Houston Forensic Science Center

Forensic Analysis Division - Toxicology

Immunoassay Batch Review Checklist

Batch Date: 02/18/2016		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

Initials/Date: Andrea Gooden

Digitally signed by Andrea Gooden
DN: cn=Andrea Gooden, o=HFSC, ou=FAD, email=AGooden@Houstonforensicscience.org, c=US
Date: 2016.02.23 13:33:21 -06'00'

Technical Review

Initials/Date: Tanuja Sathiraj

Digitally signed by Tanuja Sathiraj
DN: cn=Tanuja Sathiraj, o, ou, email=tsathiraj@houstonforensicscience.org, c=US
Date: 2016.03.07 14:17:34 -06'00'

Houston Forensic Science Center

Forensic Analysis Division - Toxicology

Immunoassay Batch QC Data

Batch Date: 02/18/2016 **Analyst:** Andrea Gooden

Digitally signed by Andrea Gooden
DN: cn=Andrea Gooden, o=HFSC, ou=FAD, email=AGooden@Houstonforensicscience.org, c=US
Date: 2016.02.23 13:26:01 -06'00'

Matrix: ☑ **BLOOD** ☐ **URINE**

Pipette(s): 2339 3263

Phosphate Buffer Saline Lot Number: 01152016-B

Control Lot Numbers:

Blank	E24906	**Oxycodone:**	
Negative	070715-LC	**Negative**	07072015-LC-5
Calibrator	10222015-PC	**Calibrator**	06222015
High	10222015-HC	**High**	10222015-OH

Kit Lot Numbers:

11-nor-9-carboxy-THC	EK13462	**Barbiturates**	EK13110
Opiates	EK13319	**Amphetamine**	EK13421
Phencyclidine	EK13322	**Carisoprodol**	EK13129
Methamphetamine	EK13516	**Methadone**	EK13478
Benzoylecgonine	EK13059	**Zolpidem**	EK13573
Benzodiazepines	EK13286	**Oxycodone**	EK13476

Comments:

Methadone-4 was opened and verified on this batch.

Alcohol/Toxicology
Work List for Andrea Gooden / Tox Screening

2/18/2016

Priority	Lab Case#/ Item#			Description	Results
000091216 1.1	2016-00023	2	2	Blood - Child Item	
000206016 1.1	2016-00020	2	2	Blood - Child Item	
000782816 1.1	2016-00018	3	2	Blood - Child Item Location of collection not on tube	
000790716 2.1	2016-00019	2	2	Blood - Child Item	
000822516 1.1	2016-00051	2	2	Blood - Child Item	
161504415 1.1	2015-17225	2	2	Blood - Child Item	
161732315 1.1	2015-17336	2	2	Blood - Child Item	
161814215 1.1	2015-17348	2	2	Blood - Child Item	
161968215 1.1	2015-17342	2	2	Blood - Child Item	
162106215 1.1	2015-17299	2	2	Blood - Child Item High	
162440315 1.1	2015-17346	3	2	Blood - Child Item	
162586615 1.1	2015-17338	2	2	Blood - Child Item	
162675315 1.1	2015-17350	2	2	Blood - Child Item	
164720315 1.1	2015-17633	2	2	Blood - Child Item	
165397315 1.1	2015-17631	2	2	Blood - Child Item	
165592015 1.1	2015-17636	2	2	Blood - Child Item	
165620215 1.1	2015-17642	2	2	Blood - Child Item	
166051015 1.1	2015-17659	2	2	Blood - Child Item	
166267515 1.1	2015-17638	3	2	Blood - Child Item	
166433915 1.1	2015-17646	2	2	Blood - Child Item High	
167647415 1.1	2016-00047	2	2	Blood - Child Item	
Total Tasks		21		High	

Please see next page for controls + kit info →

3,808

Kit / Inv #

THC : 13
OPI : 12
PCP : 10
Meth : 11
Be : 11
BZ : 12

Barb : 3
Amp : 4
Canv : 4
Mtdn : ~~3~~ 4
Zol : 4
Oxy : 4B

PBS : 011526-B
Pipettes : 2339, 3263

Opened Mtdn 4
2/18/16

Mixed Controls

Blank : E24906
Neg : 5/5/15-LL
Ceo : 1022015-PC
High : 1022015-HC

Oxy

Neg : 5/5/2015-LL5
Ceo : 0622201 5
High : 1022015-OH

02182016 ASG PBS-01152016-B Pipettes-2339, 3263

	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	16-00023 1/1	X	X	X	X	X	X	X	X	X
10	16-00020 1/1	X	X	X	X	X	X	X	X	X
11	16-00018 1/1	X	X	X	X	X	X	X	X	X
12	16-00019 2/1	X	X	X	X	X	X	X	X	X
13	16-00051 1/1	X	X	X	X	X	X	X	X	X
14	15-17225 1/1	X	X	X	X	X	X	X	X	X
15	15-17336 1/1	X	X	X	X	X	X	X	X	X
16	15-17348 1/1	X	X	X	X	X	X	X	X	X
17	15-17342 1/1	X	X	X	X	X	X	X	X	X
18	15-17299 1/1	X	X	X	X	X	X	X	X	X
19	High-3	X	X	X	X	X	X	X	X	X
20	15-17346 1/1	X	X	X	X	X	X	X	X	X
21	15-17338 1/1	X	X	X	X	X	X	X	X	X
22	15-17350 1/1	X	X	X	X	X	X	X	X	X
23	15-17633 1/1	X	X	X	X	X	X	X	X	X
24	15-17631 1/1	X	X	X	X	X	X	X	X	X
25	15-17636 1/1	X	X	X	X	X	X	X	X	X
26	15-17642 1/1	X	X	X	X	X	X	X	X	X
27	15-17659 1/1	X	X	X	X	X	X	X	X	X
28	15-17638 1/1	X	X	X	X	X	X	X	X	X
29	15-17646 1/1	X	X	X	X	X	X	X	X	X
30	High-4	X	X	X	X	X	X	X	X	X
31	16-00047 1/1	X	X	X	X	X	X	X	X	X
32	High-5	X	X	X	X	X	X	X	X	X

02182016_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	16-00023 1/1	X	X
10	16-00020 1/1	X	X
11	16-00018 1/1	X	X
12	16-00019 2/1	X	X
13	16-00051 1/1	X	X
14	15-17225 1/1	X	X
15	15-17336 1/1	X	X
16	15-17348 1/1	X	X
17	15-17342 1/1	X	X
18	15-17299 1/1	X	X
19	High-3	X	X
20	15-17346 1/1	X	X
21	15-17338 1/1	X	X
22	15-17350 1/1	X	X
23	15-17633 1/1	X	X
24	15-17631 1/1	X	X
25	15-17636 1/1	X	X
26	15-17642 1/1	X	X
27	15-17659 1/1	X	X
28	15-17638 1/1	X	X
29	15-17646 1/1	X	X
30	High-4	X	X
31	16-00047 1/1	X	X
32	High-5	X	X

02182016_ASG-Oxy PBS-01152016-B Pipettes-2339, 3263

	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	16-00023 1/1	X
10	16-00020 1/1	X
11	16-00018 1/1	X
12	16-00019 2/1	X
13	16-00051 1/1	X
14	15-17225 1/1	X
15	15-17336 1/1	X
16	15-17348 1/1	X
17	15-17342 1/1	X
18	15-17299 1/1	X
19	High-3	X
20	15-17346 1/1	X
21	15-17338 1/1	X
22	15-17350 1/1	X
23	15-17633 1/1	X
24	15-17631 1/1	X
25	15-17636 1/1	X
26	15-17642 1/1	X
27	15-17659 1/1	X
28	15-17638 1/1	X
29	15-17646 1/1	X
30	High-4	X
31	16-00047 1/1	X
32	High-5	X

IMMUNOASSAY Batch Report Blood

I-THCA

Date of Assay:	02.18.2016		
Method: thc_b.mth	KIT#:	EK13462	

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.049	0	3.11	2.6	100.00	4	
BLANK	3.161	0				4	
CALIBRATOR	1.412	10	1.35	6.1	43.59	10	
CALIBRATOR	1.295	10				10	
NEGATIVE	1.947	5	1.94	0.8	62.33	7	
NEGATIVE	1.924	5				7	
HIGH	0.756	20	0.72	6.7	23.25	18	
HIGH	0.688	20				20	
16-00023 1/1	2.9				93.40	5	
16-00020 1/1	0.172				5.54	79	pos
16-00018 1/1	0.885				28.50	15	pos
16-00019 2/1	3.112				100.23	4	
16-00051 1/1	3.098				99.77	4	
15-17225 1/1	2.871				92.46	5	
15-17336 1/1	2.628				84.64	5	
15-17348 1/1	0.437				14.07.	31	pos
15-17342 1/1	3.02				97.26	4	
15-17299 1/1	1.73				55.72	8	
High-3	0.791				25.48 ·	17	pos
15-17346 1/1	3.205				103.22	4	
15-17338 1/1	3.216				103.57	4	
15-17350 1/1	0.777				25.02 ·	17	pos
15-17633 1/1	2.16				69.57	6	
15-17631 1/1	1.852				59.65	7	
15-17636 1/1	0.089				2.87 ·	152	pos
15-17642 1/1	0.126				4.06 ·	107	pos
15-17659 1/1	0.349				11.24 ·	39	pos
15-17638 1/1	0.496				15.97 ·	27	pos
15-17646 1/1	3.189				102.71	4	
High-4	0.797				25.67	17	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

16-00047 1/1	0.085				2.74	159	pos
High-5	0.855				27.54	16	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

02182016_[signature]

IMMUNOASSAY Batch Report Blood

OPIATES (OPI)

Date of Assay: 02.18.2016

Method: opi_b.mth ✓ KIT#: EK13319 ✓

Sample ID	Absorbance	ng/ml	Avg. Abs	(abs)	binding	num.value	Results
BLANK	3.618	0	3.65	1.1 ✓	100.00	11	
BLANK	3.674	0				11	
CALIBRATOR	2.134	20	1.99	10.3	54.55 ✓	19	
CALIBRATOR	1.844	20			✓	22	
NEGATIVE	2.445	10	2.49	2.6	68.29	16	
NEGATIVE	2.535	10				16	
HIGH	1.296	40	1.28	1.8	35.09	31	
HIGH	1.263	40				31	
16-00023 1/1	3.686				101.10	11	
16-00020 1/1	3.745				102.72	11	
16-00018 1/1	3.665				100.52	11	
16-00019 2/1	3.734				102.41	11	
16-00051 1/1	3.811				104.53	10	
15-17225 1/1	3.635				99.70	11	
15-17336 1/1	3.656				100.27	11	
15-17348 1/1	3.671				100.69	11	
15-17342 1/1	3.597				98.66	11	
15-17299 1/1	3.613				99.09	11	
High-3	1.233				33.82	32	pos ✓
15-17346 1/1	3.591				98.49	11	
15-17338 1/1	3.567				97.83	11	
15-17350 1/1	3.126				85.74	13	
15-17633 1/1	0.838				22.98	47	pos
15-17631 1/1	3.659				100.36	11	
15-17636 1/1	3.613				99.09	11	
15-17642 1/1	3.639				99.81	11	
15-17659 1/1	3.695				101.34	11	
15-17638 1/1	3.611				99.04	11	
15-17646 1/1	3.504				96.11	11	
High-4	1.174				32.20	34	pos ✓

Examiner: [signature] Date: 2/23/16

Reviewer: TB Date: 3/7/16

16-00047 1/1	3.591				98.49	11	
High-5	1.047				28.72	38	pos

Examiner: [signature] Date: 2/23/16

Reviewer: [signature] Date: 3/7/16

02182016 [signature]

IMMUNOASSAY Batch Report Blood

PHENCYCLIDINE (PCP)

Date of Assay: 02.18.2016

Method: pcp_b.mth KIT#: EK13322

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.517	0	3.53	0.7	100.00	3	
BLANK	3.551	0				3	
CALIBRATOR	0.998	10	0.94	9.2	26.51	9	
CALIBRATOR	0.876	10				11	
NEGATIVE	1.66	5	1.64	1.3	46.53	6	
NEGATIVE	1.629	5				6	
HIGH	0.553	20	0.55	0.9	15.55	17	
HIGH	0.546	20				17	
16-00023 1/1	3.541				100.20	3	
16-00020 1/1	3.511				99.35	3	
16-00018 1/1	0.266				7.53	35	pos
16-00019 2/1	3.532				99.94	3	
16-00051 1/1	3.452				97.68	3	
15-17225 1/1	3.457				97.82	3	
15-17336 1/1	3.556				100.62	3	
15-17348 1/1	3.491				98.78	3	
15-17342 1/1	3.526				99.77	3	
15-17299 1/1	3.592				101.64	3	
High-3	0.511				14.46	18	pos
15-17346 1/1	0.307				8.69	31	pos
15-17338 1/1	3.597				101.78	3	
15-17350 1/1	0.397				11.23	24	pos
15-17633 1/1	3.603				101.95	3	
15-17631 1/1	3.651				103.31	3	
15-17636 1/1	0.588				16.64	16	pos
15-17642 1/1	3.617				102.35	3	
15-17659 1/1	3.607				102.07	3	
15-17638 1/1	0.483				13.67	19	pos
15-17646 1/1	3.568				100.96	3	
High-4	0.616				17.43	15	pos

Examiner: Date: 2/23/16

Reviewer: TB Date: 3/7/16

16-00047 1/1	3.541				100.20	3	
High-5	0.513				14.52	18	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

052182016_#1

IMMUNOASSAY Batch Report Blood

d-Methamphetamine (Meth)

Date of Assay: 02.18.2016

Method: meth_b.mth KIT#: EK13516

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.978	0	3.03	2.2	100.00	11	
BLANK	3.074	0				11	
CALIBRATOR	1.724	20	1.68	3.5	55.58	20	
CALIBRATOR	1.64	20				21	
NEGATIVE	2.006	10	2.03	1.5	66.99	17	
NEGATIVE	2.048	10				16	
HIGH	1.249	40	1.23	2.2	40.65	27	
HIGH	1.211	40				28	
16-00023 1/1	1.723				56.94	20	
16-00020 1/1	2.957				97.72	11	
16-00018 1/1	3.032				100.20	11	
16-00019 2/1	2.911				96.20	12	
16-00051 1/1	2.888				95.44	12	
15-17225 1/1	2.826				93.39	12	
15-17336 1/1	2.981				98.51	11	
15-17348 1/1	2.738				90.48	12	
15-17342 1/1	2.732				90.28	12	
15-17299 1/1	2.852				94.25	12	
High-3	1.261				41.67	27	pos
15-17346 1/1	2.841				93.89	12	
15-17338 1/1	2.936				97.03	11	
15-17350 1/1	2.928				96.76	11	
15-17633 1/1	2.882				95.24	12	
15-17631 1/1	2.785				92.04	12	
15-17636 1/1	1.253				41.41	27	pos
15-17642 1/1	2.837				93.75	12	
15-17659 1/1	2.938				97.09	11	
15-17638 1/1	2.984				98.61	11	
15-17646 1/1	2.777				91.77	12	
High-4	1.242				41.04	27	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TB Date: 3/7/16

16-00047 1/1	2.814				92.99	12	
High-5	1.089				35.99	31	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

02182016-AR

BENZOYLECGONINE (BE)

Date of Assay: 02.18.2016

Method: be_b.mth KIT#: EK13059

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.582	0	2.59	0.6	100.00	11	
BLANK	2.604	0				11	
CALIBRATOR	1.462	20	1.40	6.4	53.95	19	
CALIBRATOR	1.336	20				21	
NEGATIVE	1.565	10	1.64	6.2	63.13	18	
NEGATIVE	1.709	10				16	
HIGH	1.101	40	1.09	1.2	42.09	25	
HIGH	1.082	40				26	
16-00023 1/1	2.212				85.31	13	
16-00020 1/1	2.303				88.82	12	
16-00018 1/1	2.122				81.84	13	
16-00019 2/1	2.374				91.55	12	
16-00051 1/1	2.414				93.10	12	
15-17225 1/1	2.284				88.08	12	
15-17336 1/1	2.143				82.65	13	
15-17348 1/1	2.217				85.50	13	
15-17342 1/1	2.425				93.52	12	
15-17299 1/1	2.467				95.14	11	
High-3	1.082				41.73	26	pos
15-17346 1/1	2.469				95.22	11	
15-17338 1/1	2.409				92.90	12	
15-17350 1/1	1.885				72.70	15	
15-17633 1/1	2.293				88.43	12	
15-17631 1/1	0.289				11.15	97	pos
15-17636 1/1	2.425				93.52	12	
15-17642 1/1	2.243				86.50	12	
15-17659 1/1	1.317				50.79	21	pos
15-17638 1/1	0.266				10.26	105	pos
15-17646 1/1	2.465				95.06	11	
High-4	1.021				39.38	27	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TB Date: 3/7/16

16-00047 1/1	2.394				92.33	12	
High-5	0.968				37.33	29	pos

Examiner: [signature] Date: 2/23/16

Reviewer: [signature] Date: 3/7/16

02132016

EIA Batch Report Blood

BENZODIAZEPINES (BENZO)

Date of Assay: 02.18.2016

Method: bz_b.mth KIT#: EK13286

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.233	0	3.15	3.8	100.00	9	
BLANK	3.062	0				9	
CALIBRATOR	1.291	20	1.45	15.5	46.05	22	
CALIBRATOR	1.608	20				18	
NEGATIVE	2.293	10	2.26	2.0	71.85	13	
NEGATIVE	2.23	10				13	
HIGH	1.366	40	1.24	14.7	39.30	21	
HIGH	1.108	40				26	
16-00023 1/1	3.596				114.25	8	
16-00020 1/1	3.484				110.69	8	
16-00018 1/1	3.684				117.05	8	
16-00019 2/1	3.484				110.69	8	
16-00051 1/1	3.775				119.94	8	
15-17225 1/1	3.76				119.46	8	
15-17336 1/1	2.962				94.11	10	
15-17348 1/1	3.033				96.36	10	
15-17342 1/1	3.495				111.04	8	
15-17299 1/1	0.204				6.48	142	pos
							pos
15-17346 1/1	3.57				113.42	8	
15-17338 1/1	2.466				78.35	12	
15-17350 1/1	3.324				105.61	9	
15-17633 1/1	0.171				5.43	170	pos
15-17631 1/1	3.607				114.60	8	
15-17636 1/1	0.151				4.80	192	pos
15-17642 1/1	1.419				45.08	20	pos
15-17659 1/1	0.201				6.39	144	pos
15-17638 1/1	0.19				6.04	153	pos
15-17646 1/1	3.699				117.52	8	
							pos

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16-00047 1/1	3.604				114.50	8	
High-5	1.26				40.03	23	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

BARBITURATES (BARB)

Date of Assay: 02.18.2016

Method: barb_b.mth KIT#: EK13110

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.708	0	2.72	0.5	100.00	22	
BLANK	2.728	0				22	
CALIBRATOR	1.524	40	1.50	2.6	55.08	39	
CALIBRATOR	1.47	40				41	
NEGATIVE	1.745	20	1.66	7.1	61.15	34	
NEGATIVE	1.579	20				38	
HIGH	1.319	80	1.34	2.5	49.41	45	
HIGH	1.367	80				44	
16-00023 1/1	2.594				95.44	23	
16-00020 1/1	2.391				87.97	25	
16-00018 1/1	2.683				98.71	22	
16-00019 2/1	2.758				101.47	22	
16-00051 1/1	2.468				90.80	24	
15-17225 1/1	2.412				88.74	25	
15-17336 1/1	2.684				98.75	22	
15-17348 1/1	2.033				74.80	29	
15-17342 1/1	2.596				95.51	23	
15-17299 1/1	2.876				105.81	21	
High-3	1.475				54.27	41	pos
15-17346 1/1	2.782				102.35	22	
15-17338 1/1	2.515				92.53	24	
15-17350 1/1	2.58				94.92	23	
15-17633 1/1	2.59				95.29	23	
15-17631 1/1	2.714				99.85	22	
15-17636 1/1	2.75				101.18	22	
15-17642 1/1	2.615				96.21	23	
15-17659 1/1	2.65				97.50	23	
15-17638 1/1	2.792				102.72	21	
15-17646 1/1	2.721				100.11	22	
High-4	1.376				50.63	44	pos

Examiner: [signature] Date: 2/23/16

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16-00047 1/1	2.743				100.92	22	
High-5	1.206				44.37	50	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

AMPHETAMINES (AMP)

Date of Assay: 02.18.2016

Method: amp_b.mth KIT#: EK13421

Sample ID	Absorbance	ng/ml	Avg. Abs	(abs)	binding	num.value	Results
BLANK	3.268	0	3.31	1.8	100.00	9	
BLANK	3.35	0				8	
CALIBRATOR	1.433	20	1.39	4.4	41.99	19	
CALIBRATOR	1.346	20				21	
NEGATIVE	1.686	10	1.72	2.8	51.99	16	
NEGATIVE	1.755	10				16	
HIGH	0.872	40	0.86	2.7	25.85	32	
HIGH	0.839	40				33	
16-00023 1/1	2.805				84.77	10	
16-00020 1/1	3.184				96.22	9	
16-00018 1/1	3.13				94.59	9	
16-00019 2/1	3.173				95.89	9	
16-00051 1/1	3.197				96.62	9	
15-17225 1/1	3.191				96.43	9	
15-17336 1/1	2.99				90.36	9	
15-17348 1/1	3.195				96.55	9	
15-17342 1/1	3.141				94.92	9	
15-17299 1/1	3.301				99.76	8	
High-3	0.906				27.38	31	pos
15-17346 1/1	3.293				99.52	8	
15-17338 1/1	3.31				100.03	8	
15-17350 1/1	3.354				101.36	8	
15-17633 1/1	3.281				99.15	8	
15-17631 1/1	3.326				100.51	8	
15-17636 1/1	1.928				58.27	14	
15-17642 1/1	3.16				95.50	9	
15-17659 1/1	3.261				98.55	9	
15-17638 1/1	3.245				98.07	9	
15-17646 1/1	3.164				95.62	9	
High-4	0.844				25.51	33	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

16-00047 1/1	3.22				97.31	9	
High-5	0.799				24.15	35	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

CARISOPRODOL (CARISO)

Date of Assay: 02.18.2016

Method: cariso_b.mth KIT#: EK13129

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.949	0	2.92	1.4	100.00	187	
BLANK	2.893	0				191	
CALIBRATOR	1.123	500	1.10	2.6	37.74	491	
CALIBRATOR	1.082	500				509	
NEGATIVE	1.284	250	1.28	0.9	43.68	429	
NEGATIVE	1.268	250				435	
HIGH	0.864	1000	0.85	1.7	29.22	638	
HIGH	0.843	1000				654	
16-00023 1/1	2.912				99.69	189	
16-00020 1/1	2.881				98.63	191	
16-00018 1/1	2.801				95.89	197	
16-00019 2/1	2.799				95.82	197	
16-00051 1/1	2.713				92.88	203	
15-17225 1/1	2.678				91.68	206	
15-17336 1/1	2.761				94.52	200	
15-17348 1/1	2.554				87.44	216	
15-17342 1/1	2.975				101.85	185	
15-17299 1/1	2.922				100.03	189	
High-3	0.927				31.74	595	pos
15-17346 1/1	2.883				98.70	191	
15-17338 1/1	2.848				97.50	194	
15-17350 1/1	1.213				41.53	454	
15-17633 1/1	2.902				99.35	190	
15-17631 1/1	2.895				99.11	190	
15-17636 1/1	2.834				97.02	195	
15-17642 1/1	2.618				89.63	211	
15-17659 1/1	2.837				97.12	194	
15-17638 1/1	2.734				93.60	202	
15-17646 1/1	2.748				94.08	201	
High-4	0.788				26.98	700	pos

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16-00047 1/1	2.768				94.76	199	
High-5	0.74				25.33	745	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TB Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

METHADONE (MTDN)

Date of Assay: 02.18.2016

Method: mtdn_b.mth KIT#: EK13478

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.011	0	3.06	2.5	100.00	11	
BLANK	3.118	0				11	
CALIBRATOR	1.447	25	1.34	11.3	43.73	23	
CALIBRATOR	1.233	25				27	
NEGATIVE	2.216	12.5	2.31	6.0	75.53	15	
NEGATIVE	2.413	12.5				14	
HIGH	0.768	50	0.71	10.9	23.27	44	
HIGH	0.658	50				51	
16-00023 1/1	3.109				101.45	11	
16-00020 1/1	2.862				93.39	12	
16-00018 1/1	3.34				108.99	10	
16-00019 2/1	2.807				91.60	12	
16-00051 1/1	3.367				109.87	10	
15-17225 1/1	3.222				105.14	10	
15-17336 1/1	3.213				104.85	10	
15-17348 1/1	2.479				80.89	14	
15-17342 1/1	3.335				108.83	10	
15-17299 1/1	3.312				108.08	10	
High-3	0.879				28.68	38	pos
15-17346 1/1	3.392				110.69	10	
15-17338 1/1	3.165				103.28	11	
15-17350 1/1	3.45				112.58	10	
15-17633 1/1	3.242				105.79	10	
15-17631 1/1	3.44				112.25	10	
15-17636 1/1	3.236				105.60	10	
15-17642 1/1	3.362				109.71	10	
15-17659 1/1	3.233				105.50	10	
15-17638 1/1	3.391				110.65	10	
15-17646 1/1	3.263				106.48	10	
High-4	0.802				26.17	42	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

16-00047 1/1	3.217				104.98	10	
High-5	0.594				19.38	56	pos

Examiner: [signature] Date: 2/23/16

Reviewer: [signature] Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

ZOLPIDEM (ZOL)

Date of Assay: 02.18.2016

Method: zol_b.mth KIT#: EK13573

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	3.234	0	3.25	0.6	100.00	3	
BLANK	3.262	0				3	
CALIBRATOR	1.732	5	1.67	5.2	51.43	5	
CALIBRATOR	1.609	5				5	
NEGATIVE	2.094	2.5	2.00	6.7	61.55	4	
NEGATIVE	1.904	2.5				4	
HIGH	1.22	10	1.27	5.4	39.05	7	
HIGH	1.317	10				6	
16-00023 1/1	3.105				95.60	3	
16-00020 1/1	3.36				103.45	2	
16-00018 1/1	3.246				99.94	3	
16-00019 2/1	3.197				98.43	3	
16-00051 1/1	3.276				100.86	3	
15-17225 1/1	2.987				91.96	3	
15-17336 1/1	3.184				98.03	3	
15-17348 1/1	3.013				92.76	3	
15-17342 1/1	3.223				99.23	3	
15-17299 1/1	3.314				102.03	3	
High-3	1.383				42.58	6	pos
15-17346 1/1	3.244				99.88	3	
15-17338 1/1	3.19				98.21	3	
15-17350 1/1	3.015				92.83	3	
15-17633 1/1	3.122				96.12	3	
15-17631 1/1	3.247				99.97	3	
15-17636 1/1	3.381				104.09	2	
15-17642 1/1	3.49				107.45	2	
15-17659 1/1	3.349				103.11	2	
15-17638 1/1	3.478				107.08	2	
15-17646 1/1	3.334				102.65	3	
High-4	1.28				39.41	7	pos

Examiner: [signature] Date: 2/23/16

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16-00047 1/1	3.393				104.46	2	
High-5	1.279				39.38	7	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

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IMMUNOASSAY Batch Report Blood

OXYCODONE (OXY)

Date of Assay: 02.18.2016

Method: oxy_b.mth KIT#: EK13476

Sample ID	Absorbance	Target conc ng/ml	Avg. Abs	%CV (abs)	% binding	num.value	Results
BLANK	2.843	0	2.88	1.8	100.00	3	
BLANK	2.917	0				3	
CALIBRATOR	0.842	10	0.91	10.2	31.51	11	
CALIBRATOR	0.973	10				9	
NEGATIVE	1.478	5	1.64	14.2	57.07	6	
NEGATIVE	1.809	5				5	
HIGH	0.535	20	0.58	10.4	20.05	17	
HIGH	0.62	20				15	
16-00023 1/1	2.692				93.47	3	
16-00020 1/1	2.748				95.42	3	
16-00018 1/1	2.866				99.51	3	
16-00019 2/1	2.798				97.15	3	
16-00051 1/1	2.73				94.79	3	
15-17225 1/1	2.81				97.57	3	
15-17336 1/1	2.558				88.82	4	
15-17348 1/1	2.73				94.79	3	
15-17342 1/1	2.77				96.18	3	
15-17299 1/1	2.752				95.56	3	
High-3	0.522				18.13	17	pos
15-17346 1/1	2.845				98.78	3	
15-17338 1/1	2.811				97.60	3	
15-17350 1/1	2.401				83.37	4	
15-17633 1/1	1.056				36.67	9	
15-17631 1/1	2.822				97.99	3	
15-17636 1/1	2.823				98.02	3	
15-17642 1/1	2.71				94.10	3	
15-17659 1/1	2.72				94.44	3	
15-17638 1/1	2.791				96.91	3	
15-17646 1/1	2.697				93.65	3	
High-4	0.586				20.35	15	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

16-00047 1/1	2.8				97.22	3	
High-5	0.58				20.14	16	pos

Examiner: [signature] Date: 2/23/16

Reviewer: TS Date: 3/7/16

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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	Thc_b	Blank-1	3.049	3.105	2.5506	98.196	100		4.4392
B1	Thc_b	Blank-2	3.161			101.8			4.2819
C1	Thc_b	Cal-1	1.412	1.3535	6.1124	45.475	43.591		9.5857
D1	Thc_b	Cal-2	1.295			41.707			10.452
E1	Thc_b	Neg-1	1.947	1.9355	0.84027	62.705	62.335		6.9517
F1	Thc_b	Neg-2	1.924			61.965			7.0348
G1	Thc_b	High-1	0.756	0.722	6.6597	24.348	23.253		17.903
H1	Thc_b	High-2	0.688			22.158			19.673
A2	Thc_b	16-00023 1/1	2.9	2.9		93.398	93.398	neg	4.6672
B2	Thc_b	16-00020 1/1	0.172	0.172		5.5395	5.5395	pos	78.692
C2	Thc_b	16-00018 1/1	0.885	0.885		28.502	28.502	pos	15.294
D2	Thc_b	16-00019 2/1	3.112	3.112		100.23	100.23	neg	4.3493
E2	Thc_b	16-00051 1/1	3.098	3.098		99.775	99.775	neg	4.3689
F2	Thc_b	15-17225 1/1	2.871	2.871		92.464	92.464	neg	4.7144
G2	Thc_b	15-17336 1/1	2.628	2.628		84.638	84.638	neg	5.1503
H2	Thc_b	15-17348 1/1	0.437	0.437		14.074	14.074	pos	30.973
A3	Thc_b	15-17342 1/1	3.02	3.02		97.262	97.262	neg	4.4818
B3	Thc_b	15-17299 1/1	1.73	1.73		55.717	55.717	neg	7.8237
C3	Thc_b	High-3	0.791	0.794	0.53434	25.475	25.572	-	17.111
D3	Thc_b	15-17346 1/1	3.205	3.205		103.22	103.22	neg	4.2231
E3	Thc_b	15-17338 1/1	3.216	3.216		103.57	103.57	neg	4.2086
F3	Thc_b	15-17350 1/1	0.777	0.777		25.024	25.024	pos	17.42
G3	Thc_b	15-17633 1/1	2.16	2.16		69.565	69.565	neg	6.2662
H3	Thc_b	15-17631 1/1	1.852	1.852		59.646	59.646	neg	7.3083
A4	Thc_b	15-17636 1/1	0.089	0.089		2.8663	2.8663	pos	152.08

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	Thc_b	15-17642 1/1	0.126	0.126		4.058	4.058	pos	107.42
C4	Thc_b	15-17659 1/1	0.349	0.349		11.24	11.24	pos	38.782
D4	Thc_b	15-17638 1/1	0.496	0.496		15.974	15.974	pos	27.288
E4	Thc_b	15-17646 1/1	3.189	3.189		102.71	102.71	neg	4.2443
F4	Thc_b	High-4	0.797			25.668			16.982
G4	Thc_b	16-00047 1/1	0.085	0.085		2.7375	2.7375	pos	159.24
H4	Thc_b	High-5	0.855	0.855		27.536	27.536	pos	15.83
A5	Opi_b	Blank-1	3.618	3.646	1.0861	99.232	100		10.995
B5	Opi_b	Blank-2	3.674			100.77			10.827
C5	Opi_b	Cal-1	2.134	1.989	10.31	58.53	54.553		18.641
D5	Opi_b	Cal-2	1.844			50.576			21.573
E5	Opi_b	Neg-1	2.445	2.49	2.5558	67.06	68.294		16.27
F5	Opi_b	Neg-2	2.535			69.528			15.692
G5	Opi_b	High-1	1.296	1.2795	1.8237	35.546	35.093		30.694
H5	Opi_b	High-2	1.263			34.641			31.496
A6	Opi_b	16-00023 1/1	3.686	3.686		101.1	101.1	neg	10.792
B6	Opi_b	16-00020 1/1	3.745	3.745		102.72	102.72	neg	10.622
C6	Opi_b	16-00018 1/1	3.665	3.665		100.52	100.52	neg	10.854
D6	Opi_b	16-00019 2/1	3.734	3.734		102.41	102.41	neg	10.653
E6	Opi_b	16-00051 1/1	3.811	3.811		104.53	104.53	neg	10.438
F6	Opi_b	15-17225 1/1	3.635	3.635		99.698	99.698	neg	10.944
G6	Opi_b	15-17336 1/1	3.656	3.656		100.27	100.27	neg	10.881
H6	Opi_b	15-17348 1/1	3.671	3.671		100.69	100.69	neg	10.836
A7	Opi_b	15-17342 1/1	3.597	3.597		98.656	98.656	neg	11.059
B7	Opi_b	15-17299 1/1	3.613	3.613		99.095	99.095	neg	11.01

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	1.233	1.2035	3.4665	33.818	33.009		32.263
D7	Opi_b	15-17346 1/1	3.591	3.591		98.491	98.491	neg	11.078
E7	Opi_b	15-17338 1/1	3.567	3.567		97.833	97.833	neg	11.152
F7	Opi_b	15-17350 1/1	3.126	3.126		85.738	85.738	neg	12.726
G7	Opi_b	15-17633 1/1	0.838	0.838		22.984	22.984	pos	47.47
H7	Opi_b	15-17631 1/1	3.659	3.659		100.36	100.36	neg	10.872
A8	Opi_b	15-17636 1/1	3.613	3.613		99.095	99.095	neg	11.01
B8	Opi_b	15-17642 1/1	3.639	3.639		99.808	99.808	neg	10.932
C8	Opi_b	15-17659 1/1	3.695	3.695		101.34	101.34	neg	10.766
D8	Opi_b	15-17638 1/1	3.611	3.611		99.04	99.04	neg	11.016
E8	Opi_b	15-17646 1/1	3.504	3.504		96.105	96.105	neg	11.353
F8	Opi_b	High-4	1.174			32.2			33.884
G8	Opi_b	16-00047 1/1	3.591	3.591		98.491	98.491	neg	11.078
H8	Opi_b	High-5	1.047	1.047		28.716	28.716	pos	37.994

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	3.517	3.534	0.6803	99.519	100		2.6642
B1	Pcp_b	Blank-2	3.551			100.48			2.6387
C1	Pcp_b	Cal-1	0.998	0.937	9.2067	28.24	26.514		9.3888
D1	Pcp_b	Cal-2	0.876			24.788			10.696
E1	Pcp_b	Neg-1	1.66	1.6445	1.3329	46.972	46.534		5.6446
F1	Pcp_b	Neg-2	1.629			46.095			5.752
G1	Pcp_b	High-1	0.553	0.5495	0.90077	15.648	15.549		16.944
H1	Pcp_b	High-2	0.546			15.45			17.161
A2	Pcp_b	16-00023 1/1	3.541	3.541		100.2	100.2	neg	2.6461
B2	Pcp_b	16-00020 1/1	3.511	3.511		99.349	99.349	neg	2.6688
C2	Pcp_b	16-00018 1/1	0.266	0.266		7.5269	7.5269	pos	35.226
D2	Pcp_b	16-00019 2/1	3.532	3.532		99.943	99.943	neg	2.6529
E2	Pcp_b	16-00051 1/1	3.452	3.452		97.68	97.68	neg	2.7144
F2	Pcp_b	15-17225 1/1	3.457	3.457		97.821	97.821	neg	2.7104
G2	Pcp_b	15-17336 1/1	3.556	3.556		100.62	100.62	neg	2.635
H2	Pcp_b	15-17348 1/1	3.491	3.491		98.783	98.783	neg	2.684
A3	Pcp_b	15-17342 1/1	3.526	3.526		99.774	99.774	neg	2.6574
B3	Pcp_b	15-17299 1/1	3.592	3.592		101.64	101.64	neg	2.6086
C3	Pcp_b	High-3	0.511	0.5635	13.176	14.46	15.945		18.337
D3	Pcp_b	15-17346 1/1	0.307	0.307		8.687	8.687	pos	30.521
E3	Pcp_b	15-17338 1/1	3.597	3.597		101.78	101.78	neg	2.6049
F3	Pcp_b	15-17350 1/1	0.397	0.397		11.234	11.234	pos	23.602
G3	Pcp_b	15-17633 1/1	3.603	3.603		101.95	101.95	neg	2.6006
H3	Pcp_b	15-17631 1/1	3.651	3.651		103.31	103.31	neg	2.5664
A4	Pcp_b	15-17636 1/1	0.588	0.588		16.638	16.638	pos	15.935

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	15-17642 1/1	3.617	3.617		102.35	102.35	neg	2.5905
C4	Pcp_b	15-17659 1/1	3.607	3.607		102.07	102.07	neg	2.5977
D4	Pcp_b	15-17638 1/1	0.483	0.483		13.667	13.667	pos	19.4
E4	Pcp_b	15-17646 1/1	3.568	3.568		100.96	100.96	neg	2.6261
F4	Pcp_b	High-4	0.616			17.431			15.211
G4	Pcp_b	16-00047 1/1	3.541	3.541		100.2	100.2	neg	2.6461
H4	Pcp_b	High-5	0.513	0.513		14.516	14.516	pos	18.265
A5	Meth_b	Blank-1	2.978	3.026	2.2433	98.414	100		11.296
B5	Meth_b	Blank-2	3.074			101.59			10.943
C5	Meth_b	Cal-1	1.724	1.682	3.5313	56.973	55.585		19.513
D5	Meth_b	Cal-2	1.64			54.197			20.512
E5	Meth_b	Neg-1	2.006	2.027	1.4651	66.292	66.986		16.77
F5	Meth_b	Neg-2	2.048			67.68			16.426
G5	Meth_b	High-1	1.249	1.23	2.1846	41.276	40.648		26.934
H5	Meth_b	High-2	1.211			40.02			27.779
A6	Meth_b	16-00023 1/1	1.723	1.723		56.94	56.94	neg	19.524
B6	Meth_b	16-00020 1/1	2.957	2.957		97.72	97.72	neg	11.376
C6	Meth_b	16-00018 1/1	3.032	3.032		100.2	100.2	neg	11.095
D6	Meth_b	16-00019 2/1	2.911	2.911		96.2	96.2	neg	11.556
E6	Meth_b	16-00051 1/1	2.888	2.888		95.44	95.44	neg	11.648
F6	Meth_b	15-17225 1/1	2.826	2.826		93.391	93.391	neg	11.904
G6	Meth_b	15-17336 1/1	2.981	2.981		98.513	98.513	neg	11.285
H6	Meth_b	15-17348 1/1	2.738	2.738		90.482	90.482	neg	12.286
A7	Meth_b	15-17342 1/1	2.732	2.732		90.284	90.284	neg	12.313
B7	Meth_b	15-17299 1/1	2.852	2.852		94.25	94.25	neg	11.795

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	1.261	1.2515	1.0735	41.672	41.358		26.677
D7	Meth_b	15-17346 1/1	2.841	2.841		93.886	93.886	neg	11.841
E7	Meth_b	15-17338 1/1	2.936	2.936		97.026	97.026	neg	11.458
F7	Meth_b	15-17350 1/1	2.928	2.928		96.761	96.761	neg	11.489
G7	Meth_b	15-17633 1/1	2.882	2.882		95.241	95.241	neg	11.672
H7	Meth_b	15-17631 1/1	2.785	2.785		92.036	92.036	neg	12.079
A8	Meth_b	15-17636 1/1	1.253	1.253		41.408	41.408	pos	26.848
B8	Meth_b	15-17642 1/1	2.837	2.837		93.754	93.754	neg	11.858
C8	Meth_b	15-17659 1/1	2.938	2.938		97.092	97.092	neg	11.45
D8	Meth_b	15-17638 1/1	2.984	2.984		98.612	98.612	neg	11.273
E8	Meth_b	15-17646 1/1	2.777	2.777		91.771	91.771	neg	12.114
F8	Meth_b	High-4	1.242			41.044			27.085
G8	Meth_b	16-00047 1/1	2.814	2.814		92.994	92.994	neg	11.955
H8	Meth_b	High-5	1.089	1.089		35.988	35.988	pos	30.891

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	2.582	2.593	0.59994	99.576	100		27.091
B1	Be_b	Blank-2	2.604			100.42			26.863
C1	Be_b	Cal-1	1.462	1.399	6.3685	56.383	53.953		47.845
D1	Be_b	Cal-2	1.336			51.523			52.358
E1	Be_b	Neg-1	1.565	1.637	6.2201	60.355	63.132		44.696
F1	Be_b	Neg-2	1.709			65.908			40.93
G1	Be_b	High-1	1.101	1.0915	1.2309	42.46	42.094		63.533
H1	Be_b	High-2	1.082			41.728			64.649
A2	Be_b	16-00023 1/1	2.212	2.212		85.307	85.307	neg	31.623
B2	Be_b	16-00020 1/1	2.303	2.303		88.816	88.816	neg	30.373
C2	Be_b	16-00018 1/1	2.122	2.122		81.836	81.836	neg	32.964
D2	Be_b	16-00019 2/1	2.374	2.374		91.554	91.554	neg	29.465
E2	Be_b	16-00051 1/1	2.414	2.414		93.097	93.097	neg	28.977
F2	Be_b	15-17225 1/1	2.284	2.284		88.083	88.083	neg	30.626
G2	Be_b	15-17336 1/1	2.143	2.143		82.646	82.646	neg	32.641
H2	Be_b	15-17348 1/1	2.217	2.217		85.499	85.499	neg	31.552
A3	Be_b	15-17342 1/1	2.425	2.425		93.521	93.521	neg	28.845
B3	Be_b	15-17299 1/1	2.467	2.467		95.141	95.141	neg	28.354
C3	Be_b	High-3	1.082	1.0515	4.1021	41.728	40.551		64.649
D3	Be_b	15-17346 1/1	2.469	2.469		95.218	95.218	neg	28.331
E3	Be_b	15-17338 1/1	2.409	2.409		92.904	92.904	neg	29.037
F3	Be_b	15-17350 1/1	1.885	1.885		72.696	72.696	neg	37.109
G3	Be_b	15-17633 1/1	2.293	2.293		88.43	88.43	neg	30.506
H3	Be_b	15-17631 1/1	0.289	0.289		11.145	11.145	pos	242.04
A4	Be_b	15-17636 1/1	2.425	2.425		93.521	93.521	neg	28.845

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	15-17642 1/1	2.243	2.243		86.502	86.502	neg	31.186
C4	Be_b	15-17659 1/1	1.317	1.317		50.791	50.791	pos	53.113
D4	Be_b	15-17638 1/1	0.266	0.266		10.258	10.258	pos	262.97
E4	Be_b	15-17646 1/1	2.465	2.465		95.064	95.064	neg	28.377
F4	Be_b	High-4	1.021			39.375			68.511
G4	Be_b	16-00047 1/1	2.394	2.394		92.325	92.325	neg	29.219
H4	Be_b	High-5	0.968	0.968		37.331	37.331	pos	72.262
A5	Oxa_b	Blank-1	3.233	3.1475	3.8416	102.72	100		22.417
B5	Oxa_b	Blank-2	3.062			97.284			23.669
C5	Oxa_b	Cal-1	1.291	1.4495	15.464	41.017	46.052		56.139
D5	Oxa_b	Cal-2	1.608			51.088			45.072
E5	Oxa_b	Neg-1	2.293	2.2615	1.9698	72.851	71.851		31.607
F5	Oxa_b	Neg-2	2.23			70.85			32.5
G5	Oxa_b	High-1	1.366	1.237	14.748	43.4	39.301		53.056
H5	Oxa_b	High-2	1.108			35.203			65.411
A6	Oxa_b	16-00023 1/1	3.596	3.596		114.25	114.25	neg	20.154
B6	Oxa_b	16-00020 1/1	3.484	3.484		110.69	110.69	neg	20.802
C6	Oxa_b	16-00018 1/1	3.684	3.684		117.05	117.05	neg	19.673
D6	Oxa_b	16-00019 2/1	3.484	3.484		110.69	110.69	neg	20.802
E6	Oxa_b	16-00051 1/1	3.775	3.775		119.94	119.94	neg	19.199
F6	Oxa_b	15-17225 1/1	3.76	3.76		119.46	119.46	neg	19.275
G6	Oxa_b	15-17336 1/1	2.962	2.962		94.106	94.106	neg	24.468
H6	Oxa_b	15-17348 1/1	3.033	3.033		96.362	96.362	neg	23.895
A7	Oxa_b	15-17342 1/1	3.495	3.495		111.04	111.04	neg	20.737
B7	Oxa_b	15-17299 1/1	0.204	0.204		6.4813	6.4813	pos	355.27

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	1.172	1.157	1.8335	37.236	36.759		61.839
D7	Oxa_b	15-17346 1/1	3.57	3.57		113.42	113.42	neg	20.301
E7	Oxa_b	15-17338 1/1	2.466	2.466		78.348	78.348	neg	29.39
F7	Oxa_b	15-17350 1/1	3.324	3.324		105.61	105.61	neg	21.804
G7	Oxa_b	15-17633 1/1	0.171	0.171		5.4329	5.4329	pos	423.83
H7	Oxa_b	15-17631 1/1	3.607	3.607		114.6	114.6	neg	20.093
A8	Oxa_b	15-17636 1/1	0.151	0.151		4.7975	4.7975	pos	479.97
B8	Oxa_b	15-17642 1/1	1.419	1.419		45.083	45.083	pos	51.075
C8	Oxa_b	15-17659 1/1	0.201	0.201		6.386	6.386	pos	360.57
D8	Oxa_b	15-17638 1/1	0.19	0.19		6.0365	6.0365	pos	381.45
E8	Oxa_b	15-17646 1/1	3.699	3.699		117.52	117.52	neg	19.593
F8	Oxa_b	High-4	1.142			36.283			63.463
G8	Oxa_b	16-00047 1/1	3.604	3.604		114.5	114.5	neg	20.11
H8	Oxa_b	High-5	1.26	1.26		40.032	40.032	pos	57.52

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	2.708	2.718	0.52031	99.632	100		27.64
B1	Barb_b	Blank-2	2.728			100.37			27.438
C1	Barb_b	Cal-1	1.524	1.497	2.5507	56.071	55.077		49.114
D1	Barb_b	Cal-2	1.47			54.084			50.918
E1	Barb_b	Neg-1	1.745	1.662	7.0626	64.202	61.148		42.894
F1	Barb_b	Neg-2	1.579			58.094			47.403
G1	Barb_b	High-1	1.319	1.343	2.5273	48.528	49.411		56.748
H1	Barb_b	High-2	1.367			50.294			54.755
A2	Barb_b	16-00023 1/1	2.594	2.594		95.438	95.438	neg	28.855
B2	Barb_b	16-00020 1/1	2.391	2.391		87.969	87.969	neg	31.305
C2	Barb_b	16-00018 1/1	2.683	2.683		98.712	98.712	neg	27.898
D2	Barb_b	16-00019 2/1	2.758	2.758		101.47	101.47	neg	27.139
E2	Barb_b	16-00051 1/1	2.468	2.468		90.802	90.802	neg	30.328
F2	Barb_b	15-17225 1/1	2.412	2.412		88.742	88.742	neg	31.032
G2	Barb_b	15-17336 1/1	2.684	2.684		98.749	98.749	neg	27.887
H2	Barb_b	15-17348 1/1	2.033	2.033		74.798	74.798	neg	36.818
A3	Barb_b	15-17342 1/1	2.596	2.596		95.511	95.511	neg	28.833
B3	Barb_b	15-17299 1/1	2.876	2.876		105.81	105.81	neg	26.026
C3	Barb_b	High-3	1.475	1.4255	4.9108	54.268	52.447		50.746
D3	Barb_b	15-17346 1/1	2.782	2.782		102.35	102.35	neg	26.905
E3	Barb_b	15-17338 1/1	2.515	2.515		92.531	92.531	neg	29.761
F3	Barb_b	15-17350 1/1	2.58	2.58		94.923	94.923	neg	29.012
G3	Barb_b	15-17633 1/1	2.59	2.59		95.291	95.291	neg	28.9
H3	Barb_b	15-17631 1/1	2.714	2.714		99.853	99.853	neg	27.579
A4	Barb_b	15-17636 1/1	2.75	2.75		101.18	101.18	neg	27.218

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	15-17642 1/1	2.615	2.615		96.21	96.21	neg	28.623
C4	Barb_b	15-17659 1/1	2.65	2.65		97.498	97.498	neg	28.245
D4	Barb_b	15-17638 1/1	2.792	2.792		102.72	102.72	neg	26.809
E4	Barb_b	15-17646 1/1	2.721	2.721		100.11	100.11	neg	27.508
F4	Barb_b	High-4	1.376			50.625			54.397
G4	Barb_b	16-00047 1/1	2.743	2.743		100.92	100.92	neg	27.288
H4	Barb_b	High-5	1.206	1.206		44.371	44.371	pos	62.065
A5	Amp_b	Blank-1	3.268	3.309	1.7523	98.761	100		8.5037
B5	Amp_b	Blank-2	3.35			101.24			8.2955
C5	Amp_b	Cal-1	1.433	1.3895	4.4274	43.306	41.992		19.393
D5	Amp_b	Cal-2	1.346			40.677			20.646
E5	Amp_b	Neg-1	1.686	1.7205	2.8358	50.952	51.995		16.483
F5	Amp_b	Neg-2	1.755			53.037			15.835
G5	Amp_b	High-1	0.872	0.8555	2.7276	26.352	25.854		31.869
H5	Amp_b	High-2	0.839			25.355			33.123
A6	Amp_b	16-00023 1/1	2.805	2.805		84.769	84.769	neg	9.9073
B6	Amp_b	16-00020 1/1	3.184	3.184		96.222	96.222	neg	8.728
C6	Amp_b	16-00018 1/1	3.13	3.13		94.591	94.591	neg	8.8786
D6	Amp_b	16-00019 2/1	3.173	3.173		95.89	95.89	neg	8.7583
E6	Amp_b	16-00051 1/1	3.197	3.197		96.615	96.615	neg	8.6925
F6	Amp_b	15-17225 1/1	3.191	3.191		96.434	96.434	neg	8.7089
G6	Amp_b	15-17336 1/1	2.99	2.99		90.36	90.36	neg	9.2943
H6	Amp_b	15-17348 1/1	3.195	3.195		96.555	96.555	neg	8.698
A7	Amp_b	15-17342 1/1	3.141	3.141		94.923	94.923	neg	8.8475
B7	Amp_b	15-17299 1/1	3.301	3.301		99.758	99.758	neg	8.4187

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	0.906	0.875	5.0104	27.38	26.443		30.673
D7	Amp_b	15-17346 1/1	3.293	3.293		99.516	99.516	neg	8.4391
E7	Amp_b	15-17338 1/1	3.31	3.31		100.03	100.03	neg	8.3958
F7	Amp_b	15-17350 1/1	3.354	3.354		101.36	101.36	neg	8.2856
G7	Amp_b	15-17633 1/1	3.281	3.281		99.154	99.154	neg	8.47
H7	Amp_b	15-17631 1/1	3.326	3.326		100.51	100.51	neg	8.3554
A8	Amp_b	15-17636 1/1	1.928	1.928		58.265	58.265	neg	14.414
B8	Amp_b	15-17642 1/1	3.16	3.16		95.497	95.497	neg	8.7943
C8	Amp_b	15-17659 1/1	3.261	3.261		98.549	98.549	neg	8.5219
D8	Amp_b	15-17638 1/1	3.245	3.245		98.066	98.066	neg	8.5639
E8	Amp_b	15-17646 1/1	3.164	3.164		95.618	95.618	neg	8.7832
F8	Amp_b	High-4	0.844			25.506			32.927
G8	Amp_b	16-00047 1/1	3.22	3.22		97.31	97.31	neg	8.6304
H8	Amp_b	High-5	0.799	0.799		24.146	24.146	pos	34.781

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	2.949	2.921	1.3556	100.96	100		7.4771
B1	Cariso_b	Blank-2	2.893			99.041			7.6218
C1	Cariso_b	Cal-1	1.123	1.1025	2.6296	38.446	37.744		19.635
D1	Cariso_b	Cal-2	1.082			37.042			20.379
E1	Cariso_b	Neg-1	1.284	1.276	0.88665	43.958	43.684		17.173
F1	Cariso_b	Neg-2	1.268			43.41			17.39
G1	Cariso_b	High-1	0.864	0.8535	1.7398	29.579	29.219		25.521
H1	Cariso_b	High-2	0.843			28.86			26.157
A2	Cariso_b	16-00023 1/1	2.912	2.912		99.692	99.692	neg	7.5721
B2	Cariso_b	16-00020 1/1	2.881	2.881		98.631	98.631	neg	7.6536
C2	Cariso_b	16-00018 1/1	2.801	2.801		95.892	95.892	neg	7.8722
D2	Cariso_b	16-00019 2/1	2.799	2.799		95.823	95.823	neg	7.8778
E2	Cariso_b	16-00051 1/1	2.713	2.713		92.879	92.879	neg	8.1275
F2	Cariso_b	15-17225 1/1	2.678	2.678		91.681	91.681	neg	8.2338
G2	Cariso_b	15-17336 1/1	2.761	2.761		94.522	94.522	neg	7.9862
H2	Cariso_b	15-17348 1/1	2.554	2.554		87.436	87.436	neg	8.6335
A3	Cariso_b	15-17342 1/1	2.975	2.975		101.85	101.85	neg	7.4118
B3	Cariso_b	15-17299 1/1	2.922	2.922		100.03	100.03	neg	7.5462
C3	Cariso_b	High-3	0.927	0.8575	11.462	31.736	29.356		23.786
D3	Cariso_b	15-17346 1/1	2.883	2.883		98.699	98.699	neg	7.6483
E3	Cariso_b	15-17338 1/1	2.848	2.848		97.501	97.501	neg	7.7423
F3	Cariso_b	15-17350 1/1	1.213	1.213		41.527	41.527	neg	18.178
G3	Cariso_b	15-17633 1/1	2.902	2.902		99.35	99.35	neg	7.5982
H3	Cariso_b	15-17631 1/1	2.895	2.895		99.11	99.11	neg	7.6166
A4	Cariso_b	15-17636 1/1	2.834	2.834		97.022	97.022	neg	7.7805

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	15-17642 1/1	2.618	2.618		89.627	89.627	neg	8.4225
C4	Cariso_b	15-17659 1/1	2.837	2.837		97.124	97.124	neg	7.7723
D4	Cariso_b	15-17638 1/1	2.734	2.734		93.598	93.598	neg	8.0651
E4	Cariso_b	15-17646 1/1	2.748	2.748		94.077	94.077	neg	8.024
F4	Cariso_b	High-4	0.788			26.977			27.982
G4	Cariso_b	16-00047 1/1	2.768	2.768		94.762	94.762	neg	7.966
H4	Cariso_b	High-5	0.74	0.74		25.334	25.334	pos	29.797
A5	Mtdn_b	Blank-1	3.011	3.0645	2.4689	98.254	100		8.9007
B5	Mtdn_b	Blank-2	3.118			101.75			8.5953
C5	Mtdn_b	Cal-1	1.447	1.34	11.293	47.218	43.727		18.521
D5	Mtdn_b	Cal-2	1.233			40.235			21.736
E5	Mtdn_b	Neg-1	2.216	2.3145	6.0186	72.312	75.526		12.094
F5	Mtdn_b	Neg-2	2.413			78.74			11.107
G5	Mtdn_b	High-1	0.768	0.713	10.909	25.061	23.266		34.896
H5	Mtdn_b	High-2	0.658			21.472			40.729
A6	Mtdn_b	16-00023 1/1	3.109	3.109		101.45	101.45	neg	8.6201
B6	Mtdn_b	16-00020 1/1	2.862	2.862		93.392	93.392	neg	9.3641
C6	Mtdn_b	16-00018 1/1	3.34	3.34		108.99	108.99	neg	8.024
D6	Mtdn_b	16-00019 2/1	2.807	2.807		91.597	91.597	neg	9.5476
E6	Mtdn_b	16-00051 1/1	3.367	3.367		109.87	109.87	neg	7.9596
F6	Mtdn_b	15-17225 1/1	3.222	3.222		105.14	105.14	neg	8.3178
G6	Mtdn_b	15-17336 1/1	3.213	3.213		104.85	104.85	neg	8.3411
H6	Mtdn_b	15-17348 1/1	2.479	2.479		80.894	80.894	neg	10.811
A7	Mtdn_b	15-17342 1/1	3.335	3.335		108.83	108.83	neg	8.036
B7	Mtdn_b	15-17299 1/1	3.312	3.312		108.08	108.08	neg	8.0918

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	0.879	0.8405	6.478	28.683	27.427		30.489
D7	Mtdn_b	15-17346 1/1	3.392	3.392		110.69	110.69	neg	7.9009
E7	Mtdn_b	15-17338 1/1	3.165	3.165		103.28	103.28	neg	8.4676
F7	Mtdn_b	15-17350 1/1	3.45	3.45		112.58	112.58	neg	7.7681
G7	Mtdn_b	15-17633 1/1	3.242	3.242		105.79	105.79	neg	8.2665
H7	Mtdn_b	15-17631 1/1	3.44	3.44		112.25	112.25	neg	7.7907
A8	Mtdn_b	15-17636 1/1	3.236	3.236		105.6	105.6	neg	8.2818
B8	Mtdn_b	15-17642 1/1	3.362	3.362		109.71	109.71	neg	7.9714
C8	Mtdn_b	15-17659 1/1	3.233	3.233		105.5	105.5	neg	8.2895
D8	Mtdn_b	15-17638 1/1	3.391	3.391		110.65	110.65	neg	7.9033
E8	Mtdn_b	15-17646 1/1	3.263	3.263		106.48	106.48	neg	8.2133
F8	Mtdn_b	High-4	0.802			26.171			33.416
G8	Mtdn_b	16-00047 1/1	3.217	3.217		104.98	104.98	neg	8.3307
H8	Mtdn_b	High-5	0.594	0.594		19.383	19.383	pos	45.118

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	3.234	3.248	0.6096	99.57	100		10.33
B1	Zol_b	Blank-2	3.262			100.4			10.24
C1	Zol_b	Cal-1	1.732	1.671	5.206	53.33	51.43		19.29
D1	Zol_b	Cal-2	1.609			49.54			20.76
E1	Zol_b	Neg-1	2.094	1.999	6.721	64.47	61.55		15.96
F1	Zol_b	Neg-2	1.904			58.62			17.55
G1	Zol_b	High-1	1.22	1.269	5.407	37.56	39.05		27.39
H1	Zol_b	High-2	1.317			40.55			25.37
A2	Zol_b	16-00023 1/1	3.105	3.105		95.6	95.6	neg	10.76
B2	Zol_b	16-00020 1/1	3.36	3.36		103.4	103.4	neg	9.943
C2	Zol_b	16-00018 1/1	3.246	3.246		99.94	99.94	neg	10.29
D2	Zol_b	16-00019 2/1	3.197	3.197		98.43	98.43	neg	10.45
E2	Zol_b	16-00051 1/1	3.276	3.276		100.9	100.9	neg	10.2
F2	Zol_b	15-17225 1/1	2.987	2.987		91.96	91.96	neg	11.19
G2	Zol_b	15-17336 1/1	3.184	3.184		98.03	98.03	neg	10.49
H2	Zol_b	15-17348 1/1	3.013	3.013		92.76	92.76	neg	11.09
A3	Zol_b	15-17342 1/1	3.223	3.223		99.23	99.23	neg	10.37
B3	Zol_b	15-17299 1/1	3.314	3.314		102	102	neg	10.08
C3	Zol_b	High-3	1.383	0.3329	185.3	42.58	10.25		24.16
D3	Zol_b	15-17346 1/1	3.244	3.244		99.88	99.88	neg	10.3
E3	Zol_b	15-17338 1/1	3.19	3.19		98.21	98.21	neg	10.47
F3	Zol_b	15-17350 1/1	3.015	3.015		92.83	92.83	neg	11.08
G3	Zol_b	15-17633 1/1	3.122	3.122		96.12	96.12	neg	10.7
H3	Zol_b	15-17631 1/1	3.247	3.247		99.97	99.97	neg	10.29
A4	Zol_b	15-17636 1/1	3.381	3.381		104.1	104.1	neg	9.882

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	15-17642 1/1	3.49	3.49		107.5	107.5	neg	9.573
C4	Zol_b	15-17659 1/1	3.349	3.349		103.1	103.1	neg	9.976
D4	Zol_b	15-17638 1/1	3.478	3.478		107.1	107.1	neg	9.606
E4	Zol_b	15-17646 1/1	3.334	3.334		102.6	102.6	neg	10.02
F4	Zol_b	High-4	1.28			39.41			26.1
G4	Zol_b	16-00047 1/1	3.393	3.393		104.5	104.5	neg	9.847
H4	Zol_b	High-5	1.279	1.279		39.38	39.38	pos	26.12
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	2.843	2.88	1.817	98.72	100		6.384
B1	Oxy_b	Blank-2	2.917			101.3			6.222
C1	Oxy_b	Cal-1	0.842	0.9075	10.21	29.24	31.51		21.56
D1	Oxy_b	Cal-2	0.973			33.78			18.65
E1	Oxy_b	Neg-1	1.478	1.644	14.24	51.32	57.07		12.28
F1	Oxy_b	Neg-2	1.809			62.81			10.03
G1	Oxy_b	High-1	0.535	0.5775	10.41	18.58	20.05		33.93
H1	Oxy_b	High-2	0.62			21.53			29.27
A2	Oxy_b	16-00023 1/1	2.692	2.692		93.47	93.47	neg	6.742
B2	Oxy_b	16-00020 1/1	2.748	2.748		95.42	95.42	neg	6.605
C2	Oxy_b	16-00018 1/1	2.866	2.866		99.51	99.51	neg	6.333
D2	Oxy_b	16-00019 2/1	2.798	2.798		97.15	97.15	neg	6.487
E2	Oxy_b	16-00051 1/1	2.73	2.73		94.79	94.79	neg	6.648
F2	Oxy_b	15-17225 1/1	2.81	2.81		97.57	97.57	neg	6.459
G2	Oxy_b	15-17336 1/1	2.558	2.558		88.82	88.82	neg	7.095
H2	Oxy_b	15-17348 1/1	2.73	2.73		94.79	94.79	neg	6.648
A3	Oxy_b	15-17342 1/1	2.77	2.77		96.18	96.18	neg	6.552
B3	Oxy_b	15-17299 1/1	2.752	2.752		95.56	95.56	neg	6.595
C3	Oxy_b	High-3	0.522	0.1385	185.6	18.13	4.809		34.77
D3	Oxy_b	15-17346 1/1	2.845	2.845		98.78	98.78	neg	6.38
E3	Oxy_b	15-17338 1/1	2.811	2.811		97.6	97.6	neg	6.457
F3	Oxy_b	15-17350 1/1	2.401	2.401		83.37	83.37	neg	7.559
G3	Oxy_b	15-17633 1/1	1.056	1.056		36.67	36.67	neg	17.19
H3	Oxy_b	15-17631 1/1	2.822	2.822		97.99	97.99	neg	6.432
A4	Oxy_b	15-17636 1/1	2.823	2.823		98.02	98.02	neg	6.429

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	15-17642 1/1	2.71	2.71		94.1	94.1	neg	6.697
C4	Oxy_b	15-17659 1/1	2.72	2.72		94.44	94.44	neg	6.673
D4	Oxy_b	15-17638 1/1	2.791	2.791		96.91	96.91	neg	6.503
E4	Oxy_b	15-17646 1/1	2.697	2.697		93.65	93.65	neg	6.73
F4	Oxy_b	High-4	0.586			20.35			30.97
G4	Oxy_b	16-00047 1/1	2.8	2.8		97.22	97.22	neg	6.482
H4	Oxy_b	High-5	0.58	0.58		20.14	20.14	pos	31.29
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>PC1 --> TRUE
PC1>HPC1 --> TRUE

HOUSTON FORENSIC SCIENCE CENTER
CORRECTIVE ACTION REPORT

QUALITY DIVISION USE ONLY

Quality CAR #	2016-018	**Date Submitted:**	4/12/2016
Non-Conformance Level	CLASS III	**Date Closed:**	4/27/2016

Date of this Report:	2/22/2016	**Division:**	FAD	**FCN:** (If applicable)	Multiple
Date of Incident:	2/19/2016	**Section:**	Toxicology		

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

For 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.
4-27-16

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 Wehrman **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 (Immunalysis).

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

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

Form Complete Date/Signature:

From: Andrea Gooden
To: Dayong 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
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Houston Forensic Science Center
1301 Fannin St, Suite 170
Houston, Texas 77002