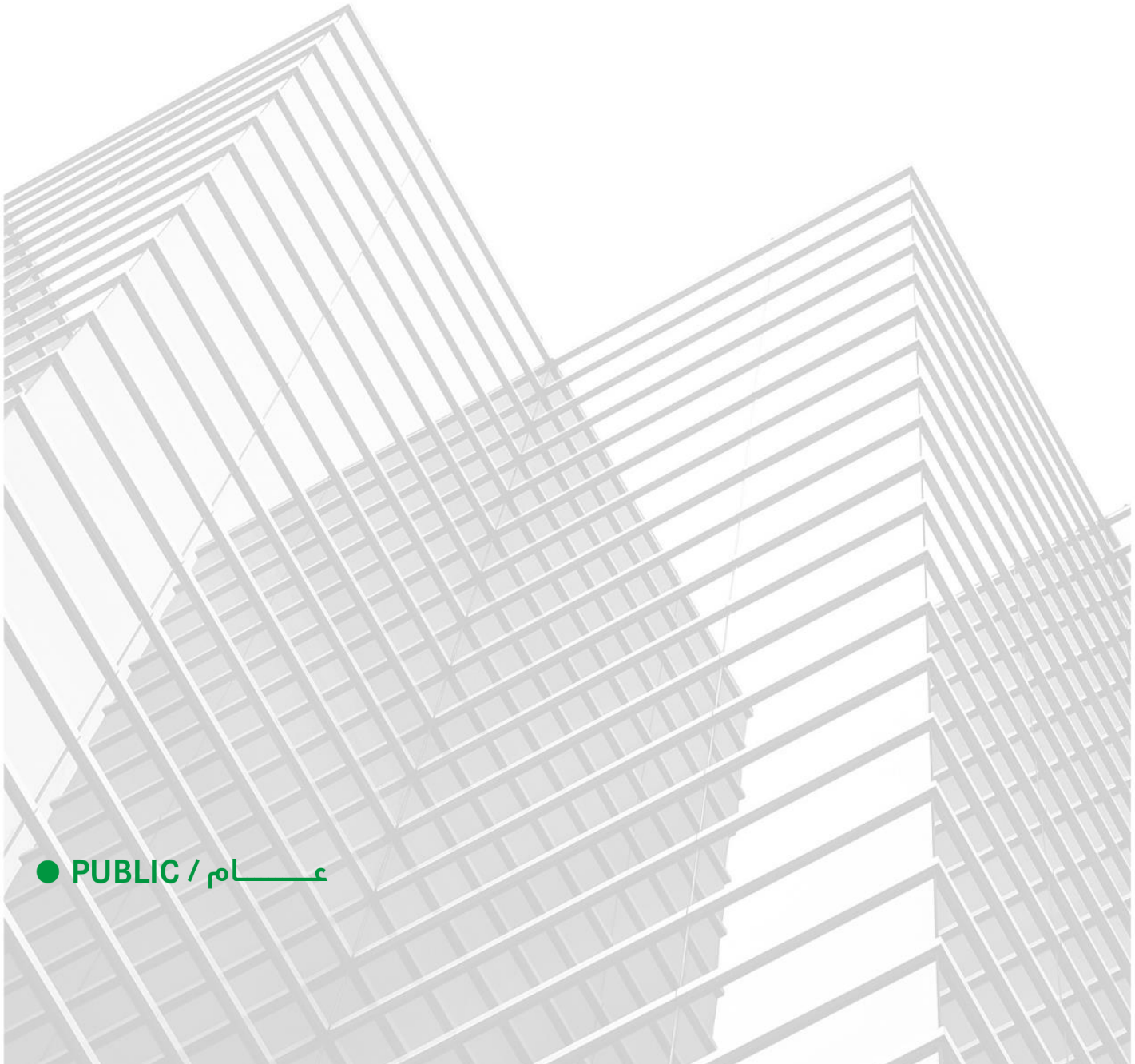
دائـــرة الـصـحـة
DEPARTMENT OF HEALTH

STANDARD FOR CLINICAL TOXICOLOGY TESTING IN CLINICAL LABORATORIES



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1. Standard Scope

The purpose of this standard is to set the minimum requirements for required testing of poisoned patients and the analytical and reporting requirements for clinical toxicology to assure accuracy, quality and safe testing for these services provided by DoH licensed clinical laboratories in Abu Dhabi.

This Standard applies to:

1.1. Healthcare facilities and professionals licensed by DoH to provide clinical laboratory services in the Emirate of Abu Dhabi; in particular, those engaged in the provision of clinical and analytical testing/screening services for drug abuse and/or misuse, overdosed patients and poisoning cases and/or forensic drug testing;

1.2. Patients admitted to emergency departments for clinical toxicology testing and who are suspected of having ingested and/or been exposed to toxic and/or poisonous substances and/or drug overdose.

2. Definitions and Abbreviations

2.1. Definitions

No.	Term	Definition
2.1.1	Biological toxins	Substances produced by living organisms, such as bacteria, fungi, insects, plants, and animals, that have toxic properties.
2.1.2	Chain of custody[3]	A forensic document that unequivocally identifies the donor of a specimen and tracks its handling from the time of collection to the completion of testing and disposal.
2.1.3	Controlled substances and products[1]	Products and substances which medical and commercial circulation require controlling actions. Such products include: 1. Toxic substances and plants. 2. Prohibited veterinary substances. 3. Narcotic and psychotropic substances, whether in form of raw materials or incorporated in a medical product. 4. Hazardous medical products.
2.1.4	Drug[1]	Any product that contains an active ingredient or a group of active ingredients that accomplish the intended purpose when applied on/in human or animal through a biological effect. This product is manufactured, sold or made available to be applied in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of illness. 2. Restoration, renovation, modification or correction of organ's functions.
2.1.5	Hazardous substances[1]	All substances such as chemical, biological or radioactive materials, leading, directly or indirectly, to harmful effects on human health or the environment.
2.1.6	Illicit drug[2]	A drug that is not legally available by medical prescription in the jurisdiction in question.
2.1.7	Narcotic and psychotropic[1]	Medical and therapeutic products and other Substances containing any of the active ingredients according to Federal Law No. 14 of 1995, and its amendments.

2.1.8	Pesticides[1]	Any substance or mixture of substances intended to prevent, eliminate or control any pest, including disease vectors transmitting pathogens to humans or animals, and unwanted plant or animal species that cause damage or interfere in any form during the production of food or agricultural products or wooden manufactures or feed, or during manufacture, storage, transport and marketing, as well as any material given to animals to control insects, spiders or other pests found in animals or on their bodies. This includes substances used to regulate plant growth, leave falling, drying, reducing fruit trees or protecting fruit from falling prematurely as well as materials used in crops either before or after harvesting to save the crop from deterioration during transport or storage.
2.1.9	Pharmaceutical product[1]	A medical pharmaceutical product that is produced in a specific approach and has specific applications for human and animal.
2.1.10	Point of care testing[3]	Testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient.
2.1.11	Semi-controlled substances[1]	Substances or drugs not listed as narcotic or psychotropic substances, however they must be controlled inside the country, as its misuse may lead to harm of public health.
2.1.12	Toxic substances and plants[1]	Substances and plants identified according to the legislations governing this type of substances or plants.

2.2. Abbreviations

No.	Abbreviation	Definition
2.2.1	ALT	Alanine transaminase
2.2.2	AST	Aspartate transaminase
2.2.3	DMPS	2,3-Dimercapto-1-propanesulfonic acid,
2.2.4	DoH	Department of Health – Abu Dhabi
2.2.5	ED	Emergency Department
2.2.6	GC/MS	Gas chromatography/mass spectrometry
2.2.7	HPLC	High-performance liquid chromatography
2.2.8	INR	International Normalized Ratio
2.2.9	LC/MS	Liquid chromatography–mass spectrometry
2.2.10	LC/MS/MS	Liquid Chromatography Tandem Mass Spectrometry
2.2.11	PDIS	Poison and Drug Information Service
2.2.12	POCT	Point-of care testing
2.2.13	PT	Pro-thrombin time
2.2.14	TAT	Turn-around Time
2.2.15	TCA	Tricyclic antidepressants
2.2.16	TDM	Therapeutic drug monitoring
2.2.17	TIBC/UIBC	Total iron-binding capacity/Unsaturated iron binding capacity
2.2.18	TLC	Thin layer chromatography

3. Standard Requirements and Specifications

3.1. Standard 1 - Pre-Analytical Considerations

3.1.1. Analytes

Clinical toxicology testing includes testing for any and/or all the following toxicants:

3.1.1.1. Pharmaceuticals, including narcotics and controlled substances;
3.1.1.2. Illicit drugs;
3.1.1.3. Alcoholic substances;
3.1.1.4. Pesticides and other chemicals (industrial and household);
3.1.1.5. Biological toxins, be it ingested and/or entering the human body via bites or other means;

3.1.2. Sample Collection Requirement

Sampling size for testing of body fluids and tissue to consider the following:

3.1.2.1. For urine specimen screening collect 5-10 mL;
3.1.2.2. For blood specimens, one standard size collection tube of sufficient volume to allow for all requested testing. It is the physician's responsibility to specify preferences for analysis priorities;
3.1.2.3. Gastric samples are excluded from the scope of this standard; however, these samples may be required for pre-mortem collection and forensic purposes. Therefore, providers are required to collect and retain these samples;
3.1.2.4. All specimens must be handled in accordance with the pre-analytic specifications detailed in the HAAD Clinical Laboratory Standards[4] including, where applicable the chain of custody and documentation processes.

3.2. Standard 2 - Analytical Considerations

3.2.1. **Screening Tests.** Initial screening tests are presumptive analyses performed to distinguish specimens that may contain target analytes (or their biotransformation products) from specimens that do not contain these analytes. Commercially available urine drug screening assays are based on the following techniques:

3.2.1.1. Point-of Care Testing (POCT) - CLIA waved card tests;
3.2.1.2. Thin Layer Chromatography (TLC);
3.2.1.3. Automated Immunoassay Analysis.

3.2.2. **Quality Assurance and Quality Control for Drugs of Abuse (DOA) Screening Tests and TDM Tests**. Requirements for QC testing for DOA screening tests may vary depending on the needs of the laboratory and how the results are to be used, considering the following:

3.2.2.1. A common practice for DOA testing is to include controls at concentrations +/- 25% of the designated cut-off;

3.2.2.2. A typical QC requirement is to run two levels of controls, one positive and one negative, once every eight hours;

3.2.2.3. At a minimum, users must refer to the manufacturer's recommendations, HAAD Clinical Laboratory V1.0 Standards[4] and UAE Laws and regulations;

3.2.2.4. If a positive result is reported without confirmation, the report must be annotated "presumptive" or with a similar statement. In addition, the laboratory must enroll in External Quality Assurance/ Proficiency Testing for each analyte.

3.2.3. **Immunoassay Cut-offs.** Qualitative assays for drugs-of-abuse testing require cut-off concentrations to distinguish between positive and negative results;

3.2.3.1. Cut-offs are set on the basis of signal-to-noise ratio considerations, which are dependent on the precision, analytical sensitivity, and specificity of the assay.

3.2.4. **Confirmation of Positive Immunoassays.** If the clinician anticipates subsequent involvement with medico-legal or social services or there is a clinical need to identify the specific drug yielding a positive immunoassay result, the physician must notify the laboratory of the need for a confirmative analysis;

3.2.4.1. When confirmation is needed, the laboratory must store these specimens in accordance with the HAAD Clinical Laboratory Standards[4] for an indefinite period or until the case is resolved;

3.2.4.2. Legal and/or police cases are usually handled by the police department which collects such samples under controlled conditions. The analysis for legal and/or police purposes is usually conducted in the Police Laboratory in the Emirate of Abu Dhabi and is outside the scope of this Standard.

3.2.5. **Confirmatory Tests Methods.** Chromatographic methods, including TLC, HPLC, GC, GC/MS, LC/MS, LC/MS/MS, are the typical confirmatory procedures. Of these, the most common procedure that is widely accepted as having the necessary specificity for confirmatory testing is the combined technique of gas chromatography/mass spectrometry (GC/MS). Further information is available from the most current edition of CLSI/NCCLS document C43-Gas Chromatography/Mass Spectrometry (GC/MS)[5];

3.2.6. **Categories of Tests***.* The clinical laboratory must provide two tiers of testing, Tier 1 and Tier 2 beside supportive investigation laboratory tests [Appendix 1, 2].

3.2.6.1. Tier 1 testing includes stats testing of selected substances quantitatively in serum or plasma and qualitatively tests in urine;

3.2.6.2. Tier 1 and supportive investigation laboratory tests must be available on 24-hour basis in all hospitals admitting cases with acute poisoning;

3.2.6.3. Tier 2 includes tests that are infrequently needed. These may be required for specific indications (e.g. heavy metals screen to evaluate encephalopathy or for occupational surveillance). For clinicians to comply with their requirements, agreements with specialty laboratories may be necessary;

3.2.6.4. Comprehensive drug testing may rarely be necessary for critical patients in whom the exposure is unknown or not identified with Tier 1 and 2 tests. This typically involves GC/MS testing and covers a large panel of pharmaceuticals and drugs of abuse commonly found in the country of residence [Appendix 4];

3.2.6.5. Testing must be performed after the patient has been stabilized and, preferably, after the responsible physician has received advice from the PDIS.

3.2.6.6. If and when samples are sent overseas for specialized testing, it is mandatory that the receiving laboratory be legally incorporated in the country of operation and accredited as a clinical laboratory by national or international authorities.

3.2.7. **Turnaround Time (TAT).** Time to obtaining results has critical importance in the management of clinical toxicology patients.

3.2.7.1. The reported TAT is defined from the time of specimen receipt within the laboratory to the availability of the test results, reported either by phone or via electronic reporting to the record;

3.2.7.2. The TAT for Tier 1 toxicology tests and supportive investigation laboratory tests is *2 hours or less*, except where otherwise noted in Appendix 1;

3.2.7.3. The interpretations of the supportive investigation laboratory tests and their importance are detailed in Appendix 1;

3.2.7.4. Tier 2 toxicology tests have different TATs based on specific indications and settings and may not necessarily be available in every hospital.

3.2.8. **Toxic Syndrome Recognition***.* Clinical laboratories must not set up specific drug testing panels based on *toxidromes* (e.g. opioid, sympathomimetic, cholinergic). These are clinical diagnoses confirmed at the bedside that often require immediate interventions. Furthermore, testing typically involves immunoassays that have several reported false positives and negatives., thereby complicating the management of the poisoned patient.

3.2.9. **Generic Screening Tests***.* The practice of ordering blanket screening tests in the absence of hard clinical evidence or specific symptoms and signs is also discouraged. Such tests (e.g. heavy metal screens for vague symptoms, hair testing), often recommended by non-experts, have little to no supporting evidence and can lead to unnecessary exposure to healthcare services and an increased cost burden. Clinical toxicology testing, particularly as it pertains to environmental toxicology, requires expert opinion and thorough social, environmental, and workplace assessments.

3.2.10. **Validation.** With regards to analytical method validation and verification of accuracy, precision, sensitivity and specificity, refer to the HAAD Clinical Laboratory Standards[4].

3.3. Standard 3 - Analysis and Reporting

3.3.1. **Post-Analytical Consideration.** The clinical use of urine for laboratory toxicology testing and interpretation of results by the treating physician should be done with the understanding of the inherent limitations of this biological matrix. Confirming a presumptive test may not be warranted in clinical settings due to the long TAT and high cost associated. The following are elements that must be considered and reported by each laboratory and include when performing testing and confirmatory testing:

3.3.1.1. Individual drugs and/or classes to be included;
3.3.1.2. Screening and if applicable confirmation methodologies;
3.3.1.3. Adulteration testing (if applicable);
3.3.1.4. Units of measure;
3.3.1.5. Cut-off levels;
3.3.1.6. Need to report quantitative results vs. qualitative results;
3.3.1.7. Reporting terminology (e.g., use of terms, presumptive; pending).
3.3.1.8. Limit of detection of for screening and confirmatory tests for tested drugs.

3.3.2. **Reporting of Results**

3.3.2.1. Retention of Records. The laboratory should have a record retention system. Worksheets, chromatograms, and instrument printouts should be kept for two years. Final reports should be maintained so they may be easily retrieved for an additional two years;
3.3.2.2. Patient specimens yielding a response greater than the cut-off are interpreted as positive;
3.3.2.3. Specimens yielding a response less than the cut-off are reported as negative;
3.3.2.4. Laboratories employing systems that produce semi-quantitative or quantitative results must not report as positive any specimen below the cut-off level;
3.3.2.5. Reports of screening assays must indicate which drug classes were evaluated. Since most individual drugs within a class react differently with the immunochemical system, the detection limits for the assay must reflect a range from the most to the least sensitive. TDM results must accurately reflect the concentration of drug relative to the therapeutic range.

3.3.3. **Confidentiality Considerations***.* All laboratory testing must be considered confidential.

3.3.3.1. Test results must be reported to the responsible physician for interpretation before information is released for treatment purposes or other actions are initiated. Telephone reports and electronic

transmissions are best avoided unless absolute confidentiality can be assured;

3.3.3.2. Healthcare professionals are encouraged to share these results with PDIS staff to better understand the reliability of the test and improve and facilitate management of cases, if applicable.

3.3.4. **Retention of Specimens**. Specimens submitted for urine drug testing must be retained for a time compatible with the use of test results. A laboratory director must determine a policy for the retention of specimens. Testing conducted in an emergency medical situation usually involves sequelae that resolve in a matter of days.

3.3.5. **Cut-off Values**. The recommended cut-off values for the various drugs using immunoassay platforms as well as the cut-offs published by the Ministry of Interior for the UAE [Appendix 3].

3.3.6. **Units of Measurement.**

3.3.6.1. Units of measurement for quantitative toxicology testing will be following the conventional rather than the SI unit to facilitate interpretation and calculations of antidote dosage when applicable.

3.3.6.1.1. For alcohols, it will be in mg/dL; and

3.3.6.1.2. For other drugs, it will be mass (mcg or ng)/mL.

3.3.6.2. Laboratories who report in SI units must also provide the conversion to conventional units as a comment in the report.

3.4. Standard 4 - Recommendations for Specific Analysis of Alcohols and Other Toxicities

3.4.1. Alcohols

3.4.1.1. Alcohol concentrations must be reported in units clearly defined by the laboratory, with a notation as to the sample matrix that was tested (serum or plasma, urine, whole blood, breath) and the test methodology.

3.4.1.2. Assays for Methanol and Ethylene Glycol. Clinical laboratories should provide direct measurements for methanol and ethylene glycol in serum and plasma. If GC, the assay should target glycolic acid, the toxic metabolite, in addition to the parent intoxicant, ethylene glycol;

3.4.1.3. Osmolality Measurements for Toxic Alcohol Surveillance. Inherent problems with the measured osmolality and calculation of the osmolal gap reduce the reliability of these measurements in the differential diagnosis of volatile and ethylene glycol alcohol intoxication in patients. A very high osmolal gap (e.g., >50 mOsm/kg) requires investigation of a toxic alcohol or other agents that can increase the osmolality;

3.4.1.4. Isopropyl Alcohol, Propylene Glycol Intoxication and Acetoacetic Acid. Quantification of isopropyl alcohol and propylene glycol by GC is the preferred approach to their identification. Measurement of lactate is appropriate for monitoring patients exposed to propylene glycol because this is the major metabolite.

3.4.2. Intentional Drug Ingestion

3.4.2.1. All Emergency Department (ED) patients who present with an intentional drug ingestion and chronic overuse secondary to chronic pain must be screened with a quantitative serum or plasma paracetamol (acetaminophen) and aspirin assay (Tier 1).

3.4.2.2. Screening for the presence of salicylate can be guided by clinical findings or acid-base abnormalities.

3.4.2.3. Other tests often required include an ethanol level, AST, ALT, INR, and other relevant baseline metabolic tests. The ED must rely on history and physical examination to identify toxidromes and treat them accordingly.

3.4.3. Anticoagulants

3.4.3.1. Patients who intentionally ingest anticoagulants, particularly the long-acting formulations, should be monitored for coagulations status by the pro-thrombin time (PT) test. Samples should be collected at 24-36 hours after exposure to monitor anticoagulation effects without prophylactic vitamin K administration. There is no statutory clinical need for determining the identity or concentration of the specific anticoagulant taken.

3.4.4. Lead Toxicity

3.4.4.1. Emergency testing for lead is not required to support ED practice; however, in cases of encephalopathy or seizures it can become an urgent test. In such cases, the result must be available within 12 hours, but not more than 24 hours;

3.4.4.2. The ED must be prepared to collect heparinized blood samples for lead testing when lead exposure is suspected; however, specific treatment is usually not initiated in the ED.

3.4.5. Iron Toxicity

3.4.5.1. The clinical laboratory must be prepared to provide serum or plasma iron results on a stat basis to aid in the diagnosis of iron overdose. Because of analytical limitations, heterogeneous assays for the total iron-binding capacity (TIBC) cannot be used to determine the absence of free iron and toxicity. Serum or plasma transferrin is a more reliable marker for estimating free and potentially toxic iron. If this assay is not available on a stat basis, the homogeneous unsaturated iron binding capacity (UIBC) assay is more useful than TIBC assays that require a pretreatment step;

3.4.5.2. Serum or plasma iron analysis, readily available in most clinical laboratories, is useful to identify iron overdose; serum/plasma iron >3500 µg/L (350 µg/dL) indicates significant exposure. If the serum/plasma iron concentration exceeds the TIBC, it has been presumed that there is free and potentially toxic iron. However, TIBC tests that require separation of

transferrin-bound iron from the added adsorbent can overestimate TIBC, producing a falsely low free-iron value and an incorrect assumption that there is no risk for iron toxicity. Measurement of transferrin is the preferred test (1 µmol of transferrin binds 2 µmol of iron). If this test is not available, direct UIBC assays are less susceptible to falsely high results attributable to iron overdose. Some patients with an iron overdose are treated with deferoxamine. It should be noted that this chelator will interfere with some dye-binding colorimetric iron methods, producing falsely low iron results. Blood specimens should be taken for iron determination before deferoxamine administration;

3.4.5.3. In the absence of probable cause, such as occupational and/or accidental environmental exposure, broad-spectrum screening for trace elements or other analytes is inappropriate and would rarely be indicated in the ED or any general office practice.

3.4.6. Pesticides

3.4.6.1. Specialized clinical laboratories must provide access to statutory pseudocholinesterase testing to screen for exposure to cholinergic agents and not for monitoring of therapy.

3.4.7. Methemoglobinemia

3.4.7.1. Co-oximetry typically uses four wavelengths to discriminate oxyhemoglobin from oxy-, deoxy-, carboxy-, and methemoglobin;

3.4.7.2. For patients suspected of having methemoglobinemia, measurement of the fraction of oxyhemoglobin (oxygen saturation) should be performed with a co-oximeter and not a pulse oximeter, as the latter over-estimates the actual O2 saturation. If a request for oxygen saturation is received, all results of a four-part co-oximetry panel should be reported even if the specific requests for carboxyhemoglobin and methemoglobin are not received.

3.5. Reference Laboratories

In order to maintain reliability, consistency, and cost-effectiveness in clinical toxicology testing, one or more reference laboratories should be established and accredited in Abu Dhabi. This will establish a gold standard for all clinical toxicology tests. More importantly, such laboratories will serve to conduct infrequent tests including comprehensive drug screenings, heavy metal assays, and other investigations that require specialized expertise and equipment [Appendix 2 and 4].

3.5.1. Medico-legal Cases

The establishment of DoH-accredited reference laboratories in Abu Dhabi will offer an invaluable resource in medico-legal contexts. For legal proceedings involving drug offenses, poisonings, or other substance-related incidents, margin of error is infinitesimal and precision and accuracy are crucial. These

labs will provide gold standard confirmatory testing that is authoritative and serves as indisputable primary point of reference in the judicial system.

3.5.2. Scope of Work

These reference laboratories are responsible for a diverse range of toxicological tests that may be infrequently requested and/or require specialized expertise and equipment. These include:

3.5.2.1. *Comprehensive Drug Screenings.* Precise detection and quantification of a wide range of prescribed, over-the-counter, or illicit drugs, as well as their metabolites, which is needed for identifying unknown samples. This is achieved by use state of the art equipment and methodology in the field of testing (e.g. LC-MS/MS, GC-MS)

3.5.2.2. *Heavy Metal Assays.* Qualitative and quantitative heavy metal assays to measure the levels of heavy metals such as lead, mercury, arsenic, and cadmium in biological samples and confirm such toxicities. This is especially important for assessing occupational exposure and identifying potential health risks or as part of screening for cases of encephalopathy or psychosis.

3.5.2.3. *Specialized Investigations.* This includes testing for rare toxins, environmental pollutants, and other substance exposures that are not common but of significant risk or importance.

3.5.2.4. *Research and Development.* These labs will also be responsible for research and development in the field of toxicology, staying updated with global best practices, and offering training to a diverse group of professionals such as toxicologists, medical practitioners, forensic teams and legal and law enforcement officers.

3.5.3. Workflow

Reference laboratories provides toxicology testing services to:

3.5.3.1. Clinical laboratories as independent facilities or as a part of healthcare facilities (e.g., hospitals, day surgical centers, polyclinics, specialty clinics)

3.5.3.2. Governmental entities (e.g., DoH, ADPHC, Abu Dhabi Police)

3.5.3.3. Healthcare professionals; only upon approval of toxicology testing request by Poison and Drug Information Service, medical toxicologist, or clinical toxicologist.

3.5.4. Certification Process

Reference laboratories must meet certification standards that underscore their credibility, precision, and stature as gold standard reference in clinical toxicology. These include:

3.5.4.1. *Accreditation*. The reference laboratory will be accredited by recognized national or international bodies that ensure its commitment to high standards of operation and output. This can be achieved through adherence to relevant guidelines and regulations.

3.5.4.2. *Quality Assurance and Quality Control.* Periodic internal and external audits, proficiency evaluation, and participation in external quality assurance programs is mandated.

3.5.4.3. *Equipment Calibration and Validation.* Regular calibration of instruments and validation of testing procedures are mandated to ensure the accuracy and reliability of results.

3.5.4.4. *Personnel Training.* The staff should be well-trained and certified in clinical toxicology testing. Continuous education and training programs must be in place to ensure they stay up-to-date with the latest developments in toxicology testing.

3.5.4.5. *Safety Protocols.* Given the nature of substances handled, the laboratory must implement safety measures, ensuring the protection of both the samples and the laboratory personnel.

4. Key stakeholder Roles and Responsibilities

4.1. Duties for Healthcare Providers. All healthcare providers, including healthcare facilities and professionals, licensed by DoH and who are engaged in the provision of clinical and analytical toxicology service must:

4.1.1. Provide clinical and analytical laboratory services in accordance with the requirements of this Standard, the recommended testing methodologies and protocols for drugs, toxic substances and poisons as detailed in Appendices 1, 2, and 3 of this Standard, and in compliance with the requirements of the HAAD Clinical Laboratory Standard[4];

4.1.2. Facilities that provide clinical care, in addition to clinical toxicology services, must ensure that patient care and treatment provided is consistent with relevant DoH Standards and international evidence-based best practice;

4.1.3. Report and submit data to DoH in accordance with the DoH Reporting of Health Statistics Policy[6] and as set out in the DoH Data Standards and Procedures;

4.1.4. Comply with DoH policies and standards on managing patient medical records, including developing effective recording systems, maintaining patient records, maintaining confidentiality, privacy and security of patient information and educating patients and fulfilling the requirements of patient consent and the DoH patients' rights and responsibilities charter[7];

4.1.5. Comply with DoH requests to inspect and audit records and cooperate with DoH authorized auditors, as required for inspections and audits by DoH.

4.2. Role of the Department of Health

4.2.1. DoH poison and drug information specialist will monitor healthcare Facilities & healthcare professionals through implementation, and enforcement of this Standard. To ensure the alignment with the best practices for applying the Clinical Laboratories Standard. The DoH is committed to maintaining the highest standards of the practice application in all emergency toxicity sittings.

5.Monitoring and Evaluation

Healthcare facilities that manage cases of poisonings shall report them through the processes defined by DoH and other health agencies. The PDIS will conduct periodic data analyses, assessments, and audits to evaluate the performance, compliance, or outcomes of these cases.

DoH will follow specific indicators that include, but are not limited to:

- Accreditation status
- Audit findings
- Data security
- Compliance with standards
- Traceability of results
- Turnaround times

6. Enforcement and Sanctions

Healthcare facilities, payers, and third-party administrators must comply with the terms and requirements of this Standard, the DoH Standard Provider Contract and the DoH Data Standards and Procedures[8]. DoH may impose sanctions in relation to any breach of requirements under this standard in accordance with the Healthcare Sector Disciplinary Regulation

7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	01 Dec 2023	Federal Law No. (8) of Year 2019 On Medical Products, the Profession of Pharmacy and Pharmaceutical Facilities*	https://mohap.gov.ae/app_content/legislations/php-law-en-95
2	01 Dec 2023	United Nations Office on Drugs and Crime. Terminology and Information on Drugs. 3rd Edition, UNODC, 2016, p. 64.	https://www.unodc.org/documents/scientific/Terminology_and_Information_on_Drugs-E_3rd_edition.pdf
3	01 Feb 2024	CLSI C52 Toxicology and Drug Testing in the Medical Laboratory. 3rd edition.	https://clsi.org/standards/products/clinical-chemistry-and-toxicology/documents/c52/
4	01 Dec 2023	HAAD Clinical Laboratory Standards Version 1.0	https://www.doh.gov.ae/-/media/Feature/Resources/Standards/Clinical-Laboratory-Standards-Version-10.ashx
5	01 Dec 2023	C43 Gas Chromatography/Mass Spectrometry Confirmation of Drugs, 2nd Edition	https://clsi.org/standards/products/clinical-chemistry-and-toxicology/documents/c43/
6	01 Dec 2023	HAAD Standards for Reporting of Public Health Statistics HAAD/RHST/ SD/VIPCD/1.2	https://www.doh.gov.ae/-/media/Feature/Resources/Standards/HAAD-Standard-for--Reporting-of-Public-Health-Statistics.ashx
7	01 Dec 2023	DoH Standard on Patient Healthcare Data Privacy DOH/SD/SS/PHDP/0.9	https://www.doh.gov.ae/-/media/Feature/Resources/Standards/2020-09-15-DOH-Standard-on-Patient-Healthcare-Data-Privacy-for-publication.ashx
8	01 Dec 2023	HAAD Data Standards and Procedures, January 2008. Revision 14 April 2014	https://shafafiyaportal.doh.gov.ae/dictionary/Standards/Datastandard/Standards.pdf?

8. APPENDICES

APPENDIX 1 – TIER 1 ASSAYS

The following laboratory investigations should be available on a 24-hour basis to all hospitals where patients with acute poisoning are admitted in the Emirate of Abu Dhabi:

- Complete blood count
- Sodium, potassium, urea, creatinine
- Glucose
- Calcium, albumin, magnesium
- International normalized ratio (INR)
- Liver function tests (transaminases)
- Bilirubin
- Anion gap (chloride and bicarbonate)
- Plasma osmolality (freezing point depression method) and osmolar gap
- Arterial blood gases
- Creatine kinase
- Lactate

Tier 1 STAT quantitative serum toxicology assays required on a 24-hour basis supporting all hospitals where patients with acute poisoning are admitted in the Emirate of Abu Dhabi.[a]

- Paracetamol[b] (acetaminophen)
- Salicylate[c]
- Ethanol[d]
- Carboxyhemoglobin, and methemoglobin[e]
- Digoxin[f]
- Theophylline[g]
- Lithium[h]
- Iron[i]
- Valproate
- Paraquat (qualitative urine test)[j]
- Phenobarbital[k]
- Transferrin[l]
- Tricyclic antidepressants (TCA)[m]

[a]TAT of 2 hours or less.

[b] levels must be obtained in all suicidal cases. The sample must be taken 4 hours after ingestion, or immediately if the patient presents after 4 hours.

[c] levels must be obtained in all suicidal cases. The sample should be taken at least 2 hours (symptomatic patients) or 4 hours (asymptomatic patients) following ingestion, since it may take several hours for peak plasma concentrations to occur and up to 12 hours for enteric coated preparations.

[d] Ethanol concentrations should be measured urgently:

- In patients with undiagnosed coma;
- In patients with a widened osmolar gap;
- In patients with suspected severe ethanol poisoning;
- In children with unexplained acidosis.

The use of different units for reporting plasma ethanol concentrations is confusing and potentially dangerous. The recommended units for reporting ethanol concentration are mg/L.

[e] Carboxyhemoglobin should be measured urgently in all patients with suspected carbon monoxide poisoning (including those with suspected smoke inhalation). It may also be elevated in patients who have ingested methylene chloride.

[f] Samples should always be taken before antibody administration. In patients with life-threatening arrhythmias due to digoxin toxicity, treatment with digoxin-specific antibodies should not be delayed pending the results of plasma digoxin concentrations.

[g] Plasma theophylline concentration measurement should be performed immediately for patients with any clinical features suggesting theophylline toxicity, including convulsions, tachycardia, hypokalemia or acidosis. Patients who have a history of theophylline poisoning but no clinical features on presentation should have their concentration determined 4 hours after exposure.

In patients with severe poisoning or theophylline concentration >60 mg/L (333 mmol/L), the theophylline concentration should be repeated every 2–4 hours, until peak concentrations have passed.

[h] Lithium concentration should be measured immediately and 6 hours later in patients with acute lithium intoxication associated with relevant symptoms and in patients with suspected acute-on-chronic or chronic toxicity.

[i] In patients with suspected severe poisoning, a sample should be taken immediately to confirm the history. In all other patients, the sample should be taken after at least 4 hours have elapsed since iron ingestion and an additional sample after a further 2 hours is desirable to determine whether the concentration is still rising.

[j] A qualitative urine test (dithionite spot test) should be performed urgently in all patients presenting with suspected paraquat poisoning to confirm exposure. If after 4 hours a urine test remains negative, there is no indication for further investigation or treatment of paraquat poisoning. In patients with a positive spot test, a blood sample should be taken for routine analysis in a specialist laboratory, as this provides valuable prognostic information.

[k] if urine barbiturates are positive.

[l] or UIBC assay if transferrin is not available.

[m] Semi quantitative immunoassay.

Tier I Stat Qualitative Urine Toxicology Assays Required Supporting an Emergency Department in the Emirate of Abu- Dhabi. [a,c]

- Cocaine
- Opiates
- Barbiturates
- Amphetamines[b]
- Cannabinoids[b]
- Benzodiazepines
- TCAs[d] (if not done in serum)

[a] TAT of 2 hours or less.

[b] Need for these assays may be based on prevalence of drug use, which may vary from region to region. Regular review of drug usage is important.

[c] In general, urine toxicology screens such as these do not correlate well with clinical effects and suffer from problems with sensitivity and specificity, as discussed in the text. Although widely available, these assays (with the exception of that for the cocaine metabolite) require clinical interpretation.

[d] Recommended only if the clinical staff fully understands the specificity limitations of this assay, i.e. results are used in conjunction with the electro-cardiograph to support a clinical suspicion of TCA toxicity, but not in cases where a positive urine drug test is the sole evidence for this suspicion.

APPENDIX 2 – TIER 2 ASSAYS

Tier 2 Quantitative Blood OR Urine Toxicology Assays Required Supporting an Emergency Department in the Emirate of Abu- Dhabi.

- Arsenic[a,o]
- Carbamazepine[b]
- Cholinesterase[c] (plasma and erythrocyte)
- Cyanide[d]
- Ethylene glycol[e]
- Isopropyl alcohol
- Lead[f,o]
- Mercury[g,o]
- Methanol[e]
- Methotrexate[h]
- Paraquat[i] (quantitative plasma assay)
- Phenobarbital[j]
- Phenytoin[k]
- Thallium[l,o]
- Thyroxine[m]
- Toxicology screen[n]

[a] Blood arsenic concentration should be available within 2 hours (24-hour urine) assay result should be available within 48 hours.
Blood arsenic concentrations should be measured in cases of suspected acute arsenic toxicity to confirm the diagnosis, particularly if chelation therapy is being contemplated. Following acute toxicity, blood arsenic concentrations decline rapidly into the normal range in spite of continuing evidence of clinical toxicity, and may be undetectable more than 4 hours after ingestion of potentially fatal amounts.

[b] An urgent result from this assay should be available within 2 hours.

[c] Should ideally be available within 3 hours, including journey time.

[d] Results from this assay should be available within 24 hours. For poisoning by cyanide, results from laboratory analysis are very unlikely to be available rapidly enough to influence the acute management of an individual patient. However, analysis of samples may inform management of further cases in the event of a release involving multiple casualties and also for medicolegal and forensic purposes.

[e] Result should be available within a maximum of 4 hours. It is reasonable to restrict use of these assays to: patients who give a history of substantial ingestion; patients with suspected severe toxicity as evidenced by metabolic acidosis, especially pH <7.2 (hydrogen ion >60 nmol/L) in the presence of an increased anion gap, with or without an increased osmolar gap, when a reliable history is unavailable.

[f] Whole blood lead concentration should be available within 48 hours. Urgent measurement of plasma lead concentration is necessary in children with suspected lead encephalopathy.

Non-urgent measurement of whole blood lead concentration is required in patients with suspected lead exposure or toxicity to confirm the diagnosis. This is particularly important if chelation therapy is being contemplated.

[g] Whole blood mercury concentration should be available within 2 hours. Whole blood mercury should always be measured prior to administration of antidotes such as DMPS. (24-hour urine) result should be available within 48 hours. Urinary mercury should be measured in patients with suspected chronic mercury intoxication.

[h] Measurement of the plasma methotrexate concentration at least 4–6 hours after the most recent ingestion is helpful. To be clinically useful, a turnaround time of <24 hours is necessary.

[i] In patients with a positive urine test, a single plasma sample should be taken for analysis in a specialist laboratory.

[j] Assays should be available within 2–4 hours.
[k] Assays should be available within 2 hours.

[l] Chelation therapy with Prussian Blue should be considered in patients with blood thallium concentrations >10 mg/L (>50 nmol/L) or urine thallium concentrations >20 mg/L (>100 nmol/L). Assays should be available within 48 hours.

[m] 6– 12 hours after thyroxine ingestion. Assays should be available within 48 hours.

[n] (The scope of the toxicology screen may vary according to local needs).

[o] Heavy metals urgent assays are rarely indicated. Samples should be taken into a metal-free container. Urgent use of these assays must be discussed with a senior local biochemist. In such cases, these results should be available for urgent cases within 2 hours.

APPENDIX 3 – URINE DRUG SCREEN

Cut-off values recommended for various drugs of abuse to be used in clinical laboratories and those published by the Ministry of Interior (MOI) for the UAE:

Analyte	Recommended cut-off for clinical laboratories	Cut-offs used by the MOI for legal cases
Urine Amphetamine	1000 ng/ml	1000 ng/ml
Urine Barbiturates	300 ng/ml	200 ng/ml
Urine Benzodiazepine	300 ng/ml	200 ng/ml
Urine Cannabinoids	50 ng/ml	50 ng/ml
Urine Cocaine	300 ng/ml	300 ng/ml
Urine Methadone	300 ng/ml	300 ng/ml
Urine Opiates	300 ng/ml	300 ng/ml
Urine Phencyclidine	25 ng/ml	Not specified
Urine TCA	1000 ng/ml	Not specified
Urine Paracetamol	5 microg/ml	Not specified
Plasma Ethanol	10mg/dL /	10mg/dL/

APPENDIX 4 – COMPREHENSIVE DRUG SCREEN GC/MS (QUALITATIVE)

Please note that the GC/MS detects drugs that are present at high overdose concentrations, this means drugs that are present at therapeutic levels may not always be detected. The list of drugs screened below includes the minimum detectable urine concentration during the validation of the method. However, it is important to note that the test isn't run in a quantitative mode, which means that the sensitivities listed should be used in conjunction with other clinical and historical data to aid in the clinical interpretation of the test results.

Tests marked by an asterisk * are performed by the Ministry of Justice Forensic Laboratory.

Drug	Detectable Urine Concentration
ACETAMINOPHEN (PARACETAMOL)	1 mcg/mL
ALFENTANIL	100 ng/mL
ALPHA-HYDROXYALPRAZOLAM (Xanax metabolite)*	10 mcg/mL
ALPRAZOLAM (Xanax)*	10 ng/mL
AMANTADINE	1 mcg/mL
7-AMINOCLONAZEPAM (Clonazepam metabolite)	1 mcg/mL
AMITRIPTYLINE *	100 ng/mL
AMPHETAMINE*	100 ng/mL
AMPHETAMINE ARTIFACT*	10 ng/mL
ATROPINE	100 ng/mL
BARBITAL	100 ng/mL
BENZOYLECGONINE (Cocaine metabolite)	20 mcg/mL
BENZTROPINE	100 ng/mL
1-BENZYLPIPERAZINE	2 mcg/mL
BROMPHENIRAMINE	10 ng/mL
BUPRENORPHINE	1 mcg/mL
BUPROPION (Wellbutrin)*	100 ng/mL
BUPROPION METABOLITE*	100 ng/mL
BUSPIRONE*	1 mcg/mL
CAFFEINE*	1 ng/mL
CARBAMAZEPINE (Tegretol)	10 ng/mL
10, 11-CARBAMAZEPINE EPOXIDE (Carbamazepine metabolite)	10 ng/mL
CARISOPRODOL	10 ng/mL
CELECOXIB (Celebrex)	10 ng/mL
CHLORDIAZEPOXIDE	100 ng/mL
CHLORPHENIRAMINE*	10 ng/mL
CHLORPROMAZINE	10 ng/mL
CHLORPROTHIXENE	10 ng/mL
CITALOPRAM / ESCITALOPRAM	10 ng/mL
CLOMIPRAMINE (Anafranil)	10 ng/mL
CLONAZEPAM	100 ng/mL
CLONIDINE	1 mcg/mL
CLOZAPINE	1 mcg/mL
CLOZAPINE METABOLITE	1 mcg/mL

COCAETHYLENE	10 ng/mL
COCAINE	100 ng/mL
CODEINE*	10 ng/mL
COTININE	100 ng/mL
CYCLOBENZAPRINE*	10 ng/mL
CYPROHEPTADINE	10 ng/mL
DELTA-9 THC COOH	10 ng/mL
DESALKYLFLURAZEPAM (Flurazepam metabolite)	10 ng/mL
DESIPRAMINE*	100 ng/mL
DESMETHYLDOXEPIN (Nordoxepin)*	1 mcg/mL
DEXTROMETHORPHAN	10 ng/mL
DEXTRORPHAN (Dextromethorphan metabolite; see LEVORPHANOL)	100 ng/mL
DIACETYLMORPHINE (Heroin)	10 ng/mL
DIAZEPAM (Valium)*	10 ng/mL
DIETHYLPROPION	10 ng/mL
DIHYDROCODEINE	10 ng/mL
DILTIAZEM	10 ng/mL
DIPHENHYDRAMINE / DIMENHYDRINATE*	10 ng/mL
DOXYLAMINE	100 ng/mL
DOXEPIN*	10 ng/mL
DULOXETINE	> 20 mcg/mL
ECGONINE METHYL ESTER (Cocaine metabolite)	10 ng/mL
EDDP (Methadone metabolite)	100 ng/mL
EPHEDRINE / PSEUDOEPHEDRINE	> 20 mcg/mL
ETHOSUXIMIDE	10 ng/mL
ETOMIDATE	10 ng/mL
FENTANYL*	>1 mcg/mL
FLUCONAZOLE	100 ng/mL
FLUNITRAZEPAM (Rohypnol)	100 ng/mL
FLUOXETINE (Prozac)*	1 mcg/mL
FLUPHENAZINE	10 mcg/mL
FLURAZEPAM	100 ng/mL
GABAPENTIN (Neurontin)	10 mcg/mL
GEMFIBROZIL	100 ng/mL
GUAIFENESIN/METHOCARBAMOL	100 ng/mL
HALOPERIDOL	1 mcg/mL
HYDROCODONE*	100 ng/mL
HYDROMORPHONE (Dilaudid)	1 mcg/mL
HYDROXYZINE (Atarax)*	1 mcg/mL
IBUPROFEN	100 ng/mL
IMIPRAMINE (Tofranil)*	10 ng/mL
JWH-018 [1-pentyl-3-(1-naphthoyl)indole]	1 mcg/mL
KETAMINE*	10 ng/mL
LAMOTRIGINE	1 mcg/mL
LEVETIRACETAM (Keppra)	100 ng/mL
LEVORPHANOL/DEXTRORPHAN (optical isomers)	100 ng/mL

LIDOCAINE (Xylocaine)	10 ng/mL
LORAZEPAM	1 mcg/mL
LOXAPINE	100 ng/mL
MAPROTILINE	100 ng/mL
MEPERIDINE*	1 ng/mL
MEPIVACAINE	100 ng/mL
MEPROBAMATE	100 ng/mL
MESCALINE	2 mcg/mL
METHADONE*	100 ng/mL
METHADONE METABOLITE (EDDP)*	100 ng/mL
METHAMPHETAMINE	100 ng/mL
METHAQUALONE (Quaalude)	10 ng/mL
METHCATHINONE	1 mcg/mL
METHOCARBAMOL	2 mcg/mL
METHSUXIMIDE	10 ng/mL
METHYL SALICYLATE	1 ng/mL
METHYLENEDIOXYAMPHETAMINE (MDA)*	1 mcg/mL
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)*	100 ng/mL
METHYLENEDIOXYPYROVALERONE	10 ng/mL
METHYLPHENIDATE (Ritalin, Concerta)	10 ng/mL
METOCLOPRAMIDE *	100 ng/mL
METOPROLOL (Lopressor)*	2 mcg/mL
METRONIDAZOLE (Flagyl)	100 ng/mL
MIDAZOLAM (Dormicum)	10 ng/mL
MIRTAZAPINE*	10 ng/mL
6-MONOACETYLMORPHINE (Heroin metabolite)	50 ng/mL
MORPHINE	1 mcg/mL
N-ACETYL PROCAINAMIDE (NAPA)	1 mcg/mL
NALBUPHINE	1 mcg/mL
NALORPHINE	100 ng/mL
NAPROXEN	1 mcg/mL
NAPROXEN METABOLITE	>20 mcg/mL
NICOTINE	100 ng/mL
NORBUPRENORPHINE	2 mcg/mL
NORDIAZEPAM*	1 ng/mL
NORFENTANYL	100 ng/mL
NORFLUOXETINE*	10 mcg/mL
NORKETAMINE*	100 ng/mL
NORMEPERIDINE	1 mcg/mL
NORMETHSUXIMIDE	100 ng/mL
NORPROPOXYPHENE*	100 ng/mL
NORTRIPTYLINE*	1 mcg/mL
NORVERAPAMIL*	1 mcg/mL
OLANZAPINE (Zyprexa)*	100 ng/mL
OXAZEPAM	20 mcg/mL
OXCARBAZEPINE (Trileptal)	>1 mcg/mL
OXCARBAZEPINE (breakdown product)	100 ng/mL

OXYCODONE (Oxycontin)*	100 ng/mL
OXYMORPHONE	1 mcg/mL
PAPAVERINE	100 ng/mL
PARA AMINOBENZOIC ACID	>20 mcg/mL
PARAXANTHINE (Caffeine metabolite)*	4 mcg/mL
PAROXETINE*	1 mcg/mL
PENTAZOCINE	100 ng/mL
PENTOBARBITAL	10 ng/mL
PENTOXIFYLLINE (Trental)	10 ng/mL
PHENCYCLIDINE (PCP)*	1 ng/mL
PHENETHYLAMINE	1 ng/mL
PHENIRAMINE	10 ng/mL
PHENOBARBITAL	100 ng/mL
PHENOTHIAZINE	10 ng/mL
PHENTERMINE*	1 mcg/mL
PHENYTOIN	100 ng/mL
PRIMIDONE	100 ng/mL
PROCAINAMIDE	1 mcg/mL
PROCAINE	1 mcg/mL
PROCHLORPERAZINE	100 ng/mL
PROMETHAZINE*	100 ng/mL
PROPRANOLOL (Inderal)	>1 mcg/mL
PROPRANOL (breakdown product)	100 ng/mL
PROPOFOL	100 ng/mL
PROPOXYPHENE*	100 ng/mL
PSILOCIN	>4 mcg/mL
PSILOCYBIN	>8 mcg/mL
QUETIAPINE (Seroquel)*	2 mcg/mL
QUINIDINE / QUININE	1 mcg/mL
REMIFENTANIL	100 ng/mL
SALICYLAMIDE	1 mcg/mL
SCOPOLAMINE	100 ng/mL
SERTRALINE (Zoloft)*	100 ng/mL
STRYCHNINE*	100 ng/mL
SUFENTANIL	100 ng/mL
TEMAZEPAM	100 ng/mL
TETRAHYDROCANNABINOL	10 ng/mL
THEOPHYLLINE	2 mcg/mL
THIOPENTAL	100 ng/mL
TICLODIPNE	10 ng/mL
TOPIRAMATE (Topamax)	100 ng/mL
TRAMADOL*	10 ng/mL
TRAZODONE*	1 mcg/mL
TRIFLUOPERAZINE	100 ng/mL
TRIFLUPROMAZINE	100 ng/mL
3-TRIFLUOROMETHYLPHENYL-PIPERAZINE	100 ng/mL
TRIHEXYPHENIDYL	100 ng/mL

TRIMETHOPRIM	1 mcg/mL
TRIMIPRAMINE	10 ng/mL
VALPROIC ACID (Depakene)	1 mcg/mL
VENLAFAXINE (Effexor)*	10 ng/mL
VERAPAMIL*	1 mcg/mL
XYLAZINE	200 ng/mL
4-HYDROXY XYLAZINE	50 ng/mL
ZALEPLON	100 ng/mL
ZOLPIDEM*	10 ng/mL
ZOPICLONE	100 ng/mL