R 325.2671 "Control sample" defined.
Rule 1. "Control sample" means a sample of known concentration, and/or identity, that is used to evaluate the performance of a given analytical method.

History: 1993 AACS; 2005 AACS; 2017 AACS.

R 325.2672 Tests; application; expression of results; filing.
Rule 2. (1) Tests to determine the presence or concentration, or both, of alcohol or other drugs, or both, may be applied to blood, urine, or other biological samples. Results of blood alcohol analysis shall be expressed in percent weight of ethyl alcohol (weight per unit volume) equivalent to grams per 100 milliliters. Results of urine alcohol analysis shall be expressed as weight per unit volume of ethyl alcohol, equivalent to either grams per 100 milliliters, or grams per 67 milliliters. Where applicable, results of analysis for drugs or other volatiles shall be expressed as weight per unit volume.

(2) Serum or plasma alcohol concentrations shall be expressed as an equivalent whole blood alcohol concentration.

(3) Tests to determine the concentration of alcohol may be applied to nonbiological samples. Results shall be expressed in percent volume of ethyl alcohol (volume per unit volume).

(4) At least 1 copy of the written method or methods or techniques that are utilized in the laboratory shall be on file in that laboratory.

History: 1993 AACS; 2005 AACS.

R 325.2673 Acceptable analytical methods.
Rule 3. The following are acceptable analytical methods for determining the presence or concentration, or both, of alcohol and other drugs in blood, urine, or other various matrices or media.

(a) Liquid chromatography/mass spectrometry method using a High Performance Liquid Chromatograph/Ultra High Performance Liquid Chromatograph (HPLC/UHPLC) and mass analyzer system including, but not limited to, a quadrupole mass spectrometer, ion trap, time of flight mass spectrometer, magnetic or electromagnetic analyzer, or any hybrid combination thereof, demonstrating satisfactory accuracy, precision, sensitivity,
and a suitable column for the identification or quantitation, or both, of drugs or compounds other than ethanol.

(b) Gas chromatograph method using a gas chromatograph that has satisfactory accuracy, precision, sensitivity, and a suitable column for direct injection or head-space gas chromatography for ethyl alcohol and other volatiles.

(c) Gas chromatography/mass spectrometry method using a gas chromatograph and mass spectrometer that have satisfactory accuracy, precision, sensitivity, and a suitable column for direct injection or head-space gas chromatography for identification or quantitation, or both, of drugs or compounds other than ethanol.

(d) Spectrophotometric methods as follows:


(e) Enzymatic and immunological methods as follows:


(f) Analyzers as follows:

(i) Abbott Diagnostics AxSym Autoanalyzer and reagent systems.

(ii) Randox Evidence Biochip Array Analyzer and reagent systems.

(g) Analyzers or kits employing indicator-labeled immunoassays in which an indicator is attached to an antigen or antibody to demonstrate that antigen-antibody binding has occurred, thereby allowing measurement of a drug or other compound in a sample. These include the following:

(i) Enzyme immunoassay (EIA), in which an enzyme is used to label an antibody or antigen.

(ii) Enzyme-linked immunosorbent assay (ELISA), in which an enzyme-labeled antibody or antigen competes in binding with an unknown substance.

(iii) Enzyme-multiplied immunoassay technique (EMIT), which is a form of EIA used frequently for assays of drugs and hormones, as well as for viral antigens.

(iv) Fluorescence immunoassay (FIA), in which a fluorescent label is used in a competitive-binding assay.

(v) Fluorescence polarization immunoassay (FPIA), which employs fluorescent indicators that produce or detect the polarization of light.

(vi) Radioimmunoassay (RIA), which employs a radiolabeled antigen or antibody.

(vii) Chemiluminescence, in which analyte binding to an antibody is coupled to the chemical production or reduction of light output.

(viii) Any assay that uses a combination of the techniques in paragraphs (i) to (vii) of this subdivision.

History: 1993 AACS; 2005 AACS; 2011 AACS; 2017 AACS.

**R 325.2674 Calibration.**

Rule 4. Calibration of the method or equipment used to test for alcohol or other drugs for which quantitative analysis is performed in blood, urine, or other biological or...
nonbiological samples shall be verified through the use of control samples each day that tests are run. Results of the control samples shall be documented and retained by the laboratory for a minimum of 1 year.

History: 1993 AACS; 2005 AACS.

**R 325.2675 Collecting and handling antemortem blood and urine samples.**

Rule 5. (1) All antemortem blood and urine samples shall be collected pursuant to section 625a of 1949 PA 300, MCL 257.625a.

(2) When collecting a blood sample, the individual drawing the sample shall use an aqueous solution of a nonvolatile antiseptic on the skin of the person from whom the sample is being collected. Neither alcohol nor any alcoholic solution shall be used as a skin antiseptic.

(3) Blood shall be drawn pursuant to either of the following provisions:

(a) With a sterile dry needle that is evacuated into a vacuum-style specimen tube that contains the solid preservative sodium fluoride, whether used alone or in combination with other preservatives or anti-coagulants.

(b) With a sterile dry needle and syringe expelled into a clean specimen tube that contains sodium fluoride. The tube shall then be capped or stoppered.

(4) Urine shall be collected pursuant to the provisions of form FSD-93, which is contained in the department of state police specimen kit. Urine shall be collected in a clean glass or plastic container. The sample shall then be transferred into a clean glass or plastic container that has a secure top.

(5) Blood and urine collection shall be witnessed to ensure that the sample can be authenticated. Each sample shall be labeled.

(6) Samples that are sent to a laboratory shall be sealed in a manner that ensures their integrity.

History: 1993 AACS; 2011 AACS.

**R 325.2676 Rescinded.**

History: 1993 AACS; 1996 AACS.

**R 325.2677 Rescinded.**

History: 1993 AACS; 1996 AACS.