



Houston Forensic Science Center

Forensic Analysis Division - Toxicology

Immunoassay Batch Review Checklist

Batch Date: 02/11/2016		Analyst Review	Technical Review
Worklist	Item tested written for each case	✓	✓
	Lot numbers for controls listed	✓	✓
	Pipette(s) used listed	✓	✓
Data	Verify "Immunoassay Batch Report" sheets have correct method and KIT# for each assay	✓	✓
	Verify % CV of Negative control	✓	✓
	Verify % Binding of Positive control	✓	✓
	Verify HIGH controls were run after every 10 samples and at end of the batch	✓	✓
	Verify absorbance readings against raw data	✓	✓
	Verify "Results" against raw data	✓	✓
	Verify "Results" against the "Immunoassay Batch Summary Report"	✓	✓
Batch QC Data Worksheet	Review batch date and analyst	✓	✓
	Review control lot numbers against worklist	✓	✓
	Review kit lot numbers against "Immunoassay Batch Report" sheets	✓	✓
	Review pipette(s) listed against worklist	✓	✓
All comments and/or strikethroughs, if any, initialed/signed		✓	✓
All pages initialed/signed		✓	✓
All pages have date of analysis		✓	✓

Analyst Review

Andrea
Gooden

Initials/Date:

Digitally signed by Andrea Gooden
DN: cn=Andrea Gooden, o=HFSC,
ou=FAD,
email=AGooden@Houstonforensicscienc
e.org, c=US
Date: 2016.02.19 10:15:46 -06'00'

Technical Review

Tanuja
Sathiraj

Initials/Date:

Digitally signed by Tanuja Sathiraj
DN: cn=Tanuja Sathiraj, o, ou,
email=tsathiraj@houstonforensics
cience.org, c=US
Date: 2016.03.07 14:33:12 -06'00'



Houston Forensic Science Center

Forensic Analysis Division - Toxicology

Immunoassay Batch QC Data

Batch Date: 02/11/2016

Analyst: Andrea Gooden

Digitally signed by Andrea Gooden
DN: cn=Andrea Gooden, o=HFSC, ou=FAD,
email=A.Gooden@Houstonforensicscience.org,
c=US
Date: 2016.02.19 10:13:41 -0600

Matrix: BLOOD URINE

Pipette(s): 2339 3263

Phosphate Buffer Saline Lot Number: 01152016-B

Control Lot Numbers:

Blank E24906
Negative 070715-LC
Calibrator 10222015-PC
High 10222015-HC

Oxycodone:
Negative 07072015-LC-5
Calibrator 06222015
High 10222015-OH

Kit Lot Numbers:

11-nor-9-carboxy-THC EK12951
Opiates EK13319
Phencyclidine EK13322
Methamphetamine EK13516
Benzoylcegonine EK13059
Benzodiazepines EK13286

Barbiturates EK13110
Amphetamine EK13421
Carisoprodol EK13129
Methadone EK13090
Zolpidem EK13573
Oxycodone EK13204

Comments:



Alcohol/Toxicology
Work List for Andrea Gooden / Tox Screening

2/10/2016

Priority	Lab Case# / Item#	Description	Results
	062356315 1.1	2015-07384 4 1 Blood - Child Item	
	115198315 1.1	2015-12478 3 1 Blood - Child Item	
	117265215 1.1	2015-12731 3 1 Blood - Child Item	
	161517915 3.3	2015-17230 9 1 Blood - Child Item	
	147466015 1.1	2015-16272 2 2 Blood - Child Item	
	147941715 1.1	2015-16280 2 2 Blood - Child Item	
	148750415 1.1	2015-16094 2 2 Blood - Child Item	
	149086615 1.1	2015-15950 3 2 Blood - Child Item	
	149561515 1.1	2015-15944 2 2 Blood - Child Item	
	149927315 1.1	2015-15942 3 2 Blood - Child Item	
	150388115 1.1	2015-15958 2 2 ^{High} Blood - Child Item	
	150874615 1.1	2015-16090 2 2 Blood - Child Item	
	150877715 1.1	2015-16089 2 2 Blood - Child Item	
	151146015 1.1	2015-16152 2 2 Blood - Child Item	
	151670715 1.1	2015-16173 2 2 Blood - Child Item	
	152832615 1.1	2015-16177 2 2 Blood - Child Item	
	152842015 1.1	2015-16179 2 2 Blood - Child Item	
	152848015 1.1	2015-16151 2 2 Blood - Child Item	
	153107715 1.1	2015-16153 2 2 Blood - Child Item	
	153260515 1.1	2015-16285 2 2 Blood - Child Item	
	154164015 1.1	2015-16409 2 2 ^{High} Blood - Child Item	

Total Tasks 21 High

kit + control info on next page - *AG*

AG



Krt/Inv#

TAC -12
OPI -12
PCP -10
Meth -11
Be -11
Bz -12

Bank: 3
Amp: 4
Cariso: 4
Mtdn: 3
Zol: 4
Oxy: 3B

PBS: 01152016-B

Pipettes: 2339, 3263

Mixed controls

Blank E24 906

Neg: 070715-LC

Cef: 10222015-PC

High: 10222015-HC

Oxy

Neg: 07072015-LGS

Cef: 06222015

High: 10222015-OH

AK

ID	205	207	208	211	206	214	210	209	231
1 Blank-1	X	X	X	X	X	X	X	X	X
2 Blank-2	X	X	X	X	X	X	X	X	X
3 Cal-1	X	X	X	X	X	X	X	X	X
4 Cal-2	X	X	X	X	X	X	X	X	X
5 Neg-1	X	X	X	X	X	X	X	X	X
6 Neg-2	X	X	X	X	X	X	X	X	X
7 High-1	X	X	X	X	X	X	X	X	X
8 High-2	X	X	X	X	X	X	X	X	X
9 15-07384 1/1	X	X	X	X	X	X	X	X	X
10 15-12478 1/1	X	X	X	X	X	X	X	X	X
11 15-12731 1/1	X	X	X	X	X	X	X	X	X
12 15-17230 3/3	X	X	X	X	X	X	X	X	X
13 15-16272 1/1	X	X	X	X	X	X	X	X	X
14 15-16280 1/1	X	X	X	X	X	X	X	X	X
15 15-16094 1/1	X	X	X	X	X	X	X	X	X
16 15-15950 1/1	X	X	X	X	X	X	X	X	X
17 15-15944 1/1	X	X	X	X	X	X	X	X	X
18 15-15942 1/1	X	X	X	X	X	X	X	X	X
19 High-3	X	X	X	X	X	X	X	X	X
20 15-15958 1/1	X	X	X	X	X	X	X	X	X
21 15-16090 1/1	X	X	X	X	X	X	X	X	X
22 15-16089 1/1	X	X	X	X	X	X	X	X	X
23 15-16152 1/1	X	X	X	X	X	X	X	X	X
24 15-16173 1/1	X	X	X	X	X	X	X	X	X
25 15-16177 1/1	X	X	X	X	X	X	X	X	X
26 15-16179 1/1	X	X	X	X	X	X	X	X	X
27 15-16151 1/1	X	X	X	X	X	X	X	X	X
28 15-16153 1/1	X	X	X	X	X	X	X	X	X
29 15-16285 1/1	X	X	X	X	X	X	X	X	X
30 High-4	X	X	X	X	X	X	X	X	X
31 15-16409 1/1	X	X	X	X	X	X	X	X	X
32 High-5	X	X	X	X	X	X	X	X	X

02112016 ASG PBS-01152016-B Pipettes-2339, 3263

	ID	232	233
1	Blank-1	X	X
2	Blank-2	X	X
3	Cal-1	X	X
4	Cal-2	X	X
5	Neg-1	X	X
6	Neg-2	X	X
7	High-1	X	X
8	High-2	X	X
9	15-07384 1/1	X	X
10	15-12478 1/1	X	X
11	15-12731 1/1	X	X
12	15-17230 3/3	X	X
13	15-16272 1/1	X	X
14	15-16280 1/1	X	X
15	15-16094 1/1	X	X
16	15-15950 1/1	X	X
17	15-15944 1/1	X	X
18	15-15942 1/1	X	X
19	High-3	X	X
20	15-15958 1/1	X	X
21	15-16090 1/1	X	X
22	15-16089 1/1	X	X
23	15-16152 1/1	X	X
24	15-16173 1/1	X	X
25	15-16177 1/1	X	X
26	15-16179 1/1	X	X
27	15-16151 1/1	X	X
28	15-16153 1/1	X	X
29	15-16285 1/1	X	X
30	High-4	X	X
31	15-16409 1/1	X	X
32	High-5	X	X

ASL7

ID	221B
1 Blank-1	X
2 Blank-2	X
3 Cal-1	X
4 Cal-2	X
5 Neg-1	X
6 Neg-2	X
7 High-1	X
8 High-2	X
9 15-07384 1/1	X
10 15-12478 1/1	X
11 15-12731 1/1	X
12 15-17230 3/3	X
13 15-16272 1/1	X
14 15-16280 1/1	X
15 15-16094 1/1	X
16 15-15950 1/1	X
17 15-15944 1/1	X
18 15-15942 1/1	X
19 High-3	X
20 15-15958 1/1	X
21 15-16090 1/1	X
22 15-16089 1/1	X
23 15-16152 1/1	X
24 15-16173 1/1	X
25 15-16177 1/1	X
26 15-16179 1/1	X
27 15-16151 1/1	X
28 15-16153 1/1	X
29 15-16285 1/1	X
30 High-4	X
31 15-16409 1/1	X
32 High-5	X

ASL

IMMUNOASSAY Batch Report Blood

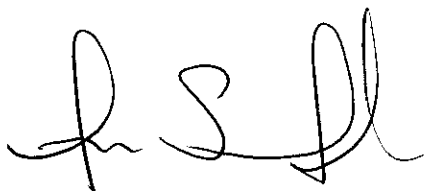
I-THCA

Date of Assay: 02.11.2016

Method: thc_b.mth ✓ KIT#: EK12951 ✓

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.862	0	2.82	1.9 ✓	100.00	4	
BLANK	2.786	0				4	
CALIBRATOR	1.182	10	1.16	3.0	40.99 ✓	10	
CALIBRATOR	1.133	10				10	
NEGATIVE	1.651	5	1.68	2.6	59.58	7	
NEGATIVE	1.714	5				7	
HIGH	0.65	20	0.65	1.1	22.84	18	
HIGH	0.64	20				18	
15-07384 1/1	2.756				97.59	4	
15-12478 1/1	2.768				98.02	4	
15-12731 1/1	2.796				99.01	4	
15-17230 3/3	2.525				89.41	5	
15-16272 1/1	0.325				11.51	36	pos
15-16280 1/1	0.303				10.73	38	pos
15-16094 1/1	2.318				82.08	5	
15-15950 1/1	0.122				4.32	95	pos
15-15944 1/1	0.12				4.25	96	pos
15-15942 1/1	0.176				6.23	66	pos
High-3	0.659				23.34	18	pos
15-15958 1/1	2.856				101.13	4	
15-16090 1/1	2.844				100.71	4	
15-16089 1/1	0.088				3.12	132	pos
15-16152 1/1	2.854				101.06	4	
15-16173 1/1	0.342				12.11	34	pos
15-16177 1/1	3.003				106.34	4	
15-16179 1/1	0.112				3.97	103	pos
15-16151 1/1	3.003				106.34	4	
15-16153 1/1	0.223				7.90	52	pos
15-16285 1/1	2.889				102.30	4	
High-4	0.723				25.60	16	pos

Examiner:



Date:

2/19/16

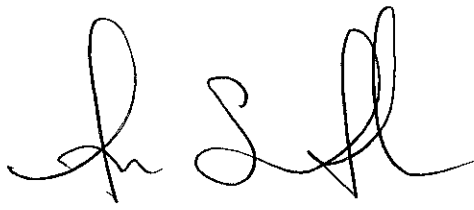
Reviewer:

TS

Date:

3/2/16

15-16409 1/1	0.073				2.58	159	pos
High-5	0.711				25.18	16	pos

Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

02112016-ASH

IMMUNOASSAY Batch Report Blood

OPIATES (OPI)

Date of Assay: 02.11.2016

Method: opi_b.mth / KIT#: EK13319 /

Sample ID	Absorbance	ng/ml	Avg. Abs	(abs)	binding	num.value	Results
BLANK	3.641	0	3.68	1.4	100.00	10	
BLANK	3.715	0				9	
CALIBRATOR	1.779	20	1.75	2.6	47.50	20	
CALIBRATOR	1.715	20				20	
NEGATIVE	2.257	10	2.38	7.1	64.61	15	
NEGATIVE	2.496	10				14	
HIGH	1.244	40	1.23	1.5	33.47	28	
HIGH	1.218	40				29	
15-07384 1/1	3.575				97.20	10	
15-12478 1/1	3.704				100.71	9	
15-12731 1/1	0.878				23.87	40	pos
15-17230 3/3	3.737				101.60	9	
15-16272 1/1	3.694				100.44	9	
15-16280 1/1	3.72				101.14	9	
15-16094 1/1	3.67				99.78	10	
15-15950 1/1	3.463				94.15	10	
15-15944 1/1	3.43				93.26	10	
15-15942 1/1	3.534				96.08	10	
High-3	1.128				30.67	31	pos
15-15958 1/1	3.573				97.15	10	
15-16090 1/1	3.56				96.79	10	
15-16089 1/1	1.369				37.22	26	pos
15-16152 1/1	3.633				98.78	10	
15-16173 1/1	3.609				98.12	10	
15-16177 1/1	3.524				95.81	10	
15-16179 1/1	3.636				98.86	10	
15-16151 1/1	3.717				101.06	9	
15-16153 1/1	3.762				102.28	9	
15-16285 1/1	3.751				101.98	9	
High-4	1.233				33.52	28	pos

Examiner:



Date:

2/19/16

Reviewer:

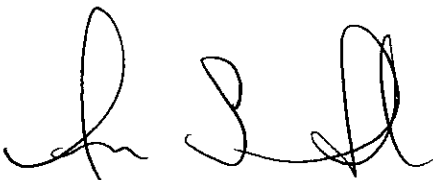
TB

Date:

3/7/16

15-16409 1/1	3.647				99.16	10	
High-5	1.139				30.97	31	pos

Examiner:



Date:

2/19/16

Reviewer:

TS

Date:

3/7/16

02112016-AR


IMMUNOASSAY Batch Report Blood

PHENCYCLIDINE (PCP)


Date of Assay: 02.11.2016

Method: pcp_b.mth ✓ KIT#: EK13322 ✓

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.413	0	3.48	2.9	100.00	4	
BLANK	3.556	0				3	
CALIBRATOR	1.224	10	1.23	1.1	35.41	10	
CALIBRATOR	1.244	10				10	
NEGATIVE	2.104	5	2.12	0.7	60.70	6	
NEGATIVE	2.126	5				6	
HIGH	0.713	20	0.68	6.3	19.59	17	
HIGH	0.652	20				19	
15-07384 1/1	3.303				94.79	4	
15-12478 1/1	3.403				97.66	4	
15-12731 1/1	3.379				96.97	4	
15-17230 3/3	3.386				97.17	4	
15-16272 1/1	3.384				97.12	4	
15-16280 1/1	3.403				97.66	4	
15-16094 1/1	3.317				95.19	4	
15-15950 1/1	3.374				96.83	4	
15-15944 1/1	3.384				97.12	4	
15-15942 1/1	0.42				12.05	29	pos
High-3	0.64				18.37	19 ✓	pos
15-15958 1/1	3.497				100.36	4	
15-16090 1/1	0.452				12.97	27	pos
15-16089 1/1	0.9				25.83	14	pos
15-16152 1/1	3.519				100.99	4	
15-16173 1/1	0.481				13.80	26	pos
15-16177 1/1	3.394				97.40	4	
15-16179 1/1	3.552				101.94	3	
15-16151 1/1	3.511				100.76	4	
15-16153 1/1	3.553				101.97	3	
15-16285 1/1	3.499				100.42	4	
High-4	0.655				18.80	19 ✓	pos

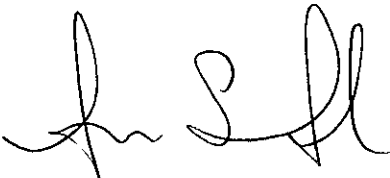
Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	3.514				100.85	4	
High-5	0.554				15.90	22	pos

Examiner: 

Reviewer: TS

Date: 2/19/14

Date: 3/7/16

02112016-ARL

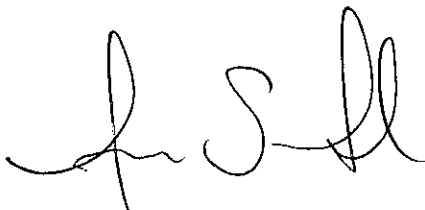
IMMUNOASSAY Batch Report Blood

d-Methamphetamine (Meth)

Date of Assay: 02.11.2016

Method: meth_b.mth / KIT#: EK13516 /

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.926	0	2.95	0.9 ✓	100.00	11	
BLANK	2.965	0				11	
CALIBRATOR	1.627	20	1.61	1.2	54.78 ✓	20	
CALIBRATOR	1.6	20				20	
NEGATIVE	1.919	10	1.92	0.4	65.34	17	
NEGATIVE	1.93	10				17	
HIGH	1.291	40	1.26	3.2	42.85	25	
HIGH	1.233	40				26	
15-07384 1/1	2.779				94.35	12	
15-12478 1/1	2.834				96.21	11	
15-12731 1/1	2.653				90.07	12	
15-17230 3/3	2.691				91.36	12	
15-16272 1/1	2.532				85.96	13	
15-16280 1/1	2.557				86.81	13	
15-16094 1/1	2.508				85.15	13	
15-15950 1/1	2.387				81.04	14	
15-15944 1/1	2.784				94.52	12	
15-15942 1/1	1.522				51.67	21	pos
High-3	1.271				43.15	25	pos
15-15958 1/1	2.736				92.89	12	
15-16090 1/1	2.679				90.95	12	
15-16089 1/1	2.644				89.76	12	
15-16152 1/1	2.572				87.32	13	
15-16173 1/1	2.53				85.89	13	
15-16177 1/1	2.25				76.39	14	
15-16179 1/1	2.862				97.17	11	
15-16151 1/1	2.594				88.07	12	
15-16153 1/1	2.405				81.65	13	
15-16285 1/1	2.475				84.03	13	
High-4	1.181				40.10	27	pos

Examiner: 

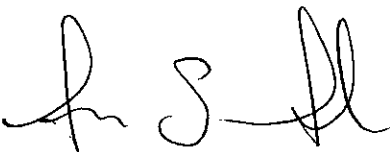
Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	2.544				86.37	13	
High-5	1.106				37.55	29	pos

✓

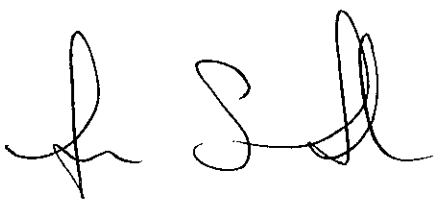
Examiner: 

Date: 2/19/14

Reviewer: TS

Date: 3/7/16

BENZOYLECGONINE (BE)							
Date of Assay:		02.11.2016					
Method: be_b.mth ✓		KIT#:		EK13059 ✓			
Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.514	0	2.52	0.6	100.00 ✓	11	
BLANK	2.534	0				11	
CALIBRATOR	1.369	20	1.42	5.5	56.42 ✓	21	
CALIBRATOR	1.479	20				19	
NEGATIVE	1.647	10	1.72	6.4	68.32	17	
NEGATIVE	1.802	10				16	
HIGH	1.145	40	1.17	2.7	46.26	25	
HIGH	1.19	40				24	
 							
15-07384 1/1	2.352				93.19	12	
15-12478 1/1	2.283				90.45	12	
15-12731 1/1	2.343				92.83	12	
15-17230 3/3	2.414				95.64	12	
15-16272 1/1	1.469				58.20	19	
15-16280 1/1	1.466				58.08	19	
15-16094 1/1	2.375				94.10	12	
15-15950 1/1	2.148				85.10	13	
15-15944 1/1	0.432				17.12	66	pos
15-15942 1/1	0.5				19.81	57	pos
High-3	1.102				43.66	26	pos
15-15958 1/1	2.492				98.73	11	
15-16090 1/1	2.563				101.55	11	
15-16089 1/1	2.431				96.32	12	
15-16152 1/1	2.719				107.73	10	
15-16173 1/1	2.517				99.72	11	
15-16177 1/1	2.461				97.50	12	
15-16179 1/1	0.991				39.26	29	pos
15-16151 1/1	2.473				97.98	12	
15-16153 1/1	2.606				103.25	11	
15-16285 1/1	2.442				96.75	12	
High-4	1.264				50.08	23	pos

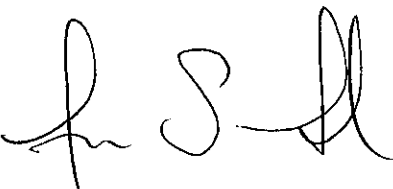
Examiner: 

Date: 2/19/16

Reviewer: TS

Date: 3/7/16

15-16409 1/1	2.533				100.36	11	
High-5	0.985				39.03	29	pos

Examiner: 

Reviewer: TS

Date: 2/19/14

Date: 3/7/16 02112016-ASH

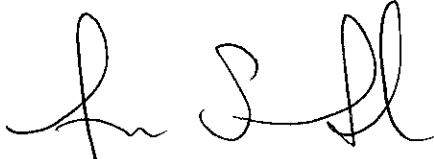
EIA Batch Report Blood

BENZODIAZEPINES (BENZO)

Date of Assay: 02.11.2016

Method: bz_b.mth KIT#: EK13286

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.548	0	3.59	1.5 ✓	100.00	9	
BLANK	3.623	0				9	
CALIBRATOR	1.592	20	1.66	6.1	46.40 ✓	21	
CALIBRATOR	1.735	20				19	
NEGATIVE	2.824	10	2.71	5.9	75.61	12	
NEGATIVE	2.598	10				13	
HIGH	1.209	40	1.15	7.1	32.12	28	
HIGH	1.094	40				30	
15-07384 1/1	0.693				19.33	48	pos
15-12478 1/1	3.16				88.13	11	
15-12731 1/1	3.566				99.46	9	
15-17230 3/3	3.652				101.85	9	
15-16272 1/1	3.658				102.02	9	
15-16280 1/1	3.456				96.39	10	
15-16094 1/1	0.132				3.68	252	pos
15-15950 1/1	0.165				4.60	202	pos
15-15944 1/1	0.17				4.74	196	pos
15-15942 1/1	3.57				99.57	9	
							pos
15-15958 1/1	3.421				95.41	10	
15-16090 1/1	3.484				97.17	10	
15-16089 1/1	0.327				9.12	102	pos
15-16152 1/1	3.5				97.62	10	
15-16173 1/1	3.588				100.07	9	
15-16177 1/1	3.312				92.37	10	
15-16179 1/1	0.229				6.39	145	pos
15-16151 1/1	3.457				96.42	10	
15-16153 1/1	3.449				96.19	10	
15-16285 1/1	3.424				95.50	10	
							pos

Examiner: 

Reviewer: B

Date: 19th 2/11/16

Date: 3/7/16

15-16409 1/1	0.658				18.35	51	pos
High-5	1.032				28.78	32	pos

Examiner:



Date: 2/19/14

Reviewer:

TB

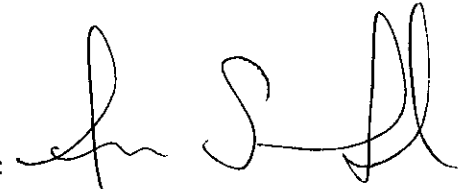
Date: 3/7/16

02112016-ASH

IMMUNOASSAY Batch Report Blood

BARBITURATES (BARB)

Date of Assay:		02.11.2016					
Method: barb_b.mth		KIT#:		EK13110			
Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.731	0	2.64	4.9	100.00	22	
BLANK	2.549	0				24	
CALIBRATOR	1.542	40	1.51	3.4	57.03	39	
CALIBRATOR	1.469	40				41	
NEGATIVE	1.589	20	1.57	2.0	59.34	38	
NEGATIVE	1.544	20				39	
HIGH	1.384	80	1.40	1.1	52.84	44	
HIGH	1.406	80				43	
15-07384 1/1	2.575				97.54	23	
15-12478 1/1	2.491				94.36	24	
15-12731 1/1	2.637				99.89	23	
15-17230 3/3	2.444				92.58	25	
15-16272 1/1	2.562				97.05	24	
15-16280 1/1	2.595				98.30	23	
15-16094 1/1	2.67				101.14	23	
15-15950 1/1	2.309				87.46	26	
15-15944 1/1	2.618				99.17	23	
15-15942 1/1	2.661				100.80	23	
High-3	1.364				51.67	44	pos
15-15958 1/1	2.649				100.34	23	
15-16090 1/1	2.552				96.67	24	
15-16089 1/1	2.679				101.48	22	
15-16152 1/1	2.983				112.99	20	
15-16173 1/1	2.719				102.99	22	
15-16177 1/1	2.766				104.77	22	
15-16179 1/1	2.499				94.66	24	
15-16151 1/1	2.541				96.25	24	
15-16153 1/1	2.298				87.05	26	
15-16285 1/1	2.467				93.45	24	
High-4	1.29				48.86	47	pos

Examiner: 

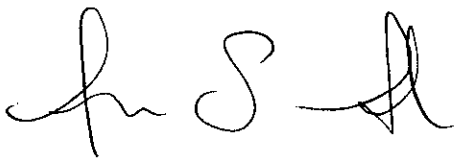
Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	1.883				71.33	32	
High-5	1.11				42.05	54	pos

ASL

Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

02/12/2016-ASL

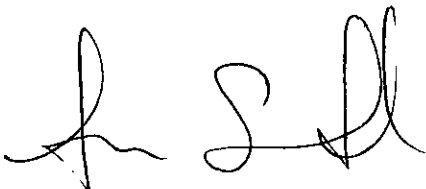
IMMUNOASSAY Batch Report Blood

AMPHETAMINES (AMP)

Date of Assay: 02.11.2016

Method: amp_b.mth KIT#: EK13421

Sample ID	Absorbance	ng/ml	Avg. Abs	(abs)	binding	num.value	Results
BLANK	3.301	0	3.26	2.0	100.00	8	
BLANK	3.211	0				9	
CALIBRATOR	1.397	20	1.38	2.2	42.26	20	
CALIBRATOR	1.355	20				20	
NEGATIVE	1.68	10	1.71	2.8	52.63	16	
NEGATIVE	1.747	10				16	
HIGH	0.904	40	0.93	3.5	28.47	30	
HIGH	0.95	40				29	
15-07384 1/1	3.234				99.32	9	
15-12478 1/1	3.009				92.41	9	
15-12731 1/1	3.156				96.93	9	
15-17230 3/3	2.867				88.05	10	
15-16272 1/1	2.923				89.77	9	
15-16280 1/1	2.934				90.11	9	
15-16094 1/1	3.17				97.36	9	
15-15950 1/1	2.963				91.00	9	
15-15944 1/1	3.269				100.40	8	
15-15942 1/1	2.661				81.73	10	
High-3	0.928				28.50	30	pos
15-15958 1/1	3.151				96.78	9	
15-16090 1/1	3.238				99.45	8	
15-16089 1/1	3.159				97.02	9	
15-16152 1/1	3.263				100.21	8	
15-16173 1/1	3.234				99.32	9	
15-16177 1/1	3.204				98.40	9	
15-16179 1/1	3.125				95.98	9	
15-16151 1/1	3.114				95.64	9	
15-16153 1/1	3.002				92.20	9	
15-16285 1/1	3.005				92.29	9	
High-4	0.955				29.33	29	pos

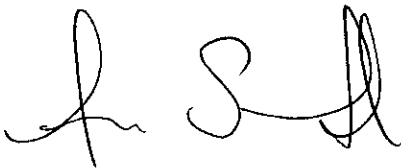
Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	3.116				95.70	9	
High-5	0.935				28.72	29	pos

Examiner: 

Reviewer: TS

Date: 2/19/16

Date: 3/7/16

02112016-AL


IMMUNOASSAY Batch Report Blood

CARISOPRODOL (CARISO)

Date of Assay: 02.11.2016

Method: cariso_b.mth KIT#: EK13129

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.008	0	3.03	1.1	100.00	188	
BLANK	3.056	0				186	
CALIBRATOR	1.178	500	1.13	5.5	37.40	481	
CALIBRATOR	1.09	500				520	
NEGATIVE	1.372	250	1.38	0.3	45.35	413	
NEGATIVE	1.378	250				411	
HIGH	0.933	1000	0.90	4.5	29.82	608	
HIGH	0.875	1000				648	
 							
15-07384 1/1	2.841				93.70	200	
15-12478 1/1	2.812				92.74	202	
15-12731 1/1	0.118				3.89	4805	pos
15-17230 3/3	2.865				94.49	198	
15-16272 1/1	2.804				92.48	202	
15-16280 1/1	2.879				94.95	197	
15-16094 1/1	0.085				2.80	6671	pos
15-15950 1/1	0.137				4.52	4139	pos
15-15944 1/1	2.825				93.17	201	
15-15942 1/1	2.856				94.20	199	
High-3	0.909				29.98	624	pos
15-15958 1/1	2.971				97.99	191	
15-16090 1/1	3.042				100.33	186	
15-16089 1/1	2.927				96.54	194	
15-16152 1/1	2.875				94.82	197	
15-16173 1/1	2.618				86.35	217	
15-16177 1/1	2.883				95.09	197	
15-16179 1/1	3.027				99.84	187	
15-16151 1/1	3.215				106.04	176	
15-16153 1/1	3.241				106.89	175	
15-16285 1/1	3.009				99.24	188	
High-4	0.932				30.74	608	pos

Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	3.089				101.88	184	
High-5	0.757				24.97	749	pos



Examiner: *[Signature]*

Date: 2/19/16

Reviewer: TB

Date: 3/7/16

02112016-*[Signature]*

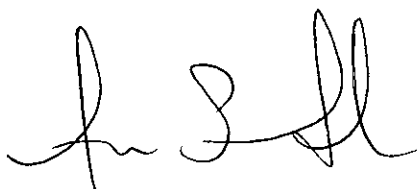
IMMUNOASSAY Batch Report Blood

METHADONE (MTDN)

Date of Assay: 02.11.2016

Method: mtdn_b.mth KIT#: EK13090

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.545	0	2.56	1.1	100.00	10	
BLANK	2.584	0				10	
CALIBRATOR	0.987	25	1.04	6.8	40.42	26	
CALIBRATOR	1.086	25				24	
NEGATIVE	1.768	12.5	1.72	3.9	67.11	15	
NEGATIVE	1.674	12.5				15	
HIGH	0.622	50	0.62	0.6	24.35	42	
HIGH	0.627	50				41	
Separator							
15-07384 1/1	2.634				102.71	10	
15-12478 1/1	2.222				86.64	12	
15-12731 1/1	2.49				97.09	10	
15-17230 3/3	2.181				85.05	12	
15-16272 1/1	2.414				94.13	11	
15-16280 1/1	2.425				94.56	11	
15-16094 1/1	2.448				95.46	11	
15-15950 1/1	1.722				67.15	15	
15-15944 1/1	2.459				95.89	11	
15-15942 1/1	2.804				109.34	9	
High-3	0.607				23.67	43	pos
15-15958 1/1	2.567				100.10	10	
15-16090 1/1	2.455				95.73	11	
15-16089 1/1	2.62				102.16	10	
15-16152 1/1	2.745				107.04	9	
15-16173 1/1	2.788				108.72	9	
15-16177 1/1	2.727				106.34	10	
15-16179 1/1	2.656				103.57	10	
15-16151 1/1	2.746				107.08	9	
15-16153 1/1	2.704				105.44	10	
15-16285 1/1	2.461				95.96	11	
High-4	0.668				26.05	39	pos

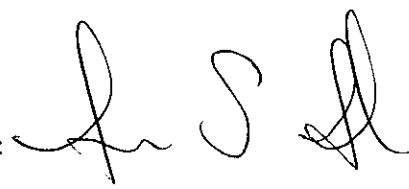
Examiner: 

Date: 2/19/16

Reviewer: TS

Date: 3/7/16

15-16409 1/1	2.485				96.90	10	
High-5	0.531				20.71	49	pos

Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

02112016 - 

IMMUNOASSAY Batch Report Blood

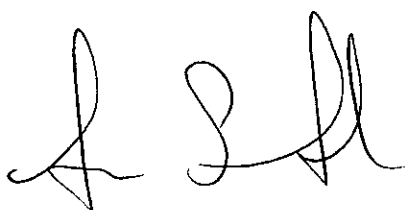
ZOLPIDEM (ZOL)

Date of Assay: 02.11.2016 ✓

Method: zol_b.mth ✓ KIT#: EK13573 ✓

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.546	0	3.51	1.5 ✓	100.00 ✓	3	
BLANK	3.47	0				3	
CALIBRATOR	1.871	5	1.83	3.1	52.18 ✓	5	
CALIBRATOR	1.79	5				5	
NEGATIVE	2.391	2.5	2.31	5.0	65.82	4	
NEGATIVE	2.227	2.5				4	
HIGH	1.371	10	1.43	5.7	40.74	7	
HIGH	1.487	10				6	
15-07384 1/1	3.374				96.18	3	
15-12478 1/1	3.446				98.23	3	
15-12731 1/1	3.228				92.02	3	
15-17230 3/3	3.296				93.96	3	
15-16272 1/1	3.161				90.11	3	
15-16280 1/1	3.199				91.19	3	
15-16094 1/1	3.254				92.76	3	
15-15950 1/1	3.114				88.77	3	
15-15944 1/1	3.426				97.66	3	
15-15942 1/1	3.494				99.60	3	
High-3	1.419				40.45	6	pos
15-15958 1/1	3.398				96.86	3	
15-16090 1/1	3.269				93.19	3	
15-16089 1/1	3.305				94.21	3	
15-16152 1/1	3.577				101.97	3	
15-16173 1/1	3.254				92.76	3	
15-16177 1/1	2.34				66.70	4	
15-16179 1/1	3.366				95.95	3	
15-16151 1/1	3.326				94.81	3	
15-16153 1/1	3.077				87.71	3	
15-16285 1/1	3.235				92.22	3	
High-4	1.299				37.03	7	pos

Examiner:




Date: 2/19/16

Reviewer:



Date: 3/7/16


15-16409 1/1	3.317				94.56	3	
High-5	1.255				35.78	7	pos

Examiner: 

Reviewer: 

Date: 2/19/16

Date: 3/7/16

02/12/16 - 

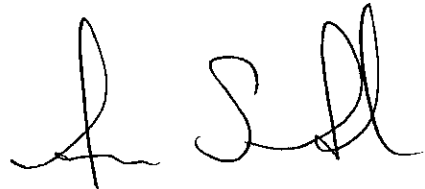
IMMUNOASSAY Batch Report Blood

OXYCODONE (OXY)

Date of Assay: 02.11.2016

Method: oxy_b.mth / KIT#: EK13204

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.793	0	2.89	4.7	100.00	3	
BLANK	2.986	0				3	
CALIBRATOR	0.675	10	0.83	26.2	28.67	12	
CALIBRATOR	0.982	10				8	
NEGATIVE	1.416	5	1.52	9.9	52.71	6	
NEGATIVE	1.63	5				5	
HIGH	0.495	20	0.51	4.2	17.65	17	
HIGH	0.525	20				16	
15-07384 1/1	2.599				89.95	3	
15-12478 1/1	2.663				92.16	3	
15-12731 1/1	1.194				41.32	7	
15-17230 3/3	2.655				91.88	3	
15-16272 1/1	2.606				90.19	3	
15-16280 1/1	2.617				90.57	3	
15-16094 1/1	2.518				87.14	3	
15-15950 1/1	2.383				82.47	3	
15-15944 1/1	2.658				91.99	3	
15-15942 1/1	2.812				97.32	3	
High-3	0.465				16.09	18	pos
15-15958 1/1	2.698				93.37	3	
15-16090 1/1	2.728				94.41	3	
15-16089 1/1	2.172				75.17	4	
15-16152 1/1	2.69				93.10	3	
15-16173 1/1	2.643				91.47	3	
15-16177 1/1	2.578				89.22	3	
15-16179 1/1	2.743				94.93	3	
15-16151 1/1	2.741				94.86	3	
15-16153 1/1	2.662				92.13	3	
15-16285 1/1	2.662				92.13	3	
High-4	0.477				16.51	17	pos

Examiner: 

Date: 2/19/16

Reviewer: 

Date: 3/7/16

15-16409 1/1	2.573				89.05	3	
High-5	0.493				17.06	17	pos

Examiner: 

Date: 2/19/14

Reviewer: TS

Date: 3/7/16

02/12/2016 

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	The_b	Blank-1	2.862	2.824	1.903	101.35	100		4.0444
B1	The_b	Blank-2	2.786			98.654			4.1547
C1	The_b	Cal-1	1.182	1.1575	2.9934	41.856	40.988		9.7927
D1	The_b	Cal-2	1.133			40.12			10.216
E1	The_b	Neg-1	1.651	1.6825	2.6477	58.463	59.579		7.0109
F1	The_b	Neg-2	1.714			60.694			6.7532
G1	The_b	High-1	0.65	0.645	1.0963	23.017	22.84		17.808
H1	The_b	High-2	0.64			22.663			18.086
A2	The_b	15-07384 1/1	2.756	2.756		97.592	97.592	neg	4.1999
B2	The_b	15-12478 1/1	2.768	2.768		98.017	98.017	neg	4.1817
C2	The_b	15-12731 1/1	2.796	2.796		99.008	99.008	neg	4.1398
D2	The_b	15-17230 3/3	2.525	2.525		89.412	89.412	neg	4.5842
E2	The_b	15-16272 1/1	0.325	0.325		11.508	11.508	pos	35.615
F2	The_b	15-16280 1/1	0.303	0.303		10.729	10.729	pos	38.201
G2	The_b	15-16094 1/1	2.318	2.318		82.082	82.082	neg	4.9935
H2	The_b	15-15950 1/1	0.122	0.122		4.3201	4.3201	pos	94.877
A3	The_b	15-15944 1/1	0.12	0.12		4.2493	4.2493	pos	96.458
B3	The_b	15-15942 1/1	0.176	0.176		6.2323	6.2323	pos	65.767
C3	The_b	High-3	0.659	0.691	6.5492	23.336	24.469		17.564
D3	The_b	15-15958 1/1	2.856	2.856		101.13	101.13	neg	4.0529
E3	The_b	15-16090 1/1	2.844	2.844		100.71	100.71	neg	4.07
F3	The_b	15-16089 1/1	0.088	0.088		3.1161	3.1161	pos	131.53
G3	The_b	15-16152 1/1	2.854	2.854		101.06	101.06	neg	4.0557
H3	The_b	15-16173 1/1	0.342	0.342		12.11	12.11	pos	33.845
A4	The_b	15-16177 1/1	3.003	3.003		106.34	106.34	neg	3.8545

- 1 Strip method names
- 2 Sample ID 1
- 3 Difference data
- 4 Difference data - Mean
- 5 Difference data - Variation coefficient
- 6 b/b0
- 7 b/b0 - Mean
- 8 Cutoff results
- 9 CONC

	1	2	3	4	5	6	7	8	9
B4	Thec_b	15-16179 1/1	0.112	0.112		3.966	3.966	pos	103.35
C4	Thec_b	15-16151 1/1	3.003	3.003		106.34	106.34	neg	3.8545
D4	Thec_b	15-16153 1/1	0.223	0.223		7.8966	7.8966	pos	51.906
E4	Thec_b	15-16285 1/1	2.889	2.889		102.3	102.3	neg	4.0066
F4	Thec_b	High-4	0.723			25.602			16.01
G4	Thec_b	15-16409 1/1	0.073	0.073		2.585	2.585	pos	158.56
H4	Thec_b	High-5	0.711	0.711		25.177	25.177	pos	16.28
A5	Opi_b	Blank-1	3.641	3.678	1.4227	98.994	100		9.5963
B5	Opi_b	Blank-2	3.715			101.01			9.4051
C5	Opi_b	Cal-1	1.779	1.747	2.5904	48.369	47.499		19.64
D5	Opi_b	Cal-2	1.715			46.629			20.373
E5	Opi_b	Neg-1	2.257	2.3765	7.1112	61.365	64.614		15.481
F5	Opi_b	Neg-2	2.496			67.863			13.998
G5	Opi_b	High-1	1.244	1.231	1.4935	33.823	33.469		28.087
H5	Opi_b	High-2	1.218			33.116			28.686
A6	Opi_b	15-07384 1/1	3.575	3.575		97.2	97.2	neg	9.7734
B6	Opi_b	15-12478 1/1	3.704	3.704		100.71	100.71	neg	9.433
C6	Opi_b	15-12731 1/1	0.878	0.878		23.872	23.872	pos	39.795
D6	Opi_b	15-17230 3/3	3.737	3.737		101.6	101.6	neg	9.3497
E6	Opi_b	15-16272 1/1	3.694	3.694		100.44	100.44	neg	9.4586
F6	Opi_b	15-16280 1/1	3.72	3.72		101.14	101.14	neg	9.3925
G6	Opi_b	15-16094 1/1	3.67	3.67		99.782	99.782	neg	9.5204
H6	Opi_b	15-15950 1/1	3.463	3.463		94.154	94.154	neg	10.09
A7	Opi_b	15-15944 1/1	3.43	3.43		93.257	93.257	neg	10.187
B7	Opi_b	15-15942 1/1	3.534	3.534		96.085	96.085	neg	9.8868

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
C7	Opi_b	High-3	1.128	1.1805	6.2894	30.669	32.096		30.975
D7	Opi_b	15-15958 1/1	3.573	3.573		97.145	97.145	neg	9.7789
E7	Opi_b	15-16090 1/1	3.56	3.56		96.792	96.792	neg	9.8146
F7	Opi_b	15-16089 1/1	1.369	1.369		37.221	37.221	pos	25.522
G7	Opi_b	15-16152 1/1	3.633	3.633		98.777	98.777	neg	9.6174
H7	Opi_b	15-16173 1/1	3.609	3.609		98.124	98.124	neg	9.6814
A8	Opi_b	15-16177 1/1	3.524	3.524		95.813	95.813	neg	9.9149
B8	Opi_b	15-16179 1/1	3.636	3.636		98.858	98.858	neg	9.6095
C8	Opi_b	15-16151 1/1	3.717	3.717		101.06	101.06	neg	9.4001
D8	Opi_b	15-16153 1/1	3.762	3.762		102.28	102.28	neg	9.2876
E8	Opi_b	15-16285 1/1	3.751	3.751		101.98	101.98	neg	9.3148
F8	Opi_b	High-4	1.233			33.524			28.337
G8	Opi_b	15-16409 1/1	3.647	3.647		99.157	99.157	neg	9.5805
H8	Opi_b	High-5	1.139	1.139		30.968	30.968	pos	30.676

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

Exp. Group Num 2

Validation criteria : Difference data

NC2>LPC2 --> TRUE

LPC2>PC2 --> TRUE

PC2>HPC2 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Pcp_b	Blank-1	3.413	3.4845	2.9019	97.948	100		3.6156
B1	Pcp_b	Blank-2	3.556			102.05			3.4702
C1	Pcp_b	Cal-1	1.224	1.234	1.146	35.127	35.414		10.082
D1	Pcp_b	Cal-2	1.244			35.701			9.9196
E1	Pcp_b	Neg-1	2.104	2.115	0.73552	60.382	60.697		5.865
F1	Pcp_b	Neg-2	2.126			61.013			5.8043
G1	Pcp_b	High-1	0.713	0.6825	6.3199	20.462	19.587		17.307
H1	Pcp_b	High-2	0.652			18.711			18.926
A2	Pcp_b	15-07384 1/1	3.303	3.303		94.791	94.791	neg	3.736
B2	Pcp_b	15-12478 1/1	3.403	3.403		97.661	97.661	neg	3.6262
C2	Pcp_b	15-12731 1/1	3.379	3.379		96.972	96.972	neg	3.652
D2	Pcp_b	15-17230 3/3	3.386	3.386		97.173	97.173	neg	3.6444
E2	Pcp_b	15-16272 1/1	3.384	3.384		97.116	97.116	neg	3.6466
F2	Pcp_b	15-16280 1/1	3.403	3.403		97.661	97.661	neg	3.6262
G2	Pcp_b	15-16094 1/1	3.317	3.317		95.193	95.193	neg	3.7202
H2	Pcp_b	15-15950 1/1	3.374	3.374		96.829	96.829	neg	3.6574
A3	Pcp_b	15-15944 1/1	3.384	3.384		97.116	97.116	neg	3.6466
B3	Pcp_b	15-15942 1/1	0.42	0.42		12.053	12.053	pos	29.381
C3	Pcp_b	High-3	0.64	0.6475	1.6381	18.367	18.582		19.281
D3	Pcp_b	15-15958 1/1	3.497	3.497		100.36	100.36	neg	3.5287
E3	Pcp_b	15-16090 1/1	0.452	0.452		12.972	12.972	pos	27.301
F3	Pcp_b	15-16089 1/1	0.9	0.9		25.829	25.829	pos	13.711
G3	Pcp_b	15-16152 1/1	3.519	3.519		100.99	100.99	neg	3.5067
H3	Pcp_b	15-16173 1/1	0.481	0.481		13.804	13.804	pos	25.655
A4	Pcp_b	15-16177 1/1	3.394	3.394		97.403	97.403	neg	3.6358

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Pcp_b	15-16179 1/1	3.552	3.552		101.94	101.94	neg	3.4741
C4	Pcp_b	15-16151 1/1	3.511	3.511		100.76	100.76	neg	3.5147
D4	Pcp_b	15-16153 1/1	3.553	3.553		101.97	101.97	neg	3.4731
E4	Pcp_b	15-16285 1/1	3.499	3.499		100.42	100.42	neg	3.5267
F4	Pcp_b	High-4	0.655			18.798			18.84
G4	Pcp_b	15-16409 1/1	3.514	3.514		100.85	100.85	neg	3.5117
H4	Pcp_b	High-5	0.554	0.554		15.899	15.899	pos	22.274
A5	Meth_b	Blank-1	2.926	2.9455	0.93625	99.338	100		11.029
B5	Meth_b	Blank-2	2.965			100.66			10.884
C5	Meth_b	Cal-1	1.627	1.6135	1.1833	55.237	54.778		19.834
D5	Meth_b	Cal-2	1.6			54.32			20.169
E5	Meth_b	Neg-1	1.919	1.9245	0.40417	65.15	65.337		16.816
F5	Meth_b	Neg-2	1.93			65.524			16.72
G5	Meth_b	High-1	1.291	1.262	3.2498	43.83	42.845		24.996
H5	Meth_b	High-2	1.233			41.86			26.172
A6	Meth_b	15-07384 1/1	2.779	2.779		94.347	94.347	neg	11.612
B6	Meth_b	15-12478 1/1	2.834	2.834		96.215	96.215	neg	11.387
C6	Meth_b	15-12731 1/1	2.653	2.653		90.07	90.07	neg	12.164
D6	Meth_b	15-17230 3/3	2.691	2.691		91.36	91.36	neg	11.992
E6	Meth_b	15-16272 1/1	2.532	2.532		85.962	85.962	neg	12.745
F6	Meth_b	15-16280 1/1	2.557	2.557		86.81	86.81	neg	12.62
G6	Meth_b	15-16094 1/1	2.508	2.508		85.147	85.147	neg	12.867
H6	Meth_b	15-15950 1/1	2.387	2.387		81.039	81.039	neg	13.519
A7	Meth_b	15-15944 1/1	2.784	2.784		94.517	94.517	neg	11.591
B7	Meth_b	15-15942 1/1	1.522	1.522		51.672	51.672	pos	21.202

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
C7	Meth_b	High-3	1.271	1.226	5.1908	43.151	41.623		25.389
D7	Meth_b	15-15958 1/1	2.736	2.736		92.887	92.887	neg	11.795
E7	Meth_b	15-16090 1/1	2.679	2.679		90.952	90.952	neg	12.046
F7	Meth_b	15-16089 1/1	2.644	2.644		89.764	89.764	neg	12.205
G7	Meth_b	15-16152 1/1	2.572	2.572		87.32	87.32	neg	12.547
H7	Meth_b	15-16173 1/1	2.53	2.53		85.894	85.894	neg	12.755
A8	Meth_b	15-16177 1/1	2.25	2.25		76.388	76.388	neg	14.342
B8	Meth_b	15-16179 1/1	2.862	2.862		97.165	97.165	neg	11.275
C8	Meth_b	15-16151 1/1	2.594	2.594		88.067	88.067	neg	12.44
D8	Meth_b	15-16153 1/1	2.405	2.405		81.65	81.65	neg	13.418
E8	Meth_b	15-16285 1/1	2.475	2.475		84.026	84.026	neg	13.038
F8	Meth_b	High-4	1.181			40.095			27.324
G8	Meth_b	15-16409 1/1	2.544	2.544		86.369	86.369	neg	12.685
H8	Meth_b	High-5	1.106	1.106		37.549	37.549	pos	29.177

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

Exp. Group Num 2

Validation criteria : Difference data

NC2>LPC2 --> TRUE

LPC2>PC2 --> TRUE

PC2>HPC2 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Be_b	Blank-1	2.514	2.524	0.56031	99.604	100		28.321
B1	Be_b	Blank-2	2.534			100.4			28.098
C1	Be_b	Cal-1	1.369	1.424	5.4622	54.239	56.418		52.009
D1	Be_b	Cal-2	1.479			58.597			48.141
E1	Be_b	Neg-1	1.647	1.7245	6.3556	65.254	68.324		43.23
F1	Be_b	Neg-2	1.802			71.395			39.512
G1	Be_b	High-1	1.145	1.1675	2.7255	45.365	46.256		62.183
H1	Be_b	High-2	1.19			47.147			59.832
A2	Be_b	15-07384 1/1	2.352	2.352		93.185	93.185	neg	30.272
B2	Be_b	15-12478 1/1	2.283	2.283		90.452	90.452	neg	31.187
C2	Be_b	15-12731 1/1	2.343	2.343		92.829	92.829	neg	30.388
D2	Be_b	15-17230 3/3	2.414	2.414		95.642	95.642	neg	29.495
E2	Be_b	15-16272 1/1	1.469	1.469		58.201	58.201	neg	48.468
F2	Be_b	15-16280 1/1	1.466	1.466		58.082	58.082	neg	48.568
G2	Be_b	15-16094 1/1	2.375	2.375		94.097	94.097	neg	29.979
H2	Be_b	15-15950 1/1	2.148	2.148		85.103	85.103	neg	33.147
A3	Be_b	15-15944 1/1	0.432	0.432		17.116	17.116	pos	164.81
B3	Be_b	15-15942 1/1	0.5	0.5		19.81	19.81	pos	142.4
C3	Be_b	High-3	1.102	1.183	9.6831	43.661	46.87		64.61
D3	Be_b	15-15958 1/1	2.492	2.492		98.732	98.732	neg	28.571
E3	Be_b	15-16090 1/1	2.563	2.563		101.55	101.55	neg	27.78
F3	Be_b	15-16089 1/1	2.431	2.431		96.315	96.315	neg	29.288
G3	Be_b	15-16152 1/1	2.719	2.719		107.73	107.73	neg	26.186
H3	Be_b	15-16173 1/1	2.517	2.517		99.723	99.723	neg	28.288
A4	Be_b	15-16177 1/1	2.461	2.461		97.504	97.504	neg	28.931

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Be_b	15-16179 1/1	0.991	0.991		39.263	39.263	pos	71.847
C4	Be_b	15-16151 1/1	2.473	2.473		97.979	97.979	neg	28.791
D4	Be_b	15-16153 1/1	2.606	2.606		103.25	103.25	neg	27.322
E4	Be_b	15-16285 1/1	2.442	2.442		96.751	96.751	neg	29.156
F4	Be_b	High-4	1.264			50.079			56.329
G4	Be_b	15-16409 1/1	2.533	2.533		100.36	100.36	neg	28.109
H4	Be_b	High-5	0.985	0.985		39.025	39.025	pos	72.284
A5	Oxa_b	Blank-1	3.548	3.5855	1.4791	98.954	100		23.443
B5	Oxa_b	Blank-2	3.623			101.05			22.957
C5	Oxa_b	Cal-1	1.592	1.6635	6.0785	44.401	46.395		52.246
D5	Oxa_b	Cal-2	1.735			48.389			47.939
E5	Oxa_b	Neg-1	2.824	2.711	5.8947	78.762	75.61		29.453
F5	Oxa_b	Neg-2	2.598			72.459			32.015
G5	Oxa_b	High-1	1.209	1.1515	7.0619	33.719	32.115		68.797
H5	Oxa_b	High-2	1.094			30.512			76.028
A6	Oxa_b	15-07384 1/1	0.693	0.693		19.328	19.328	pos	120.02
B6	Oxa_b	15-12478 1/1	3.16	3.16		88.133	88.133	neg	26.321
C6	Oxa_b	15-12731 1/1	3.566	3.566		99.456	99.456	neg	23.324
D6	Oxa_b	15-17230 3/3	3.652	3.652		101.85	101.85	neg	22.775
E6	Oxa_b	15-16272 1/1	3.658	3.658		102.02	102.02	neg	22.738
F6	Oxa_b	15-16280 1/1	3.456	3.456		96.388	96.388	neg	24.067
G6	Oxa_b	15-16094 1/1	0.132	0.132		3.6815	3.6815	pos	630.11
H6	Oxa_b	15-15950 1/1	0.165	0.165		4.6019	4.6019	pos	504.09
A7	Oxa_b	15-15944 1/1	0.17	0.17		4.7413	4.7413	pos	489.26
B7	Oxa_b	15-15942 1/1	3.57	3.57		99.568	99.568	neg	23.298

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
C7	Oxa_b	High-3	1.143	1.1135	3.7467	31.878	31.056		72.769
D7	Oxa_b	15-15958 1/1	3.421	3.421		95.412	95.412	neg	24.313
E7	Oxa_b	15-16090 1/1	3.484	3.484		97.169	97.169	neg	23.873
F7	Oxa_b	15-16089 1/1	0.327	0.327		9.1201	9.1201	pos	254.36
G7	Oxa_b	15-16152 1/1	3.5	3.5		97.615	97.615	neg	23.764
H7	Oxa_b	15-16173 1/1	3.588	3.588		100.07	100.07	neg	23.181
A8	Oxa_b	15-16177 1/1	3.312	3.312		92.372	92.372	neg	25.113
B8	Oxa_b	15-16179 1/1	0.229	0.229		6.3868	6.3868	pos	363.21
C8	Oxa_b	15-16151 1/1	3.457	3.457		96.416	96.416	neg	24.06
D8	Oxa_b	15-16153 1/1	3.449	3.449		96.193	96.193	neg	24.116
E8	Oxa_b	15-16285 1/1	3.424	3.424		95.496	95.496	neg	24.292
F8	Oxa_b	High-4	1.084			30.233			76.73
G8	Oxa_b	15-16409 1/1	0.658	0.658		18.352	18.352	pos	126.41
H8	Oxa_b	High-5	1.032	1.032		28.783	28.783	pos	80.596

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

Exp. Group Num 2

Validation criteria : Difference data

NC2>LPC2 --> TRUE

LPC2>PC2 --> TRUE

PC2>HPC2 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Barb_b	Blank-1	2.731	2.64	4.8748	103.45	100		27.563
B1	Barb_b	Blank-2	2.549			96.553			29.531
C1	Barb_b	Cal-1	1.542	1.5055	3.4287	58.409	57.027		48.816
D1	Barb_b	Cal-2	1.469			55.644			51.242
E1	Barb_b	Neg-1	1.589	1.5665	2.0313	60.189	59.337		47.373
F1	Barb_b	Neg-2	1.544			58.485			48.753
G1	Barb_b	High-1	1.384	1.395	1.1152	52.424	52.841		54.389
H1	Barb_b	High-2	1.406			53.258			53.538
A2	Barb_b	15-07384 1/1	2.575	2.575		97.538	97.538	neg	29.233
B2	Barb_b	15-12478 1/1	2.491	2.491		94.356	94.356	neg	30.219
C2	Barb_b	15-12731 1/1	2.637	2.637		99.886	99.886	neg	28.546
D2	Barb_b	15-17230 3/3	2.444	2.444		92.576	92.576	neg	30.8
E2	Barb_b	15-16272 1/1	2.562	2.562		97.045	97.045	neg	29.381
F2	Barb_b	15-16280 1/1	2.595	2.595		98.295	98.295	neg	29.008
G2	Barb_b	15-16094 1/1	2.67	2.67		101.14	101.14	neg	28.193
H2	Barb_b	15-15950 1/1	2.309	2.309		87.462	87.462	neg	32.601
A3	Barb_b	15-15944 1/1	2.618	2.618		99.167	99.167	neg	28.753
B3	Barb_b	15-15942 1/1	2.661	2.661		100.8	100.8	neg	28.288
C3	Barb_b	High-3	1.364	1.327	3.9432	51.667	50.265		55.187
D3	Barb_b	15-15958 1/1	2.649	2.649		100.34	100.34	neg	28.416
E3	Barb_b	15-16090 1/1	2.552	2.552		96.667	96.667	neg	29.496
F3	Barb_b	15-16089 1/1	2.679	2.679		101.48	101.48	neg	28.098
G3	Barb_b	15-16152 1/1	2.983	2.983		112.99	112.99	neg	25.235
H3	Barb_b	15-16173 1/1	2.719	2.719		102.99	102.99	neg	27.685
A4	Barb_b	15-16177 1/1	2.766	2.766		104.77	104.77	neg	27.214

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Barb_b	15-16179 1/1	2.499	2.499		94.659	94.659	neg	30.122
C4	Barb_b	15-16151 1/1	2.541	2.541		96.25	96.25	neg	29.624
D4	Barb_b	15-16153 1/1	2.298	2.298		87.045	87.045	neg	32.757
E4	Barb_b	15-16285 1/1	2.467	2.467		93.447	93.447	neg	30.513
F4	Barb_b	High-4	1.29			48.864			58.353
G4	Barb_b	15-16409 1/1	1.883	1.883		71.326	71.326	neg	39.976
H4	Barb_b	High-5	1.11	1.11		42.045	42.045	pos	67.815
A5	Amp_b	Blank-1	3.301	3.256	1.9545	101.38	100		8.3369
B5	Amp_b	Blank-2	3.211			98.618			8.5705
C5	Amp_b	Cal-1	1.397	1.376	2.1583	42.905	42.26		19.699
D5	Amp_b	Cal-2	1.355			41.615			20.31
E5	Amp_b	Neg-1	1.68	1.7135	2.7649	51.597	52.626		16.381
F5	Amp_b	Neg-2	1.747			53.655			15.753
G5	Amp_b	High-1	0.904	0.927	3.5088	27.764	28.471		30.442
H5	Amp_b	High-2	0.95			29.177			28.968
A6	Amp_b	15-07384 1/1	3.234	3.234		99.324	99.324	neg	8.5096
B6	Amp_b	15-12478 1/1	3.009	3.009		92.414	92.414	neg	9.1459
C6	Amp_b	15-12731 1/1	3.156	3.156		96.929	96.929	neg	8.7199
D6	Amp_b	15-17230 3/3	2.867	2.867		88.053	88.053	neg	9.5989
E6	Amp_b	15-16272 1/1	2.923	2.923		89.773	89.773	neg	9.415
F6	Amp_b	15-16280 1/1	2.934	2.934		90.111	90.111	neg	9.3797
G6	Amp_b	15-16094 1/1	3.17	3.17		97.359	97.359	neg	8.6814
H6	Amp_b	15-15950 1/1	2.963	2.963		91.001	91.001	neg	9.2879
A7	Amp_b	15-15944 1/1	3.269	3.269		100.4	100.4	neg	8.4185
B7	Amp_b	15-15942 1/1	2.661	2.661		81.726	81.726	neg	10.342

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
C7	Amp_b	High-3	0.928	0.9415	2.0278	28.501	28.916		29.655
D7	Amp_b	15-15958 1/1	3.151	3.151		96.775	96.775	neg	8.7337
E7	Amp_b	15-16090 1/1	3.238	3.238		99.447	99.447	neg	8.4991
F7	Amp_b	15-16089 1/1	3.159	3.159		97.021	97.021	neg	8.7116
G7	Amp_b	15-16152 1/1	3.263	3.263		100.21	100.21	neg	8.434
H7	Amp_b	15-16173 1/1	3.234	3.234		99.324	99.324	neg	8.5096
A8	Amp_b	15-16177 1/1	3.204	3.204		98.403	98.403	neg	8.5893
B8	Amp_b	15-16179 1/1	3.125	3.125		95.977	95.977	neg	8.8064
C8	Amp_b	15-16151 1/1	3.114	3.114		95.639	95.639	neg	8.8375
D8	Amp_b	15-16153 1/1	3.002	3.002		92.199	92.199	neg	9.1672
E8	Amp_b	15-16285 1/1	3.005	3.005		92.291	92.291	neg	9.1581
F8	Amp_b	High-4	0.955			29.33			28.817
G8	Amp_b	15-16409 1/1	3.116	3.116		95.7	95.7	neg	8.8318
H8	Amp_b	High-5	0.935	0.935		28.716	28.716	pos	29.433

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

Exp. Group Num 2

Validation criteria : Difference data

NC2>LPC2 --> TRUE

LPC2>PC2 --> TRUE

PC2>HPC2 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Cariso_b	Blank-1	3.008	3.032	1.1194	99.208	100		7.5399
B1	Cariso_b	Blank-2	3.056			100.79			7.4215
C1	Cariso_b	Cal-1	1.178	1.134	5.4872	38.852	37.401		19.253
D1	Cariso_b	Cal-2	1.09			35.95			20.807
E1	Cariso_b	Neg-1	1.372	1.375	0.30856	45.251	45.35		16.531
F1	Cariso_b	Neg-2	1.378			45.449			16.459
G1	Cariso_b	High-1	0.933	0.904	4.5367	30.772	29.815		24.309
H1	Cariso_b	High-2	0.875			28.859			25.92
A2	Cariso_b	15-07384 1/1	2.841	2.841		93.701	93.701	neg	7.9831
B2	Cariso_b	15-12478 1/1	2.812	2.812		92.744	92.744	neg	8.0654
C2	Cariso_b	15-12731 1/1	0.118	0.118		3.8918	3.8918	pos	192.2
D2	Cariso_b	15-17230 3/3	2.865	2.865		94.492	94.492	neg	7.9162
E2	Cariso_b	15-16272 1/1	2.804	2.804		92.48	92.48	neg	8.0884
F2	Cariso_b	15-16280 1/1	2.879	2.879		94.954	94.954	neg	7.8777
G2	Cariso_b	15-16094 1/1	0.085	0.085		2.8034	2.8034	pos	266.82
H2	Cariso_b	15-15950 1/1	0.137	0.137		4.5185	4.5185	pos	165.55
A3	Cariso_b	15-15944 1/1	2.825	2.825		93.173	93.173	neg	8.0283
B3	Cariso_b	15-15942 1/1	2.856	2.856		94.195	94.195	neg	7.9412
C3	Cariso_b	High-3	0.909	0.9205	1.7668	29.98	30.359		24.95
D3	Cariso_b	15-15958 1/1	2.971	2.971		97.988	97.988	neg	7.6338
E3	Cariso_b	15-16090 1/1	3.042	3.042		100.33	100.33	neg	7.4556
F3	Cariso_b	15-16089 1/1	2.927	2.927		96.537	96.537	neg	7.7485
G3	Cariso_b	15-16152 1/1	2.875	2.875		94.822	94.822	neg	7.8887
H3	Cariso_b	15-16173 1/1	2.618	2.618		86.346	86.346	neg	8.6631
A4	Cariso_b	15-16177 1/1	2.883	2.883		95.086	95.086	neg	7.8668

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Cariso_b	15-16179 1/1	3.027	3.027		99.835	99.835	neg	7.4926
C4	Cariso_b	15-16151 1/1	3.215	3.215		106.04	106.04	neg	7.0544
D4	Cariso_b	15-16153 1/1	3.241	3.241		106.89	106.89	neg	6.9978
E4	Cariso_b	15-16285 1/1	3.009	3.009		99.241	99.241	neg	7.5374
F4	Cariso_b	High-4	0.932			30.739			24.335
G4	Cariso_b	15-16409 1/1	3.089	3.089		101.88	101.88	neg	7.3422
H4	Cariso_b	High-5	0.757	0.757		24.967	24.967	pos	29.96
A5	Mtdn_b	Blank-1	2.545	2.5645	1.0753	99.24	100		8.1454
B5	Mtdn_b	Blank-2	2.584			100.76			8.0224
C5	Mtdn_b	Cal-1	0.987	1.0365	6.7538	38.487	40.417		21.003
D5	Mtdn_b	Cal-2	1.086			42.347			19.088
E5	Mtdn_b	Neg-1	1.768	1.721	3.8622	68.941	67.109		11.725
F5	Mtdn_b	Neg-2	1.674			65.276			12.384
G5	Mtdn_b	High-1	0.622	0.6245	0.56614	24.254	24.352		33.328
H5	Mtdn_b	High-2	0.627			24.449			33.062
A6	Mtdn_b	15-07384 1/1	2.634	2.634		102.71	102.71	neg	7.8702
B6	Mtdn_b	15-12478 1/1	2.222	2.222		86.645	86.645	neg	9.3294
C6	Mtdn_b	15-12731 1/1	2.49	2.49		97.095	97.095	neg	8.3253
D6	Mtdn_b	15-17230 3/3	2.181	2.181		85.046	85.046	neg	9.5048
E6	Mtdn_b	15-16272 1/1	2.414	2.414		94.131	94.131	neg	8.5874
F6	Mtdn_b	15-16280 1/1	2.425	2.425		94.56	94.56	neg	8.5485
G6	Mtdn_b	15-16094 1/1	2.448	2.448		95.457	95.457	neg	8.4681
H6	Mtdn_b	15-15950 1/1	1.722	1.722		67.148	67.148	neg	12.038
A7	Mtdn_b	15-15944 1/1	2.459	2.459		95.886	95.886	neg	8.4303
B7	Mtdn_b	15-15942 1/1	2.804	2.804		109.34	109.34	neg	7.393

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
C7	Mtdn_b	High-3	0.607	0.6375	6.766	23.669	24.859		34.152
D7	Mtdn_b	15-15958 1/1	2.567	2.567		100.1	100.1	neg	8.0756
E7	Mtdn_b	15-16090 1/1	2.455	2.455		95.73	95.73	neg	8.444
F7	Mtdn_b	15-16089 1/1	2.62	2.62		102.16	102.16	neg	7.9122
G7	Mtdn_b	15-16152 1/1	2.745	2.745		107.04	107.04	neg	7.5519
H7	Mtdn_b	15-16173 1/1	2.788	2.788		108.72	108.72	neg	7.4354
A8	Mtdn_b	15-16177 1/1	2.727	2.727		106.34	106.34	neg	7.6018
B8	Mtdn_b	15-16179 1/1	2.656	2.656		103.57	103.57	neg	7.805
C8	Mtdn_b	15-16151 1/1	2.746	2.746		107.08	107.08	neg	7.5492
D8	Mtdn_b	15-16153 1/1	2.704	2.704		105.44	105.44	neg	7.6664
E8	Mtdn_b	15-16285 1/1	2.461	2.461		95.964	95.964	neg	8.4234
F8	Mtdn_b	High-4	0.668			26.048			31.033
G8	Mtdn_b	15-16409 1/1	2.485	2.485		96.9	96.9	neg	8.3421
H8	Mtdn_b	High-5	0.531	0.531		20.706	20.706	pos	39.04

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

Exp. Group Num 2

Validation criteria : Difference data

NC2>LPC2 --> TRUE

LPC2>PC2 --> TRUE

PC2>HPC2 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Zol_b	Blank-1	3.546	3.508	1.532	101.1	100		10.32
B1	Zol_b	Blank-2	3.47			98.92			10.55
C1	Zol_b	Cal-1	1.871	1.831	3.129	53.34	52.18		19.57
D1	Zol_b	Cal-2	1.79			51.03			20.45
E1	Zol_b	Neg-1	2.391	2.309	5.022	68.16	65.82		15.31
F1	Zol_b	Neg-2	2.227			63.48			16.44
G1	Zol_b	High-1	1.371	1.429	5.74	39.08	40.74		26.7
H1	Zol_b	High-2	1.487			42.39			24.62
A2	Zol_b	15-07384 1/1	3.374	3.374		96.18	96.18	neg	10.85
B2	Zol_b	15-12478 1/1	3.446	3.446		98.23	98.23	neg	10.62
C2	Zol_b	15-12731 1/1	3.228	3.228		92.02	92.02	neg	11.34
D2	Zol_b	15-17230 3/3	3.296	3.296		93.96	93.96	neg	11.11
E2	Zol_b	15-16272 1/1	3.161	3.161		90.11	90.11	neg	11.58
F2	Zol_b	15-16280 1/1	3.199	3.199		91.19	91.19	neg	11.44
G2	Zol_b	15-16094 1/1	3.254	3.254		92.76	92.76	neg	11.25
H2	Zol_b	15-15950 1/1	3.114	3.114		88.77	88.77	neg	11.76
A3	Zol_b	15-15944 1/1	3.426	3.426		97.66	97.66	neg	10.69
B3	Zol_b	15-15942 1/1	3.494	3.494		99.6	99.6	neg	10.48
C3	Zol_b	High-3	1.419	0.3398	185.4	40.45	9.685		25.8
D3	Zol_b	15-15958 1/1	3.398	3.398		96.86	96.86	neg	10.77
E3	Zol_b	15-16090 1/1	3.269	3.269		93.19	93.19	neg	11.2
F3	Zol_b	15-16089 1/1	3.305	3.305		94.21	94.21	neg	11.08
G3	Zol_b	15-16152 1/1	3.577	3.577		102	102	neg	10.23
H3	Zol_b	15-16173 1/1	3.254	3.254		92.76	92.76	neg	11.25
A4	Zol_b	15-16177 1/1	2.34	2.34		66.7	66.7	neg	15.65

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Zol_b	15-16179 1/1	3.366	3.366		95.95	95.95	neg	10.88
C4	Zol_b	15-16151 1/1	3.326	3.326		94.81	94.81	neg	11.01
D4	Zol_b	15-16153 1/1	3.077	3.077		87.71	87.71	neg	11.9
E4	Zol_b	15-16285 1/1	3.235	3.235		92.22	92.22	neg	11.32
F4	Zol_b	High-4	1.299			37.03			28.18
G4	Zol_b	15-16409 1/1	3.317	3.317		94.56	94.56	neg	11.04
H4	Zol_b	High-5	1.255	1.255		35.78	35.78	pos	29.17
A6	Zol_b		0			0			NoCalc
D7	Zol_b		0			0			NoCalc
G8	Zol_b		0			0			NoCalc
C10	Zol_b		0			0			NoCalc
E11	Zol_b		0			0			NoCalc
G12	Zol_b		0			0			NoCalc

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PC1 --> TRUE

PC1>HPC1 --> TRUE

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
A1	Oxy_b	Blank-1	2.793	2.89	4.723	96.66	100		5.933
B1	Oxy_b	Blank-2	2.986			103.3			5.549
C1	Oxy_b	Cal-1	0.675	0.8285	26.2	23.36	28.67		24.55
D1	Oxy_b	Cal-2	0.982			33.99			16.87
E1	Oxy_b	Neg-1	1.416	1.523	9.936	49.01	52.71		11.7
F1	Oxy_b	Neg-2	1.63			56.41			10.17
G1	Oxy_b	High-1	0.495	0.51	4.159	17.13	17.65		33.47
H1	Oxy_b	High-2	0.525			18.17			31.56
A2	Oxy_b	15-07384 1/1	2.599	2.599		89.95	89.95	neg	6.376
B2	Oxy_b	15-12478 1/1	2.663	2.663		92.16	92.16	neg	6.222
C2	Oxy_b	15-12731 1/1	1.194	1.194		41.32	41.32	neg	13.88
D2	Oxy_b	15-17230 3/3	2.655	2.655		91.88	91.88	neg	6.241
E2	Oxy_b	15-16272 1/1	2.606	2.606		90.19	90.19	neg	6.358
F2	Oxy_b	15-16280 1/1	2.617	2.617		90.57	90.57	neg	6.332
G2	Oxy_b	15-16094 1/1	2.518	2.518		87.14	87.14	neg	6.581
H2	Oxy_b	15-15950 1/1	2.383	2.383		82.47	82.47	neg	6.953
A3	Oxy_b	15-15944 1/1	2.658	2.658		91.99	91.99	neg	6.234
B3	Oxy_b	15-15942 1/1	2.812	2.812		97.32	97.32	neg	5.893
C3	Oxy_b	High-3	0.465	0.1177	185.2	16.09	4.075		35.63
D3	Oxy_b	15-15958 1/1	2.698	2.698		93.37	93.37	neg	6.142
E3	Oxy_b	15-16090 1/1	2.728	2.728		94.41	94.41	neg	6.074
F3	Oxy_b	15-16089 1/1	2.172	2.172		75.17	75.17	neg	7.629
G3	Oxy_b	15-16152 1/1	2.69	2.69		93.1	93.1	neg	6.16
H3	Oxy_b	15-16173 1/1	2.643	2.643		91.47	91.47	neg	6.269
A4	Oxy_b	15-16177 1/1	2.578	2.578		89.22	89.22	neg	6.427

1 Strip method names

2 Sample ID 1

3 Difference data

4 Difference data - Mean

5 Difference data - Variation coefficient

6 b/b0

7 b/b0 - Mean

8 Cutoff results

9 CONC

	1	2	3	4	5	6	7	8	9
B4	Oxy_b	15-16179 1/1	2.743	2.743		94.93	94.93	neg	6.041
C4	Oxy_b	15-16151 1/1	2.741	2.741		94.86	94.86	neg	6.045
D4	Oxy_b	15-16153 1/1	2.662	2.662		92.13	92.13	neg	6.225
E4	Oxy_b	15-16285 1/1	2.662	2.662		92.13	92.13	neg	6.225
F4	Oxy_b	High-4	0.477			16.51			34.74
G4	Oxy_b	15-16409 1/1	2.573	2.573		89.05	89.05	neg	6.44
H4	Oxy_b	High-5	0.493	0.493		17.06	17.06	pos	33.61
A6	Oxy_b		0			0			NoCalc
D7	Oxy_b		0			0			NoCalc
G8	Oxy_b		0			0			NoCalc
C10	Oxy_b		0			0			NoCalc
E11	Oxy_b		0			0			NoCalc
G12	Oxy_b		0			0			NoCalc

QC Validation criteria

Exp. Group Num 1

QC Validation criteria : Difference data

NC1>LPC1 --> TRUE

LPC1>PCI --> TRUE

PCI>HPCI --> TRUE



HOUSTON FORENSIC SCIENCE CENTER CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #

Date Submitted:

Non-Conformance Level

Date Closed:

Date of this Report:

Division:

FCN:
(If applicable)

Date of Incident:

Section:

Description of Discrepancy/Non-conformance:

On 02/19/2016, an analyst noticed the pH buffer control stock solutions used to complete performance checks of the pH meter were expired since October 2015. The secondary pH buffer control containers did not have the expiration date written on them. The expired pH buffer controls were used during performance checks on 11/02/2015 and 01/15/2016 to measure the pH of the phosphate buffered saline (PBS) for immunoassay screening. The pH meter met the performance check each time according to manufacturer's acceptance criteria which included checking and documenting the slope and mV. However, it has not been our practice to record the pH levels of the pH buffer control solutions. This PBS is added to all samples in a batch, including the cutoff, positive, and negative controls as well as case samples.

The PBS (made on 11/02/2015 and 01/15/2016) was used in a total of 30 immunoassay batches (approximately 630 cases):

11032015_ASG & 11092015_ASG
11042015_ASG & 11052015_ASG
11102015_ASG
11132015_ASG
11192015_ASG
11232015_ASG
12022015_ASG
12142015_ASG
12162015_ASG
01052016_ASG
01062016_ASG
01252016_ASG
01282016_ASG-Verification Run
01292016_ASG
02052016_ASG
02102016_ASG
02112016_ASG



HOUSTON FORENSIC SCIENCE CENTER CORRECTIVE ACTION REPORT

02172016_ASG
02182016_ASG
Urine Cases
11102015_ASG
11132015_ASG
11172015_ASG & 11182015_ASG
11182015_ASG
11192015_ASG
11232015_ASG
01052016_ASG
01062015_ASG
01202016_ASG & 01212016_ASG-Oxy
02012016_ASG

- Actions Taken:**
1. New pH buffer solutions were ordered immediately and the expired solutions were discarded.
 2. The new solutions were used to complete a performance check on the new pH meter and the pH of the current PBS solution was verified. The new pH meter arrived in the toxicology lab on April 4, 2016 and the pH of the current PBS solution (Lot # 01152016-B) was measured on April 5, 2016, at a pH of 6.83 +/- 0.022. Refer to email from Immunalysis, dated February 29, 2016, which shows this pH is acceptable for use on casework.
 3. The "pH Meter Performance Check" (LAB-48) worksheet was updated to include columns for recording the pH at levels 4, 7, and 10 (with acceptance criteria). Additionally, pH buffer control solution lot numbers and expiration dates are being checked on a weekly basis.
 4. The expiration dates were written on the transfer containers for each pH buffer control solution when they were transferred from the stock solution containers.

If not discovered at this point, where else in the process would this incident have been discovered?
 This incident would have been discovered during the next internal audit.

Technical Personnel: [Signature] Date: 4/27/16
 Immediate Supervisor: [Signature] Date: 4/27/16
 Section Manager: [Signature] Date: 4/26/2016
 CODIS Administrator (if applicable): n/a Date: _____
 Division Director: [Signature] Date: 4-27-16

In an email dated 3-3-16, ^{ref.} the old pH Meter, customer service was contacted by Tox supervisor regarding a 2.44 that flashed on the pH meter screen. Due to actions taken to address 2.44 flashing, which did not resolve the issue, a new pH meter was ordered.
 [Signature] 4-27-16

Corrective Action Report
 Issued by: Quality Director
 Uncontrolled When Printed

HFSC-QDiv-CAR
 Issue Date: October 30, 2015
 Page 2 of 3



HOUSTON FORENSIC SCIENCE CENTER CORRECTIVE ACTION REPORT

Summary of Root Cause Analysis:

The root cause of this discrepancy was the lack of expiration dates written on the pH buffer control transfer containers. Although expiration dates were included on the parent bottles, analysts did not refer to these containers before using the aliquoted buffer solutions. Lab 48 also did not require this information to be recorded prior to the revision.

Additional Information/Follow-Up:

Toxicology Section Follow-Up:

The possibility of this incident causing false positive results is minimal because immunoassay is a presumptive screening test. All screened-positive cases are confirmed by a secondary, more specific and sensitive technique (gas chromatograph/mass spectrometry or liquid chromatograph/mass spectrometry). The possibility of this incident causing false negative results is also minimal because the PBS is added to all samples including the cutoff controls. If the PBS somehow had suppressed the signal, then it would have affected the cutoff control based on which qualitative determination (i.e., positive vs negative) is made. Furthermore, according to Immunalysis (the manufacturer of the immunoassay kits), if the PBS was lower (pH = 6) or higher (pH = 8) than expected (pH = 7), it would not affect the results of the immunoassay screen; the email correspondence with Immunalysis is enclosed at the end of the report. Additionally, an analyst measured the pH of the PBS with the BDH pH Test Strip (the Certificate of Analysis enclosed) and confirmed the pH to be 7. Another analyst verified the result. Hence the toxicology section concluded that the PBS whose pH was measured using the expired pH buffer solutions was 1) prepared correctly at pH of 7 as described in the SOP and 2) would not have changed the results of the case samples.

Based upon the information provided by section experts and supported by Immunalysis, results from casework are valid and reanalysis is not necessary.

Quality Division Follow-Up:

On April 8, 2016, the Quality Division did a follow up with the Toxicology section to check that reagent and chemical containers were labeled appropriately. The main focus of this follow up was to ensure that the secondary bottles containing pH buffers were labeled with expiration dates. Some chemicals and in-house prepared reagents were also checked to ensure they were appropriately labeled. Refer to Appendix A for more information on chemicals and reagents which were checked.

All pH stock buffer solutions and secondary containers were labeled with their corresponding expiration dates. In addition, all of in-house created reagents were labeled with contents, initials of preparer, date, expiration date and verification date when applicable.

It was noted that a total of 3 methylene chloride bottles (a non-critical reagent) were expired. Two of these bottles were unopened and sealed. As for the 3rd bottle, this solvent was used to make extractions for in-house validation studies. All of the expired methylene chloride solvent was disposed. For extractions, the same solvent is used throughout all samples and they are also checked with controls.

Quality Director: _____

J. Webber

Date: _____

4/27/2016

Appendix A: Toxicology Reagent/Chemical Follow up CAR 2016-018

pH Buffer	Expiration Date
Thermo Scientific pH: 4.01	2/2018
Thermo Scientific pH: 7.00	2/2018
Thermo Scientific pH: 10.01	2/2018
Thermo Scientific pH: 4.01	11/2017
Thermo Scientific pH: 7.00	11/2017
Thermo Scientific pH: 10.01	11/2017
pH: 4.01 secondary container	11/2017
pH: 7.00 secondary container	11/2017
pH: 10.01 secondary container	11/2017

Chemical Name	Opened	Expiration Date	Additional Info
Hexafluoro-2-propanol (HFIP)	8/26/2015	n/a	
Isopropyl Alcohol	11/6/2012	n/a	
Isopropyl Alcohol	3/11/2016	n/a	
n-hexane 95%	3/23/2016	n/a	
4L Methyl Alcohol, Anhydrous (2 bottles)	n/a	n/a	retest date: 09/18/2019
4L Methyl Alcohol, Anhydrous (2 bottles)	n/a	n/a	retest date: 07/8/2020
Acetone 1L (3 bottles)	n/a	n/a	Retest date: 9/27/2020
4L Chloroform (1 bottle)	n/a	n/a	
1L n-propyl alcohol (3 bottles)	n/a	n/a	
1L n-propyl alcohol (1 bottle)	n/a	n/a	
4L Hexane (1 bottle)	3/23/2016	n/a	
1L Acetone	n/a	n/a	retest date: 09/27/2020
1L Acetone	1/26/2016	n/a	retest date: 09/27/2020
4L Methylene Chloride (2 bottle)	n/a	6/9/2015	Disposed
4L Methylene Chloride (1 bottle)	10/27/2014	6/9/2015	Disposed
4L Methylene Chloride (1 bottle)	n/a	5/11/2017	
1-chlorobutane	n/a	n/a	
Ethyl Acetate	3/10/2016	n/a	

In-house prepared reagents/buffers	Preparation Date	Expiration Date	Verification Date
Dibasic Phosphate buffer	10/14/2015	4/14/2016	n/a
0.01% n-propanol (buffer bottle attached to Hamilton 7903)	1/25/2016	7/25/2016	1/26/2016
0.01% n-propanol (buffer bottle attached to Hamilton 1742)	2/18/2016	8/18/2016	2/18/2016
1M NaOH	12/23/2015	12/23/2016	n/a
1M Acetic Acid	11/9/2015	11/9/2016	n/a
0.1 M HCl	11/19/2015	11/19/2016	11/25/2015
10 M KOH	1/5/2016	1/5/2017	1/7/2016
1M HCl	6/23/2015	6/23/2016	6/25/2015
100 mM Phosphate Buffer (pH 6)	2/3/2016	8/3/2016	n/a

Alcohol Curve & Controls

Ethanol	Lot Number	Expiration Date	Additional Info
200mg	FN05211403	7/2019	
100ug	FN03251502	5/2020	
500ug	FN01301506	2/2020	
1000ug	FN06041502	9/2020	Not in discovery website because it has not been used in casework
4000ug	FN01301503	4/2020	
500ug	FN07031402	8/2019	
Whole Blood Ethanol Control Level 1	BQC1 #140703 (3 bottles)	07/2018	



Houston Forensic Science Center

INTEROFFICE MEMO

To: File
Melinda Wilson-Hohler, PhD, Senior Forensic Analyst – Toxicology
Melinda K. Wilson Hohler

From: Dayong Lee, PhD, Manager – Toxicology
Dayong Lee

cc: Lori Wilson, Quality Director

Date: March 16, 2016

Re: pH

This memo is to document that pH of the buffer solutions used in immunoassay and method validation can be measured with the pH meter or pH test strips.

The Toxicology Section's practice has been to prepare the forensic diluent (section 16.3.5. of the analytical manual) using the pH meter to measure the pH of the buffer used in the immunoassay. Section 9.5.3 of the analytical manual states that use of a 3-point performance check is a preferred method when an accuracy of ± 0.1 or better is required. In preparation of the forensic diluent for immunoassay, two buffers (monobasic sodium phosphate and dibasic sodium phosphate) are mixed together so that the solution can be used in the assay to dilute control and calibrator sub-stock standards. The drugs that are being tested are acidic, basic, and neutral in composition and the use of one buffer simplifies the process of preparing casework solutions. The procedure does not require accuracy of the solution pH to be within ± 0.1 of the target (pH 7.0); please see the attached email correspondence from the representative of the immunoassay kit manufacturer (Immunoanalysis).

The pH of the current buffer, measured using the pH Test Strips BDH® (certificate of analysis enclosed), was determined to be 7. The measurement was further verified by another analyst to be 7. This pH will be documented on the reagent preparation log and saved with a signature. The verification adds an additional step to ensure the pH measurement is correct. This indicates that for the purpose of preparing the immunoassay buffer, the pH test strips can be used in substitution of the pH meter, which is currently out of service.

Similarly, during the method development process for the opioid confirmation assay using gas chromatography-mass spectrometry (GC-MS), a phosphate buffer at the approximate pH of 6 is used. While it has been our practice to use the pH meter to measure the pH of buffer solutions, the phosphate buffer for the opioid confirmation assay does not need the level of accuracy that the pH meter provides. During the validation phase for this quantitative confirmation, which will start in the near future, two preparations of the buffer will be used. These solutions were prepared and their pH values were determined to be 6, using the pH test strip. This pH will be documented on the reagent preparation log and saved with a signature. The verification of the pH by another analyst adds an additional step to ensure the pH measurement is correct. Furthermore, if the validation study shows that the assay is fit for use, this will demonstrate that the buffer whose pH was adjusted using the pH test strip produces accurate and reliable results.

The pH accuracy of 0.1 is not required by the current SOP for preparation of buffer solutions for the immunoassay or the opioid confirmation assay. When the new pH meter is available, pH of the buffer solutions will be measured to verify that it is at pH of 7 for the immunoassay buffer and at pH of 6 for the opioid assay buffer.



Certificate of Analysis

Catalog No.: BDH35309.606
Product Name: BDH PH TEST STRIP 0-14
Lot No.: 10BDH4135 (5113)
Gradation/Range: pH 0-1-2-3-4-5-6-7-8-9-10-11-12-13-14
Expiration Date: 2017-12

This document confirms that the above mentioned product has successfully passed the Manufacturer's quality control system in accordance with ISO 9001:2008 and meets the specific quality criteria.

This product has been tested in standard buffer solutions of suitable concentrations. The quality of colour assignment of the reaction colour and colour scale determines the quality of the product supplied.

Date of Examination: December 13, 2013

This document has been produced electronically and is valid without a signature.

Distributed Exclusively by
VWR 

Dayong Lee, Ph.D.

From: Laura Mayor, MS
Sent: Thursday, March 03, 2016 2:47 PM
To: Dayong Lee, Ph.D.; Lori Wilson, BS ASQ CQA
Cc: Quality; Andrea Gooden; Irma Rios, MBA
Subject: RE: Corrective Action Report regarding expired pH buffer

Quality,

We contacted customer service, and the guy I talked to said that the 2.44 that flashed on the screen had to do with the software, but the three dashes is not normal. He suggested to take out the batteries and remove the back panel for a day, it may have gotten wet inside. He then said if that doesn't work, he said look for a new meter. The company has stop manufacturing the meter we have.

Taking out the batteries did not work. So, we are buying a new pH meter.

What do we need to do about the corrective action now? Is the data that we gave Jackie sufficient (the pH readings from the last time it was used)?

Thanks,
Laura

From: Dayong Lee, Ph.D.
Sent: Monday, February 22, 2016 3:59 PM
To: Lori Wilson, BS ASQ CQA
Cc: Quality; Andrea Gooden; Laura Mayor, MS; Irma Rios, MBA
Subject: Corrective Action Report regarding expired pH buffer

Lori,

Enclosed is a draft of the Corrective Action Report on expired pH buffer for which I notified last Friday. I understand that a meeting with Quality needs to be occurred to determine whether this should be a CA or incident report. But we went ahead and wrote a draft to give you more information.

I will be out of office for the rest of the week but Laura and Andrea will be available to discuss the incident this week.

Thank you for your help.

Dayong

Dayong Lee, Ph.D.
Toxicology Manager
Ofc: 713-308-2640
Cell: 832-993-0175
Houston Forensic Science
1301 Fannin St, Suite 170
Houston, Texas 77002



Houston Forensic Science Center

Forensic Analysis Division - Toxicology

pH Meter Performance Check

Manufacturer: Thermo Scientific

Model: STARA2140

Serial Number: X29761

Weekly Maintenance:

Refill electrode and verify expiration date

Rinse electrode

Date: _____

Verify electrode storage solution and expiration date

Verify pH buffer solution expiration dates

Signature: _____

Comments: _____

Date	Signature	pH 4.01*	pH 7.00*	pH 10.01*	Slope (%) (90-110%)	Pass/Fail
		Temperature (°C)	Temperature (°C)	Temperature (°C)		

***Target pH at the reported temperature: ± 0.022
Refer to pH buffer solution bottle label.**

Form Complete Date/Signature:

From: [Andrea Gooden](#)
To: [Dayona Lee, Ph.D.](#)
Subject: Fw: pH of PBS Buffer
Date: Monday, March 14, 2016 2:59:19 PM

From: Timbang, Rochelle <RTimbang@immunalysis.com>
Sent: Monday, February 29, 2016 11:54 AM
To: Andrea Gooden
Subject: RE: pH of PBS Buffer

Andrea,

There shouldn't be an effect if the pH is slightly below 7 (6 or 8) to the assay.

Thank you,
Rochelle

From: Andrea Gooden [<mailto:AGooden@houstonforensicscience.org>]
Sent: Monday, February 29, 2016 9:52 AM
To: Timbang, Rochelle
Subject: pH of PBS Buffer

Rochelle,

I just have a question about the pH of the phosphate buffer solution (PBS). What would happen to the samples or controls if the PBS was at a lower or higher pH (lets say 6 or 8)?

Thank you in advance,
Andrea

Andrea Gooden
Forensic Analyst
Ofc: 713-308-2628
Cell:
Houston Forensic Science Center
1301 Fannin St, Suite 170
Houston, Texas 77002



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