

Minimum Levels of Controlled Substances or Their Metabolites in Blood to Establish Presence of Controlled Substance

[44 Pa.B. 132]

[Saturday, January 4, 2014]

Under 75 Pa.C.S. § 1547(c)(4) (relating to chemical testing to determine amount of alcohol or controlled substance), as amended by the act of September 30, 2003 (P. L. 120, No. 24), the Department of Health (Department) is publishing a notice of the minimum levels of Schedule I, nonprescribed Schedule II and nonprescribed Schedule III controlled substances or their metabolites that must be present in a person's blood for the test results to be admissible in a prosecution for a violation of 75 Pa.C.S. § 1543(b)(1.1), § 3802(d)(1), (2) or (3) or § 3808(a)(2) (relating to driving while operating privilege is suspended or revoked; driving under influence of alcohol or controlled substance; and illegally operating a motor vehicle not equipped with ignition interlock).

Although there are hundreds of controlled substances in Schedules I, II and III, quantitation limits are listed only for commonly abused controlled substances for which testing procedures are readily available. The limit of quantitation (LOQ) for any laboratory will depend on the equipment and procedures employed for confirmatory testing. The minimum quantitation limits listed for each controlled substance or metabolite are the lowest concentrations that one or more of the laboratories in the Department's approval program for facilities offering these testing services specified they can reliably determine. Laboratories approved by the Department to test blood for controlled substances or their metabolites will have LOQs at or below the minimum quantitation limits listed in this notice.

The Department recognizes that testing may be required for other controlled substances and metabolites not listed in this notice. When testing for a controlled substance not listed is required, interested parties should contact the laboratory performing the test to inquire as to that laboratory's specific method of testing, the equipment used and any policies or procedures employed by that laboratory to ensure that the test results are valid.

Prior to 2012, the Department only listed the parent drug for cannabinoids, Delta-9-Tetrahydrocannabinol (THC). The Department's notice published at 42 Pa.B. 110 (January 7, 2012) included multiple listings for cannabinoids for the first time. In addition to the parent drug, two metabolites of THC were listed: 11-Hydroxy-Delta-9-Tetrahydrocannabinol and 11-Nor-9-Carboxy-Delta-9-Tetrahydrocannabinol. Multiple listings for THC were published because approved laboratories may test for the parent drug, one of its metabolites or a combination of the three cannabinoids. A

laboratory need not obtain a test result for the parent drug and the two metabolites for the test result to be admissible into evidence. A laboratory only needs to test for at least one of the cannabinoids listed and meet the minimum detection level for that cannabinoid. In addition, the 2012 notice listed, for the first time, Methylenedioxy-amphetamine and Methylenedioxy-methamphetamine under the classification of amphetamines.

Clinical laboratories that operate in this Commonwealth and that perform analyses of blood to determine controlled substance content must be approved by the Department in accordance with 28 Pa. Code § 5.50 (relating to approval to provide special analytical services) and be listed in notices published in the *Pennsylvania Bulletin*. The approval process requires laboratories to demonstrate an acceptable level of proficiency in determining the presence of controlled substances or their metabolites in blood.

Testing for controlled substances in blood is normally a two-step process. The first step involves screening of the blood using a relatively rapid and inexpensive technique to presumptively determine which specimens may contain a substance or a metabolite of a substance for which the blood is being tested. The second step utilizes a more sensitive and specific procedure to substantiate the presence and concentration of the substance or its metabolite that was presumptively detected in the initial screening procedure.

Confirmatory analyses employed to substantiate the presence of a controlled substance or metabolite generally focus on identifying and quantitatively determining the concentration of the parent drug or a primary metabolite. The detection limits listed were developed by reviewing the minimum reportable concentrations for confirmatory analyses that laboratories in the Department's approval program specified they could measure.

In subsequent notices, the Department will revise, as needed, minimum quantitation limits of those controlled substances or their metabolites already listed and add new controlled substances or their metabolites when the data received from approved laboratories warrants their inclusion. Questions regarding this list should be directed to Dr. James R. Lute, Assistant Bureau Director, Department of Health, Bureau of Laboratories, P. O. Box 500, Exton, PA 19341-0500, (610) 280-3464.

Persons with a disability who require an alternative format of this notice (for example, large print, audiotope or Braille) may contact Dr. James R. Lute at the previously referenced address or phone number. Persons who are speech or hearing impaired may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT).

Class Substance	Schedule	Minimum Quantitation Limits (nanograms/milliliter)
Amphetamines		
Amphetamine	II	5
Methamphetamine	II	5
Methylenedioxyamphetamine (MDA)	I	5
Methylenedioxymethamphetamine (MDMA, Ecstasy)	I	5
Analgesics		
Methadone	II	6.2
Cannabinoids		
Delta-9-THC (THC)*	I	0.4
11-Hydroxy-Delta-9-THC (THC-OH)	I	1
11-Nor-9-Carboxy-Delta-9-THC (THC- COOH)	I	1
Cocaine		
Cocaine	II	4
Benzoylcegonine	II	1
Hallucinogens		
Phencyclidine	II	0.5
Opiates		
Codeine	II	2
Hydrocodone	II	2
Hydromorphone	II	1.25
6-Monoacetylmorphine	II	0.5
Morphine	II	2
Oxycodone	II	2
Sedatives/Hypnotics		
Amobarbital	II	40
Pentobarbital	II	40
Secobarbital	II	40

*THC = tetrahydrocannabinol

MICHAEL WOLF,
Secretary