

SECTION .0100 - DEFINITIONS

13 NCAC 20 .0101 DEFINITIONS

As used in G.S. 95, Article 20 and this Chapter:

- (1) "All actions" means procedures performed on the sample to detect, identify, or measure controlled substances. Examples include, but are not limited to, "examinations and screening for controlled substances," "controlled substances testing," "drug testing," "screening," "screening test," "confirmation," and "confirmation test".
- (2) "Chain of custody" means the process of establishing the history of the physical custody or control of the sample from the time the examiner provides the container for the sample to the examinee through the later of:
 - (a) The reporting of the negative result to the examiner;
 - (b) The 90 day period specified in G.S. 95-232(d); or
 - (c) The completion of the retesting described in G.S. 95-232(f).
- (3) "On-site" means any location, other than an approved laboratory, at which a screening test is performed on prospective employees. For example, "on-site" locations include, but are not limited to, the examiner's place of business or a hospital, physician's office, or third-party commercial site operated for the purpose of collecting samples to be used in controlled substance examinations.
- (4) "Sample" means the examinee's urine, blood, hair or oral fluids obtained in a minimally invasive manner and determined to meet the reliability and accuracy criteria accepted by laboratories for the performance of drug testing.
- (5) "Employer or person charged" means an examiner found by the Commissioner to have violated G.S. 95, Article 20.
- (6) "Preliminary screening procedure" means a controlled substance examination that uses a single-use test device that:
 - (a) Is portable and can be administered on-site;
 - (b) Meets the requirements of the U.S. Food and Drug Administration for commercial distribution contained in Title 21, Part 807 of the Code of Federal Regulations; and
 - (c) Meets the generally accepted cutoff levels contained in the Mandatory Guidelines for Federal Workplace Drug Testing Programs adopted by the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration in 69 FR 19644.
- (7) "Single-use test device" means the reagent-containing unit of a test system that:
 - (a) Is in the form of a sealed container or cartridge that has a validity check, a nonresealable closure, or an evidentiary tape that ensure detection of any tampering;
 - (b) Is self-contained and individually packaged;
 - (c) Is discarded after each test; and
 - (d) Does not allow any test component or constituent of a test system to interact between tests.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Temporary Amendment Eff. January 16, 2002;
Amended Eff. July 1, 2003;
Temporary Amendment Eff. November 30, 2006;
Amended Eff. February 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

SECTION .0200 - GENERAL PROVISIONS

13 NCAC 20 .0201 COMPUTING TIME PERIODS

In computing any period of time described in G.S. 95, Article 20 or this Chapter, the day of the triggering act or event shall not be counted. If the last day of the period falls on a Saturday, Sunday or a legal holiday, it shall not be counted and the period shall end at the close of the next day which is not a Saturday, Sunday, or a legal holiday. The Commissioner shall use Rule 6 of the NC Rules of Civil Procedure, G.S. 1A-1, Rule 6(a), as a guide in interpretation of this Rule. "Legal holiday" means the legal holidays observed by the Superior Courts of North Carolina. A list of legal

holidays is available from the Administrative Office of the Courts and each local Clerk of Superior Court in North Carolina.

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0202 APPLICABILITY

The provisions of G.S. 95, Article 20 and this Chapter regarding the collection and handling of samples apply whenever an on-site screening test is performed.

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0203 CONFIRMATION OF SAMPLES

For confirmation of positive results or for retesting of confirmed positive results, the approved laboratory shall use gas chromatography with mass spectrometry (GC/MS) or the examiner shall bear the burden of proof to show that the substitute testing method used is an equivalent scientifically accepted method.

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

SECTION .0300 - USE OF CONTRACTORS

13 NCAC 20 .0301 EXAMINER OPTIONS

In collecting and transporting the sample to the approved laboratory, the examiner may:

- (1) Collect and transport the sample itself; or
- (2) Send the examinee to the approved laboratory for the collection; or
- (3) Contract with a third party to collect and transport the sample. Examples of a third party include physicians, medical clinics, hospitals, or consortia established to negotiate rates for these services.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0302 CURRENT EMPLOYEES

13 NCAC 20 .0303 PROSPECTIVE EMPLOYEES

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Temporary Repeal Eff. November 30, 2006;
Repealed Eff. February 1, 2007.

13 NCAC 20 .0304 CONTRACTOR PROCEDURES

If the examiner contracts with a third party for collection, screening, or confirmation testing, the examiner shall ensure that the contractor's procedures comply with requirements of G.S. 95, Article 20 and this Chapter. Compliance with the requirements of the United States Department of Health and Human Services (DHHS), 59 Federal Register No. 110, pages 29908 through 29931 (June 9, 1994), for all aspects of the controlled substance examination shall meet the requirements of G.S. 95, Article 20 and this Chapter. Compliance with the requirements of the College of American

Pathologists' (CAP) Forensic Urine Drug Test Inspection Checklist shall meet the requirements of G.S. 95, Article 20 and this Chapter for screening, confirmation and retesting of confirmed samples. If the examiner adopts alternative procedures, the examiner shall ensure that the alternative procedures meet the requirements of G.S. 95, Article 20 and this Chapter. However, nothing in the DHHS or CAP requirements shall be interpreted to:

- (1) require the examiner to use the services of a medical review officer; or
- (2) allow the examiner to conduct on-site screening for current employees.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0305 LABORATORY INSTRUCTIONS

The examiner shall follow procedural instructions of the approved laboratory regarding the controlled substance examination, unless the examiner follows equally reliable procedures which it has previously adopted in writing. The examiner shall bear the burden of proof to show these alternative procedures are equally reliable. Examples of procedural instructions include, but are not limited to, instructions regarding:

- (1) collection of samples;
- (2) reasonable and sanitary conditions for collection;
- (3) chain of custody;
- (4) preservation of examinees' individual dignity;
- (5) prevention of substitution or adulteration of samples;
- (6) prevention of interference with the collection, examination, or screening of samples;
- (7) on-site screening;
- (8) confirmation of positive tests;
- (9) any other action to be taken with regard to the collection, labeling, packaging, transportation, screening, documentation, or preservation of samples used for controlled substance examinations.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0306 RETESTING LABORATORY INSTRUCTIONS

If the examinee chooses to have the confirmed positive sample retested, the examiner and, where applicable, the examiner's agent (the original testing laboratory) shall follow the retesting laboratory's instructions in facilitating the retest of the positive sample.

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

SECTION .0400 - NOTICE TO EXAMINEES

13 NCAC 20 .0401 INITIAL NOTICE TO EXAMINEES

At the time of the provision of the sample, the examiner shall provide examinees with written notice of their rights and responsibilities under the Controlled Substance Examination Regulation Act.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0402 POST-TESTING NOTICE TO EXAMINEES

Within 30 days from the time that the results are mailed or otherwise delivered to the examiner, the examiner shall give notice to the examinee, in writing:

- (1) of any positive result of a controlled substance examination; and
- (2) of the examinee's rights and responsibilities regarding retesting under G.S. 95-232(f).

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

SECTION .0500 - CONFIDENTIALITY

13 NCAC 20 .0501 CONFIDENTIALITY OF INFORMATION RELATED TO CONTROLLED SUBSTANCE EXAMINATIONS

In order to preserve individual dignity and privacy, examiners and their agents shall keep information confidential relating to examinees' controlled substance examinations, unless otherwise authorized by law or this Chapter.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0502 EXAMPLES

Examples of confidential information include: controlled substance examination results or information provided by examinees about their medical histories and lawful prescription drug use.

History Note: Authority G.S. 95-231; 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0503 RELEASE OF CONFIDENTIAL INFORMATION

Examiners and their agents may release information which would otherwise be confidential under this Chapter in the following circumstances:

- (1) to the examinee or to any other person upon written authorization signed by the examinee;
- (2) to laboratories performing screening, confirmation tests, or retests of confirmed positive results;
- (3) for employment-related reasons. Examples of employment-related reasons include: performance evaluations, discipline and provision of references; or
- (4) to a government agency, court or other tribunal having jurisdiction over any claim or proceeding involving the examinee and the examiner.

History Note: Authority G.S. 95-231, 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

SECTION .0600 - PAYMENT OF EXPENSES

13 NCAC 20 .0601 PAYMENT OF EXPENSES

The examiner shall pay expenses related to all controlled substance examinations except examinee-requested retests. The examinee shall pay all reasonable expenses for retests of confirmed positive results.

History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.

13 NCAC 20 .0602 REASONABLE EXPENSES

"Reasonable expenses for retesting" means:

- (1) the actual cost of the retest charged by the approved laboratory;
- (2) fees assessed by the approved laboratory for expenses associated with the retest. Examples of laboratory expenses include chain of custody procedures and shipping;
- (3) a maximum of fifteen dollars (\$15.00) for the examiner's expenses, if any, to comply with chain of custody procedures related to the retest. The amount of fifteen dollars (\$15.00) for the expenses described in this Item shall be deemed to be a reasonable amount. The examiner may charge more than fifteen dollars (\$15.00) for the expenses described in this item if the examiner proves the actual cost of expenses greater than fifteen dollars (\$15.00); and
- (4) the actual cost of any shipping expenses the examiner incurs related to the retest.

*History Note: Authority G.S. 95-232; 95-234;
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 5, 2016.*