

SUMMARY OF LABORATORY'S WRITTEN METHOD FOR METHADONE DRUG ANALYSIS

1. Name of laboratory:

2. Laboratory Address:

City

Zip

3. CERTIFICATION BY PERSON REVIEWING AND APPROVING THIS FORM FOR THE LABORATORY:

Print or Type Name:

Signature:

Date:

COMPLETE ONE FORM E FOR EACH METHOD USED FOR URINE TESTING BY THIS LABORATORY. ATTACH THE CORRESPONDING CURRENT, DETAILED WRITTEN DESCRIPTION OF EACH METHOD. (See the back of this page for instructions for preparing written method descriptions.)

4. Name of Method

5. Used For: Initial Test

Alternative (Confirmatory) Test

6. The Principle of Analysis:

Gas Chromatography

Thin Layer Chromatography

Immunochemical

Other (Specify) _____

7. The drugs analyzed by this method and its limits of detection are:

Methadone _____ $\mu\text{g/mL}$

Methadone metabolite (primary) _____ $\mu\text{g/mL}$

Morphine (free and conjugated) _____ $\mu\text{g/mL}$

Codeine _____ $\mu\text{g/mL}$

Amphetamine _____ $\mu\text{g/mL}$

Methamphetamine _____ $\mu\text{g/mL}$

Phenobarbital _____ $\mu\text{g/mL}$

Pentobarbital _____ $\mu\text{g/mL}$

Secobarbital _____ $\mu\text{g/mL}$

8. A copy of this method is immediately available to the person performing urinalysis.

Yes No. If no, explain: _____

INSTRUCTIONS FOR PREPARING THE CURRENT, DETAILED, WRITTEN DESCRIPTION OF EACH OF YOUR
LABORATORY'S METHODS FOR METHADONE DRUG ANALYSIS

1. Each written method description must include current, detailed, and stepwise instructions, which are used by persons in your laboratory in performing methadone drug analysis.
2. The description must include full and explicit directions and information relating to: the collection and handling of samples, equipment used, the preparation and/or quality control program, calculations and/or expression of analytical results, and reporting of analytical results. Include any precautionary recommendations or notes needed by the analysts for the accurate performance of methadone drug analysis. Examples of, or photocopies of, such items as commercial package inserts, journal articles, or published versions of methods are not acceptable as substitutes for your own written directions for methadone drug analysis in your laboratory.
3. Prepare your method description as a set of instructions to persons performing the analysis in accord with the following format:
 - a. TITLE OF METHOD
 - b. INTRODUCTION
 - c. PRINCIPLE OF ANALYSIS
 - d. REAGENTS
 - e. EQUIPMENT
 - f. PROCEDURES, including
 - (1) Collection and handling of samples
 - (2) Calibration procedures
 - (3) The quality control program
 - (4) Analysis of samples
 - g. CALCULATIONS AND/OR EXPRESSION OF ANALYTICAL RESULTS
 - h. DISCUSSION, including information to demonstrate the method's capability for meeting the standards of performance contained in the Regulations (such information must be in the form of your laboratory's data adequately demonstrating this capability)
 - i. LITERATURE REFERENCE CITATIONS
4. After preparation of the written method description, ascertain that you have included all of the details, which are necessary for the accurate performance of methadone drug analysis so that it fully complies with the requirements of the Regulations. An incomplete method description, or a method description containing inaccuracies, will be returned to the submitter for revision and correction and can cause long delay in, or denial or, approval or your application for a laboratory license or approval of the method.