0.076	104	+0.3	5.76	6.22	Acceptable
	HV2-04	3.91	3.940	0.075	104	-0.4	3.71	4.17	Acceptable
	HV2-05	2.43	2.516	0.130	107	-0.7	2.12	2.91	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100



The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507904

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

ORIGINAL EVALUATION

IDR-A 2014 Infectious Disease, Respiratory

INSTITUTION: Theranos Inc
Palo Alto CA 94304-1111

ATTENTION: Langly Gee BS

CAP NUMBER: 7540853-01 **Kit#** 1

KIT INFORMATION:

Kit ID:	Kit Mailed:	Original Evaluation:	Next Mailing Date:
27354436	3/10/2014	4/9/2014	7/14/2014

COPIED TO: CMS (05D2025714)

LEGEND: **Exception Reason Codes appearing in this evaluation:**
[26] = Educational challenge.

Reviewed By

4/11/2014
Date

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507905

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Influenza A virus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	POSITIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]
Influenza A Subtype				
BIOFIRE DIAG (IDAHO)	**IDR-01**	SUBTYPING NOT PERFORMD		[26]
	IDR-02	PANDEMIC 2009 H1N1		[26]
	IDR-03	SUBTYPING NOT PERFORMD		[26]
	IDR-04	SUBTYPING NOT PERFORMD		[26]
	IDR-05	SUBTYPING NOT PERFORMD		[26]
	IDR-06	SUBTYPING NOT PERFORMD		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507906

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Influenza B virus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	POSITIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	POSITIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]
Parainfluenza virus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	POSITIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507907

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Parainfluenza Subtype				
BIOFIRE DIAG (IDAHO)	**IDR-01**	SUBTYPING NOT PERFORMD		[26]
	IDR-02	SUBTYPING NOT PERFORMD		[26]
	IDR-03	TYPE 2		[26]
	IDR-04	SUBTYPING NOT PERFORMD		[26]
	IDR-05	SUBTYPING NOT PERFORMD		[26]
	IDR-06	SUBTYPING NOT PERFORMD		[26]
RSV				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	POSITIVE		[26]
	IDR-06	NEGATIVE		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507908

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Rhinovirus/Enterovirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	POSITIVE		[26]
	IDR-05	POSITIVE		[26]
	IDR-06	NEGATIVE		[26]
Rhinovirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	POSITIVE		[26]
	IDR-05	POSITIVE		[26]
	IDR-06	NEGATIVE		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507909

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Enterovirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]
Metapneumovirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	POSITIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507910

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Adenovirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	POSITIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	NEGATIVE		[26]
Coronavirus				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NEGATIVE		[26]
	IDR-02	NEGATIVE		[26]
	IDR-03	NEGATIVE		[26]
	IDR-04	NEGATIVE		[26]
	IDR-05	NEGATIVE		[26]
	IDR-06	POSITIVE		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507911

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27354436
Kit Mailed: 3/10/2014
Original Evaluation: 4/9/2014

EVALUATION
ORIGINAL

IDR-A 2014 Infectious Disease, Respiratory

Test / Method	Specimen	Your Result	Intended Response	Your Grade
Coronavirus Strain				
BIOFIRE DIAG (IDAHO)	**IDR-01**	NOT PERFORMED		[26]
	IDR-02	NOT PERFORMED		[26]
	IDR-03	NOT PERFORMED		[26]
	IDR-04	NOT PERFORMED		[26]
	IDR-05	NOT PERFORMED		[26]
	IDR-06	229E		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507912

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

ORIGINAL EVALUATION

CM-A 2014 Clinical Microscopy

INSTITUTION: Theranos Inc
Palo Alto CA 94304-1111

ATTENTION: Langly Gee BS

CAP NUMBER: 7540853-01 **Kit#** 1

KIT INFORMATION:

Kit ID:	Kit Mailed:	Original Evaluation:	Next Mailing Date:
27068088	2/17/2014	4/24/2014	9/8/2014

COPIED TO: CMS (05D2025714)

IMPORTANT NOTES:

LEGEND: **Exception Reason Codes appearing in this evaluation:**
[11] = Unable to analyze (documentation to be provided by laboratory).

Reviewed By

4/29/14
Date

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507913

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27068088
Kit Mailed: 2/17/2014
Original Evaluation: 4/24/2014

EVALUATION
ORIGINAL

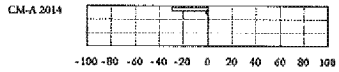
CM-A 2014 Clinical Microscopy

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade	Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation (Survey -100----------Mean----------+100)
Osmolality-Urine	CMP1-01								[11]	
	CMP1-02								[11]	
	CMP1-03								[11]	

Test / Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
hCG, urine					
OTHER	CMP1-01	POSITIVE	POSITIVE		Good
	CMP1-02	POSITIVE	POSITIVE		Good
	CMP1-03	POSITIVE	POSITIVE		Good

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Spec Gravity, urine	CMP1-01	1.005	1.0080	0.0014	327	-2.2	0.998	1.019	Acceptable
	CMP1-02	1.003	1.0032	0.0005	315	-0.4	0.993	1.014	Acceptable
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	CMP1-03	1.008	1.0080	0.0014	328	0.0	0.997	1.018	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation (Survey -100----------Mean----------+100)



The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507914

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27068088
Kit Mailed: 2/17/2014
Original Evaluation: 4/24/2014

EVALUATION
ORIGINAL

CM-A 2014 Clinical Microscopy

Test Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
pH, urine					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	7.0	7.0	6.0	Good
	CMP1-02	8.0	8.0 8.5 >/= 9.0	7.5	Good
	CMP1-03	7.0	7.0	8.0	Good
Protein,urine,qual,Mtd					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	100-200 mg/dL	100-200 mg/dL	30-70 mg/dL 300-600 mg/dL	Good
	CMP1-02	100-200 mg/dL	100-200 mg/dL	30-70 mg/dL 300-600 mg/dL	Good
	CMP1-03	100-200 mg/dL	100-200 mg/dL	30-70 mg/dL 300-600 mg/dL	Good
Glucose,urine,Mtd2					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	> 500, >/= 1k, 2k mg/dL	150 - 300 mg/dL 500 mg/dL > 500, >/= 1k, 2k mg/d	30-100 mg/dL	Good
	CMP1-02	NEGATIVE	NEGATIVE		Good
	CMP1-03	150 - 300 mg/dL	150 - 300 mg/dL 500 mg/dL > 500, >/= 1k, 2k mg/d	30-100 mg/dL	Good

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507915

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

CAP Number: 7540853-01 Kit# 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27068088
Kit Mailed: 2/17/2014
Original Evaluation: 4/24/2014

EVALUATION
ORIGINAL

CM-A 2014 Clinical Microscopy

Test / Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
Reducing substances					
	CMP1-01				[11]
	CMP1-02				[11]
	CMP1-03				[11]
Ketones,urine,Mtd3					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	CMP1-01	15-20 mg/dL	15-20 mg/dL	5-10 mg/dL 40-60 mg/dL	Good
	CMP1-02	NEGATIVE	NEGATIVE		Good
	CMP1-03	15-20 mg/dL	15-20 mg/dL	5-10 mg/dL 40-60 mg/dL	Good
Bilirubin,urine,Mtd1					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	CMP1-01	POSITIVE / MODERATE	POSITIVE / MODERATE	TRACE / SMALL LARGE	Good
	CMP1-02	NEGATIVE	NEGATIVE		Good
	CMP1-03	POSITIVE / MODERATE	POSITIVE / MODERATE	TRACE / SMALL LARGE	Good

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507916

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27068088
Kit Mailed: 2/17/2014
Original Evaluation: 4/24/2014

EVALUATION
ORIGINAL

CM-A 2014 Clinical Microscopy

Test Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
Blood/Hgb,urine,Mtdl					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	MARKED POS / LARGE	MARKED POS / LARGE	POSITIVE / MODERATE	Good
	CMP1-02	MARKED POS / LARGE	MARKED POS / LARGE	POSITIVE / MODERATE	Good
	CMP1-03	MARKED POS / LARGE	MARKED POS / LARGE	POSITIVE / MODERATE	Good
Leuko Esterase,urine,M					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	250 OR 500 uL	250 OR 500 uL POSITIVE	75 OR 100 uL	Good
	CMP1-02	NEGATIVE	NEGATIVE		Good
	CMP1-03	250 OR 500 uL	250 OR 500 uL POSITIVE	75 OR 100 uL	Good
Nitrite, urine					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	**CMP1-01**	POSITIVE	POSITIVE		Good
	CMP1-02	NEGATIVE	NEGATIVE		Good
	CMP1-03	POSITIVE	POSITIVE		Good

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507917

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

CAP Number: 7540853-01 Kit# 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 27068088
Kit Mailed: 2/17/2014
Original Evaluation: 4/24/2014

EVALUATION
ORIGINAL

CM-A 2014 Clinical Microscopy

Test / Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
Urobilinogen, urine					
IRIS iChemVELOCITY RGT IRIS iChemVELOCITY	CMP1-01	4.0/6.0 mg/dL / 70 umol/L	4.0/6.0 mg/dL / 70 umo POSITIVE	2.0/3.0 mg/dL / 34or35 >/= 8 or 12 mg/dL / 14	Good
	CMP1-02	1.0/<2.0 mg/dL / 16 umol/L	Neg / 0.2 mg/dL / <3.2 1.0/<2.0 mg/dL / 16 um		Good
	CMP1-03	4.0/6.0 mg/dL / 70 umol/L	4.0/6.0 mg/dL / 70 umo POSITIVE	2.0/3.0 mg/dL / 34or35 >/= 8 or 12 mg/dL / 14	Good
Urine Sediment ID	CMP-04	CHOLESTEROL CRYSTALS	CHOLESTEROL CRYSTALS		Good
	CMP-05	SQUAMOUS EPITHELIAL	SQUAMOUS EPITHELIAL		Good
	CMP-06	FATTY CAST	FATTY CAST		Good
	CMP-07	FAT DROPLETS	FAT DROPLETS		Good
CSF & Body Fluid	CMP-08				[11]
	CMP-09				[11]
	CMP-10				[11]
	CMP-11				[11]
	CMP-12				[11]
	CMP-13				[11]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

Confidential THPFM0004507918

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

ORIGINAL EVALUATION

VR3-A 2014 Infectious Disease Serology

INSTITUTION: Theranos Inc
Palo Alto CA 94304-1111

ATTENTION: Langly Gee BS

CAP NUMBER: 7540853-01 **Kit#** 1

KIT INFORMATION:

Kit ID:	Kit Mailed:	Original Evaluation:	Next Mailing Date:
26565854	3/17/2014	5/6/2014	11/3/2014

COPIED TO: CMS (05D2025714)

LEGEND: **Exception Reason Codes appearing in this evaluation:**
[26] = Educational challenge.

Reviewed By

5/17/14
Date

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507919

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 26565854
Kit Mailed: 3/17/2014
Original Evaluation: 5/6/2014

EVALUATION
ORIGINAL

VR3-A 2014 Infectious Disease Serology

Test Method	Specimen	Your Result	Intended Response	Your Grade
CMV, IgG DIASORIN LIAISON	**VR3-01**	ABSENT	ABSENT	Good
CMV, IgM DIASORIN LIAISON	**VR3-01**	PRESENT	PRESENT	Good
EBV, VCA, IgG DIASORIN LIAISON	**VR3-02**	ABSENT		[26]
EBV, VCA, IgM DIASORIN LIAISON	**VR3-02**	ABSENT		[26]
EBV, EA, IgG DIASORIN LIAISON	**VR3-02**	ABSENT		[26]
EBV, EBNA, IgG DIASORIN LIAISON	**VR3-02**	ABSENT		[26]
H pylori, IgG SIEMENS IMMUL 2000/XPi	**VR3-03**	ABSENT	ABSENT	Good
HSV I, IgG DIASORIN LIAISON	**VR3-04**	ABSENT	ABSENT	Good
HSVII, IgG DIASORIN LIAISON	**VR3-04**	PRESENT	PRESENT	Good
Rubeola, IgG DIASORIN LIAISON	**VR3-06**	PRESENT	PRESENT	Good

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507920

Confidential

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 7540853-01 **Kit#** 1
Institution: Theranos Inc
Attention: Langly Gee BS
City / State: Palo Alto CA 94304-1111

Kit ID: 26565854
Kit Mailed: 3/17/2014
Original Evaluation: 5/6/2014

EVALUATION
ORIGINAL

VR3-A 2014 Infectious Disease Serology

Test Method	Specimen	Your Result	Intended Response	Your Grade
Toxo, IgG DIASORIN LIAISON	**VR3-07**	ABSENT	ABSENT	Good
Toxo, IgM DIASORIN LIAISON	**VR3-07**	ABSENT	ABSENT	Good
VZV, IgG DIASORIN LIAISON	**VR3-08**	PRESENT	PRESENT	Good
Mumps IgG DIASORIN LIAISON	**VR3M-01**	PRESENT		[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

THPFM0004507921