



Technical Note

Performance of the MethChek Immunoassay Wipe Kits

Introduction

The SKC MethChek® semi-quantitative immunoassay wipe method was developed by the U.S. National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC) to aid professionals involved in pre and post-remediation evaluation of clandestine methamphetamine laboratories*. MethChek indicates surface methamphetamine residue on-site at lower limits of identification (LLOI) relevant to multi-state cleanup guidelines. Kits with an LLOI of 0.05, 0.1, 0.5, or 1.5 µg/100 cm² are available. Results should be verified by wipe samples with laboratory analysis if required by the individual state.

Studies were performed to determine the accuracy and sensitivity of MethChek Immunoassay Wipe Kits. Correlation studies were also performed at crime scenes to compare MethChek Wipe Kits with wipe sampling and laboratory analysis developed by DataChem Laboratories (Draft Method 9111) to demonstrate the integrity and reliability of the MethChek Wipe Kits.

* *MethChek also has applications for home and commercial building inspection and crime investigations.*

Methodology

SKC MethChek Immunoassay Wipe Kits

The user sprays a cotton swab or gauze pad with a wetting reagent. The wetted swab/pad is used to wipe the surface within a disposable 10 x 10-cm template. On-site, the sample is extracted from the swab with an extracting reagent. An aliquot of the extract is pipetted into the sample well of a test cartridge. A line in the cartridge test window only indicates the presence of meth above a specific concentration. A line in both the test window and the reference window of the cartridge indicate a negative result. A line in the reference window only indicates an invalid test. ***Of the MethChek Kits, MethChek 50 has the lowest limit of identification of 0.05 µg per 100 cm².*** Results appear within one to five minutes and remain visible for several months before fading.

Wipes with Laboratory Analysis (Draft Method 9111 [LC-MS])

DataChem Laboratories (Salt Lake City, UT) developed a wipe sample method with laboratory analysis (Draft Method 9111) for methamphetamine residue in which cotton gauze moistened with isopropyl alcohol or methanol is used to sample surfaces. Samples are sent to DataChem Laboratories for analysis by Liquid Chromatography-Mass Spectrometry (LC-MS) with isotopic dilution (ID). ***The lower limit of identification (LLOI) of the laboratory analysis is 0.05 µg per wipe and the reporting limit, a verified value of method/media/instrument sensitivity, is 0.1 µg per wipe.***

Results and Discussion

Determination of MethChek 50 Lower Limit of Identification:

Serial two-fold solutions were plated onto polyethylene weigh boats and dried. The MethChek Wipe Kits were used as described in the kit instructions. The practical lower limit of identification (LLOI) is shown in detail in Table 1. The data indicate that it is possible to get responses at less than the stated limit. Sensitivity depends on many factors including the operator, the surface being wiped, and the type of methamphetamine that is present. ***After three trials with one trained operator, the practical LLOI for MethChek 50 test cartridges was determined to be approximately 0.05 µg/ml (50 ng/ml) based on the data in Table 1.***

Table 1. Determination of MethChek 50 LLOI

| Methamphetamine/ml | | Trial 1 | Trial 2 | Trial 3 |
|--------------------|------|----------|-----------|----------|
| µg | ng | | | |
| 1 | 1000 | Positive | Positive | Positive |
| 0.5 | 500 | Positive | Positive | Positive |
| 0.25 | 250 | Positive | Positive | Positive |
| 0.125 | 125 | Positive | Positive | Positive |
| 0.031 | 31 | Positive | Equivocal | Negative |
| 0.015 | 15 | Negative | Negative | Negative |
| 0 | 0 | Negative | Negative | Negative |

Determination of MethChek Accuracy:

MethChek Wipe Kit accuracy tests were conducted with 10 untrained volunteers. Ceramic tiles were spiked with known concentrations of methamphetamine in buffer solution and allowed to dry overnight. Volunteers performed wipe tests on the tiles with either cotton swabs (MethChek 50), 2 x 2-inch cotton wipes (MethChek 100), or 3 x 3-inch cotton wipes (MethChek 500) as described in the kit instructions. **Overall accuracy of MethChek Wipe Kits was ≥ 97 % when the actual sample was ± 20% of the stated method cut off. No false positives were reported (n=480 tests). See Tables 2 through 4.**

Table 2. MethChek 50 Accuracy

| Test # | Meth (ng) | 50 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|--------|-----------|-----------------------|--------------|--------------|---------------|
| 1 | 0 | 0 | 0 | 100 | 0 |
| 2 | 0 | 0 | 0 | 100 | 0 |
| 3 | 0 | 0 | 0 | 100 | 0 |
| 4 | 0 | 0 | 0 | 100 | 0 |
| 5 | 0 | 0 | 0 | 100 | 0 |
| 6 | 50 | CO | 90 | 10 | 0 |
| 7 | 50 | CO | 90 | 10 | 0 |
| 8 | 50 | CO | 100 | 0 | 0 |
| 9 | 40 | 80 | 90 | 10 | 0 |
| 10 | 60 | 120 | 100 | 0 | 0 |

* CO = Cut off

Table 3. MethChek 100 Accuracy

| Test # | Meth (ng) | 100 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|--------|-----------|------------------------|--------------|--------------|---------------|
| 1 | 0 | 0 | 0 | 100 | 0 |
| 2 | 0 | 0 | 0 | 100 | 0 |
| 3 | 0 | 0 | 0 | 100 | 0 |
| 4 | 0 | 0 | 0 | 100 | 0 |
| 5 | 0 | 0 | 0 | 100 | 0 |
| 6 | 100 | CO | 100 | 0 | 0 |
| 7 | 100 | CO | 100 | 0 | 0 |
| 8 | 100 | CO | 100 | 0 | 0 |
| 9 | 80 | 80 | 100 | 0 | 0 |
| 10 | 120 | 120 | 100 | 0 | 0 |

* CO = Cut off

Table 4. MethChek 500 Accuracy

| Test # | Meth (ng) | 500 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|--------|-----------|---------------------|--------------|--------------|---------------|
| 1 | 0 | 0 | 0 | 100 | 0 |
| 2 | 0 | 0 | 0 | 100 | 0 |
| 3 | 0 | 0 | 0 | 100 | 0 |
| 4 | 0 | 0 | 0 | 100 | 0 |
| 5 | 0 | 0 | 0 | 100 | 0 |
| 6 | 500 | CO | 100 | 0 | 0 |
| 7 | 500 | CO | 100 | 0 | 0 |
| 8 | 500 | CO | 100 | 0 | 0 |
| 9 | 400 | 80 | 90 | 10 | 0 |
| 10 | 600 | 120 | 100 | 0 | 0 |

* CO = Cut off

Determination of MethChek Sensitivity:

MethChek Wipe Kit sensitivity tests were conducted with 10 untrained volunteers. Ceramic tiles were spiked with known concentrations of methamphetamine in buffer solution and allowed to dry overnight. Volunteers performed wipe tests on the tiles with either cotton swabs (MethChek 50), 2 x 2-inch cotton wipes (MethChek 100), or 3 x 3-inch cotton wipes (MethChek 500 and 1500) as described in the kit instructions. **Overall sensitivity of MethChek Wipe Kits was $\geq 96\%$ when the actual sample was $\pm 50\%$ of the stated method cut off. No false positives were reported (n=480 tests). See Tables 5 through 8.**

Table 5. MethChek 50 Sensitivity

| ng Meth | 50 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|---------|--------------------|--------------|--------------|---------------|
| 0 | 0 | 0 | 100 | 0 |
| 25 | -50 | 60 | 40 | 0 |
| 38 | -25 | 80 | 20 | 0 |
| 50 | CO | 100 | 0 | 0 |
| 63 | +25 | 100 | 0 | 0 |
| 75 | +50 | 100 | 0 | 0 |

* CO = Cut off

Table 6. MethChek 100 Sensitivity

| ng Meth | 100 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|---------|---------------------|--------------|--------------|---------------|
| 0 | 0 | 0 | 100 | 0 |
| 50 | -50 | 90 | 10 | 0 |
| 75 | -25 | 90 | 10 | 0 |
| 100 | CO | 100 | 0 | 0 |
| 125 | +25 | 100 | 0 | 0 |
| 150 | +50 | 100 | 0 | 0 |

* CO = Cut off

Table 7. MethChek 500 Sensitivity

| ng Meth | 500 ng Cut Off (%)* | Positive (%) | Negative (%) | Equivocal (%) |
|---------|---------------------|--------------|--------------|---------------|
| 0 | 0 | 0 | 100 | 0 |
| 250 | -50 | 90 | 10 | 0 |
| 380 | -25 | 90 | 10 | 0 |
| 500 | CO | 100 | 0 | 0 |
| 630 | +25 | 100 | 0 | 0 |
| 750 | +50 | 100 | 0 | 0 |

* CO = Cut off

Table 8. MethChek 1500 Sensitivity

| ng Meth | 1500 ng Cut Off (%) [*] | Positive (%) | Negative (%) | Equivocal (%) |
|---------|----------------------------------|--------------|--------------|---------------|
| 0 | 0 | 0 | 100 | 0 |
| 375 | -75 | 0 | 100 | 0 |
| 750 | -50 | 0 | 100 | 0 |
| 1125 | -25 | 70 | 30 | 0 |
| 1500 | CO | 100 | 0 | 0 |
| 1875 | +25 | 100 | 0 | 0 |
| 2250 | +50 | 100 | 0 | 0 |

^{*} CO = Cut off

Comparison of MethChek Wipe Kits to Wipes with Laboratory Analysis (Draft Method 9111):

MethChek Immunoassay Wipe Kits: Ceramic tiles were spiked with known concentrations of methamphetamine in buffer solution and allowed to dry overnight. For the MethChek Wipe Kits, volunteers performed wipe tests on the tiles with either cotton swabs (MethChek 50), 2 x 2-inch cotton wipes (MethChek 100), or 3 x 3-inch cotton wipes (MethChek 500) as described in the kit instructions.

Wipes with Laboratory Analysis (Draft Method 9111 [LC-MS/ID]): Ceramic tiles were spiked with known concentrations of methamphetamine in buffer solution and allowed to dry overnight. In a separate methamphetamine-free laboratory, 3 x 3-inch wipes were wet with 1-ml reagent grade methanol (Sigma-Aldrich, St. Louis, MO) and individually placed into plastic centrifuge tubes and sealed. Upon entering the detection area, the gauze was taken out of the tubes prior to wiping the designated surface. After sampling, the wipes were put back into the centrifuge tubes and sent to DataChem Laboratories for analysis with LC-MS/ID using in-house Draft Method 9111. *See Table 9.*

Table 9. Comparison of MethChek Wipe Kits to Wipe Samples with Laboratory Analysis (Draft Method 9111)

| Amount of Meth on Surface (ng/100 cm ²) | MethChek 50 (n=9) | Draft 9111 with Lab Analysis |
|---|--------------------|----------------------------------|
| 0 | 100% negative | ND [*] |
| 38 | 100% positive | Below reporting limit (< 100 ng) |
| 50 | 100% positive | Below reporting limit (< 100 ng) |
| 63 | 100% positive | Below reporting limit (< 100 ng) |
| Amount of Meth on Surface (ng/100 cm ²) | MethChek 100 (n=9) | Draft 9111 |
| 0 | 100% negative | ND [*] |
| 75 | 100% positive | Below reporting limit (< 100 ng) |
| 100 | 100% positive | 94 ± 7 ng |
| 125 | 100% positive | 118 ± 4 ng |
| Amount of Meth on Surface (ng/100 cm ²) | MethChek 500 (n=9) | Draft 9111 |
| 0 | 100% negative | ND [*] |
| 380 | 100% positive | 400 ± 11 ng |
| 500 | 100% positive | 490 ± 12 ng |
| 630 | 100% positive | 581 ± 31 ng |

^{*} ND = None detected

Field Evaluation and Validation of Tests

MethChek Wipe Kits were field tested in clandestine methamphetamine laboratories in Ohio and Kentucky. Upon invitation from law enforcement and public health agencies, NIOSH researchers performed entry into suspect clandestine laboratories. Wipe samples for methamphetamine were collected by wiping a 100 cm² area with either sterile cotton swabs for immunochemical analysis or sterile 3 x 3-inch gauze wipes for either colorimetric detection or chemical analysis. Cross contamination of sampling sites was minimized by using separate pairs of gloves between sample locations. On-site methamphetamine detection was performed with MethChek as described in the *Methodology* section. For wipe samples that were laboratory analyzed using LC-MS/ID, 3 x 3-inch wipes were wetted with one ml of reagent-grade methanol and individually placed into plastic centrifuge tubes prior to entering the methamphetamine cook area. After entering the cook area, the gauze was taken out of the tubes and the designated surfaces wiped. After sampling, the wipes were put back into the centrifuge tubes and sent to DataChem Laboratories for analysis using Draft Method 9111.

Field Evaluation Results:

In field tests at multiple clandestine labs (7 sites and 105 samples), *MethChek Wipe Kits were able to detect methamphetamine residues on surfaces greater than 95% of the time when the presence of methamphetamine was confirmed by laboratory analysis (Draft Method 9111)*. Results from a typical clandestine laboratory (in a motel room) are presented in Table 10.

Table 10. Field Performance Comparison of MethChek Wipe Kits and Wipe Samples with Laboratory Analysis (Draft Method 9111)

| Location | Pre-remediation | | | During Remediation | | |
|-------------|-----------------|--------------|---|--------------------|--------------|---|
| | MethChek 50 | MethChek 500 | Wipes with Analysis (µg/100 cm ²) | MethChek 50 | MethChek 500 | Wipes with Analysis (µg/100 cm ²) |
| Dresser A | Positive | Positive | 11.00 | Positive | Negative | 0.34 |
| Dresser B | Positive | Positive | 14.00 | Positive | Negative | 0.07 |
| TV Stand | Positive | Positive | 12.00 | Positive | Positive | 0.40 |
| TV | Positive | Positive | 4.80 | Negative | Negative | ND* |
| AC Vent | Positive | Positive | 24.00 | Positive | Positive | 1.20 |
| AC Return | Positive | Positive | 26.00 | Positive | Positive | 3.20 |
| Wall | Positive | Positive | 4.20 | Positive | Positive | 0.89 |
| Table | Positive | Positive | 1500.00 | Positive | Positive | 4.80 |
| Window | Positive | Positive | 2.10 | Negative | Negative | ND* |
| Night Stand | Positive | Positive | 5.50 | Positive | Negative | 1.07 |
| Drapes | Positive | Negative | 0.78 | Positive | Negative | 0.13 |

* ND = None detected

Interferences

MethChek Wipe Kits were tested for cross-reactivity with several substances. MDMA (Ecstasy) is 100% cross-reactive with MethChek. Other drugs of abuse (Heroin, powder cocaine, and street cocaine) and methamphetamine precursors are less than 10% cross-reactive. There are no known negative interferences.

Stability of MethChek Wipe Kits

Sealed MethChek tests were exposed to a variety of temperature and humidity extremes that may be encountered during field use. Accuracy and sensitivity of the tests was not affected by extremes of temperature (> 100 F) and humidity (approx. 90%). MethChek Wipe Kits can store for one year at 38 to 78 F with no loss in accuracy or sensitivity. However, cold conditions (< 40 F) may increase test result development time.

Discussion

In the field, MethChek Wipe Kits demonstrated greater than 95% agreement with wipes with laboratory analysis (Draft Method 9111). As a tool to perform initial site assessment, MethChek 50 and MethChek 500 correlate well with results from wipes with laboratory analysis (Table 10) and can assist in a process-driven remediation. However, many states require wipe sampling with laboratory analysis using a specific method (usually mass spectroscopy with isotopic dilution [MS/ID]) for site clearance. If state assessment and cleanup guidelines are followed, additional sampling may be needed with traditional wipe samples and laboratory analysis to further substantiate the level of methamphetamine present.

Conclusion

Data show the MethChek Wipe Kits to be sensitive and effective in the laboratory and on-site at clandestine meth labs. MethChek results correlated well when used in a side-by-side comparison with wipes with laboratory analysis (Draft Method 9111). Many state cleanup guidelines require laboratory results to clear a building for re-occupancy. In addition to quantitative wipe sampling, professionals and state health department officials may use MethChek Wipe Kits as a practical timesaving tool for pre-remediation assessments, cleanup plan development, and post-remediation assessments to determine the need for further cleaning. MethChek 50, in particular, has been shown to be very effective in measuring very low surface levels of methamphetamine. Therefore, this product has applications in home and commercial building inspection and crime investigations.

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