

TECH NOTES



Conformance of MethAlert to NIJ Standard-0604.01

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The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC), developed and validated a colorimetric surface-wipe method for the detection of methamphetamine residues that meets the test methods described in National Institute of Justice (NIJ) Standard-0604.01, *Color Test Reagents/Kits for Preliminary Identification of Drugs of Abuse*. The method and final product, SKC MethAlert, meets the essential requirements contained in NIJ Standard-0604.01.

The following demonstrates MethAlert Kit and product insert conformance to sections in the NIJ Standard-0604.01 criteria. Additional supporting data can be found in Figure 1 (Section 5.2) and Tables 1 and 2 (Section 5.3).

4. REQUIREMENTS

4.1 User Information: The kit shall include the following information.

4.1.1 Drugs Detected: A list of the drugs for which each reagent in the kit can be used to make a tentative identification

MethAlert Operating Instructions (Form 37207) identify the kit as a presumptive surface-wipe test for the colorimetric detection of methamphetamine above 15 µg/100 cm² and lists possible positive interferences.

4.1.2 Instructions: Clear instructions for performing the chemical test and for interpreting the results, including the time for the final color to appear

MethAlert Kits contain two types of instructions: 1) Six-page MethAlert Operating Instructions (Form 37207) describe test limit and range and how results appear within one minute (a final result within five minutes), and 2) A concise full-color plastic-laminated Quick Guide (Form 37134) illustrates steps and final color result. NIOSH laboratory results show that the color response is typically immediate for "street grade" and reagent-grade concentrations of methamphetamine.

4.1.3 Safety Precautions: A) Warning of the hazards of the flammable and corrosive chemicals contained in the kit. B) Steps to follow and antidotes to use if hazardous reagents are taken internally or come in contact with parts of the body or clothes. C) Procedures for safely discarding used reagents and containers.

See www.skcinc.com for detailed Safety Data Sheets (SDS) for MethAlert that include instructions for safe handling of reagents, proper use of personal protective equipment (PPE), and appropriate precautions for avoiding contact and inhalation hazards. SKC advises disposal in accordance with federal, state, and local regulations.

4.1.4 General: A) A statement that the kit is intended to be used for presumptive identification purposes only, and that all substances tested should be subjected to more definitive examination by qualified scientists in a properly equipped crime laboratory

MethAlert was developed originally for use outside of law enforcement (i.e., public health, industrial hygiene). The following disclaimer appears in the MethAlert Operating Instructions (Form 37207): "MethAlert is a colorimetric test that provides an indication of the presence of methamphetamine residues on surfaces in the range of 15 to 5000 µg. Results should not be used for clearance purposes." This statement is fundamentally equivalent to the guideline statement.

B) A statement that users of the kit should receive appropriate training in its use and should be taught that the reagents can give false-positive as well as false-negative results

MethAlert Operating Instructions (Form 37207) are clearly written and contain step-by-step photographs. The instructions state: "MethAlert is ideal for use by health and safety professionals, industrial hygienists, law enforcement personnel, first-responders, social services, real estate agents, or anyone who needs to determine if methamphetamine residue is present on a specific surface." A list of possible positive interferences is included. There are no known negative interferences.

C) A discussion of the possibility of reagent and/or sample contamination and consequent misleading results

MethAlert Operating Instructions (Form 37207) state that the user should use new, clean gloves for each test. The instructions also direct users to thoroughly wash the exterior of bottles with soap and water before sampling at another site to avoid cross contamination. There are no known negative interferences.

Reagent bottles contain airtight adhesive foil seals and are packaged in a polyethylene zip-locked bag separate from other kit components.

D) A discussion of proper kit storage in buildings and vehicles

MethAlert Operating Instructions (Form 37207) provide clear directions for storage of kit components during laboratory and field use.

4.2 Labeling

Each reagent container shall have a label that either directly or by reference:

- A) Identifies the reagent
- B) Identifies the drug or drugs it can detect
- C) Is prominently marked "Danger" where appropriate
- D) Gives a discard date where appropriate

All MethAlert reagents are clearly marked with kit component name and step number. The actual chemical makeup of the reagent is not included on the label as the reagents are a trade secret. The MethAlert name identifies methamphetamine as the drug of interest by reference. Instructions are provided on bottle labels and each reagent bottle contains a label with an expiration date.

4.3 Workmanship

Visual inspection of the kit shall show no broken or inoperative catches, hinges, or containers. There shall be no evidence of reagent leakage.

MethAlert Kits are shipped in protective, sealed, and refrigerated packaging. Products are guaranteed to arrive in good condition and without material defects. Reagent bottles feature airtight adhesive foil seals and are packaged in a polyethylene zip-locked bag.

4.4 Safe-disposal Materials

The kit shall contain chemicals for neutralizing strongly acidic and basic reagents and/or acid/base-resistant containers into which used reagents and containers can be deposited and safely disposed of at a later time in accordance with Section 4.1.3.C.

MethAlert Kits contain instructions for safe disposal of test products and reagents.

4.5 Color Samples

The kit shall include samples or reproductions of the color or colors produced by each reagent in the kit when reacted with each drug listed on the reagent container label.

MethAlert Kits each contain a full-color, laminated Quick Guide (Form 37134) that provides a clear example of a positive test color for methamphetamine. MethAlert Operating Instructions (Form 37207) describe the blue color bloom reaction.

4.6 Test Color and Sensitivity

Each reagent in the kit shall produce the color or colors specified by the manufacturer in the form of color samples (Section 4.5) or have the same color hue and color saturation as those colors, for each of five replicate tests, performed in accordance with Section 5.2 at the drug detection limit listed in Table 2 or specified by the manufacturer in accordance with Section 4.7. If a reagent produces the same color with more than one drug, this test should be performed from only one of those reagent/drug combinations.

Each MethAlert Kit contains a full-color Quick Guide (Form 37134) that provides a visual example of a positive test color. Possible positive interferences and a description of their color reactions are provided in the MethAlert Operating Instructions (Form 37207).

4.7 Drug Detection Limit

The manufacturer shall specify the drug detection limit, determined in accordance with Section 5.3, for each drug/reagent combination listed on a reagent container label, other than those listed in Table 2.

MethAlert Operating Instructions (Form 37207) state clearly that the kit is designed to measure only methamphetamine at a Lower Limit of Identification (LLOI) of 15 µg/100 cm².

4.8 Specificity

The kit shall include sufficient reagents to permit differentiation between each drug listed in accordance with Section 4.1.1 and the other substances listed in Table 3. The differentiation may be accomplished by the use of a single reagent or by a combination of reagents. Acceptable differentiation occurs if the final colors of the test are not in the color vicinity of one another when checked in accordance with Section 5.4.

The MethAlert Kit is designed and intended to detect and measure only methamphetamine at the stated Lower Limit of Identification of 15 µg/100 cm².

5.1 General Test Conditions

At the time of the tests, the ambient temperature shall be between 50 and 104 F (10 and 40 C); the relative humidity shall be between 10 and 90%. Recommended Safety Precautions (see Appendix B) and Storage Precautions (see Appendix C) shall be followed.

MethAlert was tested in the laboratory and under field conditions during validation of the method. Ambient conditions fell within the prescribed ranges.

5.2 Test Color

Place 500 µg of the drug, either as powder or dissolved in chloroform, in each of three wells of the porcelain test plate (except for Appendix A.3, where glass culture tubes are used). If the kit is packaged with the reagents in sealed glass tubes for single test field purposes, break the reagent tubes in suitable individual containers such as small beakers or test tubes. Use a disposable pasteur-type pipette to transfer one drop (approximately 0.1 ml) of each reagent being tested, in the sequence specified by the manufacturer, if appropriate, to each of the three wells.¹ Compare the color or colors produced within the specified time limits to those provided by the manufacturer, in accordance with Section 4.5, and determine whether the colors are essentially the same. (¹When two or more reagents are used sequentially, transfer the minimum number of drops of each reagent equivalent to the ratio specified by the manufacturer [i.e., three drops to one drop, etc.]).

If the colors do not match, check the drug solution and test procedure by repeating the above procedure using fresh reagent prepared as directed in Appendix A or by the manufacturer. This paragraph is not applicable to reagents not listed in Appendix A unless information similar to that in Appendix A is supplied by the manufacturer.

MethAlert was tested in the laboratory by applying known concentrations of three grades of methamphetamine (~ 50% street grade, ~ 99% street grade, and Aldrich USP reagent grade) to methamphetamine-free 3 x 3-inch ceramic tile test surfaces. Surface samples were collected as described in the MethAlert Kit Operating Instructions (Form 37207). Samples were extracted from the wipes and read in a spectrophotometer at 550 nm (dark blue). Methamphetamine concentrations ranged from 0 to 500 µg (Figure 1).

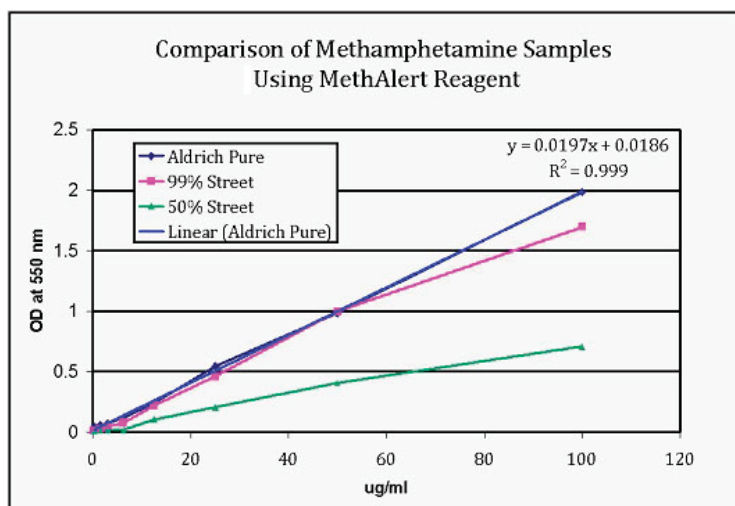


Figure 1. Comparison of Methamphetamine Samples Using MethAlert Reagent

5.3 Drug Detection Limit Determination

Prepare a 1.0 µg/µl solution (or lower if necessary) of the selected drug in chloroform or methanol. Using a micropipette, transfer five samples of this solution to the test wells or tubes. Add reagent as described in Section 5.2. Change the quantity of drug transferred by varying either the solution concentration or the volume transferred and repeat the test until the smallest mass of transferred drug is determined, to one significant figure, for which five out of five color changes are observed. As a safety factor, multiply this quantity by 10 and use the product as the operational drug detection limit.

MethAlert was tested in the laboratory by applying known concentrations of methamphetamine (0 to 500 µg) in methanol to methamphetamine-free test surfaces (3 x 3-inch ceramic tiles). After drying, surface wipe samples were collected using three types of sample collection methods (cotton wipes, creped wipes, and cotton swabs) as described in the MethAlert Kit Operating Instructions (Form 37207). Results are included in Tables 1 and 2.

Table 1. Determination of MethAlert Lower Limit of Identification

µg Meth	3 x 3 Cotton	2 x 2 Cotton	Crepe
500	Positive	Positive	Positive
100	Positive	Positive	Positive
50	Positive	Positive	Positive
25	Positive	Positive	Positive
12.5	Positive	Positive	Positive
6.25	Positive	Positive	Positive
3.125	Negative	Positive	Negative
1.56	Negative	Negative	Negative
0.78	Negative	Negative	Negative
0	Negative	Negative	Negative

Table 2. Evaluation of Cotton Swab Wipe Test Using MethAlert Reagent

µg Meth	Trial 1	Trial 2	Trial 3
500	Positive	Positive	Positive
100	Positive	Positive	Positive
50	Positive	Positive	Positive
25	Positive	Positive	Positive
12.5	Positive	Positive	Positive
6.25	Positive	Positive	Positive
3.125	Positive	Positive	Positive
1.56	Positive	Positive	Negative
0	Negative	Negative	Negative

5.4 Specificity Test

For each reagent in the kit other than those listed in Appendix A, determine the final color, if any, when mixed with each substance listed in Table 3.

MethAlert Kit Operating Instructions (Form 37207) include the following possible positive interferences and colorimetric reactions:

- *MDMA (Ecstasy) - very dark/deep blue color reaction*
- *Ritalin[®] (Methylphenidate) - pale violet color reaction*
- *Methcathinone (Cat) - pale blue color reaction*
- *MDA (3,4-Methylenedioxyamphetamine) - pinkish rose color reaction*
- *MDEA (Methyl Diethanol Amine) - deep blue to muddy brown at higher concentrations*
- *Some secondary amines can cause a color reaction*

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