

**2007**

**STATE OF NEBRASKA**

Regulations Relating to:

**ANALYSES FOR THE DETERMINATION OF THE DRUG CONTENT  
IN URINE WHILE DRIVING  
UNDER THE INFLUENCE OF DRUGS**

**TITLE 177 NAC 7**

**NEBRASKA DEPARTMENT OF  
HEALTH AND HUMAN SERVICES**

Division of Public Health



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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

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

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 Division of Public 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 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 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 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 hours of training covering the topics in 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 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 1, 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 State the identity of the method(s) that has been selected for use from the list of approved methods in 177 NAC 7-006.04.

7-006.02B2 Submit 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.

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 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 177 NAC 7-006.03 and 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 177 NAC 7-006.03 applies to initial screen permit applicants, and as defined in 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 is an approved initial screen method. Testing must be performed according to the instrument manufacturer's instructions.

7-006.04B FLUORESCENCE POLARIZATION IMMUNOASSAY (FPIA).

7-006.04B1 The fluorescence polarization immunoassay method is an approved initial screen method. Testing must be performed according to the instrument manufacturer's instructions.

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 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.

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 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 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 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 Chromatograph/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.

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 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 2, 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 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 177 NAC 7-006.03. All provisions in 177 NAC 7-006.03, except 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.

7-007.04A GC/MS analysis which shall include scientifically accepted techniques that have been validated by the laboratory utilizing them.

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 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.

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 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 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:	August 27, 2007
Approved by Governor:	September 14, 2007
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Nebraska Department of Health and Human Services



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

ATTACHMENT 1

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

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 177 NAC 7-006.03.

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(type or print name of applicant)

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(age)

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Attachment 1, Continued

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 #: \_\_\_\_\_

Nebraska Department of Health and Human Services



Division of Public Health  
Credentialing Division  
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ATTACHMENT 2

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

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:

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

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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?               | <input type="checkbox"/> yes |
| B. | Operating Procedure of the Instrument?        | <input type="checkbox"/> yes |
| C. | Calibration of the Instrument?                | <input type="checkbox"/> yes |
| D. | Maintenance of the Instrument?                | <input type="checkbox"/> yes |
| E. | The Steps in the Technique of Drug Detection? | <input type="checkbox"/> 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 177 NAC 7-006.03.

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(type or print name of applicant)

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(age)

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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