**STATE OF MAINE**

**SAMPLE COLLECTION AND DRUG TESTING RULE**

**FOR SUSPECTED OPERATING UNDER THE INFLUENCE CASES**

**10-144 CODE OF MAINE RULES**

**CHAPTER 270**



Department of Health and Human Services

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**10-144 DEPARTMENT OF HEALTH AND HUMAN SERVICES**

 **MAINE CENTER FOR DISEASE CONTROL AND PREVENTION**

**Chapter 270: SAMPLE COLLECTION AND DRUG TESTING RULE FORSUSPECTED OPERATING UNDER THE INFLUENCE CASES**

**SUMMARY**

The Department of Health and Human Services (Department) is authorized to implement regulations governing sample collection and testing procedures to be used in suspected cases of operating under the influence of intoxicants (OUI). This rule is intended to ensure that subjects are afforded accurate and reliable blood and urine testing results.

**TABLE OF CONTENTS**

**SECTION 1.** DEFINITIONS **1**

**SECTION 2.** COLLECTION AND STORAGE OF SAMPLES **1**

**SECTION 3.** SUBSTANCES FOR WHICH TESTING IS PERMITTED **4**

**SECTION 4.** ANALYTICAL PROCEDURES **4**

**SECTION 5.** REQUIREMENTS FOR TESTING LABORATORIES **5**

**STATUTORY AUTHORITY AND HISTORY** **9**

**SECTION 1. DEFINITIONS**

**A. Definitions**

 As used in this chapter, unless otherwise indicated, the following terms have the following meanings.

 1. **Negative** or **none detected** **test result** means a test result that indicates:

 a. Particular substance(s) was/were absent within the limitations of the test(s) performed; or

 b. A substance of use is present in the tested sample in a concentration below the detection level.

 2. **Positive test result** means a test result that indicates a particular substance has been identified in accordance with the laboratory protocols.

 3. **Substance use test** means any test procedure designed to take and analyze body fluids or materials from the body for the purpose of detecting the presence of substances of use. The term does not include tests designed to determine alcohol concentration levels from a sample of an individual's breath.

 4. **Substance of use** means any scheduled drug, alcohol or other drug, or any of their metabolites.

 a. **Drug** means any natural or artificial intoxicating chemical substance that, when taken into the human body, can impair the ability of the person to safely operate a motor vehicle or machinery.

b. **Scheduled drug** means any intoxicating or impairing drug named or described in 17-A MRS §1102 as a Schedule W, X, Y or Z drug.

 5. **Analytical testing**

 a. **Screening test** means a test designed to preliminarily detect the presence of a drug or drug category in the specimen. Any positive results are considered to be tentative and must be verified with a confirmatory test.

 b. **Confirmatory test** means a second analytical test performed through the use of gas chromatography/mass spectrometry or liquid chromatography/mass spectrometry to verify the presence of a substance of use indicated by an initial positive screening test result*.*

6*.* **Drug Recognition Expert (DRE)** means a police officer specially trained to recognize impairment in drivers under the influence of drugs other than, or in addition to, alcohol.

**SECTION 2. COLLECTION AND STORAGE OF SPECIMENS**

A. For all testing under this rule, the specimen to be collected must be the subject's urine or blood. The collection of any specimen for use in a substance use test must be performed in a manner that is consistent with specimen collection and labeling standards contained in this rule and the professional training of the person collecting the specimen.

1. **Specimen collection and labeling**

a. Urine samples may be collected only within a law enforcement or healthcare facility. (29-A §2527(2).) The collection area for urine must be a toilet facility equipped with a toilet and a sink for washing after specimen collection. The facility must be enclosed in such a way as to ensure the subject privacy from observation, except as provided in Section 2(A)(1), paragraph d, below. Except in the case of emergency, no other person, other than a law enforcement officer or law enforcement representative or a healthcare practitioner, is permitted to enter the toilet facility during collection.

 b. Urine specimens must be collected in new, clean containers manufactured for the purpose of urine collection. The container must be sealed and labeled immediately after collection and specimen assessment in a manner which will prevent or reveal tampering with the specimen. The specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the subject from whom the specimen was obtained. A responsible person who performed or witnessed the collection and who assumes responsibility for the chain of custody must initial or sign and mark the time and date for each specimen on the kit collection worksheet.

 c. To ensure accurate and reliable testing and to protect the privacy of the person providing the sample, only a law enforcement officer or law enforcement agency employee of the same sex as the person providing the sample, or a health care practitioner, may observe the individual giving the urine sample. Such observation must be conducted in such a manner as to minimize the violation of the subject's privacy.

 d. Blood specimens must be collected in HETL-approved collection kits or a collection tube normally used in a laboratory. All samples must be sealed with tamperproof seals upon submission. Blood specimens must be collected by a qualified person, as described in 29-A MRS §2524(1). Each specimen container must be clearly and indelibly labeled with the date and time of collection and the name or other identifier associated with the person from whom the specimen was obtained. The time and date for each specimen must be initialed or signed by a responsible person who performed or witnessed the collection and who assumes responsibility for the chain of custody.

e. Whenever possible, the Health and Environmental Testing Laboratory (HETL) must reserve a portion of the specimen collected to ensure that enough remains for subsequent re-analysis, if required or requested. At the request and expense of the person charged, the HETL will segregate an available portion of the sample collected for that person's own further testing. Any segregated samples will be released for further testing upon approval from the agency that submitted the sample or the District Attorney’s office.

f. The HETL will provide to law enforcement agencies upon request approved specimen collection kits which include acceptable materials for packing and transportation of urine and blood samples.

2. **Specimen handling**

a. A chain-of-custody form must accompany specimens from the place of collection to the laboratory and be designed for compliance with 29-A MRS §2431(2)(J). The chain-of-custody form must include: the individual(s) or location(s) transferring and receiving the item(s); the item(s) being transferred; and the chronological order of all transfers, minimally including the date, and may be incorporated in the laboratory request form. HETL, upon receipt of the sample, will document the handling, analysis and storage of the specimen on a separate form.

b. Handling, storage, and transportation of a specimen from one individual or place to another must be completely and accurately documented on the chain-of-custody form.

c. The chain-of-custody form must be completed by personnel with custody of the specimen.

d. Every effort must be made to minimize the number of persons handling a specimen.

e. Individual specimens must be properly sealed during transportation and stored in such a manner as to minimize the possibility of degradation, contamination, tampering and damage in shipment.

f. The condition of the external package, including whether it is sealed or unsealed, must be documented upon receipt at the laboratory, either on the requisition form that accompanies the specimen(s), in the log book, on the external chain-of custody form, or on other documents that constitute normal laboratory records.

g. Acceptable means of transporting specimens to the laboratory include hand-delivery, national postal service, or a private or government courier service, and must comply with all requirements regarding the continuity of custody of physical evidence.

3. **Specimen Receipt**

a. The means of delivery of specimens must be recorded by the receiving laboratory.

b. Shipping containers must be opened only in a secure area and only by an individual designated to record receipt of specimens. A "secure area" is an area to which unauthorized individuals either do not have access, or have access only when escorted by authorized personnel.

c. A record of receipt of the specimen must be permanently maintained. This record may be computer-generated, typed, or hand-written.

d. Specimens must be logged-in immediately upon receipt, or as soon as is practicable thereafter, and stored in a refrigerator or freezer, depending on sample type, to prevent sample degradation.

e. The integrity of the individual specimen container and the condition of each specimen must be checked to ensure no obvious damage, tampering or leakage has occurred. Any issues with the condition of the specimen or discrepancies between the submitted paperwork and the sample must be recorded.

**SECTION 3. SUBSTANCES FOR WHICH TESTING IS PERMITTED**

A. Testing is permitted for the substances and groups of substances set forth below. If a sample is submitted by a Drug Recognition Expert, the DRE must specify to the testing laboratory which substances are to be tested for in each specimen or group of specimens.

B. Laboratories conducting OUI testing shall have the ability to test for substances or groups of substances including central nervous system stimulants, central nervous system depressants, inhalants, narcotic-analgesics, hallucinogens, dissociate anesthetics*,* cannabinoids, and alcohol. If testing for a substance or group of substances is not available, arrangements for further testing may be made with an alternate ISO 17025-accredited Forensic Testing Laboratory.

**SECTION 4. ANALYTICAL PROCEDURES**

A. Standard operating procedure Manual

 The Department is authorized to perform chemical tests on blood and urine (29-A MRS §2524(4) and will comply with the following standard operating procedures when conducting testing of persons suspected of operating under the influence of intoxicating liquor or drugs to ensure results are reliable and legally defensible. Other laboratories must operate consistently with certification or licensing requirements (29-A MRS §2524(2) and also comply with the following operating standards when conducting testing of persons suspected of operating under the influence of intoxicating liquor or drugs to ensure results are reliable and legally defensible:

1. The laboratory must have a procedure manual(s) that are complete, up-to-date, and available to all personnel who are performing tests.

2. The manual(s) must include detailed descriptions of procedures for sample receiving, chain-of-custody, analysis, quality assurance and quality control, review of data, and reporting.

3. The manual(s) must include administrative procedures, as well as analytical methods and must be reviewed, signed, and dated whenever it is first placed into use or changed.

 4. The manual(s) must include the following:

1. Control and maintenance of documentation of case records and procedure manuals;
2. The laboratory’s procedures for ensuring that measurements are traceable to appropriate standards, where available;
3. The type and extent of examinations conducted by the laboratory;
4. Validation of test procedures used;
5. Handling evidence;
6. The use of standards and controls in laboratory procedures;
7. Calibration and maintenance of equipment;
8. Practices for ensuring continued competence of examiners including interlaboratory comparisons, proficiency testing programs, and internal quality control schemes (e.g. technical review);
9. Corrective action taken whenever analytical discrepancies are detected;
10. Laboratory protocol permitting departures from documented policies and procedures; and
11. Audits and quality system review.

Required documentation applicable to new assays must be added as each test is performed for the first time. The laboratory must maintain outdated copies of the procedure manual(s) and provide a means for their retrieval from archival storage.

 B. Confirming the presence of a drug

 As a general matter of scientific and forensic principle, the analytical scheme will begin with a screening test. All positive screening results will be subject to confirmation (see Section 1(A)(5)(a) above). Only those results confirmed with GC/MS, LC/MS or other validated instrumentation will be reported as detected or confirmed in the sample. A negative test result will be reported when no compounds of interest are present or compounds are present but do not meet established acceptability criteria, based on the specific testing procedure being performed. Established acceptance criteria can be found in the specific testing procedure manuals maintained by the Department.

C. Analysis of blood for alcohol level

 1. Replicate analyses must be performed at different times to minimize the possibility of undetected errors. Results must be expressed in terms of % w/v, that is, grams of alcohol per 100 milliliters of blood, rounded downward.

2. Analytical procedure for determining alcohol in blood must meet the following performance requirements:

1. The accuracy and sensitivity of the procedure must consistently attain results within 5% of the known value over the range of 0.10% and greater, or + 0.005 of the known value for values less than 0.10%, in the analysis of appropriate reference materials of known ethyl alcohol concentration for blood determinations.
2. The blank values yielded by the procedure in analyses of alcohol - free blood specimen consistently may not be greater than 0.01%.

**SECTION 5. REQUIREMENTS FOR TESTING LABORATORIES**

 Laboratories conducting chemical tests for drugs other than alcohol must comply with the following:

 A. Laboratory Accreditation

 Laboratories testing for substances of use under this rule must be accredited as a Forensic Testing Laboratory to ISO 17025 standards by an accrediting body, such as ANSI National Accreditation Board (ANAB).

B. Analyst Certification

1. Analysts testing for substances of use under this rule must be certified by the Department for such testing. Analysts seeking certification must demonstrate that they are under the control and supervision of an ISO 17025 accredited Forensic Testing Laboratory, as defined herein. Analyst certification is initially obtained by successful completion of a Health and Environmental Testing Laboratory Forensic Chemistry training program and the passing of a competency test, as described in the Forensic Chemistry Quality Manual. This certification is issued by the Department and signed by the Forensic Technical Laboratory Director and Associate Director of Laboratory Operations.

2. The term of the analyst certificate may not exceed six months for blood alcohol analysis and one year for toxicology drug analysis, from the date of issue. To maintain certification, the successful completion of a discipline-specific proficiency test must occur prior to the expiration date of the current certification. If these requirements are met, a new certification will be issued for the next term. Records of this certification will be maintained by the Forensic Technical Laboratory Director and the certified analyst.

 C. Personnel

1. Laboratory Technical Director

a. The forensic toxicology laboratory must be directed by a person who is qualified by reason of appropriate education and experience to assume the required professional, organizational, educational, managerial and administrative responsibilities.

b. Alternative acceptable qualifications include a doctoral degree in one of the natural or physical sciences and at least three years of full-time laboratory experience in forensic toxicology; or a Master's degree in one of the natural or physical sciences and at least five years of full-time laboratory experience in forensic toxicology; or a Bachelor's degree in one of the natural sciences and at least seven years of full-time laboratory experience in forensic toxicology.

c. The laboratory technical director must also have documented training and/or experience in the forensic applications of analytical toxicology (such as court testimony, research, participation in continuing education programs, and/or peer review of appropriate manuscripts in the field), including a knowledge of evidentiary procedures that apply when toxicological specimens are acquired, processed, and stored and when toxicological data are submitted as part of a legal proceeding.

d. The laboratory technical director is responsible for ensuring that the laboratory personnel are adequately trained and experienced to conduct the work of the laboratory.

e. The laboratory technical director is responsible for maintaining the competency of laboratory personnel by monitoring their work performance and verifying their skills. This training and experience must be documented.

f. The laboratory technical director and/or section supervisor is responsible for the development of complete, up-to-date procedures and quality assurance manuals that are available to and followed by all personnel performing tests.

 2. Analyst

a. Analysts must possess at least a baccalaureate degree in chemistry, biochemistry, or other physical or biological science, and received at least 20 semester hours of training in chemistry, and have experience comparable to that required by the laboratory’s accrediting body.

b. The analyst must have training in the theory and practice of the procedures used, and understanding of quality control concepts. In addition, the analyst must have had at least one year of experience in analytical chemistry, or have completed successfully special training provided or approved by the Department. Periodic verification of skills must be documented.

 D. Quality Assurance

1. The laboratory must have clear written procedures describing the chain of custody of all samples, the security requirements for all sections of the laboratory, including the security of record keeping, and for all laboratory testing procedures and quality assurance procedures. Screening and confirmatory methods of testing shall be as defined in Section 1(A)(5).

2. The laboratory analyst must demonstrate satisfactory performance in the proficiency testing program of an approved vendor accredited to ISO 17043 for each discipline for which testing services are offered. Results must be reported to the accrediting body for each discipline listed on the scope of testing document.

Satisfactory performance is defined as follows:

 a. Qualitative proficiency tests will be evaluated by comparing the achieved result to the expected result. If a compound is part of the current testing menu, if applicable to the section, the test will be considered passing if all achieved results match expected results. If a compound is part of the current testing menu and is not identified by the analyst, the test will be considered failed unless a root cause investigation determines an acceptable reason for the missed compound.

b. Blood alcohol quantitative proficiency tests will be evaluated by comparing the achieved quantitative values to the expected quantitative values. The test will be considered passing if all achieved quantitative values are within ±2 standard deviations or ±10% of the reported mean value. If a quantitative value falls outside of those ranges, the test is considered failed, unless a root cause investigation determines an acceptable reason for the difference.

c. Records must be maintained indicating that proficiency samples are processed as routine specimens, identify the analyst performing the test, and indicate supervisory review and corrective action for unsatisfactory results.

d. An analyst who does not perform satisfactorily, as defined in Subsection 5(D)(2) above, is subject to loss of certification to perform testing for substances of use. If authorization is revoked, the laboratory will perform remedial action in accordance with ISO 17025 Forensic Testing accreditation standards and the Department’s Quality Manual.

e. The laboratory must have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation analytical procedures.

i. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process.

ii. Quality control procedures must include validation of the performance of all equipment used to analyze samples and data processing equipment. Records must be maintained concerning the repair and maintenance of all equipment. Records shall be maintained for at least two years on site, and 18 years in long-term, offsite storage.

f. All positive specimens must be retained in secure storage for at least six months. It is the burden of the party requesting longer retention of the sample(s) to make prior arrangements with the laboratory for the return of the sample to an appropriate agent and the Department may, upon request, store positive specimens beyond six months.

g. All laboratory reports, including the screening, confirmation and quality control data must be reviewed before being certified as accurate. The report must identify the drugs confirmed in the sample.

1. The results of all analyses must be recorded on a standard form approved by the Department.
2. A certified copy of the report must be sent to: the arresting or correctional officer, the appropriate District Attorney, the appropriate department (Department of Public Safety, Department of Inland, Fisheries or Wildlife, or Department of Marine Resources) or its agent, and to the Secretary of State. (29-A MRS §2431(2)(C.))

E. A laboratory or analyst aggrieved by any decision of the Department regarding certification has the rights of appeal specified in The Maine Administrative Procedure Act, 5 MRS Ch. 375, and the Department’s Administrative Hearings Regulations, 10-144 CMR Ch.1.

**STATUTORY AUTHORITY AND HISTORY**

STATUTORY AUTHORITY:

 22 MRS §42(1)

 22-A MRS §205(2)

 29-A MRS §§ 2431, 2524 & 2527

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