

TITLE 177 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 7 RULES AND REGULATIONS RELATING TO ANALYSES FOR THE
DETERMINATION OF THE DRUG CONTENT IN URINE WHILE DRIVING
UNDER THE INFLUENCE OF DRUGS

7-001 DEFINITIONS

7-001.01 Categories of Permits Issued by the Department of Health and Human Services are:

001.01A CLASS D PERMIT, which means a permit to perform a chemical test to analyze an individual's urine for drug content by an approved chemical laboratory method(s).

7-001.02 Methods and techniques approved by the Department of Health and Human Services are defined as:

7-001.02A Method means the name of the principle of analysis. The method may be a LABORATORY METHOD, which in these rules and regulations means a method of chemical analysis for drug content.

7-001.02B Technique means a set of written instructions which describe the procedure, equipment, and equipment preventive maintenance necessary to obtain an accurate drug content test result.

7-001.03 Test run means the performance of test(s) which begin at a time and are carried to completion for a sample, or samples grouped in a consecutive manner.

7-001.04 Drug analysis means the use of a chemical test to find the presence of a drug in the urine.

7-001.05 Chemical test means an examination which measure's the presence of a drug by a chemical reaction, or chemical detection using a laboratory instrument.

7-001.06 Test means a chemical test.

7-001.07 Initial screen means an immunoassay which has the ability to recognize the presence or absence of drugs in the urine.

7-001.08 Confirmatory test means an analysis of the urine for drug content by using a Gas Chromatograph/Mass Spectrometer.

7-001.09 Metabolite means the specific substance produced when the human body metabolizes a drug as it passes through the body and is excreted in the urine. Chemical tests of drug metabolites may be used as specified in these regulations to determine the presence of drugs.

7-001.10 Cutoff level means the amount of drug detected which determines the absence or presence of drug. The amount of drug shall be stated in nanograms per milliliter (ng/ml).

7-001.11 Body fluid refers to urine for purposes of this regulation.

7-001.12 ng/ml means nanograms per milliliter.

7-001.13 Drug means any of the following. Marijuana, cocaine, morphine, codeine, phencyclidine, amphetamine, or methamphetamine.

7-001.14 Analyst means a holder of a Class D permit.

7-001.15 Valid permit means a permit which has been executed with proper legal authority and is in force.

7-001.16 Valid test means an analysis performed according to methods approved by the Department of Health and Human Services and by an individual possessing a valid permit.

7-001.17 Assay means a test technique for a particular drug or drug metabolite.

7-001.18 Panel means a grouping of test techniques for particular drugs or drug metabolites.

7-001.19 Instrument means an item of testing equipment used for performing chemical tests.

7-002 REPORT OF RESULTS FOR MEDICO-LEGAL PURPOSES AND VALID TESTS

7-002.01 The presence of a drug shall mean any laboratory confirmatory test result, signal, or finding that shall be equal to or greater than the cutoff level. The cutoff levels are as follows: marijuana metabolite 50 ng/ml, cocaine metabolite 500 ng/ml, morphine 500 ng/ml, codeine 500 ng/ml, phencyclidine 25 ng/ml, amphetamines 500 ng/ml, and methamphetamine 500 ng/ml. The specific metabolite of marijuana shall be delta-9-tetra-hydrocannabinol-9-carboxylic acid and the cocaine metabolite shall be benzoylecgonine.

7-002.02 The presence of a drug shall be determined by analysis using a Gas Chromatograph/Mass Spectrometer. The absence of a drug may be determined by an initial screening method.

7-003 LIMITATION OF PERMITS

7-003.01 For each permit holder, the permit shall state the class of permit, the approved method(s) in use, the name of the instrument. A permit holder shall be limited to the class, the method(s), and the instruments specified on the permit. ~~The permit shall be of the form as shown in Attachment 1, attached and incorporated herein by reference.~~

7-003.02 Permits will be issued only for approved methods, techniques, and instruments, as found in these rules and regulations.

7-003.03 Duplicate permits will not be issued. Notarized copies of an originally issued permit will be provided upon written request. Changes of information carried on a permit or replacement of a permit requires reapplication.

7-004 REVOCATION OF PERMITS

7-004.01 Class D permits are nonexpiring permits. Class D permits may be revoked by the Director of Public Health of the Department ~~Division of Public Health~~ ~~Health~~ whenever a permit holder is in noncompliance with these rules and regulations.

7-005 SPECIMEN COLLECTION AND PRESERVATION

7-005.01 The urine specimen.

7-005.01A The collection of urine shall include saving a portion of an initial urination in a clean, dry, sample container and capped.

7-005.01B Sample collection shall be in the presence of collection personnel designated by the law enforcement agency to assure that adulteration of the sample does not occur.

7-005.01C Specimen containers shall be labeled and shall show the following information on the label: name of person tested, date and time of specimen collection, and initials of person supervising the collection of the specimen.

7-005.01D Specimen containers, with collected urine, shall be sealed and refrigerated as soon as practical as described in ~~part~~ 177 NAC 7-005.01E.

7-005.01E While not in transit to a site for screening or to a site for confirmatory testing, and while not under actual testing, all urine specimens shall be in secured refrigerated storage at four (4) degrees centigrade or less.

7-005.02 The evidence seal. At the testing site the evidence seal shall be broken and the sample analyzed. The seal shall not be broken except by the Class D permit holder at the time just prior to testing.

7-005.03 Retention of specimen following testing. Any remaining specimen after testing shall be retained in a secured frozen storage for a period of not less than ~~4~~ one year, unless requested and receipted for by a defendant's legal counsel. If the defendant is acting as his/her own legal counsel, the sample shall be transferred directly to another testing site if so requested. The sample shall be analyzed within ten ~~(10)~~ days of receipt by the defendant's legal counsel at another testing site as requested in the transfer instructions.

7-006 CLASS D PERMITS FOR INITIAL SCREENS BY CHEMICAL METHODS.

7-006.01 Qualifications for Class D Permit Holder. Class D permit holder qualifications for analysis by chemical tests of an individual's urine for drug content are:

7-006.01A Be not less than the legal age of majority as established by state statutes.

7-006.01B Have knowledge of the theory of the instrument used for initial screens, the operation of the instrument, the calibration of the instrument, the maintenance of the instrument, and the steps in the technique of initial screen drug detection.

7-006.01C Have proof of knowledge and ability consisting of a letter or certificate of training provided to the Department of Health and Human Services from the instrument manufacturer certifying attendance and completion of at least sixteen ~~(16)~~ hours of training covering the topics in ~~part~~ 177 NAC 7-006.01B.

7-006.01D Have demonstrated competence to the satisfaction of the Department of Health and Human Services. Satisfactory competence shall be, for the purpose of these rules and regulations, the satisfactory performance of analysis on proficiency samples in a performance evaluation study as described in ~~subsection~~ 177 NAC 7-006.03.

7-006.02 Issuance of Class D Permits for Initial Screens.

7-006.02A Applications for Class D permits shall be made on forms provided by the Department of Health and Human Services. The application shall be of the form as shown in Attachment 12, attached and incorporated herein by reference.

7-006.02B An applicant for a Class D permit shall, at the time of making application:

7-006.02B1 Sstate the identity of the method(s) that has been selected for use from the list of approved methods in 177 NAC subsection 7-006.04.

7-006.02B2 Ssubmit the technique showing the written instructions which describes the procedure, equipment, and equipment preventive maintenance schedule.

7-006.03 Performance Evaluation Studies. A performance evaluation for permit issuance shall consist of providing copies of the results of sample testing or the graded performance from a recognized proficiency testing service.

~~A recognized proficiency testing service for the purpose of these regulations is the College of American Pathologists. For the purpose of these regulations an ASCLD-LAB approved proficiency test provider must be used.~~ Unacceptable performance is defined as a false positive result for any drug in a one shipment survey.

7-006.03A Ongoing performance evaluation studies shall be in effect, with acceptable performance, for test results to be valid. Ongoing performance evaluation shall be enrollment in ~~the drug testing survey of the College of American Pathologists~~an ASCLD-LAB approved drug proficiency testing program. Unacceptable performance is defined as a false positive result for a drug in two successive survey shipments. Copies of proficiency testing evaluations shall be provided to the Department of Health and Human Services.

7-006.03B Initial screen testing shall not be subject to participation in a recognized proficiency testing service as specified in ~~sub-section 177 NAC 7-006.03 and part 177 NAC 7-006.03A~~. Initial screen permit holders shall participate in a performance evaluation by the Department of Health and Human Services. Unacceptable performance as defined in ~~subsection 177 NAC 7-006.03~~ applies to initial screen permit applicants, and as defined in ~~part 177 NAC 7-006.03A~~ for ongoing performance evaluation surveys. An ongoing performance evaluation shall be one survey shipment annually for initial screen permit holders.

7-006.03C Reporting of test results for the presence or absence of drugs in the urine of individuals shall not occur by a permit holder who has been notified of unacceptable performance in proficiency testing.

7-006.03D A permit holder shall be allowed two attempts to produce acceptable performance after being notified of unacceptable performance.

7-006.03E A permit holder shall not resume reporting of test results for the presence or absence of drugs in the urine of individuals until the Department of Health and Human Services notifies a permit holder that he/she is again in an acceptable performance status following unacceptable performance.

7-006.04 LIST OF APPROVED METHODS AND TECHNIQUES FOR INITIAL SCREEN TESTING.

7-006.04A ENZYME MULTIPLIED IMMUNOASSAY TECHNIQUE (EMIT)

7-006.04A1 The enzyme multiplied immunoassay technique ~~using a SYVA CORPORATION EMIT/st~~ is an approved initial screen method ~~and must be performed in a manner to include at least the following technique.~~ Testing must be performed according to the instrument manufacturer's instructions.

~~006.04A1a The testing of samples shall be processed one at a time, and shall proceed uninterrupted. Two new reagent vials shall be used for each test.~~

~~006.04A1b~~ Place two new reagent vials into the vial holder. One vial for the calibrator on the left and one for the sample on the right.

~~006.04A1c~~ Remove and dispose of the screw caps. Remove the rubber stoppers and place on the work station.

~~006.04A1d~~ Wipe the diluter tubing tip with a lint-free tissue and place the tip into the calibrator bottle. Make sure the tubing touches the bottom of the bottle. Raise the diluter plunger until the top of the arrow on the plunger barrel is exposed. Remove the tubing from the calibrator bottle and look to ensure that liquid has been drawn up. Wipe the tubing tip again, place it in the calibrator vial, then lower the plunger to dispense the calibrator and diluent into the calibrator vial. Proceed immediately to step 006.04A1e.

~~006.04A1e~~ Wipe the diluter tubing tip and place it into the sample. Raise the diluter plunger completely and remove the tubing from the sample. Look and ensure that liquid has been drawn up into the tubing. Wipe the tubing tip again, place it in the sample vial, then lower plunger to dispense the sample and diluent into the sample vial.

~~006.04A1f~~ Replace the rubber stoppers on the vials. Make sure the vials are clean and dry.

~~006.04A1g~~ Shake the vial holder until the powders are dissolved. Do not shake the vials over the photometer.

~~006.04A1h~~ Place the vial holder into the photometer. Press both vials down firmly until the "insert vials" light goes off. The vial containing the calibrator is always on the left and the vial containing the sample is always on the right (as the operator faces the front of the instrument).

~~006.04A1i~~ Slide the result card into the slot on top of the photometer and position it so that the "insert card" light goes off. The card must be positioned with the color-coded block in the upper right-hand corner. Leave the card in place until the result is printed.

~~006.04A1j~~ Remove the result card and vials from the photometer after the "test-in-progress" light goes off. The result is printed on the second and third sheets of the card.

~~006.04A1k Do not leave vials in the photometer after the test is completed. Wait at least fifteen (15) seconds before inserting the vials for the next test.~~

~~006.04A1l Place a negative control and a positive control in place of a sample and perform the test sample steps as prescribed in this technique.~~

7-006.04B FLUORESCENCE POLARIZATION IMMUNOASSAY (FPIA).

~~7-006.04B1 The fluorescence polarization immunoassay method using an ABBOTT DIAGNOSTICS ADX is an approved initial screen method, and must be performed in a manner to include at least the following technique: Testing must be performed according to the instrument manufacturer's instructions.~~

~~006.04B2a Select an ADX access carousel for the Abbott ADX analyzer. Select assay or assays to be analyzed in the run.~~

~~006.04B2b Select reagent packs to be used for assays. Remove reagent cartridges from the reagent packs and invert several times. Remove vial caps and place the first reagent cartridge into the carousel position "R" of the ADX analyzer.~~

~~006.04B2c Use a loadlist to set up the carousel with the needed positions for each sample, control, and reagent cartridge. Load carousel with the appropriate number of sample cartridges, cuvettes, and reagent cartridges. Do not skip a position. Lock cuvettes into carousel.~~

~~006.04B2d For a sample run, introduce at least 0.050 milliliter of sample into sample well. For a panel run, determine minimum volume needed.~~

~~006.04B2e For a sample run, place loaded and locked carousel onto the centerpost of the analyzer. Close the door and press "run". Enter quality control and sample identification information. For a panel run, place loaded and locked carousel onto the centerpost of the analyzer. Close the door and press "panel". Enter quality control and sample identification information.~~

~~006.04B2f At completion of test run, obtain printout of data. The printout includes the blank intensity, the net polarization, and the results (which are equal to or greater than the threshold).~~

~~006.04B2g~~ Also upon completion of analysis, remove the carousel and remove the reagent packs. If the reagent packs are not to be used immediately again, remove and store at two to eight degrees centigrade. Discard the sample cartridges and cuvettes.

~~006.04B2h~~ A calibration curve shall be prepared if any of the low, medium, or high control samples results are outside of the control range. An acceptable control range shall be a coefficient of variation value of less than 16%, plus or minus, of the median target value of the control. To prepare a new calibration curve for an assay, use an ADX access carousel and at least six calibrators for each assay. An ADX analyzer calculated calibration curve shall be used to determine the final drug concentration.

~~006.04B2i~~ An acceptable calibration curve shall meet all of the following requirements. The requirements are: 1. The maximum error (polarization error) must be no greater than in the assay parameter. 2. A root mean squared error no greater than in the assay parameter. 3. The low, medium, and high controls test results shall be within the acceptable quality control range as specified in division 006.04B2h.

~~006.04B2j~~ Quality control samples shall be included in each test run and shall consist of three ranges set up in this manner; a low range, a medium range, and a high range sample. These controls shall be used to meet the requirements of 006.05D, for quality control. The controls shall also be used to determine whether or not the control samples are within the acceptable control ranges as described in division 006.04B2h above.

7-006.05 Operating Rules for Class D Permit. A Class 5 permit holder for the determination of drug content in urine shall:

7-006.05A Accept for testing only the specimen type of urine, as listed on the permit.

7-006.05B Be responsible for maintaining the legal continuity of all specimens received.

7-006.05C Perform all tests using the approved method as named on the Class D permit and in a manner that consists of the technique for the method as found in these rules and regulations.

7-006.05D Conduct all tests for each drug with the inclusion of quality control samples in the test run. The test run may include more than one person's sample for a particular drug; the quality control samples shall be of the same drug that is tested in a test run. The quality control sample result shall be used to:

7-006.05D1 Determine standard deviation data computed as shown:

Standard Deviation =

$$\sqrt{\frac{\text{sum } (X - \bar{X})^2}{N - 1}}$$

where: N = number of measurements

X = value of single measurement

\bar{X} = mean of all X's

7-006.05D2 Determine if test results are to be reported. No test results shall be reported if a quality control sample result is outside of acceptable limits. Acceptable limits for reporting test results shall be no greater than \pm three standard deviations, except for initial screen techniques that utilize an instrument that does not produce numerical data.

7-006.05D3 The EMIT technique in ~~part~~ 177 NAC 7-006.04A utilizes an instrument that does not produce numerical data, therefore, no test result shall be reported if a positive control sample does not give a positive result or if a negative control sample does not give a negative result.

~~006.05E— Make periodic reports of standard deviation data to the Department of Health as requested.~~

7-006.05F Maintain the following records:

7-006.05F1 The permit to perform chemical tests.

7-006.05F2 Records of specimen receipts, tests performed and results.

7-006.05F3 The method and description of technique steps in use by the permit holder along with documentation of validation of technique.

7-006.05F4 The records of quality control results and related data as prescribed in ~~part~~ 177 NAC 7-006.05D of this subsection.

7-006.05F5 A current copy of these rules and regulations.

7-006.05F6 The records of maintenance and repair performed on an instrument, as prescribed in ~~subsection~~ 177 NAC 7-006.06.

7-006.06 Maintenance and Repair of Instruments.

7-006.06A Maintenance of instruments shall be performed as prescribed in the operators manual that is intended for an instrument which may be utilized to produce results with a technique in this regulation. Maintenance shall be performed by a person trained by the manufacturer as specified in ~~parts~~ 177 NAC 7-006.01B and 177 NAC 7-006.01C. Maintenance may also be performed by a manufacturer's representative.

7-006.06B Repair of an instrument shall be performed by a manufacturer's representative or by a person trained by the manufacturer.

7-006.06C Malfunctions of instruments, maintenance activities, and repair occurrences shall be recorded and shall show the name of the person and the agency or business organization performing maintenance activities and repair work.

7-007 CLASS D PERMITS FOR CONFIRMATORY TESTING

7-007.01 Qualifications for Class D Permit Holder. Class D permit holder qualifications for the chemical analyses of an individual's urine, for drug content by confirmatory testing using an approved method(s) and a Gas Chromatograph/Mass Spectrometer (GC/MS) are:

7-007.01A Be not less than the legal age of majority as established by state statutes.

7-007.01B Have knowledge of the chemistry of drugs and drug metabolites. Have the ability to perform confirmatory tests for the presence of drugs in urine. Evidence of knowledge and ability consists of the following proof:

7-007.01B1 Twelve semester hours of academic work in chemistry from a recognized college or university.

7-007.01C Have knowledge of the theory of Gas Chromatography/Mass Spectrometer (GC/MS) methods, the operation of the GC/MS, including its calibration and maintenance. Evidence of knowledge and ability consists of the following proof:

7-007.01C1 ~~Documentation of education or training covering GC/MS applications, consisting of a letter or a certificate of training provided to the Department of Health from the GC/MS manufacturer certifying attendance and completion of at least sixteen (16) hours of training covering the topics in part 007.01C.~~

7-007.01D Have demonstrated competence to the satisfaction of the Department of Health and Human Services. Satisfactory competence shall be, for the purpose of these rules and regulations, the satisfactory performance of analysis on proficiency samples in a performance evaluation study as described in ~~subsection 177 NAC 7-006.03.~~

7-007.02 Issuance of Class D Permits for GC/MS Confirming tests.

7-007.02A Application for Class D permits shall be made on forms provided by the Department of Health and Human Services. The application shall be of the form as shown in Attachment 23, attached and incorporated herein by reference.

7-007.02B An applicant for a Class D permit shall, at the time of making application:

7-007.02B1 state the identity of the manufacturer of the GC/MS intended to be used. ~~The GC/MS must be one of those listed in subsection 007.04. The applicant will notify the Division of Public Health if there is a change in GC/MS information.~~

7-007.03 Performance Evaluation Studies.

7-007.03A Ongoing performance evaluation studies shall be in effect, with acceptable performance, for confirmatory tests to be valid. Ongoing performance shall be enrollment in a recognized proficiency testing service as specified in ~~subsection 177 NAC 7-006.03~~. All provisions in ~~subsection 177 NAC 7-006.03~~, except ~~part 177 NAC 7-006.03B~~, apply to confirmatory testing using a GC/MS method and technique. Copies of proficiency testing evaluations for proficiency test samples analyzed on the GC/MS shall be provided to the Department of Health and Human Services.

7-007.04 List of Approved Methods and GC/MS Instruments for Class D Permits.

7-007.04A GC/MS analysis which shall include scientifically accepted techniques that have been validated by the laboratory utilizing them. ~~GC/MS analysis using a Finnigan instrument is approved and the analysis shall include at least the steps found in subsection 007.06 for GC/MS techniques.~~

~~007.04B GC/MS analysis using a Hewlett Packard instrument is approved and the analysis shall include at least the steps found in subsection 007.06 for GC/MS techniques.~~

7-007.05 Sample Handling for GC/MS Confirmatory Testing.

7-007.05A When samples must be transported to a testing site for confirmatory testing, it is the responsibility of the originating agency to forward all positive initial screening samples to a Class D permit holder authorized to perform confirmatory testing.

7-007.05B While not in transit to a site for confirmatory testing and while not under actual testing, the sample shall be placed in secured refrigerated storage at four ~~(4)~~ degrees centigrade, or less.

7-007.05C When transporting samples to another site for confirmatory testing, the sample shall be repackaged and sealed with an evidence seal. The repackaging shall include all containers, papers, and materials submitted to the initial testing site.

7-007.06 Approved Technique for use with an approved GC/MS method.

~~7-007.06A Scientifically acceptable solid phase or liquid/liquid extraction technique which has been validated by the laboratory performing the extraction. Transfer an aliquot of a standard, a blank, and the sample into a labeled screw-cap tube and add internal standard solution.~~

~~007.06B Perform an organic extraction on each of a standard, a blank, and the sample.~~

~~007.06C Separate the organic extraction phase from the aqueous phase.~~

~~007.06D Concentrate the organic extraction phase by evaporation of the organic extraction solvent.~~

~~007.06E Derivatization is an allowed technique step to permit detection of drug metabolites. Perform the derivatization step prior to injection into the GC/MS.~~

~~007.06F Prepare the GC/MS for analysis. This preparation includes GC/MS tuning and calibration using the standard FC-43, also known as perflurotributylamine. This preparation need not be performed prior to each sample analyses, but must be performed within twenty four (24) hours prior to an analyses.~~

~~007.06G Inject the concentrated extract of a drug, or drug metabolite, with derivatization product if performed in 007.06E, into the GC/MS. Do not inject into a GC/MS which is not prepared and calibrated for analysis.~~

~~007.06H Obtain and record the GC/MS data for the extract injected in part 007.06G. From this data, obtain and record the principle ion data of the drug, or drug metabolite, or derivatization product of a drug or drug metabolite.~~

~~007.06I Using the principle ion data obtained in 007.06H, identify the drug or drug metabolite detected. Report the results as prescribed in section 002.~~

7-007.07 Operating Rules for Class D Perm for GC/MS Confirmatory Tests.

7-007.07A A Class D permit holder for the confirmatory tests to determine the presence of a drug in urine shall follow all of the provisions in ~~subsection 177~~ NAC 7-006.05.

7-007.08 Maintenance and Repair of GC/MS Instruments

7-007.08A Maintenance of GC/MS instruments shall be performed as prescribed in the operators manual that is intended for the GC/MS which may be utilized to produce results with a confirmatory testing technique in this regulation. Maintenance shall be performed by a person trained by the manufacturer as specified in ~~parts 177 NAC 7-007.01C~~ and 177 NAC 7-007.01C1. Maintenance may also be performed by a manufacturer's representative.

7-007.08B Repair of an instrument shall be performed by a manufacturer's representative or by a person trained by the manufacturer.

7-007.08C Malfunctions of the GC/MS, maintenance activities, and repair occurrences shall be recorded and shall show the name of the person and the agency or business organization performing maintenance activities and repair work.

Approved by Attorney General: ~~May 27, 1993~~
Approved by Governor: ~~February 2, 1994~~
Filed with Secretary of State: ~~February 3, 1994~~
Effective Date: ~~February 8, 1994~~



Department of Regulation and Licensure
Credentialing Division
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

PERMIT TO TEST FOR DRUG CONTENT DEPARTMENT OF HEALTH
Lincoln, Nebraska

Permit class number

This permit is issued to the person named hereon, pursuant to section 39-669.11 R.R.S. Nebraska (1943) and the Nebraska Department of Health Rules and Regulations, entitled 177 NAC 7, and is a permit to determine drug content as set forth below.

Name of person this permit issued to:

Approved method is:

Approved technique is:

Permit limited to specimen type of:

Date this permit issued:

(SEAL)

(Director, Division of Laboratories)

(Director, Department of Health)



Division of Public Health
Credentialing Division
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

Application for Class D Permit to Perform Chemical Tests to Determine Drug Content by Initial Screening

~~This space for Department of Health Use:~~

The undersigned applicant hereby makes application for a Class D permit to perform chemical tests to determine drug content as prescribed in 177 NAC 7 of the Nebraska Department of Health and Human Services and as set forth below.

1. Identify method from the list of approved methods for a Class D permit:

ENZYME MULTIPLIED IMMUNOASSAY TECHNIQUE (EMIT)

FLUORESCENCE POLARIZATION IMMUNOASSAY (FPIA)

2. Is the Laboratory Technique attached to this application? yes no

3. Indicate the type of specimen to be tested: urine

4. Proof of knowledge and ability consists of a letter or certificate of attendance and completion of at least 16 hours of training covering instrument operation.

Check below for each of the topics, if the training covered the topic:

A. Theory of Instrument Operation? yes

B. Operating Procedure of the Instrument? yes

C. Calibration of the Instrument? yes

D. Maintenance of the Instrument? yes

E. The Steps in the Technique of Drug Detection? yes

Is a letter of certificate of training from the instrument manufacturer stating your attendance and completion of training covering each of the topics above attached to this certificate? yes

5. A Performance Evaluation Study is required as prescribed for Class D Permits in 177 NAC 7 of the Department of Health and Human Services. A copy of your performance evaluation will be required as prescribed in section-177 NAC 7-006.03.

(type or print name of applicant)

(age)

~~Type of Address of Testing Performance is:
 Residence address as given on next page
 Business (or Laboratory) Address as given
on next page~~

~~(more continued on next page)~~

Address: _____

 _____ (city) _____ (state) _____ (zip)

 (signed name of applicant)

 =
 Affirmed to before me and subscribed in my presence on this ____ day of _____, 19 ____

PERFORMANCE EVALUATION STUDY

Number of Audit Sample	Your Analysis Results	FOR DEPARTMENT OF HEALTH USE	
		Value of Audit Sample	Total Deviation From Mean Value

Signature of person performing evaluation study above

_____ Date of Analyses _____

Name and Address of Agency: _____

Agency Name: _____

Agency Address: _____

Agency Phone #: _____



Division of Public Health
Credentialing Division
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

Application for Class D Permit to Perform Chemical Tests to Determine Drug Content by Confirmatory Tests

~~This space for Department of Health Use:~~

The undersigned applicant hereby makes application for a Class D permit to perform chemical tests to determine drug content as prescribed in 177 NAC 7 of the Nebraska Department of Health and Human Services and as set forth below.

1. Identify method from the list of approved methods for a Class D permit:

ρ Gas Chromatograph/Mass Spectrometer (GC/MS); State the identity of the manufacturer of the GC/MS intended to be used:

2. Is the Laboratory Technique attached to this application? ρ yes ρ no

3. Indicate the type of specimen to be tested: ρ urine

4. Proof of knowledge and ability consists of a letter or certificate of attendance and completion of at least 16 hours of training covering instrument operation.

Check below for each of the topics, if the training covered the topic:

- A. Theory of Instrument Operation? ρ yes
- B. Operating Procedure of the Instrument? ρ yes
- C. Calibration of the Instrument? ρ yes
- D. Maintenance of the Instrument? ρ yes
- E. The Steps in the Technique of Drug Detection? ρ yes

Is a letter of certificate of training from the instrument manufacturer stating your attendance and completion of training covering each of the topics above attached to this certificate? ρ yes

5. A Performance Evaluation Study is required as prescribed for Class D Permits in 177 NAC 7 of the Department of Health and Human Services. A copy of your performance evaluation will be required as prescribed in section-177 NAC 7-006.03.

—

(type or print name of applicant)

(age)

Type of Business Address of Testing

Performance is:

~~ρ Residence address as given on next page~~

ρ Business (or Laboratory) Address as given

~~— on next page~~

(more-continued on next page)

Address: _____

 _____ (city) _____ (state) _____ (zip)

 (signed name of applicant)

 Affirmed to before me and subscribed in my presence on this _____ day of _____, 19 _____

PERFORMANCE EVALUATION STUDY

Number of Audit Sample	Your Analysis Results	FOR DEPARTMENT OF HEALTH USE	
		Value of Audit Sample	Total Deviation From Mean Value

Signature of person performing evaluation study above

 Date of Analyses

Name and Address of Agency: _____

Agency Name: _____

Agency Address: _____

Agency Phone #: _____

2007