DEPARTMENT OF HEALTH

On-Site Inspection Checklist

Analyte(s): Methamphetamine, Pseudoephedrine and Ephedrine

Matrix: Swab

Technology: Liquid or Gas Chromatography/Mass Spectrometry

Method: Performance-based

Sample Preservation/Sample Storage

Criteria	Yes	No	Remarks
Samples are stored at 4°C until extraction.			

Sample Size for Preparation

Criteria	Yes	No	Remarks
Swabs: Gauze sponges 3"X 3" - 4 ply, rayon/polyester blend or equivalent. Note: sponges must hold (absorb) solvent and sponge matrix does not interfere with mass spectral identification.			

Sample Preparation

Criteria	Yes	No	Remarks
Swabs: Gauze sponges are prewetted or wetted in the field. Methanol is the primary solvent. Water is used for delicate/perishable surfaces.			
Isotopically labeled (e.g. D9) internal standards for methamphetamine and pseudoephedrine or ephedrine are added after sample collection or prior to the beginning of sample processing.			
Sample preparation procedures (e.g. extraction, mixing, filtering) are defined and identical for all samples and quality control.			

Holding Time

Criteria	Yes	No	Remarks
Samples are extracted within 14 days.			
Samples are analyzed within 40 days of extraction.			

Method Validation-Initial Demonstration of Capability

Criteria	Yes	No	Remarks
Each analyst has performed an initial demonstration of capability.			

Detection Limits

Criteria	Yes	No	Remarks
Detection limit is established according to criteria in regulation [40 CFR 136, Appendix B].			

Reporting Limits

Criteria	Yes	No	Remarks
Reporting limits are established for each analyte of interest.			

Equipment and Equipment Maintenance

Criteria	Yes	No	Remarks
Instrument is maintained per manufacturer's recommendations. Maintenance logbooks are up to date.			

Reagents and Standards, Expiration Check

Criteria	Yes	No	Remarks
The standards are prepared in accordance with the laboratory's standard operating procedures and quality assurance manual.			
Reagents and standards are appropriately labeled in accordance with the requirements in Minnesota Rules, Chapter 4740 (e.g. contents, date of preparation, date of expiration, identification of the preparer).			
Reagents and standards are discarded prior to expiration.			

Pre-calibration Requirements

Criteria	Yes	No	Remarks
For GC/MS: specific information is provided as to how the instrument is set up. This information must include, at a minimum:			
 If samples are analyzed by GC/MS the mass spec tune meets acceptance criteria of 8270C method (if DFTPP is used) or the acceptance criteria as defined by the laboratory. 			
 The mass spec tune meets acceptance criteria prior to analysis and every 12 hours. 			
 Analyte retention times and respective acceptance windows are determined for all compounds. 			
 Target ions and their relative intensities are defined for each analyte. 			

Criteria	Yes	No	Remarks
This information must be the same for all calibration curve, samples, and QC (i.e. the electron multiplier voltage for the calibration curve must be the same as that of the samples).			
For LC/MS, LC/MS/MS or LC/MSnth: specific information is provided as to how the instrument is set up. This information must include, at a minimum:			
 The laboratory documents the mass spectral tune results. 			
 Analyte retention times and respective acceptance windows are determined for all compounds. 			
 Molecular, primary fragment, secondary fragment, etc. ions (if applicable) are defined for each analyte. 			
 Molecular, primary fragment, secondary fragment, etc. ions and expected primary/secondary fragment ion ratios (if applicable) are defined along with acceptance criteria. 			
This information must be the same for all calibration curve, samples, and QC (i.e. the electron multiplier voltage for the calibration curve must be the same as that of the samples).			

Initial Calibration Requirements and Linear Range

Criteria	Yes	No	Remarks
The calibration curve is constructed of at least five standards. Concentrations of the standards are recorded.			
The lowest standard in the curve is at or below the reporting limit of the compounds.			
The criteria for acceptance of the initial calibration curve are defined.			
Acceptance criteria for internal standard abundances are defined.			

Calibration Verification Requirements

Criteria	Yes	No	Remarks
At least two continuing calibration verification (CCV) standards will be analyzed prior to sample analysis. One of the CCV standard mixes must be at or below the report level of the analytes of interest. Acceptance limits and abundance criteria must be documented for the CCV standards. Continuing calibration verification must occur prior to batch analysis and every 12 hours.			

Procedure

Crit	eria	Yes	No	Remarks
Ret rela refe	ention times of the target compounds are within 0.06 ative retention time units of the measured standard erence compounds.			
For	GC/MS:			
Ì	All ions present in the standard mass spectrum at a relative intensity greater than 10 percent must be present in the sample spectrum.			
Ì	The relative intensities of the ions in (1) above must agree within + 20 percent between the standard and sample spectrum.			
For	LC/MS, LC/MS/MS or LC/MSnth:			
1	All ions (e.g. molecular, primary fragment, secondary fragment, etc.) monitored in the standard mass spectrum must be present in the sample spectrum.			
1	The relative intensities of the ion ratios (e.g. primary/secondary fragment ion ratio) in (1) above must agree within + 30 percent between the standard and sample spectrum.			

QC Accuracy

Criteria	Yes	No	Remarks
A Quality Control Sample (QCS) or solution of target analytes of known concentration obtained from a second source or from a different lot number from the calibration solutions is analyzed with each calibration curve or quarterly (whichever is more frequent). Acceptance limits are defined for the QCS.			
Midlevel continuing calibration check standard containing each compound is analyzed every batch or every 20 samples, which ever is most frequent.			
When the values for external reference standards fall outside the acceptance range established by in-house limits, appropriate corrective action is taken.			

QC Precision

Criteria	Yes	No	Remarks
An LCS and LCSD (spike two clean gauze sponges with a known amount of the compounds and analyze each separately) are analyzed per batch or every 20 samples, whichever is most frequent.curve or quarterly (whichever			

Criteria	Yes	No	Remarks
is more frequent). Acceptance limits are defined for the QCS.			
Acceptance criteria for laboratory control spikes are defined.			
Spiking concentration is reasonable to the concentrations present in the calibration curve.			
At least one duplicate is run as part of every analysis set.			
At least ten percent of all samples are run in duplicate. Acceptance limits are defined for the duplicate samples.			

QC Blanks

Criteria	Yes	No	Remarks
At least one method blank is included in each preparation batch. Acceptance limits are defined for the method blank.			

Calculations

Criteria	Yes	No	Remarks
Quantitation is based on the internal standard technique.			
All samples are diluted and re-analyzed if the measured concentration is above the highest calibration level.			
Because pseudoephedrine and ephedrine are stereo isomers they are reported as an isomeric pair.			

Report to Client

Criteria	Yes	No	Remarks
Reports to the client include the date the sample was analyzed.			
Reports to the client include a reference to the method used.			
Reports to the client include the unique sample identification used by the laboratory.			
Reports to the client include the units of measurement.			
Reports to the client indicate any deviation from the specified procedures.			

Laboratory Documentation

Criteria	Yes	No	Remarks
Because this is a PBMS method, the laboratory must have a specific corrective action policy for each area of the			

Criteria	Yes	No	Remarks
analysis when the laboratory's defined criteria are not met.			
The laboratory's actual practice conforms to the current standard operating procedure on file.			

Minnesota Department of Health Environmental Laboratory Accreditation Program 601 Robert Street North P.O. Box 64899 Saint Paul, Minnesota 55164-0899 651-201-5324 <u>Methamphetamine Testing (MNELAP)</u> https://www.health.state.mn.us/communities/environment/mnelap/mapbmsmeth.html www.health.state.mn.us

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To obtain this information in a different format, call: 651-201-5324.