Houston Forensic Science Center

Comparative and Analytical Division - Toxicology

Immunoassay Batch Review Checklist

Batch Name: EIA-20180626U-AAJ		**Analyst Review**	**Technical Review**
Worklist	Batch name written and item(s) tested for each case listed	✓	✓
	Pipette(s) used listed	✓	✓
	Lot numbers for calibrators, controls, and reagents are listed	✓	✓
	Inventory number(s) listed	✓	✓
Sequence	Verify batch file name is consistent	✓	✓
	Reviewer verified, initialed, and dated sequence	✓	✓
	Verify appropriate calibrator and controls were analyzed, and appropriate controls were run at least after every 10 case samples	✓	✓
	Verify all cases were processed and have data	N/A	N/A
Magellan Data	Verify average absorbance of blank replicates is above 1.000	✓ AAJ 6/26/18	✓
	Verify calibrators and controls are acceptable	✓	✓
	Verify case samples are bracketed by acceptable positive controls	N/A	N/A
	Verify correct method was run	✓ AAJ 6/27/18	✓
Immunoassay Case Summary Report	Verify absorbance readings on Immunoassay Case Summary Report against Magellan data	N/A	N/A
	Verify results on Immunoassay Case Summary Report against Magellan data	↓	↓
	Verify analyst, matrix, instrument, and batch name(s)	↓	↓
	Verify forensic case number and item tested	✓	↓
Immunoassay Batch QC Data Worksheet	Verify batch and analyst names	✓	✓
	Verify preparation of calibrators, controls, and reagents	✓	✓
	Verify pipette(s) against those listed on the worklist	✓	✓
	Verify lot numbers and expiration dates of calibrators, controls, and reagents	✓	✓
	Verify kit lot numbers and expirations dates against Drug Standard Database	✓	✓
Verify all quality controls were added to QC Logs		✓	✓
All comments and/or strikethroughs, if any, initialed		✓	✓
All pages contain batch name and are initialed		✓	✓

Houston Forensic Science Center

Comparative and Analytical Division - Toxicology

Notes from Technical Review CIA_20180626U_AAJ

- Check marks left off checklist "Magellan Data" section.
- Incorrect batch name on QC datasheet.
- Values transcribed incorrectly in QC log: carisoprodol (all), methadone (neg abs.), and oxycodone (cal % binding).

- emc 06/27/18

Analyst Review

Signature/Date: 6/26/18

Technical Review

Signature/Date: 06/27/18

Houston Forensic Science Center

Comparative and Analytical Division - Toxicology

Immunoassay Batch QC Data

Batch: EIA-20180626U ~~EIA062618~~ - AAJ aaj 6/27/18 **Analyst:** Ashley Ann Johnson

Matrix: ☐ Blood ☑ Urine

Instrument: ☐ Tecan ☑ Tecan-2

Pipette(s): 0395 2350

Phosphate Buffer Saline Lot Number: 040918-PBS7 **Expiration Date:** 10/9/18

Controls:	Lot Number	Expiration	Oxycodone:	Lot Number	Expiration
Blank	101017U	10/10/18			
Negative	050718U-NEG	10/27/18	Negative	050718U-Q-50	10/9/18
Calibrator	050418U-MXC	10/27/18	Calibrator	050418U-C-100	10/9/18
Positive	050718U-MXP	10/27/18	Positive	050718U-Q-200	10/9/18

	Kit Lot Number	Expiration		Kit Lot Number	Expiration
Amphetamine	EK16566	2/19	Methadone	EK16418	12/18
Barbiturates	EK16588	2/19	Methamphetamine	EK16296	11/18
Benzodiazepines	EK16701	3/19	Opiates	EK16544	2/19
Benzoylecgonine	EK16643	3/19	Phencyclidine	EK16593	2/19
Cannabinoids	EK16653	3/19	Zolpidem	N/A	N/A
Carisoprodol	EK16763	4/19	Oxycodone	EK16167	10/18

Comments: Verification following maintenance. aaj 6/26/18

aaj

Batch: GIA_20160626U_AAJ

Inventory #	Exp.
AMP - 17	2/19
BARB - 16	2/19
BZ - 7	3/19
BE - 4	3/19
THC - 6	3/19
CARISO - 17	4/19
MTDN - 16	12/18
METH - 4	11/18
OPI - 4	2/19
PCP - 20	2/19
ZOL - n/a	
OXY - 7U	10/18

PBS: 040918-PBS7 Exp. 10/9/18

Pipettes: 0395, 235D

Controls:

Blank: 101017U Exp. 10/10/18

Mixed		Exp.	Oxy		Exp.
Neg:	050718U-MXN	10/27/18	Neg:	050718U-A-50	10/9/18
Cal:	050418U-MXC	↓	Cal:	050418U-C-100	↓
Pos:	050718U-MXP		Pos:	050418U-A-200	
TMB:	aaj 6/26/18		Zol TMB:	aaj 6/26/18	
STOP:					

Notes:

Verification following maintenance. aaj 6/26/18

aaj

Tuesday, June 26, 2018 10:22:01 AM Houston
Forensic Science Center Page 1 of 2
EIA_20180626U_AAJ PBS: 040918-PBS7 Pipettes: 235D, 0395 Verification

	ID	209	210	214	206	205	231	232	211	207
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	Negative-1	X	X	X	X	X	X	X	X	X
4	Negative-2	X	X	X	X	X	X	X	X	X
5	Calibrator-1	X	X	X	X	X	X	X	X	X
6	Calibrator-2	X	X	X	X	X	X	X	X	X
7	Positive-1	X	X	X	X	X	X	X	X	X
8	Positive-2	X	X	X	X	X	X	X	X	X
9	Oxy Negative-1	O	O	O	O	O	O	O	O	O
10	Oxy Negative-2	O	O	O	O	O	O	O	O	O
11	Oxy Calibrator-1	O	O	O	O	O	O	O	O	O
12	Oxy Calibrator-2	O	O	O	O	O	O	O	O	O
13	Oxy Postive-1	O	O	O	O	O	O	O	O	O
14	Oxy Positive-2	O	O	O	O	O	O	O	O	O
15	050718U-MXN	X	X	X	X	X	X	X	X	X
16	050418U-MXC	X	X	X	X	X	X	X	X	X
17	050718U-MXP	X	X	X	X	X	X	X	X	X
18	050718U-Q-50	O	O	O	O	O	O	O	O	O
19	050418U-C-100	O	O	O	O	O	O	O	O	O
20	050718U-Q-200	O	O	O	O	O	O	O	O	O

SEQUENCE VERIFIED
6/26/18
AAJ

AAJ

EIA_20180626U_AAJ PBS: 040918-PBS7 Pipettes: 235D, 0395 Verification

	ID	208	221
1	Blank-1	X	X
2	Blank-2	X	X
3	Negative-1	X	O
4	Negative-2	X	O
5	Calibrator-1	X	O
6	Calibrator-2	X	O
7	Positive-1	X	O
8	Positive-2	X	O
9	Oxy Negative-1	O	X
10	Oxy Negative-2	O	X
11	Oxy Calibrator-1	O	X
12	Oxy Calibrator-2	O	X
13	Oxy Postive-1	O	X
14	Oxy Positive-2	O	X
15	050718U-MXN	X	O
16	050418U-MXC	X	O
17	050718U-MXP	X	O
18	050718U-Q-50	O	X
19	050418U-C-100	O	X
20	050718U-Q-200	O	X

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

	1	2	3	4	5	6	7	8
A1	209	Blank-1	3.51	3.4805	1.1987	100.85	100	
B1	209	Blank-2	3.451			99.152		
C1	209	Negative-1	1.813	1.728	6.9565	52.09	49.648	
D1	209	Negative-2	1.643			47.206		
E1	209	Calibrator-1	1.077	1.039	5.1723	30.944	29.852	
F1	209	Calibrator-2	1.001			28.76		
G1	209	Positive-1	0.57	0.5575	3.1709	16.377	16.018	
H1	209	Positive-2	0.545			15.659		
A2	209	050718U-MXN	1.528	1.528		43.902	43.902	neg
B2	209	050418U-MXC	0.919	0.919		26.404	26.404	POS
C2	209	050718U-MXP	0.515	0.515		14.797	14.797	POS
A3	210	Blank-1	3.384	3.4175	1.3863	99.02	100	
B3	210	Blank-2	3.451			100.98		
C3	210	Negative-1	1.626	1.5905	3.1565	47.579	46.54	
D3	210	Negative-2	1.555			45.501		
E3	210	Calibrator-1	1.266	1.2425	2.6748	37.045	36.357	
F3	210	Calibrator-2	1.219			35.669		

EIA_20180626CU-MAJ

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

	1	2	3	4	5	6	7	8
G3	210	Positive-1	0.89	0.9165	4.0891	26.042	26.818	
H3	210	Positive-2	0.943			27.593		
A4	210	050718U-MXN	1.583	1.583		46.32	46.32	neg
B4	210	050418U-MXC	1.364	1.364		39.912	39.912	neg
C4	210	050718U-MXP	0.913	0.913		26.715	26.715	POS

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

	1	2	3	4	5	6	7	8
A1	214	Blank-1	2.797	2.749	2.4693	101.75	100	
B1	214	Blank-2	2.701			98.254		
C1	214	Negative-1	1.035	1.088	6.8891	37.65	39.578	
D1	214	Negative-2	1.141			41.506		
E1	214	Calibrator-1	0.55	0.5715	5.3203	20.007	20.789	
F1	214	Calibrator-2	0.593			21.571		
G1	214	Positive-1	0.311	0.3095	0.6854	11.313	11.259	
H1	214	Positive-2	0.308			11.204		
A2	214	050718U-MXN	1.095	1.095		39.833	39.833	neg
B2	214	050418U-MXC	0.421	0.421		15.315	15.315	POS
C2	214	050718U-MXP	0.311	0.311		11.313	11.313	POS
A3	206	Blank-1	2.493	2.5265	1.8752	98.674	100	
B3	206	Blank-2	2.56			101.33		
C3	206	Negative-1	1.83	1.8155	1.1295	72.432	71.858	
D3	206	Negative-2	1.801			71.284		
E3	206	Calibrator-1	1.599	1.617	1.5743	63.289	64.002	
F3	206	Calibrator-2	1.635			64.714		

EIA_20180626U-AAJ

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

	1	2	3	4	5	6	7	8
G3	206	Positive-1	1.447	1.407	4.0205	57.273	55.69	
H3	206	Positive-2	1.367			54.106		
A4	206	050718U-MXN	1.85	1.85		73.224	73.224	neg
B4	206	050418U-MXC	1.565	1.565		61.943	61.943	POS
C4	206	050718U-MXP	1.442	1.442		57.075	57.075	POS

EIA-20180626U-AAJ

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

	1	2	3	4	5	6	7	8
A1	205	Blank-1	2.964	2.9765	0.59391	99.58	100	
B1	205	Blank-2	2.989			100.42		
C1	205	Negative-1	1.977	1.9735	0.25081	66.42	66.303	
D1	205	Negative-2	1.97			66.185		
E1	205	Calibrator-1	1.57	1.512	5.4249	52.747	50.798	
F1	205	Calibrator-2	1.454			48.849		
G1	205	Positive-1	0.802	0.8065	0.78908	26.944	27.096	
H1	205	Positive-2	0.811			27.247		
A2	205	050718U-MXN	2.109	2.109		70.855	70.855	neg
B2	205	050418U-MXC	1.605	1.605		53.922	53.922	neg
C2	205	050718U-MXP	0.786	0.786		26.407	26.407	POS
A3	231	Blank-1	3.096	3.1255	1.3348	99.056	100	
B3	231	Blank-2	3.155			100.94		
C3	231	Negative-1	1.98	2.0365	3.9235	63.35	65.158	
D3	231	Negative-2	2.093			66.965		
E3	231	Calibrator-1	1.662	1.658	0.34119	53.175	53.048	
F3	231	Calibrator-2	1.654			52.92		

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

	1	2	3	4	5	6	7	8
G3	231	Positive-1	1.214	1.201	1.5308	38.842	38.426	
H3	231	Positive-2	1.188			38.01		
A4	231	050718U-MXN	2.067	2.067		66.133	66.133	neg
B4	231	050418U-MXC	1.674	1.674		53.559	53.559	neg
C4	231	050718U-MXP	1.299	1.299		41.561	41.561	POS

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

	1	2	3	4	5	6	7	8
A1	232	Blank-1	1.74	1.758	1.448	98.976	100	
B1	232	Blank-2	1.776			101.02		
C1	232	Negative-1	0.495	0.492	0.86233	28.157	27.986	
D1	232	Negative-2	0.489			27.816		
E1	232	Calibrator-1	0.246	0.2565	5.7892	13.993	14.59	
F1	232	Calibrator-2	0.267			15.188		
G1	232	Positive-1	0.138	0.1395	1.5207	7.8498	7.9352	
H1	232	Positive-2	0.141			8.0205		
A2	232	050718U-MXN	0.593	0.593		33.732	33.732	neg
B2	232	050418U-MXC	0.313	0.313		17.804	17.804	neg
C2	232	050718U-MXP	0.14	0.14		7.9636	7.9636	POS
A3	211	Blank-1	2.398	2.4485	2.9168	97.938	100	
B3	211	Blank-2	2.499			102.06		
C3	211	Negative-1	1.153	1.128	3.1343	47.09	46.069	
D3	211	Negative-2	1.103			45.048		
E3	211	Calibrator-1	0.742	0.7665	4.5203	30.304	31.305	
F3	211	Calibrator-2	0.791			32.305		

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

	1	2	3	4	5	6	7	8
G3	211	Positive-1	0.565	0.5675	0.623	23.075	23.177	
H3	211	Positive-2	0.57			23.28		
A4	211	050718U-MXN	0.918	0.918		37.492	37.492	neg
B4	211	050418U-MXC	0.721	0.721		29.447	29.447	POS
C4	211	050718U-MXP	0.434	0.434		17.725	17.725	POS

ETA-20180626U-AAJ

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

OPI

PCP

	1	2	3	4	5	6	7	8
A1	207	Blank-1	3.099	3.0925	0.29725	100.21	100	
B1	207	Blank-2	3.086			99.79		
C1	207	Negative-1	0.514	0.5485	8.8952	16.621	17.736	
D1	207	Negative-2	0.583			18.852		
E1	207	Calibrator-1	0.317	0.329	5.1582	10.251	10.639	
F1	207	Calibrator-2	0.341			11.027		
G1	207	Positive-1	0.199	0.189	7.4826	6.4349	6.1116	
H1	207	Positive-2	0.179			5.7882		
A2	207	050718U-MXN	0.602	0.602		19.466	19.466	neg
B2	207	050418U-MXC	0.309	0.309		9.9919	9.9919	POS
C2	207	050718U-MXP	0.176	0.176		5.6912	5.6912	POS
A3	208	Blank-1	2.951	3.0025	2.4257	98.285	100	
B3	208	Blank-2	3.054			101.72		
C3	208	Negative-1	1.384	1.406	2.2129	46.095	46.828	
D3	208	Negative-2	1.428			47.56		
E3	208	Calibrator-1	0.906	0.9155	1.4675	30.175	30.491	
F3	208	Calibrator-2	0.925			30.808		

EIA-20180626CU-AAJ

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

	1	2	3	4	5	6	7	8
G3	208	Positive-1	0.619	0.6095	2.2043	20.616	20.3	
H3	208	Positive-2	0.6			19.983		
A4	208	050718U-MXN	1.474	1.474		49.092	49.092	neg
B4	208	050418U-MXC	0.943	0.943		31.407	31.407	neg
C4	208	050718U-MXP	0.575	0.575		19.151	19.151	POS

CIA_20180626C4-AAJ

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

	1	2	3	4	5	6	7	8
A1	221	Blank-1	3.278	3.2635	0.62835	100.44	100	
B1	221	Blank-2	3.249			99.556		
C1	221	Oxy Negative-1	1.519	1.513	0.56082	46.545	46.361	
D1	221	Oxy Negative-2	1.507			46.177		
E1	221	Oxy Calibrator-1	1.34	1.3355	0.47652	41.06	40.922	
F1	221	Oxy Calibrator-2	1.331			40.784		
G1	221	Oxy Postive-1	1.064	1.0605	0.46674	32.603	32.496	
H1	221	Oxy Positive-2	1.057			32.389		
A2	221	050718U-Q-50	1.564	1.564		47.924	47.924	neg
B2	221	050418U-C-100	1.332	1.332		40.815	40.815	POS
C2	221	050718U-Q-200	1.08	1.08		33.093	33.093	POS

EIA-20180626U-AAJ