



Verification of Screening Methods and Reportable Qualitative Methods

Purpose	To verify blood calibrator solution (221013C-CB-Mix) is acceptable for use in casework.
Analyte	GCMS Drug Screen and Qualitative Confirmation
Units of Measure	ng/mL
Analyst Performing Verification Studies	Andrea Gooden
Responsible Supervisor	Corissa Rodgers, Dayong Lee
Start Date	November 15, 2022
Completion Date	November 15, 2022
Primary Matrix	Blood
Secondary Matrices	N/A
Cut-off Calibrator	Ketamine (50 ng/mL), Diphenhydramine (50 ng/mL), Doxylamine (50 ng/mL), Tramadol (50 ng/mL), Chlorpheniramine (10 ng/mL), Venlafaxine (50 ng/mL), Brompheniramine (50 ng/mL), Methadone (50 ng/mL), Dextromethorphan (50 ng/mL), Amitriptyline (10 ng/mL), Imipramine (25 ng/mL), Cyclobenzaprine (50 ng/mL), Sertraline (25 ng/mL), and Zolpidem (10 ng/mL)
Equipment/Instrument	GCMS-5
Instrument Serial Number	US1609M002
Method	BSD.M

Verification Approval

Analyst: **Andrea Gooden** Digitally signed by Andrea Gooden
Date: 2022.12.14 10:16:41 -06'00' 12/14/2022
Date

Responsible Supervisor: **Corissa L. Rodgers, M.S.** Digitally signed by Corissa L. Rodgers, M.S.
Date: 2022.12.13 13:13:24 -06'00' 12/13/2022
Date

Responsible Supervisor: **Dayong Lee** Digitally signed by Dayong Lee
Date: 2022.12.14 10:26:52 -06'00' 12/14/2022
Date

Verification

Analyte: GC/MS Drug Screen and Qualitative Confirmation
 Units: ng/mL
 Instrument: GC/MS-5

Match Percentage

Analyst: A. Gooden
 Study Dates: 11/15/2022 to 11/15/2022
 Matrix: Blood

Batch Name	Drug	Cut-off 1	Cut-off 2	Cut-off 3	Positive 1	Positive 2	Positive 3
BSD_20221115B_ASG	Ketamine	90	90	90	90	90	90
	Diphenhydramine	87	90	87	90	90	89
	Doxylamine	85	84	85	85	84	85
	Tramadol	86	88	86	87	88	88
	Chlorpheniramine	93	93	93	94	93	94
	Venlafaxine	71	80	70	82	82	82
	Brompheniramine	93	93	92	94	94	94
	Methadone	73	73	73	73	73	74
	Dextromethorphan	88	87	87	88	88	88
	Amitriptyline	86	88	86	88	88	88
	Imipramine	93	94	93	94	94	94
	Cyclobenzaprine	86	87	87	87	87	88
	Sertraline	86	86	86	87	86	87
	Zolpidem	91	91	92	93	93	93

Results: All cut-off and positive samples showed acceptable match percentage.

Comments: N/A

Acceptance Criteria: All Cut-off Calibrator and Positive Samples must have a percent match greater than or equal to 60%.

Verification

Analyte: GCMS Drug Screen and Qualitative Confirmation
 Units: ng/mL
 Instrument: GCMS-5

Concentration

Analyst: A. Gooden
 Study Dates: 11/15/2022 to 11/15/2022
 Matrix: Blood

Batch Name	Drug	Cut-off 1	Cut-off 2	Cut-off 3	Positive 1	Positive 2	Positive 3
BSD_20221115B_ASG	Ketamine	50	50	50	103	103	110
	Diphenhydramine	50	52	48	98	100	103
	Doxylamine	50	53	48	103	105	108
	Tramadol	50	54	50	106	110	112
	Chlorpheniramine	10	11	10	20	20	20
	Venlafaxine	50	55	51	108	112	115
	Brompheniramine	50	54	49	103	103	104
	Methadone	50	52	48	96	96	102
	Dextromethorphan	50	52	47	101	101	104
	Amitriptyline	10	11	10	24	24	25
	Imipramine	25	27	24	50	50	51
	Cyclobenzaprine	50	54	48	104	106	108
	Sertraline	25	32*	24	62	61	55
	Zolpidem	10	12	11	25	25	25

Results: All cut-off and positive samples showed acceptable match at and double the cut-off concentration.

Comments: * Concentration > 20% of target value

Acceptance Criteria: The cut-off calibrator < positive control. The new cut-off calibrators' semi-quantitative value should be within $\pm 20\%$ of the target value.

Response Comparison

Analyst: A. Gooden
 Study Dates: 11/15/2022 to 11/15/2022
 Matrix: Blood

Verification

Analys: GC/MS Drug Screen and Qualitative Confirmation
 Units: ng/mL
 Instrument: GC/MS

BSD_20221115E_ASG	Cut-off 1	Cut-off 1	Cut-off 2 IS	Cut-off 2 IS	Cut-off 2 IS	Cut-off 3 IS	Cut-off 3 IS	Cut-off Average	Cut-off IS Average	Cut-off RF	Positive 1	Positive 1 IS	Positive 2	Positive 2 IS	Positive 3	Positive 3 IS	Positive Average	Positive Average/2	Positive IS Average	Positive RF	Positive RF as Cutoff	%Difference
Ketamine	6640	39598	7299	43987	7195	43153	7044.7	42246	8.338	14735	43962	14941	44519	15543	43648	15073.0	7536.5	44043.0	34.223	8.556	8.556	2.6
Diphenhydramine	11208	39598	12812	43987	11739	43153	11919.7	42246	14.107	24291	43962	28688	44519	28672	43648	25217.0	12608.5	44043.0	57.255	14.314	14.314	1.5
Doxylamine	7373	39598	9042	43987	8067	43153	8160.7	42246	9.659	16982	43962	18224	44519	17773	43648	17659.7	8829.8	44043.0	40.096	10.024	10.024	3.8
Tramadol	11866	39598	14126	43987	12823	43153	12838.3	42246	15.313	27037	43962	28221	44519	28540	43648	27932.7	13966.3	44043.0	63.421	15.855	15.855	3.5
Chlorpheniramine	1914	39598	2268	43987	2042	43153	2074.7	42246	0.491	4181	43962	4344	44519	4270	43648	4265.0	2132.5	44043.0	1.937	0.484	0.484	-1.4
Venlafaxine	13152	39598	15795	43987	14373	43153	14440.0	42246	17.080	30467	43962	33355	44519	34141	43648	32654.3	16327.2	44043.0	74.142	18.535	18.535	8.5
Brompheniramine	6111	39598	7272	43987	6456	43153	6613.0	42246	7.827	13758	43962	13887	44519	13553	43648	13732.7	6866.3	44043.0	31.180	7.795	7.795	-0.4
Methadone	18517	39598	21435	43987	19228	43153	19726.7	42246	23.347	40085	43962	39881	44519	41426	43648	40464.0	20232.0	44043.0	91.874	22.968	22.968	-1.6
Dextromethorphan	3323	39598	3855	43987	3489	43153	3555.7	42246	4.208	7648	43962	7801	44519	7915	43648	7788.0	3894.0	44043.0	17.683	4.421	4.421	5.0
Amphetamine	3267	39598	3834	43987	3561	43153	3554.0	42246	0.841	8334	43962	9147	44519	9057	43648	8846.0	4423.0	44043.0	4.017	1.004	1.004	19.4
Imipramine	2395	39598	2797	43987	2474	43153	2555.3	42246	1.512	5233	43962	5329	44519	5457	43648	5339.7	2669.8	44043.0	6.062	1.515	1.515	0.2
Cyclobenzaprine	15652	39598	19106	43987	16794	43153	17164.0	42246	20.358	36797	43962	38018	44519	37627	43648	37480.7	18740.3	44043.0	85.100	21.275	21.275	4.6
Sertraline	1050	39598	1502	43987	1100	43153	1217.3	42246	0.720	2945	43962	3017	44519	2617	43648	2893.7	1429.8	44043.0	3.246	0.812	0.812	12.7
Zolpidem	2406	39598	3209	43987	2903	43153	2839.3	42246	0.672	6886	43962	7186	44519	7203	43648	7095.0	3547.5	44043.0	3.222	0.805	0.805	19.8

Comments: Comparison of responses of all analytes in calibrator against the current verified control solution (220922L-QB-MX) show agreement within 20%. RF = response factor.

Acceptance Criteria:

N/A

SUMMARY OF VERIFICATION PERFORMANCE

Analyte: GCMS Drug Screen and Qualitative Confirmation

Units: ng/mL

Instrument: GCMS-5

Analyst: A. Gooden

Study Dates: 11/15/2022 to 11/15/2022

Matrix: Blood

The intent of this summary is to capture and document important information about the performance of this method outside the required measurements for verification.

Failed Runs (include dates/reasons):

Date	Reason
N/A	N/A

Deviations from SOP:

N/A

Other Observations:

As described in Toxicology Analytical Manual v.3.8 (SOP) section 8.13.3, if the current calibration solution is unacceptable, performance of the new solution will be evaluated according to the acceptance criteria of the method. In applying this clause, all acceptance criteria were met for the new calibrator (221013C-CB-Mix).

Because the current calibrator expired (211102C-CB-Mix) on 10/31/2022, it could not be used as a reference for verification of the new calibrator (221013C-CB-Mix). Instead, calibrator replicate 1 was set as the reference and used to calculate the concentration of all samples in the verification batch. The screen data passed; however, the semi-quantitative value of sertraline in calibrator-2 was greater than 20% of the target value.

The responses of the calibrator solution 221013C-CB-Mix were further compared to the current verified positive control solution (220922L-QB-MX) on page 4 of this packet. The added data demonstrate the two solutions are comparable.

Working Standards and Reagents Verified in Verification:

Calibrator: 221013C-CB-Mix

Sample Preparation Steps:

Refer to Toxicology Analytical Manual v3.8, "Drug Screen and Qualitative Confirmation by Gas Chromatography-Mass Spectrometry" section titled "Extraction Procedure".

Location of Raw Data:

Toxicology section shared electronic storage.

Conclusion:

This new calibrator solution is acceptable for use on casework for GCMS qualitative confirmation analysis in blood.