



Verification for Qualitative Test Methods

Purpose	To show that the instrument is fit for use after Tecan preventative maintenance was performed.
Analytes	Amphetamine, Barbiturates, Benzodiazepines, Cocaine and metabolites, Cannabinoids, Carisoprodol, Fentanyl, Methadone, Methamphetamine, Opiates, Phencyclidine, Zolpidem (Blood only), and Oxycodone
Units of Measure	ng/mL
Analyst Performing Validation Study	V. Coronado and D. Mike
Responsible Supervisor	Dayong Lee, Ph.D.
Start Date	September 8, 2020
Completion Date	September 17, 2020
Primary Matrix	Blood & Urine
Calibrator Concentration (Blood &Urine)	d-Amphetamine (20 & 200 ng/mL); Secobarbital (50 & 300 ng/mL); Oxazepam (20 & 100 ng/mL); Benzoylcegonine (20 & 150 ng/mL); 11-nor-9-carboxy-THC (5 & 20 ng/mL); Carisoprodol (500 & 500 ng/mL); Fentanyl (1 & 1 ng/mL); Methadone (25 & 300 ng/mL); d-Methamphetamine (20 & 200 ng/mL); Morphine (10 & 200 ng/mL); Phencyclidine (10 & 25 ng/mL); Zolpidem (10 ng/mL); and Oxycodone (10 & 100 ng/mL)
Equipment/Instrument	Tecan-2
Instrument Serial Number	1010008386
Method	ELISA

Verification Approval

Analyst: _____ Date

Analyst: _____ Date

Responsible Supervisor: _____ Date

Verification Study

ELISA CONTROL CRITERIA

Method **ELISA**
 Units: **ng/mL**
 Instrument: **Tecan-2**

Analyst: **V. Coronado and D. Mike**
 Study Dates: **9/8/20 to 9/17/20**
 Matrix: **Blood**

Batch Name	Analyte	Blank % CV	Average Absorbance			Average % Binding			Average Absorbance and % Binding Acceptable	
			Blank	Negative	Calibrator	Positive	Negative	Calibrator		Positive
	<i>Acceptance Criteria</i>	<20	>1.0						<i>Blank>Negative>Cal>Positive</i>	
EIA_20200908B_VC	Amphetamine	0.24	3.18	2.92	2.33	1.95	91.82	73.26	61.37	Yes
	Barbiturates	2.77	2.89	1.84	1.33	1.16	63.78	46.16	40.07	Yes
	Cocaine and Metabolites	1.46	3.35	2.41	2.10	1.83	71.75	62.64	54.56	Yes
	Cannabinoids	1.30	2.61	2.07	1.66	0.83	79.37	63.43	31.84	Yes
	Carisoprodol	0.61	3.26	2.04	1.12	0.84	62.69	34.46	25.70	Yes
	Fentanyl	0.69	2.55	1.44	1.11	0.88	56.71	43.43	34.40	Yes
	Methadone	4.18	3.11	1.37	0.86	0.60	44.07	27.71	19.27	Yes
	Methamphetamine	0.16	3.04	2.19	1.74	1.46	72.15	57.24	48.05	Yes
	Opiates	0.80	3.02	2.10	1.68	1.30	69.71	55.53	43.13	Yes
	Phencyclidine	2.22	2.84	1.28	0.92	0.66	44.96	32.42	23.39	Yes
	Zolpidem	0.41	3.24	2.01	1.48	1.26	62.05	45.63	38.91	Yes
	Oxycodone	0.31	3.18	1.38	0.73	0.47	43.33	22.86	14.68	Yes

Batch Name	Analyte	Blank % CV	Average Absorbance			Average % Binding			Average Absorbance and % Binding Acceptable	
			Blank	Negative	Calibrator	Positive	Negative	Calibrator		Positive
	<i>Acceptance Criteria</i>	<20	>1.0						<i>Blank>Negative>Cal>Positive</i>	
EIA_20200917B_DM	Amphetamine	0.04	3.15	2.81	2.22	1.87	89.19	70.36	59.15	Yes
	Barbiturates	0.72	2.86	1.87	1.35	1.13	65.58	47.30	39.39	Yes
	Benzodiazepines	5.76	2.17	1.22	0.86	0.73	55.97	39.63	33.60	Yes
	Cocaine and Metabolites	1.44	3.53	2.48	2.16	1.79	70.30	61.23	50.75	Yes

Comments:

Verification Study

ELISA CONTROL CRITERIA

Method **ELISA**
 Units: **ng/mL**
 Instrument: **Tecan-2**

Analyst: **V. Coronado and D. Mike**
 Study Dates: **9/8/20 to 9/17/20**
 Matrix: **Urine**

Batch Name	Analyte	Blank % CV	Average Absorbance			Average % Binding			Average Absorbance and % Binding Acceptable	
			Blank	Negative	Calibrator	Positive	Negative	Calibrator		Positive
	<i>Acceptance Criteria</i>	<20	>1.0						<i>Blank>Negative>Cal>Positive</i>	
EIA_20200908U_VC	Amphetamine	0.38	3.13	1.52	0.87	0.64	48.63	27.86	20.30	Yes
	Barbiturates	2.74	2.76	1.29	1.01	0.75	46.61	36.47	27.21	Yes
	Benzodiazepines	1.24	1.60	0.55	0.30	0.22	34.15	18.73	13.76	Yes
	Cocaine and Metabolites	0.20	3.26	2.16	1.94	1.68	66.38	59.50	51.54	Yes
	Cannabinoids	3.87	2.58	1.96	1.47	1.17	76.05	57.17	45.49	Yes
	Carisoprodol	1.26	3.24	1.88	1.44	1.10	57.88	44.42	33.83	Yes
	Fentanyl	3.68	2.32	1.63	1.15	1.00	70.16	49.49	42.97	Yes
	Methadone	3.44	3.12	1.04	0.55	0.41	33.28	17.71	13.00	Yes
	Methamphetamine	0.73	3.11	1.66	1.17	1.06	53.28	37.64	33.99	Yes
	Opiates	0.66	2.90	0.69	0.43	0.35	23.81	14.94	12.18	Yes
	Phencyclidine	4.65	2.51	0.97	0.61	0.48	38.69	24.19	19.15	Yes
	Oxycodone	1.32	3.33	1.53	1.31	1.12	46.02	39.26	33.59	Yes

Comments: Values from the reinjection analysis (EIA_20200908U_VC2) used for Amphetamine, Barbiturates, Benzodiazepines, and Cocaine and Metabolites analytes.

Acceptance Criteria: Refer to the Drug Screen by Enzyme-Linked Immunosorbent Assay (ELISA) section 12.9 of the Analytical Manual Standard Operating Procedures Version 3.4.

Analyte: Amphetamine					Analyte: Barbiturates				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: d-Amphetamine					Target Analyte: Secobarbital				
Cal Conc: 20 ng/mL		Sample Volume: 10 µL		Cal Conc: 50 ng/ml		Sample Volume: 20 µL			
Neg QC Conc: 10 ng/mL				Neg QC Conc: 10 ng/ml					
Pos QC Conc: 40 ng/mL				Pos QC Conc: 100 ng/ml					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200908B_VC	1	2.974	1.952	93.566	61.413	EIA_20200908B_VC	1	1.811	1.165
	2	2.863	1.949	90.074	61.318		2	1.871	1.148
	3	2.816	1.786	88.595	56.190		3	1.909	1.109
EIA_20200917B_DM	1	2.851	1.840	90.393	58.339	EIA_20200917B_DM	1	1.877	1.097
	2	2.775	1.891	87.984	59.956		2	1.871	1.154
	3	2.888	1.663	91.566	52.727		3	1.975	1.174
	Mean	2.861	1.847	90.363	58.324		Mean	1.886	1.141
	Stdev	0.068	0.110	2.029	3.378		Stdev	0.054	0.031
	% CV	2.372	5.980	2.245	5.792		% CV	2.866	2.727
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes
Analyte: Benzodiazepines					Analyte: Cocaine and Metabolites				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: Oxazepam					Target Analyte: Benzoyllecgonine				
Cal Conc: 20 ng/mL		Sample Volume: 30 µL		Cal Conc: 20 ng/mL		Sample Volume: 75 µL			
Neg QC Conc: 10 ng/mL				Neg QC Conc: 10 ng/mL					
Pos QC Conc: 40 ng/mL				Pos QC Conc: 40 ng/mL					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200917B_DM	1	1.259	0.742	57.952	34.154	EIA_20200908B_VC	1	2.451	1.837
	2	1.173	0.718	53.993	33.049		2	2.360	1.821
	3	1.145	0.691	52.704	31.807		3	2.449	1.801
	Mean	1.192	0.717	54.883	33.003	EIA_20200917B_DM	1	2.521	1.682
	Stdev	0.059	0.026	2.735	1.174		2	2.458	1.898
	% CV	4.983	3.559	4.983	3.558		3	2.492	1.842
	Acceptable?	Yes	Yes	Yes	Yes		Mean	2.452	1.814
							Stdev	0.055	0.072
							% CV	2.236	3.977
							Acceptable?	Yes	Yes
Analyte: Cannabinoids					Analyte: Carisoprodol				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: 11-nor-9-carboxy-THC					Target Analyte: Carisoprodol				
Cal Conc: 5 ng/mL		Sample Volume: 50 µL		Cal Conc: 500 ng/mL		Sample Volume: 10 µL			
Neg QC Conc: 2.5 ng/mL				Neg QC Conc: 100 ng/mL					
Pos QC Conc: 20 ng/mL				Pos QC Conc: 1000 ng/mL					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200908B_VC	1	2.087	0.808	79.195	30.958	EIA_20200908B_VC	1	2.087	0.837
	2	2.076	0.854	79.540	32.720		2	1.999	0.838
	3	2.104	0.817	80.613	31.303		3	1.785	0.784
	Mean	2.082	0.826	79.783	31.660		Mean	1.957	0.820
	Stdev	0.019	0.024	0.739	0.934		Stdev	0.155	0.031
	% CV	0.927	2.950	0.927	2.949		% CV	7.937	3.769
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes
Analyte: Fentanyl					Analyte: Methadone				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: Fentanyl					Target Analyte: Methadone				
Cal Conc: 1 ng/mL		Sample Volume: 75 µL		Cal Conc: 25 ng/mL		Sample Volume: 25 µL			
Neg QC Conc: 0.5 ng/mL				Neg QC Conc: 12.5 ng/mL					
Pos QC Conc: 2 ng/mL				Pos QC Conc: 50 ng/mL					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200908B_VC	1	1.460	0.872	57.334	34.243	EIA_20200908B_VC	1	1.380	0.569
	2	1.428	0.880	56.077	34.557		2	1.364	0.631
	3	1.495	0.918	58.708	36.049		3	1.338	0.610
	Mean	1.461	0.890	57.373	34.950		Mean	1.361	0.603
	Stdev	0.034	0.025	1.316	0.965		Stdev	0.021	0.032
	% CV	2.294	2.761	2.294	2.761		% CV	1.558	5.226
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes
Analyte: Methamphetamine					Analyte: Opiates				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: d-Methamphetamine					Target Analyte: Morphine				
Cal Conc: 20 ng/mL		Sample Volume: 25 µL		Cal Conc: 10 ng/mL		Sample Volume: 10 µL			
Neg QC Conc: 10 ng/mL				Neg QC Conc: 5 ng/mL					
Pos QC Conc: 40 ng/mL				Pos QC Conc: 20 ng/mL					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200908B_VC	1	2.203	1.403	72.575	46.220	EIA_20200908B_VC	1	2.238	1.306
	2	2.177	1.514	71.718	49.878		2	1.971	1.298
	3	2.078	1.389	68.457	45.759		3	2.199	1.218
	Mean	2.153	1.435	70.917	47.285		Mean	2.136	1.274
	Stdev	0.066	0.068	2.173	2.256		Stdev	0.144	0.049
	% CV	3.064	4.771	3.064	4.770		% CV	6.752	3.820
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes
Analyte: Phencyclidine					Analyte: Zolpidem				
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood	
Target Analyte: Phencyclidine					Target Analyte: Zolpidem				
Cal Conc: 10 ng/mL		Sample Volume: 10 µL		Cal Conc: 10 ng/mL		Sample Volume: 100 µL			
Neg QC Conc: 5 ng/mL				Neg QC Conc: 2.5 ng/mL					
Pos QC Conc: 20 ng/mL				Pos QC Conc: 20 ng/mL					
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)			Negative QC (Abs)	Positive QC (Abs)
EIA_20200908B_VC	1	1.308	0.657	46.048	23.130	EIA_20200908B_VC	1	2.028	1.299
	2	1.246	0.672	43.866	23.658		2	1.996	1.224
	3	1.224	0.649	43.091	22.848		3	2.123	1.176
	Mean	1.259	0.659	44.335	23.212		Mean	2.049	1.233
	Stdev	0.044	0.012	1.533	0.411		Stdev	0.066	0.062
	% CV	3.459	1.771	3.458	1.771		% CV	3.224	5.028
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes
Analyte: Oxycodone									
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Blood						
Target Analyte: Oxycodone									
Cal Conc: 10 ng/mL		Sample Volume: 10 µL							
Neg QC Conc: 5 ng/mL									
Pos QC Conc: 20 ng/mL									
		Negative QC (Abs)	Positive QC (Abs)	Negative QC (% Binding)	Positive QC (% Binding)				
EIA_20200908B_VC	1	1.343	0.453	42.259	14.254				
	2	1.411	0.480	44.399	15.104				
	3	1.270	0.436	39.962	13.719				
	Mean	1.341	0.456	42.207	14.359				
	Stdev	0.071	0.022	2.219	0.698				
	% CV	5.257	4.862	5.257	4.864				
	Acceptable?	Yes	Yes	Yes	Yes				

Analyte: Amphetamine					Analyte: Barbiturates						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: d-Amphetamine			Sample Volume: 10 µL		Target Analyte: Secobarbital			Sample Volume: 10 µL			
Cal Conc: 200 ng/mL					Cal Conc: 300 ng/ml						
Neg QC Conc: 100 ng/mL					Neg QC Conc: 150 ng/ml						
Pos QC Conc: 400 ng/mL					Pos QC Conc: 900 ng/ml						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	1.617	0.635	51.653	20.284	EIA_20200908U_VC	1	1.252	0.735	45.338	26.616
	2	1.428	0.636	45.616	20.316		2	1.322	0.768	47.873	27.811
	3	1.584	0.544	50.599	17.377		3	1.327	0.740	48.054	26.797
	Mean	1.543	0.605	49.289	19.326		Mean	1.300	0.748	47.088	27.075
	Stdev	0.101	0.053	3.225	1.688		Stdev	0.042	0.018	1.519	0.644
	% CV	6.542	8.732	6.542	8.733		% CV	3.225	2.379	3.225	2.379
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes
Analyte: Benzodiazepines					Analyte: Cocaine and Metabolites						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: Oxazepam			Sample Volume: 40 µL		Target Analyte: Benzoylcegonine			Sample Volume: 20 µL			
Cal Conc: 100 ng/mL					Cal Conc: 150 ng/mL						
Neg QC Conc: 50 ng/mL					Neg QC Conc: 75 ng/mL						
Pos QC Conc: 300 ng/mL					Pos QC Conc: 300 ng/mL						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	0.572	0.217	35.705	13.546	EIA_20200908U_VC	1	2.032	1.639	62.417	50.346
	2	0.522	0.224	32.584	13.983		2	2.290	1.717	70.342	52.742
	3	0.464	0.282	28.964	17.603		3	2.325	1.587	71.418	48.748
	Mean	0.519	0.241	32.418	15.044		Mean	2.216	1.648	68.059	50.612
	Stdev	0.054	0.036	3.374	2.227		Stdev	0.160	0.065	4.916	2.010
	% CV	10.407	14.805	10.407	14.803		% CV	7.222	3.971	7.223	3.972
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes
Analyte: Cannabinoids					Analyte: Carisoprodol						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: 11-nor-9-carboxy-THC			Sample Volume: 50 µL		Target Analyte: Carisoprodol			Sample Volume: 10 µL			
Cal Conc: 20 ng/mL					Cal Conc: 500 ng/mL						
Neg QC Conc: 10 ng/mL					Neg QC Conc: 250 ng/mL						
Pos QC Conc: 60 ng/mL					Pos QC Conc: 1000 ng/mL						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	1.990	1.023	77.237	39.705	EIA_20200908U_VC	1	1.886	1.063	58.156	32.778
	2	1.929	1.321	74.869	51.271		2	1.868	1.131	57.601	34.875
	3	2.021	1.102	78.440	42.771		3	1.743	1.012	53.747	31.206
	Mean	1.980	1.149	76.849	44.582		Mean	1.832	1.069	56.501	32.953
	Stdev	0.047	0.154	1.817	5.992		Stdev	0.078	0.060	2.401	1.841
	% CV	2.364	13.440	2.364	13.440		% CV	4.251	5.587	4.250	5.586
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes
Analyte: Fentanyl					Analyte: Methadone						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: Fentanyl			Sample Volume: 75 µL		Target Analyte: Methadone			Sample Volume: 10 µL			
Cal Conc: 1 ng/mL					Cal Conc: 300 ng/mL						
Neg QC Conc: 0.5 ng/mL					Neg QC Conc: 150 ng/mL						
Pos QC Conc: 2 ng/mL					Pos QC Conc: 600 ng/mL						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	1.609	0.975	69.279	41.981	EIA_20200908U_VC	1	0.987	0.402	31.614	13.004
	2	1.650	1.021	71.044	43.961		2	1.091	0.410	34.946	13.133
	3	1.637	1.038	70.484	44.693		3	0.932	0.383	29.853	12.268
	Mean	1.632	1.011	70.269	43.545		Mean	1.003	0.398	32.138	12.802
	Stdev	0.021	0.033	0.902	1.403		Stdev	0.081	0.014	2.587	0.467
	% CV	1.284	3.223	1.284	3.222		% CV	8.048	3.482	8.048	3.645
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes
Analyte: Methamphetamine					Analyte: Opiates						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: d-Methamphetamine			Sample Volume: 10 µL		Target Analyte: Morphine			Sample Volume: 10 µL			
Cal Conc: 200 ng/mL					Cal Conc: 200 ng/mL						
Neg QC Conc: 100 ng/mL					Neg QC Conc: 100 ng/mL						
Pos QC Conc: 400 ng/mL					Pos QC Conc: 400 ng/mL						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	1.600	0.930	51.447	29.904	EIA_20200908U_VC	1	0.700	0.322	24.117	12.179
	2	1.714	1.184	55.113	38.071		2	0.682	0.385	23.497	13.264
	3	1.625	0.953	52.251	30.643		3	0.645	0.302	22.222	10.405
	Mean	1.646	1.022	52.937	32.873		Mean	0.676	0.336	23.279	11.949
	Stdev	0.060	0.140	1.927	4.517		Stdev	0.028	0.043	0.966	1.443
	% CV	3.640	13.741	3.640	13.741		% CV	4.150	12.879	4.151	12.078
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes
Analyte: Phencyclidine					Analyte: Oxycodone						
Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine		Instrument: Tecan-2 Analyst: V. Coronado and D. Mike			Study Dates: 9/8/20 to 9/17/20 Matrix: Urine			
Target Analyte: Phencyclidine			Sample Volume: 10 µL		Target Analyte: Oxycodone			Sample Volume: 40 µL			
Cal Conc: 25 ng/mL					Cal Conc: 100 ng/mL						
Neg QC Conc: 12.5 ng/mL					Neg QC Conc: 50 ng/mL						
Pos QC Conc: 50 ng/mL					Pos QC Conc: 200 ng/mL						
		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)		Negative QC (Abs)	Positive QC (Abs)	Negative QC Binding (%)	Positive QC (% Binding)	
EIA_20200908U_VC	1	1.019	0.447	40.606	17.812	EIA_20200908U_VC	1	1.564	1.120	46.967	33.634
	2	0.923	0.514	36.780	20.482		2	1.501	1.117	45.075	33.544
	3	1.023	0.467	40.765	18.609		3	1.560	1.080	46.847	32.432
	Mean	0.988	0.476	39.384	18.968		Mean	1.542	1.106	46.296	33.203
	Stdev	0.057	0.034	2.256	1.371		Stdev	0.035	0.022	1.059	0.670
	% CV	5.728	7.226	5.729	7.226		% CV	2.288	2.015	2.288	2.016
	Acceptable?	Yes	Yes	Yes	Yes		Acceptable?	Yes	Yes	Yes	Yes

SUMMARY OF VERIFICATION PERFORMANCE

Analyte: **Multiple**
Units: **ng/mL**
Instrument: **Tecan-2**

Analyst: **V. Coronado and D. Mike**
Dates of Validation: **9/8/20 to 9/17/20**
Matrix: **Blood & Urine**

Failed Runs (include dates/reasons):

EIA_20200908B_VC: The third positive blood mixed control (Positive-3) failed to meet acceptance criteria for the benzodiazepine assay. Therefore, all blood mixed controls and calibrators were reinjected for the benzodiazepine assay (EIA_20200908B_VC2). Upon reinjection, the curve for the benzodiazepine assay failed to meet acceptance criteria (Average absorbance and % binding Blank>Negative>Calibrator<Positive). Therefore, this assay was reanalyzed and that data was used.

EIA_20200908U_VC: The curve for the following assays failed to meet acceptance criteria for the initial urine analysis, EIA_20200908U_VC, (Average absorbance and % binding Blank>Negative>Calibrator<Positive): amphetamine, barbiturates, benzodiazepines, and cocaine and metabolites. Upon reinjection, values obtained met acceptance criteria for these four assays, which were used for data entry.

Deviations from SOP:

N/A

Other Observations:

Abbreviations:

ELISA - Enzyme-Linked Immunosorbent Assay
% Binding - Percent Binding
Avg. Abs. - Average Absorbance
Cal - Calibrator
Neg - Negative Control
Pos - Positive Control
% CV - Percent Coefficient of Variation
QC - Quality Control

A slight misalignment in how the robotic manipulator arm, or RoMa, was placing the plate back onto the deck after it was washed was observed in the first two plate positions. There was a follow up visit where it was discovered that the hydroflex plate washer was in a slightly different position on the stand than before the preventative maintenance was performed causing this alignment. The washer position was adjusted and an additional run of assays in the first two plate positions was performed on 09/17/2020 to verify the adjustment, including visual observation of plate placement after the washing step. This adjustment only affects the smoothness of the plate placement and did not affect any method parameters.

Lot Numbers:

Blank: E38588, 191210U; Mixed Calibrator: 200722B-MXC, 200624U-MXC; Mixed Negative: 200721B-MXN, 200624U-MXN; Mixed Positive: 200721B-MXP, 200624U-MXP; Oxycodone Calibrator: 200722B-C-10, 200722U-C-100; Oxycodone Negative: 200721B-Q-5, 200721U-Q-50; Oxycodone Positive: 200721B-Q-20, 200721U-Q-200; PBS: 200617-PBS7

Conclusion:

Method is fit for purpose for analysis of urine samples using the amphetamine, barbiturates, benzodiazepines, cocaine and metabolites, cannabinoids, carisoprodol, fentanyl, methadone, methamphetamines, opiates, phencyclidine, and oxycodone assays. Method is fit for purpose for analysis of blood samples using the amphetamine, barbiturates, benzodiazepines, cocaine and metabolites, cannabinoids, carisoprodol, fentanyl, methadone, methamphetamines, opiates, phencyclidine, zolpidem, and oxycodone assays.