

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

A. 510(k) Number:

k080183

B. Purpose for Submission:

510(k) premarket notification package to manufacture and market the Roche Drug Mixture Control Materials

C. Measurand:

Control materials for Amphetamines (d-methamphetamine), Barbiturates (secobarbital), Benzodiazepines (nordiazepam), Cannabinoids (Δ^9 THC-COOH), Cocaine (benzoylecgonine), Methadone (dl-methadone), Methaqualone (methaqualone), Opiates (d-morphine), PCP (phencyclidine), Propoxyphene (propoxyphene).

D. Type of Test:

Not Applicable

E. Applicant:

Roche Diagnostics Corp.

F. Proprietary and Established Names:

Control Set DAT I, Control Set DAT II, Control Set DAT III, Control Set Amphetamine 1000, Control Set Amphetamine 500

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIF	Class I-reserved	862.3280	Toxicology (91)

H. Intended Use:

The Control Set DAT I is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

The Control Set DAT II is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

The Control Set DAT III is for use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers as indicated in the System Information.

None of these above named products can be used with the Roche Abuscreen OnLine assay for Amphetamines or the COBAS INTEGRA Amphetamines cobas c pack (AMPS). The package insert or method sheet for information regarding the controls has appropriate instructions for use with these assays.

The Control Set Amphetamine 1000 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines cobas c pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

The Control Set Amphetamine 500 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines and the COBAS INTEGRA Amphetamines **cobas c** pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.

2. Indication(s) for use:
See Intended Use.
3. Special conditions for use statement(s):
For Prescription Use Only.
4. Special instrument requirements:
Roche/Hitachi 911/912/917/MODULAR P analyzers
Roche/Hitachi **cobas c** 501/c 311
COBAS Integra 400/400plus/700/800

I. Device Description:

These are drug mixture control materials in a human urine matrix. The three sets of controls (Control Set DAT I, II and III) each have two levels of various drug-control mixtures, while the amphetamine controls have two levels of d-amphetamine and are sold ready for use and no preparation is required. The sponsor recommends that before use, the user record the date the control was opened on the bottle label. Donors for the pools of human urine used in the preparation of this product all screened negative in annual serum testing for hepatitis B surface antigen (HBsAg), and for antibodies to HIV type 1, HIV type 2, and hepatitis C (anti-HCV).

J. Substantial Equivalence Information:

1. Predicate device name(s):
TDM CONTROL SET, MODEL CAT# 04521536
2. Predicate K number(s):
k070200
3. Comparison with predicate:

Item	Control Set DAT I , DAT II, DAT III	TDM Control Set
Intended Use	The Control Set DAT I, II and III are to be used as assayed controls in the Roche test system for the qualitative and semi-quantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Analytes	Amphetamines (d-methamphetamine) Barbiturates (secobarbital) Benzodiazepines (nordiazepam) Cannabinoids (Δ^9 THC-COOH) Cocaine (benzoylecgonine) Methadone (dl-methadone) Methaqualone (methaqualone) Opiates (d-morphine) PCP (phencyclidine) Propoxyphene (propoxyphene)	Acetaminophen Amikacin Carbamazepine Digoxin Gentamicin Lidocaine Phenobarbital Phenytoin Primidone Procainamide Quinidine Salicylate Theophylline Tobramycin Valproic acid Vancomycin.
Traceability	Gas Chromatography/Mass Spectrometry (GC/MS)	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3
	New Device	Predicate Device
Item	Control Set Amphetamine 1000, 500	TDM Control Set
Intended Use	The Control Set Amphetamine 1000 is for use as an assayed control with the Roche Abuscreen OnLine assay for Amphetamines	The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified

	and the COBAS INTEGRA Amphetamines cobas c pack (AMPS) for the qualitative and semiquantitative determination of amphetamines in human urine on automated clinical chemistry analyzers.	in the value sheet.
Analytes	Amphetamines (d-amphetamine)	Acetaminophen Amikacin Carbamazepine Digoxin Gentamicin Lidocaine Phenobarbital Phenytoin Primidone Procainamide Quinidine Salicylate Theophylline Tobramycin Valproic acid Vancomycin
Traceability	GC/MS	USP Standards
Matrix	Human urine based	Human serum based
Number of Levels	2	3

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

1. Medical devices - Application of risk management to medical devices (14971:2000)
2. Bundling Multiple Devices or Multiple Indications in a Single Submission - Guidance for Industry and FDA Staff (<http://www.fda.gov/cdrh/mdufma/guidance/1215.html>)
3. Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material (<http://www.fda.gov/cdrh/oivd/guidance/2231.html>)
4. Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use. (<http://www.fda.gov/cdrh/ocd/guidance/4444.html>).

L. Test Principle:

Not Applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not Applicable.

- b. *Linearity/assay reportable range:*
Not Applicable.
- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The assigned values of the Control Set DAT I, Control Set DAT II, Control Set DAT III, and Control Set Amphetamine 1000, Control Set Amphetamine 500 are traceable to Gas Chromatography / Mass Spectrometry (GC/MS) Reference Testing. For each analyte the GC-MS is calibrated with master calibrators. These are made fresh from a concentrated stock stored at -20°C. The concentration of the frozen stock is verified every three months by an independent GC-MS laboratory. Five calibrator levels are used to generate the calibration curve on the GC-MS.
The material has a closed vial stability claim of 12 months. Real Time stability was assessed by GC/MS testing of unopened, refrigerated vials. After opening the reagents are good for 30 days or until the expiration date, whichever comes first at 2-8°C.
- d. *Detection limit:*
Not Applicable.
- e. *Analytical specificity:*
Not Applicable.
- f. *Assay cut-off:*
Not Applicable.
- 2. Comparison studies:
 - a. *Method comparison with predicate device:*
Not Applicable.
 - b. *Matrix comparison:*
Not Applicable.
- 3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not Applicable.
 - b. *Clinical specificity:*
Not Applicable.
 - c. Other clinical supportive data (when a. and b. are not applicable):
Not Applicable.
- 4. Clinical cut-off:
Not Applicable.
- 5. Expected values/Reference range:
Not Applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.