

## Abbott Quantisal verification to Appendix C2 of AS\NZS 4760:2019

DRUG	CUT-OFF LEVEL (ng/mL)	-50%	+50%
		(ng/mL)	(ng/mL)
A-008 d-Amphetamine (FE05241804; exp 06/23)	50	25	75
M-020 d-Methamphetamine (FE06071602; exp 06/21)	50	25	75
M-013 MDMA (FE06141804; exp 07/23)	50	25	75
M-005 Morphine (FE08221801; exp 01/24 )	50	25	75
B-004 Benzoylcegonine (FE02261903; exp 04/24 )	50	25	75
O-002 Oxycodone (FE01081501; exp 02/20)	40	20	60
T-005 Δ <sup>9</sup> -THC (FE08221804; exp 09/23)	15	7.5	22.5

All drug standards used in this verification procedure were Cerilliant certified reference standards.

Calibrated volumetric pipettes or syringes were used, throughout.

Calibrated Mettler Analytical Balance was used for Part 2 of the study.

Quantisal Oral Fluid Collection device Lot# EK17874, expiry 2021-04-30. The Quantisal device has a dilution of one part oral fluid to 3 parts buffer.

### 1. Drug Recovery Study

#### Criteria:

- Minimum drug recovery of 70% at a concentration of +50% of the cut off concentration.
- Minimum of 10 devices
- 90% of devices must meet 70% recovery

#### Procedure:

- Stock solution prepared in methanol containing all drugs (0.75/2.0/2.5µg/L).
- +50% working solution prepared by adding 30µL of the stock solution to 1mL of fresh oral fluid.
- 1mL spiked oral fluid added to Quantisal tube via the collection pad.
- Samples left overnight at room temperature.
- Samples analysed in duplicate by LCMS using RASL's NATA accredited method.
- Assess the results according to the criteria.

Results:

See **Table 1** (attached) for percent recoveries for all drug groups. As can be seen from the results table, minimum drug recovery of 70% was achieved in all drug groups for all devices. This complies with the AS\NZS 4760:2019 Standard, Appendix C2 requirements for drug recovery.

## 2. Dilution Verification Study

Criteria:

- 90% of devices must be within 10% of the manufacturer's specifications (dilution of 3 parts buffer and 1 part oral fluid). Specimen dilution is therefore 0.25; acceptable range is 0.225 – 0.275.
- Minimum of 20 devices.

Procedure:

- The collector and collection tube were weighed and masses recorded.
- 20x 1.1mL of blank oral fluid were added to glass scintillation vials. The collector was placed in the vial until the indicator window turned blue. The collector was then placed in the collection tube and reweighed.
- Assess the results according to the criteria.

Results:

See **Table 2** (attached). As can be seen, all specimen dilutions are within the required range of 0.225 – 0.275. This complies with the AS\NZS 4760:2019 Standard, Appendix C2 requirements for specimen dilution.

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Table 1: Drug Recovery for Quantisal Oral Fluid Collection Device

Amphetamine			
	average (µg/L)	% recovery	>70% - Pass
1	69.8	104.8	Pass
2	69.9	105.0	Pass
3	67.3	101.1	Pass
4	62.3	93.5	Pass
5	63.9	95.9	Pass
6	68.2	102.4	Pass
7	63.1	94.7	Pass
8	60.9	91.4	Pass
9	59.0	88.5	Pass
10	64.5	96.8	Pass
Spike	66.6		Pass
Blank	-0.1		

Benzoylcegonine			
	average (µg/L)	% recovery	>70% - Pass
1	64.6	94.4	Pass
2	65.3	95.5	Pass
3	58.5	85.5	Pass
4	58.8	85.9	Pass
5	58.7	85.7	Pass
6	62.6	91.5	Pass
7	55.8	81.6	Pass
8	54.2	79.2	Pass
9	53.9	78.7	Pass
10	57.5	84.0	Pass
Spike	68.4		Pass
Blank	0.0		

MDMA			
	average (µg/L)	% recovery	>70% - Pass
1	68.1	104.1	Pass
2	70.2	107.3	Pass
3	66.5	101.7	Pass
4	59.6	91.1	Pass
5	63.0	96.3	Pass
6	65.4	99.9	Pass
7	63.0	96.3	Pass
8	60.8	93.0	Pass
9	58.7	89.7	Pass
10	66.2	101.1	Pass
Spike	65.4		Pass
Blank	-0.6		

Methamphetamine			
	average (µg/L)	% recovery	>70% - Pass
1	67.1	103.6	Pass
2	66.0	101.9	Pass
3	67.8	104.7	Pass
4	58.6	90.6	Pass
5	58.3	90.1	Pass
6	66.8	103.2	Pass
7	64.9	100.2	Pass
8	59.9	92.6	Pass
9	64.1	99.1	Pass
10	63.6	98.3	Pass
Spike	64.7		Pass
Blank	-0.1		

Morphine			
	average (µg/L)	% recovery	>70% - Pass
1	61.8	96.3	Pass
2	60.9	94.8	Pass
3	58.5	91.0	Pass
4	56.2	87.5	Pass
5	55.7	86.8	Pass
6	61.5	95.7	Pass
7	55.5	86.4	Pass
8	53.6	83.4	Pass
9	53.1	82.6	Pass
10	57.5	89.5	Pass
Spike	64.2		Pass
Blank	-0.4		

Oxycodone			
	average (µg/L)	% recovery	>70% - Pass
1	57.8	105.7	Pass
2	58.1	106.2	Pass
3	56.5	103.2	Pass
4	56.1	102.5	Pass
5	55.3	101.1	Pass
6	59.1	108.0	Pass
7	56.3	102.8	Pass
8	55.2	100.8	Pass
9	53.7	98.2	Pass
10	58.3	106.5	Pass
Spike	54.7		Pass
Blank	0.2		

THC			
	average (µg/L)	% recovery	>70% - Pass
1	16.6	89.0	Pass
2	17.8	95.4	Pass
3	17.0	91.1	Pass
4	15.9	85.2	Pass
5	17.2	92.2	Pass
6	17.5	94.1	Pass
7	17.2	92.5	Pass
8	16.1	86.3	Pass
9	16.1	86.3	Pass
10	16.6	89.0	Pass
Spike	18.6		Pass
Blank	0.1		

Table 2: Dilution Verification of Quantisal Oral Fluid Collection device

	Mass of collector (mg)	Mass of collection tube (mg)	Mass of collection tube, collector and OF (mg)	Mass of OF (mg)	Specimen Dilution	Pass? (range 0.225 - 0.275)
1	1036.00	9126.08	11161.05	998.97	0.250	Pass
2	1045.19	9127.57	11251.07	1078.31	0.264	Pass
3	1028.40	9194.60	11300.40	1077.40	0.264	Pass
4	1018.95	9231.25	11318.71	1068.51	0.263	Pass
5	1029.06	9248.33	11340.62	1063.23	0.262	Pass
6	1048.90	9173.30	11293.92	1071.72	0.263	Pass
7	1046.70	9193.90	11244.67	1004.07	0.251	Pass
8	1043.94	9242.37	11280.86	994.55	0.249	Pass
9	1027.81	9178.83	11188.07	981.43	0.247	Pass
10	1037.41	9185.16	11299.55	1076.98	0.264	Pass
11	1044.52	9163.42	11129.51	921.57	0.235	Pass
12	1051.42	9204.06	11244.06	988.58	0.248	Pass
13	1034.83	9191.79	11211.86	985.24	0.247	Pass
14	1006.75	9227.75	11208.67	974.17	0.245	Pass
15	1024.48	9188.93	11265.74	1052.33	0.260	Pass
16	1033.76	9189.28	11226.45	1003.41	0.251	Pass
17	1039.38	9163.95	11162.47	959.14	0.242	Pass
18	1030.83	9130.11	11093.67	932.73	0.237	Pass
19	1033.84	9183.54	11202.57	985.19	0.247	Pass
20	1046.37	9188.35	11236.77	1002.05	0.250	Pass