

BECKMAN COULTER SYSTEMS
DRUGS OF ABUSE ASSAYS (DAT)
CERTIFICATE OF ANALYSIS

PRE-SHIP

MICROGENICS PART NUMBER 1604
BECKMAN COULTER PART NUMBER 474985
MICROGENICS LOT NUMBER 74985014

A. CALIBRATOR/MANUFACTURE INFORMATION

PRODUCT DESCRIPTION	OPIATE 300 HIGH CALIBRATOR (1000 NG/ML)
MICROGENICS PART NUMBER	1604
BECKMAN COULTER PART NUMBER	474985
VENDOR (MGC) LOT NUMBER	74985014
PLATFORM USED FOR MANUFACTURE TESTING	DXC
MANUFACTURE DATE	2023-08-11
EXPIRATION DATE	2025-02-28
QUANTITY	6
STORAGE CONDITION	2° TO 8° C

B. MATERIALS USED FOR TESTING

		BCI P/N	MGC P/N	LOT NUMBER	EXPIRATION
1. CALIBRATORS FROM MOST RECENTLY APPROVED LOT					
NEGATIVE CALIBRATOR		445803	0555	74772771	2024-06-30
OPIATE 300 LOW CALIBRATOR (300 ng/mL)		474982	1602	74838262	2024-07-31
OPIATE 300 HIGH CALIBRATOR (1000 ng/mL)		474985	1604	74682196	2024-01-31
2. GOLD STANDARDS					
OPIATE 1000 ng/mL GOLD STANDARD		NA	2069	74927656	2027-06-06
3. REAGENTS					
OPIATE 300	ANTIBODY	445963	10007370	74948588	2024-12-31
	ENZYME	445962	0550	74948589	2024-12-31

C. TESTING*

	SPECIFICATION	RESULT	PASS/FAIL
1. FILL VOLUME	5.2 ± 0.2 mL	5.2 mL	PASS
2. APPEARANCE	YELLOWISH CLEAR SOLUTION; ESSENTIALLY FREE OF PARTICULATE	YELLOWISH CLEAR SOLUTION; ESSENTIALLY FREE OF PARTICULATE	PASS
3. UPN/GS1 BARCODE	Meets SCD specifications (Yes or No)	Yes	PASS
4. ANALYTE CONCENTRATION (BY GC/MS)			
OPIATE 1000 ng/mL	900 ng/mL TO 1100 ng/mL	962 ng/mL	PASS

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C. Testing* (Continued)

5. COMPARISON TO GOLD STANDARD AND MOST RECENTLY APPROVED LOT ON A SYNCHRON
SYSTEM AT 37 °C USING BECKMAN DEFINED PARAMETERS:

SPECIFICATION:	THE RATE IN mA/min MUST BE WITHIN $\pm 5\%$ OF GOLD STANDARD AND MOST RECENTLY APPROVED LOT.					
	SAMPLE RESULT	GOLD STANDARD		RECENT LOT		PASS/FAIL
		RESULT	PERCENT	RESULT	PERCENT	
OPIATE 300	470	474	-1%	474	-1%	PASS

D. TREND ANALYSIS DATA

DATA ATTACHED	BY	DATE
YES	YUTING ZHOU	9/7/2023

E. COMMENTS:

* Testing performed on a Synchron Automated Chemistry Analyzer at 37 °C.

TESTED BY:

Yuting Zhou

DATE:

09/07/2023

APPROVED BY:

[Signature]

DATE:

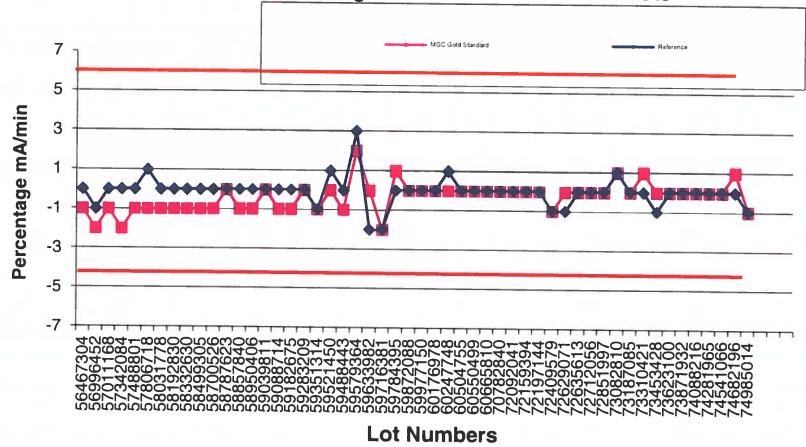
09/15/2023

QUALITY CONTROL

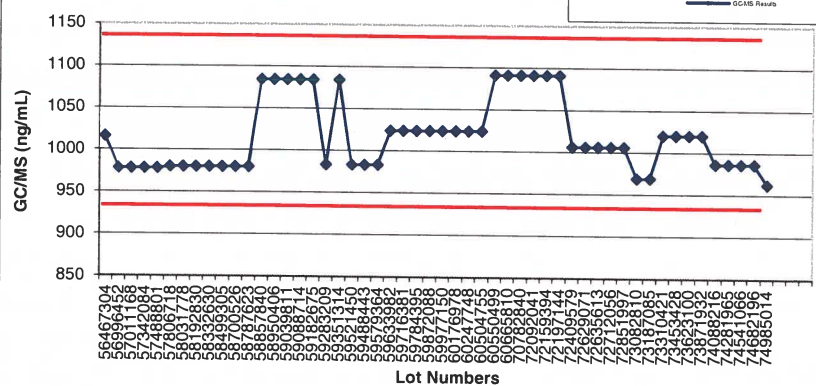
Opiate 300 High Calibrator (1000 ng/mL)
BCI P/N: 474985
MGC P/N: 1604

Lot Numbers	MGC Gold Standard	Reference	GC/MS Results
56467304	-1	0	1016
56996452	-2	-1	978
57011168	-1	0	978
57342084	-2	0	978
57488801	-1	0	978
57806718	-1	1	980
58031778	-1	0	980
58192830	-1	0	980
58332630	-1	0	980
58499305	-1	0	980
58700526	-1	0	980
58787623	0	0	980
58857840	-1	0	1084
58950406	-1	0	1084
59039811	0	0	1084
59088714	-1	0	1084
59182675	-1	0	1084
59283209	0	0	983
59351314	-1	-1	1084
59521450	0	1	983
59488443	-1	0	983
59579364	2	3	983
59633982	0	-2	1024
59716381	-2	-2	1024
59784395	1	0	1024
59872088	0	0	1024
59977150	0	0	1024
60176978	0	0	1024
60247748	0	1	1024
60504755	0	0	1024
60550499	0	0	1091
60665810	0	0	1091
70782840	0	0	1091
72092041	0	0	1091
72159394	0	0	1091
72197144	0	0	1091
72409579	-1	-1	1006
72629071	0	-1	1006
72635613	0	0	1006
72712056	0	0	1006
72851997	0	0	1006
73082810	1	1	969
73187085	0	0	969
73310421	1	0	1020
73453428	0	-1	1020
73623100	0	0	1020
73871932	0	0	1020
74088216	0	0	986
74281965	0	0	986
74541066	0	0	986
74682196	1	0	986
74985014	-1	-1	962

Opiate 1000 ng/mL Calibrator
Opiate 300 Percentage of mA/min to Reference Lots



Opiate Calibrator 1000 ng/mL
GC/MS Results



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