

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K040758

B. Purpose of Submission: The MGC DAU Control Sets are being modified from it's predicate device Multi-Drug Control Set and DAU Multi-Drug Control

C. Analyte: Primary- Benzoyllecgonine, EDDP, d-Methamphetamine, Methadone, Methaqualone, Opiates, Benzodiazapenes, Phencyclidine, Propoxyphene, Barbituates; Clinical- Benzoyllecgonine, EDDP, d-Methamphetamine, Methadone, Methaqualone, Opiates, Benzodiazapenes, Phencyclidine, Propoxyphene, Barbituates; Select- 6-Acetylmorphine, Benzoyllecgonine, LSD, MDMA, Benzodiazepines.

D. Type of Test: Validation Control Material

E. Applicant: Microgenics Corporation

F. Proprietary and Established Names: MGC DAU Control Sets: Primary, Clinical, and Select

G. Regulatory Information:

1. Regulation section: 21 CFR §862.3280
2. Classification: Class I (general controls)
3. Product Code: DIF
4. Panel: 91

H. Intended Use:

1. Intended use(s):

The MGC DAU Control Set consists of high and low controls intended for use in the validation of drug of abuse assays performed using human urine.

2. Indication(s) for use:

The MGC DAU Control Set is liquid ready-to-use and consists of controls intended for use in the validation of drug of abuse assays performed using human urine.

3. Special condition for use statement(s): For Prescription Use
4. Special instrument Requirements: The intended instruments are stated in the package insert for primary, clinical, and select configuration.

I. Device Description: Each configuration of the MGC DAU Control Sets is prepared in human urine matrix, with stabilizers and preservatives added. As is shown in the table 1 below, the MGC DAU Control Set is offered in three configurations, known as “Primary”, “Clinical” and “Select” differing only in the concentrations and number of analytes offered. Three configurations of MGC DAU Control Set, each consisting of low and high controls will be placed in commercial distribution to satisfy specific requirements of the laboratory community.

Table 1. Three Configurations of MGC DAU Control Set, analytes available and their concentrations

Configuration	Drug	Low (ng/mL)	High (ng/mL)
Primary	Benzoyllecgonine	225	375
	EDDP	750	1250
	d-Methamphetamine	750	1250
	Methadone	225	375
	Methaqualone	225	375
	Opiates ¹	1500	2500
	Benzodiazepenes ²	225	375
	Phencyclidine	19	31
	Propoxyphene	225	375
	Barbituates ³	225	375
Clinical	Benzoyllecgonine	225	375
	EDDP	75	125
	d-Methamphetamine	375	625
	Methadone	225	375
	Methaqualone	225	375
	Opiates ¹	225	375
	Benzodiazepenes ²	225	375
	Phencyclidine	19	31
	Propoxyphene	225	375
	Barbituates ³	225	375
Select	6-Acetylmorphine	7.5	12.5
	Benzoyllecgonine	112.5	187.5
	LSD	0.3	0.7
	MDMA	375	625
	Benzodiazepenes ⁴	225	375

¹Morphine ²Oxazepam ³Secobarbital ⁴Nitrazepam

J. Substantial Equivalence Information:1. Predicate device name(s):

Multi-Drug Control Set and DAU Multi-Drug Control

2. Predicate K number(s): K951135, and K9651573. Comparison with predicate:

Devis Characteristics	Subject Device	Predicate Device (K951135)	Predicate Device (K965157)
Intended Use	The MGC DAU Control Set consists of controls intended for use in the validation of drug of abuse assays performed using human urine.	The Multi-Drug Controls are for use as unassayed control material with drugs of abuse assays.	The Multi-Drug Controls are for use as unassayed control material with drugs of abuse assays.
Analytes	<p>Primary:</p> <p style="padding-left: 40px;">Benzoyllecgonine EDDP d-Methamphetamine Methadone Methaqualone Opiates¹ Benzodiazepenes² Phencyclidine Propoxyphene Barbituates³</p> <p>Clinical:</p> <p style="padding-left: 40px;">Benzoyllecgonine EDDP d-Methamphetamine Methadone Methaqualone Opiates¹ Benzodiazepenes² Phencyclidine Propoxyphene Barbituates³</p> <p>Select:</p> <p style="padding-left: 40px;">6-Acetylmorphine Benzoyllecgonine LSD MDMA Benzodiazepenes⁴</p>	<p>Benzoyllecgonine EDDP LSD d-Methamphetamine Methadone Methaqualone Opiates¹ Benzodiazepenes² Phencyclidine Propoxyphene Barbituates³</p>	<p>Primary:</p> <p style="padding-left: 40px;">Benzoyllecgonine EDDP* LSD d-Methamphetamine Methadone Methaqualone Opiates¹ Benzodiazepenes⁴ Phencyclidine Propoxyphene Barbituates³</p> <p>Clinical:</p> <p style="padding-left: 40px;">Benzoyllecgonine EDDP* LSD d-Methamphetamine Methadone Methaqualone Opiates¹ Benzodiazepenes⁴ Phencyclidine Propoxyphene Barbituates³</p> <p>Specialty:</p> <p style="padding-left: 40px;">Benzoyllecgonine EDDP* d-Methamphetamine Opiates¹ Benzodiazepenes⁴ Barbituates³</p>
Matrix	Urine	Urine	Urine
Control Form	Liquid	Liquid	Liquid
Control Levels	Two: Low and High	Two: Low and High	Two: Low and High
Storage	2 °C to 8 °C until expiration date	2 °C to 8 °C until expiration date	2 °C to 8 °C until expiration date

Devise Characteristics	Subject Device	Predicate Device (K951135)	Predicate Device (K965157)
Stability	Until expiration date noted on vial label	Until expiration date noted on vial label	Until expiration date noted on vial label

¹Morphine ²Oxazepam ³Secobarbital ⁴Nitrazepam

*EDDP was cleared under K023617. It was not included in predicate device K965157, 510(k) submission and was added post-clearance of K965157.

K. Standard/Guidance Document Referenced (if applicable):

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material”.

L. Test Principle: NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: Intra-assay reproducibility (or within-run precision) was determined according to a modified NCCLS protocol (NCCLS EP-5A) by assaying 21 replicates of both low and high controls in commercially available assays for determination of various drugs of abuse. Reproducibility was determined for each of the three configurations using either the representative CEDIA[®] or DRI[®] DAU Assay or both assay formats. Intra-assay reproducibility is defined as the coefficient of variation (CV) for the average rate, expressed in milliabsorbance (mA) units, observed for both the High and Low Controls in either the CEDIA[®], DRI[®] or both assay formats. CV is expressed as a percentage, calculated as the standard deviation of the average rate divided by the average and multiplied by 100 (SD/Avg*200). The results provided indicate that the intra-assay reproducibility for the Low and High Controls were all <5% for each configuration in both assay formats.

b. Linearity/assay reportable range: NA

c. Traceability (controls, calibrators, or method): No information was provided about traceability.

The MGC DAU Control Set is prepared in human urine. The Control Set consists of low and high controls. Each configuration of the MGC DAU Control Set is formulated in human urine matrix with desired concentration range of each analyte confirmed by gas chromatography with mass spectrometry. Representative GC/MS values for each configuration of the MGC DAU Control Set are provided, and specifications indicate that GC/MS values must be within 90%- 110% of target values. Regardless of the configuration, each of the MGC DAU Control Sets is used for validation of drugs of abuse assays. The target concentrations are presented in the Package Insert with appropriate storage instructions.

Kit Stability: The materials and final formulation for the three configurations of the MGC DAU Control Set are virtually identical to the predicate device, i.e., the Multi-Drug Control Set (K951135), and CEDIA DAU Multi-Drug Control Sets (K965157). As the three configurations of the MGC DAU Control Set are formulated, manufactured and filled in the same manner as the predicate device, we expect the MGC DAU Control Set to exhibit similar stability and, as such, have conservatively defined the shelf life at 12 months stored at 2-8 °C. Modifications to shelf life will be based on results observed from real-time stability studies which are currently in progress.

d. Detection limit: NA

e. Analytical specificity: NA

f. Assay cut-off: NA

2. Comparison studies:

a. Method comparison with predicate device: NA

b. Matrix comparison: NA

3. Clinical studies:

a. Clinical sensitivity: NA

b. Clinical specificity: NA

c. Other clinical supportive data (when a and b are not applicable):NA

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

N. Conclusion:

The submitted material in this premarket notification for MGC DAU Control Sets: Primary, Clinical and Select is complete and supports a substantially equivalence decision.