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Designer drugs

Substance abuse is one of the United States' largest health problems, yet an all-inclusive reference chart for Cutoff and Toxicity Levels for Dugs-of-Abuse Testing is partial, at best. The reason? The ever-changing horizon of chemical compounds.

While limits for opiates, hallucinogens, and stimulants are readily available, two trending "designer drugs," specifically, bath salts and synthetic cannabinoids, are not. In fact, *MLO* was advised it wouldn't be useful to include either of these drugs because as soon as the chart is published, it's likely those specific compounds would no longer be relevant. Due to these constantly changing compounds, no accurate studies exist to determine urine detection windows, therapeutic doses, etc.

Bath salts are synthetic stimulants, or cathinones; a family of drugs containing one or more synthetic chemicals related to cathinone, a stimulant found naturally in the khat shrub in East Africa and southern Arabia. Synthetic cathinones can be purchased online and in drug paraphernalia stores under a variety of brand names, including Bliss, Cloud Nine, Lunar Wave, Vanilla Sky, and White Lightning.[1] In many cases, synthetic cathinones are specifically created to evade detection, being introduced and reintroduced into the market in quick succession to dodge law enforcement efforts to address their manufacture and sale.

Public health officials refer to synthetic cathinones as "new psychoactive substances" (NPS).[2] NPS are unregulated psychoactive mind-altering substances with no legitimate medical use and are made to copy the effects of controlled substances. Often undetectable by typical urinalysis, NPS can be detected in urine and hair using gas chromatography-mass spectrometry or liquid chromatography-mass spectrometry.

Similarly, synthetic cannabinoids are not one drug and are not detectable on most standard in-house hospital drug screens, including assays for tetrahydrocannabinol (THC).[3] A number of commercial labs offer testing for synthetic cannabinoids, however, the panels are often limited. These chemicals are called cannabinoids because they are similar to chemicals found in cannabis. Because of this similarity, synthetic cannabinoids are sometimes misleadingly called "synthetic marijuana" (also known as K2, Spice, AK-47, Mr. Happy, Scooby Snax, and Black Mamba[5]), and are often marketed as safe, legal alternatives. In fact, they are not safe and may affect the brain much more powerfully than marijuana; their actual effects unpredictable and, in some cases, more dangerous or even life-threatening.[4]

Redwood Toxicology Laboratory (RTL), the government services division of Alere Toxicology, and one of the nation's largest drug and alcohol testing laboratories, claims to be the first lab in the world to develop a urine-based metabolite test and oral fluid parent drug test for "synthetic marijuana," targeting 19 of the most common chemical compounds found in synthetic cannabinoids.[5]

ARUP laboratories offers a Bath Salts Panel for urine which, "may be useful in the assessment of exposure to bath salts up to several days post-exposure. For the assessment of acute exposure, Bath Salts Panel, Serum or Plasma (2011411) may be useful." The methodology? Quantitative high performance liquid chromatography/tandem mass spectrometry.

Quest Diagnostics states they are, "Working collaboratively with the oil and gas industry and other laboratories to refine our synthetic drug testing panel based on information from the National Forensic Laboratory Information System (NFLIS), the Drug Enforcement Administration (DEA), peer-reviewed scientific literature, and industry-observed trends and usage."[6] Their intention? Providing a standardized panel that can detect the most relevant drugs from an ever-changing list of substances.

Although substance abuse and designer drugs will continue to come and go, as laboratorians, the goal remains steadfast: Being privy to accurate drug detection tools with the ultimate goal of discouraging addiction.

Please visit mlo-online.com for references.

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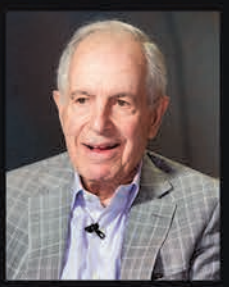

Dr. Ray Gambino is credited with "inventing" MLO-Medical Laboratory Observer 50 years ago. Now retired, residing in sunny Florida, Gambino's fame goes back to 1969.

Around this time the editors of *Medical Economics* were trying to develop a new medically-oriented publication. The editors were directed to Dr. Ray Gambino, Director of Clinical Laboratories at Englewood Hospital in New Jersey.

During his NJ tenure, Gambino shocked the hospital's medical staff by restricting the order of tests he considered inappropriate, offering unlimited consultations to help guide appropriate laboratory utilization. His model was, "one clinician and one patient at a time."

Gambino served Columbia Presbyterian Hospital in NYC until his retirement in 2014.

The "clinical laboratory consultation" model was developed in its most advanced form by Dr. Michael Laposata when he served as director of the clinical laboratories at Massachusetts General Hospital. Laposata developed a rigorous coagulation consultative service to fill the knowledge gap that physicians had regarding appropriate laboratory testing. Laposta currently serves as Chairman, Department of Pathology, University of Texas, Galveston, TX.

Consultative relationships between clinical laboratory experts and clinicians have been challenging, to say the least. Fifty years ago, most laboratories were "tolerated" by clinicians. Dr. Gambino worked to change that mentality by teaching courses on how to better manage hospital clinical laboratories. Among his students were Dr. Paul Brown (who would later found MetPath, predecessor company to Quest Diagnostics), and Dr. James Powell, (one of the founders of Biomedical Reference Laboratories, a key part of what became Roche Biomedical Laboratories, and later LabCorp).

These business-oriented pathologists developed reference laboratories designed to support clinicians. Both entrepreneurs provided medical and technical experts to assist clinicians with test selection and interpretation. Fifty years later, the two reference laboratories grew tremendously in size in part due to the close relationship fostered with clinicians.

Dr. Gambino joined MetPath as president of the eastern division, later served as its first Chief Medical Officer, and went on to become first Chief Medical Officer, Emeritus. His contribution is reflected in the highest quality award at Quest Diagnostics—the Gambino Award. This prestigious award has recognized and encouraged excellence in laboratory quality for more than 20 years.

Gambino Quality Award

The Gambino Quality Award honors Dr. Raymond Gambino, Emeritus's Chief Medical Officer. It is awarded each year based on regional medical quality scorecard, proficiency testing, medical quality audits, and timeliness of adoption of Standard Operating Procedures (SOPs) for both anatomic and clinical pathology. Established in 1997 to encourage and recognize quality excellence within Quest Diagnostics, the award has two levels: (1) a "Challenger" level with criteria that are very difficult to achieve, and (2) a "Winner" level that highlights the extraordinary commitment of a region to specific quality measures.[1]

Guiding appropriate lab utilization

Over the past fifty years, in addition to the development of independent laboratories, the *in vitro* diagnostic industry exploded along with regulatory oversight. Most notable, the Clinical Laboratory Improvement Act (CLIA '67) and the CLIA Amendment of 1988. Immunohistochemistry and molecular diagnostics opened new doors to understanding disease and medical risk. Quality control and quality systems became embedded in our culture. Yet, the consultative role in the clinical laboratory remains largely elusive. Many clinical pathologists and medical scientists still operate on the one-on-one consultation model along with broader communications through newsletters, lectures, webinars, and courses.

Triple Aim principles:

(1) Improve the patient experience of care
(2) Improve the health of populations
(3) Reduce the per capita cost of healthcare

Fast forward to present day. The groundwork set forth by Dr. Gambino to establish quality laboratory practices aligned with the needs of patients has evolved to another level with the development of laboratory stewardship. This is a phrase that typically refers to the use of laboratory data to guide appropriate utilization of services and minimize inappropriate use. Clinical laboratories are embarking on a path that allows rules embedded in electronic medical records (EMRs) to guide appropriate laboratory utilization and limit inappropriate utilization.

Roots of laboratory stewardship

Laboratory stewardship has its roots in blood bank committees that oversee appropriate blood utilization. Even though blood banks are closely associated with the other clinical laboratories, these practices did not extend far to the other side. Clinical labs have touched upon other "utilization" teams. Infectious control committees have focused on appropriate antibiotic use within hospitals. And pharmacy committees have often focused on use of less expensive comparable medicines.

While laboratory stewardship has its foundation in blood bank utilization management, it is fundamentally more expansive. Laboratory stewardship focuses on principles of the framework of the Triple Aim: (1) Improving the patient experience of care (quality and satisfaction); (2) improving the health of populations; and (3) reducing the per capita cost of healthcare.

As pressure mounts on costs associated with healthcare, laboratory utilization management focuses increasingly on cost control to understand who is ordering which tests—especially expensive tests and referral testing.

Laboratory stewardship enters our vocabulary

Laboratory stewardship has been in practice by some labs for several years, although interest has grown significantly in the past two years. An article in *Journal of Applied Laboratory Medicine*, published in October 2017, put laboratory stewardship on the map.[2]

In January 2019, AACC announced a new quarterly section on laboratory stewardship in *Clinical Laboratory News*. Just as with other innovations in laboratories, this one builds on prior building blocks including utilization management and patient safety. Most importantly, laboratory stewardship requires data—and lots of it—in a form that can be analyzed and delivered almost immediately. It provides a framework not only for retrospective reviews but adds the ability to send messages in advance care and point-of-care delivery.

The term "laboratory stewardship" is important to use because it conveys a growing practice across institutions that focuses on value, not just utilization and costs. Stewardship implies that laboratory managers are taking responsibility for the viability of laboratory resources that have been entrusted to our care. We are likely to gain more engagement by strongly advocating for the protection of a vital resource (the clinical laboratory) and its appropriate role than by simply focusing on utilization.

Dr. Gambino relied on chart review, daily rounds, and generally, one-on-one interactions. Laboratory stewardship relies on "big data." Specifically, clinical and laboratory data extraction, standardization of data elements, and analysis are core aspects of data use. Data is generally applied to identified problems that can be improved. New tools including artificial intelligence (AI) may also uncover issues that are hidden in the data. Today, the resources to analyze and intervene large data sets exists, as does the financial desire to improve health outcomes and control costs. When the clinical lab applies the strength of the data to address the Triple Aim, laboratorians will likely become more integrated into clinical care teams.

Getting laboratory stewardship well-rooted

Laboratory stewardship requires governance with organizational alignment, processes, and procedures. Governance includes alignment with hospital committees, as well as internal alignment to the clinical lab. All clinical departments are impacted by laboratory stewardship and broad representation is often helpful. A leadership team can involve fewer individuals to provide overall support without managing activities within each department. Governance typically evolves as the power of laboratory stewardship is recognized.

Often, the best first step is to start with small demonstration projects that are likely to succeed. After a few successes, building a sustainable model with broader representation may be appropriate. Finding

partners for the first few projects starts with finding people who already understand the value of such activities.

IDEAS is five-step model for projects:

1. **I**dentify amendable problems; define project charter or scope.
2. **D**evelop project team (may be standing committee).
3. **E**xtract, standardize, and analyze data.
4. **A**pply solutions to the problem (input).
5. **S**ize the change and reiterate until problem is rectified, resolved (output) with process to assure monitoring; also involves communications.

For lab managers that do not have specific projects to consider, two key resources may yield insights into areas for attention: The Choosing Wisely campaign (choosingwisely.org) initiated by the American Board of Medicine and PLUGS. Choosing Wisely focuses more on what **not** to do than what to do. It aims to reduce or eliminate activities that have little benefit or may cause harm. Many of the recommendations have already been adopted. The other key resource is PLUGS, (Patient-centered Laboratory Utilization Guidance Services) which is a non-profit laboratory stewardship collaboration within Seattle Children's Hospital Department of Laboratories, a consortium of more than 70 organizations. PLUGS is a leading resource center for laboratory stewardship with templates, webinars, newsletters, conferences, and individual support and consultation. PLUGS describes four basic elements:[2]

- Governance
- Intervention
- Data extraction and monitoring
- Review of data coupled with strategies and tactics for improvement.

Real world examples

One laboratory stewardship project that I've been involved in included review of duplicate orders for molecular diagnostic tests. In this study, nearly every circumstance involved orders from two or more physicians who did not review pending orders. Another project involved an unusual test whose order code reflected two inverted digits. In these examples, the problems were identified and exploration uncovered the causes. Applying strategies such as Six Sigma Quality or standard QA tools helped to identify the root causes. Wrapping these activities into laboratory stewardship provides a framework to assign resources to gather issues, prioritize, and solve.

Laboratory stewardship can be even more impactful by identifying patterns of utilization and specifically, potential underutilization, and over-utilization. Although there is a tendency to focus on high-cost services, examining low-cost services has the potential to reduce waste, too. For example, routine ordering of CBCs in patients without out-of- range results and no deterioration in medical status can be wasteful. Creating checkpoints to order high cost tests or tests ordered "too frequently" can act as a road bump that reduces inappropriate test utilization. Creating checklists that apply to common conditions can act as reminders for appropriate test utilization.

Another avenue for laboratory stewardship is clinical decision support (CDS). CDS involves rules that are triggered by prior test results, test ordering, other clinical measures or events, and time. For example, specific ages of patients can trigger reminders about immunizations. Another example is patients with diabetes should have at least one HbA1c test every six months (patients with diabetes can be identified by ICD-10 codes, prescription of hypoglycemic agents, or prior evidence of diabetes, e.g., multiple elevated HbA1c or fasting glucose results).

Coverage and reimbursement

Finally, a key aspect of laboratory stewardship is obtaining appropriate payment for services provided. This includes obtaining CPT codes from the American Medical Association CPT Editorial Panel, coverage policies that cover the intended use of clinical lab testing and services, and proper reimbursement. The laboratory community must be committed to voicing the necessity for appropriate coverage and reimbursement as a way to provide patients with testing and services that meet their needs.

In conclusion

Many clinical laboratory initiatives have presented themselves in the past 50 years. However, laboratory stewardship is one that will continue to flourish. We have come a long way since MLO started with Dr. Gambino's one-on-one approach to educating clinicians about the strengths and limitations of clinical laboratory testing. As a result, we can now better leverage learnings among institutions and the data that sits in our data repositories. Laboratory stewardship provides a new, more ambitious model with access to big data that encourages us to focus on improving the health of patients.

I, like so many other physicians, laboratory technologists, and medical professionals, have been inspired and influenced by Dr. Ray Gambino. Thank you Dr. Gambino for pioneering a path that has lead us to best serve clinicians and their patients.

REFERENCES

1. The 2019 Gambino Quality Award. Quest Diagnostics. http://blog.questdiagnostics.com/2019/05/2019-gambino-quality-award/. Accessed July 8, 2019.

2. Dickerson JA, Fletcher AH, Procop G, et al., Transforming laboratory utilization review into laboratory stewardship: Guidelines by the PLUGS national committee for laboratory stewardship. *Journal of Applied Laboratory Medicine*. 2017.

Harvey W. Kaufman, MD, serves as Senior Medical Director, Medical Informatics, **Quest Diagnostics.** Kauffman has worked with Dr. Ray Gambino and others at Quest Diagnostics for 27 years in a variety of roles including its first Chief Laboratory Officer. Kaufman now focuses on application and licensing of healthcare data, with the goal of providing insights and improving health outcomes.

ADULT

CLINICAL CHEMISTRY		LOW LIMIT		HIGH LIMIT	
Test	Units	Mean (SD)	Range	Mean (SD)	Range
Glucose	mmol/L mg/dL	2.6 (0.4) 46 (7)	1.7-3.9 30-70	26.9 (8.0) 484 (144)	6.1-55.5 110-1000
Potassium	mmol/L	2.8 (0.3)	2.5-3.6	6.2 (0.4) 8.0 (hemolyzed)	5.0-8.0
Calcium	mmol/L mg/dL	1.65 (0.17) 6.6 (0.7)	1.25-2.15 5.0-8.6	3.22 (0.22) 12.9 (0.9)	2.62-3.49 10.5-14.0
Sodium	mmol/L	120 (5)	110-137	158 (6)	145-170
CO_2 content	mmol/L	11 (2)	5-20	40 (3)	35-50
Magnesium	mmol/L mg/dL	0.41 (0.16) 1.0 (0.4)	0.21-0.74 0.5-1.8	2.02 (0.82) 4.9 (2.0)	1.03-5.02 2.5-12.2
Phosphorus	mmol/L mg/dL	0.39 (0.10) 1.2 (0.3)	0.26-0.65 0.8-2.0	2.87 (0.48) 8.9 (1.5)	2.26-3.23 7.0-10.0
Bilirubin	µmol/L mg/dL	— —	— —	257 (86) 15 (5)	86-513 5-30
Chloride	mmol/L	75 (8)	60-90	126 (12)	115-156
Osmolality	mmol/kg	250 (13)	230-280	326 (18)	295-375
Urea nitrogen	mmol/L mg/dL	— —	— —	37.1 (21.1) 104 (59)	14.3-107.1 40-300
Uric acid	µmol/L mg/dL	— —	— —	773 (119) 13 (2)	595-892 10-15
CSF glucose	mmol/L mg/dL	2.1 (0.6) 37 (10)	1.1-2.8 20-50	24.3 (11.4) 438 (206)	13.9-38.9 250-700
Creatinine	µmol/L mg/dL	— —	— —	654 (380) 7.4 (4.3)	177-1326 2.0-15.0
Ionized calcium[4]	mmol/L mg/dL	0.82 (0.14) 3.29 (0.56)	0.50-1.07 2.00-4.29	1.55 (0.19) 6.21 (0.76)	1.30-2.00 5.21-8.02
Lactate	mmol/L mg/dL	— —	— —	3.4 (1.3) 30.6 (11.7)	2.3-5.0 20.7-45.0
HEMATOLOGY					
Hematocrit	L/L	0.18 (0.05)	0.12-0.30	0.61 (0.06)	0.54-0.80
Hemoglobin	g/L	66 (17)	40-120	199 (27)	170-300
Platelets	$\times 10^9$/L	37 (18)	10-100	910 (147)	555-1000
WBC count	$\times 10^9$/L	2.0 (0.7)	1.0-4.0	37.0 (20.7)	10.0-100.0
PT	s	—	—	27 (9)	14-40
PTT	s	—	—	68 (33)	32-150
Fibrinogen	g/L	0.88 (0.17)	0.50-1.00	7.75 (2.63)	5.00-10.00
BLOOD GASES AND PH					
pCO_2	mm Hg	19 (3)	9-25	67 (6)	50-80
pH		7.21 (0.06)	7.00-7.35	7.59 (0.03)	7.50-7.65
pO_2	mm Hg kPa	43 (6) 5.7 (0.8)	30-55 4.0-7.3	— —	— —

Adult table modified with permission by ***JAMA***, Vol. 263, pp. 704-707, 1990. CSF, cerebrospinal fluid; WBC, white blood cell; PT, prothrombin time; PTT, partial thromboplastin time. Qualitative critical results for adults[1] include the following: For ***blood bank*** and ***immunology***—incompatible crossmatch, tests positive for syphilis (RPR or VDRL). For ***microbiology*** and ***parasitology***—positive results from Gram stain or in culture from blood, cerebrospinal fluid, or body cavity fluid; positive India ink preparation; positive rapid antigen detection by agglutination tests for ***Cryptococcus***, group B streptococci, ***Haemophilius influenzae b***, or ***Neisseria meningitidis***, positive results from acid-fast bacillus stain or culture; ***Salmonella, Shigella***, or ***Campylobacter*** on stool culture; presence of malarial parasites. For ***clinical microscopy*** and ***urinalysis***—elevated white blood cell count in CSF; presence of malignant cells, blasts, or microorganisms in CSF or body fluids; combination of strongly positive test results for glucose and for ketones in urine; presence of pathologic crystals (urate, cysteine, leucine, or tyrosine) on urinalysis. For ***hematology***—listed frequently are the presence of blasts on blood smear; new diagnosis or findings of leukemia; presence of sickle cells (or aplastic crisis). Listed occasionally are plasma cells, band cells, atypical lymphocytes, and abnormal reticulocyte count.

Critical limits define boundaries of life-threatening values of laboratory test results. Critical results or values are those that fall outside high and low critical limits. Urgent clinician notification of critical results is the lab's responsibility. The system of critical value reporting was first implemented in a hospital by George D. Lundberg, MD, and first published in *MLO* in 1972. These tables are based on three national surveys by Gerald J. Kost, MD, PhD, MS, FACB, of the University of California-Davis Health System. Adapted with permission from his articles,[1-4] the tables summarize critical limits used by 92 responding U.S. medical centers, including 20 trauma centers, and 39 children's hospitals. Mean and standard deviation (SD) data are presented. The frequency with which critical limits were listed can be found in the original articles.

As a rule of thumb, the "mean low" and "mean high" figures may be considered the critical limits for each test listed. Each institution should establish its own set of critical limits and clinician notification policy.

Dr. Kost conducted an independent national survey of U.S. medical centers and children's hospitals to determine ionized calcium critical limits.[4] His extensive overview of critical limits and patient outcomes appeared in the March 1993 issue of *MLO*.[3]

Critical results of tests and diagnostic procedures fall significantly outside the normal range and may indicate a life-threatening situation. The objective is to provide the responsible licensed caregiver these results without delay so that the patient can be treated promptly.

The Joint Commission identifies critical values in current National Patient Safety Goals (NPSG).[5] One goal is to report critical results of tests and diagnostic procedures on a timely basis. Inspectors check for compliance on this topic.

Elements of Performance for NPSG.02.03.01: (1) Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following: the definition of critical results of tests and diagnostic procedures; by whom and to whom critical results of tests and diagnostic procedures are reported; the acceptable length of time between availability and reporting of critical results of tests and diagnostic procedures; (2) implement the procedures for managing the critical results of tests and diagnostic procedures; and (3) evaluate the timeliness of reporting the critical results of tests and diagnostic procedures.

In "Global trends in critical values practices and their harmonization,"[6] Kost and Hale investigate trends in critical values practices including improving preanalytical processing, streamlining urgent notifications, assuring effective critical limits, assessing decision levels, and using visual logistics. Special considerations for pediatrics are addressed since newborns/neonatals must adapt to the extrauterine environment with its demands for striking physiological changes. Identifying existing personal adverse events clustered by time/location could be used to predict a patient's future adverse events. Customizing critical values is possible for some unmet needs like comparing critical values lists to national norms and clarifying protocols for repeat critical values testing. Also, site-neutral policies encourage timely

reporting, recording, and integrating critical values into a patient's closed-loop EMR.

Worldwide harmonization seems to be advancing one country at a time. Australia is moving toward harmonizing critical result management throughout the country.[7] In Europe, the most accepted standard for accreditation and certification of clinical labs is ISO EN 15189:2012, which includes immediate notification of critical values as a special requisite. In the United States, CLSI published a new guideline.[8] National standards of care must be considered and compared in order to harmonize critical values practices, but other than simply mentioning standard of care for reporting times in a tabular summary, the CLSI guideline does not adequately address, analyze, or compare standards of care in different countries.

A key contemporary challenge is the harmonization of actual quantitative and qualitative triggers for emergency notifications, not just harmonization of terminology. The reader can purchase GP47[8] for $140 to learn three suggested nomenclature categories (critical-risk results, significant-risk results, and alert thresholds) and consult Appendix B therein for CAP Q-Probes critical values (renamed "alert thresholds" in a tabular summary in SI units) or access the same data free in reference 9. However, as discussed in recent MLO articles,[10-11] courts may not deem such Q-Probes subscriber data admissible in establishing the standard of care during litigation. Additionally, the complexities of three categories and how individual tests with their thresholds are assigned to each of the three categories would be difficult to explain to a jury.

Although controversial, repeat testing of hematology and coagulation critical values, especially in regards to pediatrics, should be noted.[12]

REFERENCES

1. Kost GJ. Critical limits for urgent clinician notification at U.S. medical centers. *JAMA*. 1990;263:704-707.

2. Kost GJ. Critical limits for emergency clinician notification at U.S. children's hospitals. *Pediatrics*. 1991;88:597-603.

3. Kost GJ. Using critical limits to improve patient outcome. *MLO*. 1993;25(3):22-27.

4. Kost GJ. The significance of ionized calcium in cardiac and critical care. Availability and critical limits at U.S. medical centers and children's hospitals. *Arch Pathol Lab Med*. 1993;117:890-896.

5. The Joint Commission. NPSG.02.03.01 Report critical results of tests and diagnostic procedures on a timely basis.

6. Kost GJ, Hale KN. Global trends in critical values practices and their harmonization. *Clin Chem Lab Med*. 2011;49(2):167-176.

7. Campbell C, Horvath A. Towards harmonization of critical laboratory result management—review of the literature and survey of Australian practices. *Clin Biochem Rev*. 2012;33(4):149-160.

8. Young AB, et al. Management of critical- and significant-risk results. Wayne, PA: CLSI GP47. 2015.

9. Wagar EA, et al. Critical values comparison: A College of American Pathologists Q-Probes survey of 163 clinical laboratories. Arch Pathol Lab Med. 2007;131:1769-1775.

10. Kost GJ. Co-creating critical limits for enhanced acute care: proven need and web knowledge base. Part 1: A call to action! *MLO* 2015. Dec;47(12):34, 36-37.

11. Kost GJ. Co-creating critical limits for enhanced acute care: proven need and web knowledge base. Part 2: Standard of care, what it means and how it is applied. *MLO* 2016. Jan;48(1):28-29.

12. Sun SP, Garcia J, Hayden JA. Repeat critical hematology and coagulation values wastes resources, lengthens turnaround time, and delays clinical action. *Am J Clin Path*. 2018;149(3);247-252.

CHILDREN

CLINICAL CHEMISTRY		LOW LIMIT		HIGH LIMIT	
Test	Units	Mean (SD)	Range	Mean (SD)	Range
Glucose	mmol/L	2.6 (0.5)	1.7-3.3	24.7 (8.9)	13.9-55.5
Potassium	mmol/L	2.8 (0.3)	2.0-3.5	6.4 (0.5)	5.0-8.0
Calcium	mmol/L	1.62 (0.17)	1.25-1.87	3.17 (0.22)	2.74-3.74
Sodium	mmol/L	121 (5)	110-130	156 (5)	150-170
CO_2 content	mmol/L	11 (2)	6-18	39 (3)	33-45
Magnesium	mmol/L	0.45 (0.04)	0.41-0.49	1.77 (0.45)	1.23-3.00
Phosphorus	mmol/L	0.42 (0.16)	0.16-0.65	2.87 (0.39)	2.26-3.23
Bilirubin	µmol/L	—	—	257 (68)	86-342
Chloride	mmol/L	77 (8)	70-90	121 (5)	115-130
Osmolality	mmol/kg	253 (12)	240-270	318 (10)	300-330
Urea nitrogen	mmol/L	—	—	19.6 (11.4)	3.9-53.6
Uric acid	µmol/L	—	—	714 (119)	595-892
CSF glucose	mmol/L	1.7 (0.7)	1.1-2.8	—	—
Creatinine	µmol/L	—	—	336 (212)	221-884
Ionized calcium[4]	mmol/L	0.85 (0.13)	0.60-1.08	1.53 (0.11)	1.35-1.75
Lactate	mmol/L	—	—	4.1 (1.2)	2.4-5.5
Albumin	g/L	17 (5)	10-25	68 (10)	60-80
Ammonia	µmol/L	—	—	109 (50)	35-200
Protein	g/L	34 (5)	30-40	95 (6)	90-100
CSF protein	mg/L	—	—	1875 (854)	1000-3000
HEMATOLOGY					
Hematocrit	L/L	0.20 (0.06)	0.10-0.30	0.62 (0.05)	0.54-0.70
Hemoglobin	g/L	69 (13)	50-100	208 (29)	170-250
Platelets	$\times 10^9$/L	53 (25)	20-100	916 (220)	600-1500
WBC count	$\times 10^9$/L	2.1 (0.9)	0.5-3.5	42.9 (25.1)	15.0-100.0
PT	s	—	—	21 (6)	15-35
PTT	s	—	—	62 (21)	40-100
Fibrinogen	g/L	0.77 (0.30)	0.20-12.0	—	—
Bleeding time	min	—	—	14.0 (4.0)	9.5-20.0
BLOOD GASES AND PH					
pCO_2	mm Hg	21 (6)	15-40	66 (23)	50-150
pH	—	7.21 (0.05)	7.10-7.30	7.59 (0.04)	7.50-7.70
pO_2	mm Hg	45 (7)	30-55	124 (25)	100-150

NEWBORN			LOW LIMIT		HIGH LIMIT	
Test	Facility	Units	Mean (SD)	Range	Mean (SD)	Range
Glucose	CH	mmol/L	1.8 (0.4)	1.1-2.8	18.2 (3.6)	16.7-27.8
Potassium	CH	mmol/L	2.8 (0.4)	2.5-3.7	7.8 (0.5)	6.5-8.0
Modified potassium	CH	mmol/L	2.8 (0.4)	2.5-3.7	6.5	(See Ref. 3)
Bilirubin	CH	µmol/L	—	—	222 (86)	86-308
Hemoglobin	USMC	g/L	95 (35)	50-150	223 (23)	210-250
Hematocrit	USMC	L/L	0.33 (0.08)	0.24-0.45	0.71 (0.04)	0.65-0.75
pO_2	USMC	mm Hg	37 (7)	30-50	92 (12)	70-100

Children and newborn tables modified with permission by ***Pediatrics***, Vol. 88, pp. 597-603, 1991. CSF, cerebrospinal fluid; WBC, white blood cell; PT, prothrombin time; PTT, partial thromboplastin time; CH, Children's Hospital; USMC, U.S. Medical Centers. Qualitative critical results for children[2] include the following: For ***hematology***—presence of blasts in the blood smear; new diagnosis or findings of leukemia; presence of drepanocytes (sickle cells); atypical lymphocytes, or abnormal reticulocyte count; abnormal erythrocyte indices (mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration). For ***clinical microscopy*** and ***urinalysis***—elevated white blood cells in cCSF; presence of malignant cells, blasts, or microorganisms in CSF or body fluids; combination of strongly positive test results for glucose and for ketones in urine. For ***microbiology*** and ***parasitology***—positive results from Gram stain or culture from blood, CSF, or body cavity fluid; presence of malarial parasites.

CUTOFF AND TOXICITY LEVELS FOR DRUGS-OF-ABUSE TESTING

This table summarizes information for the interpretation of drugs-of-abuse assays; originally developed by the late Daniel M. Baer, MD, and updated by Richard A. Paulson, MT(ASCP), supervisor of Chemistry and Toxicology, VA Medical Center, Portland, OR. The table was updated and reviewed this year by Allison B. Chambliss, PhD, DABCC, FACC, Director of Clinical Chemistry and Point of Care Testing, LAC and USC Medical Center, Assistant Professor of Clinical Pathology, Keck School of Medicine of USC (University of Southern California).

	Drug (and example trade names)	Common street names	Typical duration in urine after last dose	Common positive cutoff concentrations for urine screening assay*	Toxic blood level	Blood reference (therapeutic range)
OPIATES	Heroin (Diacetylmorphine)	Horse, Stuff, Smack, Junk	1-2 days (total opiate)	2000 ng/mL (as morphine) 150 ng/mL (as 6-monacetyle morphine)	>200 ng/mL	None detected
	Morphine (Duramorph)	M, Junk, Morpho, White stuff	2 days	2000 ng/mL 300 ng/mL	>200 ng/mL	10-80 ng/mL
	Methadone (Dolophine, Amidone)	Methadose	3 days	300 ng/mL 200 ng/mL 150 ng/mL	>2000 ng/mL	For narcotic stabilization: 300-1000 ng/mL For pain: 100-400 ng mL
	Meperidine (Demerol, Pethidine)	Fortis, Demies	2-3 days	200 ng/mL	>1000 ng/mL	70-500 ng/mL
	Codeine (Analgesics with codeine)	Rabo, School boy	2 days	2000 ng/mL 300 ng/mL	>1000 ng/mL	10-100 ng/mL
	Tramadol (Ultram, Tramal Ultracet)	Ultra T	6 hours to 2 days	Not established	Not established	Variable by patient
	Oxycodone (Oxycontin, OxyIR, Percocet, Percodan)	Oxy, OC, Oxycotton, Killer	1-3 days	100 ng/mL 300 ng/mL	>200 ng/mL	10-100 ng/mL
	Hydrocodone (Lorcet, Vicodin, Lortab, Hycodan)	Vikes, Hydro, Norco	1-2 days	300 ng/mL 100 ng/mL 50 ng/mL	>100 ng/mL	10-40 ng/mL
	Hydromorphone (Dilaudid)	Dust, Juice, Smack, D, Footballs	1-2 days	2000 ng/mL 300 ng/mL	>100 ng/mL	10-30 ng/mL
	Fentanyl (Sublimaze, Duragesic, Actiq, Fentora)	Percopop, Apache, China girl, China white, Dance fever, Friend, Goodfella, Jackpot, Murder 8, TNT, Tango and Cash	1-2 days	2 ng/mL 20 ng/mL	>34 ng/mL >3 ng/mL (naïve patients)	1-3 ng/mL (highly variable; depends on dose and route of administration)
HALLUCINOGENS	Lysergic acid, diethylamide (LSD	Acid, Microdot, White lightning	1-5 days	0.5 ng/mL 100 pg/mL	>2 ng/mL	None detected
	Marijuana and cannabinoids	Weed, Mary Jane, Hashish, Bhang, Ganja, Sensemilla	Single use: 2-7 days (as Δ9-THC-COOH) Prolonged use: 1-2 months (as Δ9-THC-COOH)	15-100 ng/mL	50-200 ng/mL	None detected
	Phencyclidine	PCP, Angel dust, Killer weed, Hog	Single use: 1 week Prolonged use: 2-4 weeks	25 ng/mL	100 ng/mL	None detected
STIMULANTS	Cocaine	Coke, Crack, Flake, Snow	Single use: 1-3 days Prolonged use: 4 days	300 ng/mL 150 ng/mL (as metabolite benzoylecgonine)	>1000 ng/mL	100-500 ng/mL
	Amphetamine (Benzedrine, Dexedrine)	Speed, Bennies, Uppers, Dexies	Single use: 48 hours Prolonged use: 7-10 days	500 ng/mL 1000 ng/mL	>200 ng/mL	20-30 ng/mL
	Methylene-3,4 dioxy-Methamphetamine (MDMA)	Ecstasy, Adam, XTC, Love drug, Hug drug	Single use: 24 hours	300 ng/mL 500 ng/mL	100-1000 ng/mL	20-30 ng/mL
	Methamphetamine (Desoxyn, Methedrine)	Speed, Meth, Crystal ice, Crank	Single use: 48 hours Prolonged use: 7-10 days	500 ng/mL 1000 ng/mL	>500 ng/mL	10-50 ng/mL

*Based on common screening assays currently in use (2019) and CAP Proficiency Testing reporting (2009-2019) unless otherwise indicated.
Confirmation results by Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography-Mass Spectrometry/Mass Spectrometry (LC-MS/MS) vary by laboratory.

	Drug (and example trade names)	Common street names	Typical duration in urine after last dose	Common positive cutoff concentrations for urine screening assay*	Toxic blood level	Blood reference (therapeutic range)
BARBITURATES	Pentobarbital (Nembutal)	Goof balls, Downers, Nembies, Yellow jackets, Yellow submarine	2 days	300 ng/mL 200 ng/mL	>10 µg/mL	1-5 µg/mL
	Secobarbital (Seconal)	Bullets, Pink ladies, Reds	2 days	300 ng/mL 200 ng/mL	>5 µg/mL	1-2 µg/mL
	Butabarbital (Butisol)	Goof balls, Candy, Peanuts, Stoppers	2 days	300 ng/mL 200 ng/mL	20 µg/mL	3-25 µg/mL
	Butalbital (Fiorinal)	Goof balls, Sleepers, Stoppers, Peanuts	2 days	300 ng/mL 200 ng/mL	20 µg/mL	5-15 µg/mL
	Phenobarbital	Barbs, Downers	1-3 weeks	300 ng/mL 200 ng/mL	>40 µg/mL	10-40 µg/ml
ALCOHOLS, DIOLS, & METABOLITES	Ethanol	Booze, Hooch	<1 day	10 mg/dL	80-400 mg/dL	100-150 mg/dL (for treatment of toxic alcohols)
	Methanol	Wood alcohol	<1 day	5 mg/dL (GC)	>20 mg/dL	<0.15 mg/dL
	Isopropanol	Rubbing alcohol	<1 day	5 mg/dL (GC)	>50 mg/dL	None detected
	Acetone		<1 day	5 mg/dL (GC)	>33 mg/dL	<1.0 mg/dL
	Ethylene Glycol	Antifreeze	<1 day	5 mg/dL (GC)	>50 mg/dL	None detected
SEDATIVES/HYPNOTICS/ANESTHETICS	Diazepam (Valium)	Tranks, Downers, Blues, Yellows, Blue Magoo, V	Single use: Not detected Prolonged use: 5-7 days (up to 30 days)	300 ng/mL 200 ng/mL 150 ng/mL	Drug plus Metabolite: >5.0 µg/mL	Drug plus Metabolite: 0.1-1.0 µg/mL
	Oxazepam (Serax)	Tranks, Downers, Blues, Yellows,	Single use: Not detected Prolonged use: 5-7 days	300 ng/mL 200 ng/mL 150 ng/mL	>2.0 µg/mL	0.2-1.4 µg/mL
	Alprazolam (Xanax)	Tranks, Downers, Blues, Yellows	Single use: Not detected Prolonged use: 5-7 days	300 ng/mL 200 ng/mL 150 ng/mL	>350 ng/mL	20-30 ng/mL
	Clonazepam (Klonopin)	Tranks, Downers, Blues, Yellows	Single use: Not detected Prolonged use: 5-14 days	300 ng/mL 200 ng/mL 150 ng/mL	>80 ng/mL	20-70 ng/mL
	Chlordiazepoxide (Librium)	Tranks, Downers, Blues, Yellows	Single use: Not detected Prolonged use: 5-7 days	300 ng/mL 200 ng/mL 150 ng/mL	>5 µg/mL	0.7-1.0 µg/mL
	Lorazepam (Ativan, Loraz)	Tranks, Downers, Blues, Yellows	Single use: Not detected Prolonged use: 5-7 days	300 ng/mL 200 ng/mL 150 ng/mL	0.3-0.6 µg/mL	50-240 ng/mL
	Flunitrazepam (Rohypnol)	Roofies, Rib, Rope, Roach-2, R-2	72 hours	0.1-60 ng/mL (immunoassay)	50 ng/mL	5-15 ng/mL
	Gamma-Hydroxybutyrate (Somatomax)	GHB, G-Caps Geebers, Fantasy, Liquid Ecstasy	12 hours	1-10 mg/L (GC; GC-MS)	>250 mg/L	48-125 mg/L (for narcolepsy)
	Ketamine Hydrochloride (Ketajet)	Special K, Lady Kay, Vitamin K, Jet, Cat Valium	<72 hours	5-10 ng/mL (GC-MS)	>7-27 µg/mL (highly variable)	0.5-5.0 µg/mL

Specimen	Test	Conventional Units	Conversion Factor (multiply by)	SI Units
S	Albumin*	3.5-5.2 g/dL	10	35-52 g/L
B	Base excess (men)	-3.3 to +1.2 mmol/L	1	-3.3 to +1.2 mmol/L
B	Base excess (women)	-2.4 to +2.3 mmol/L	1	-2.4 to +2.3 mmol/L
P	Bicarbonate	21-29 mmol/L	1	21-29 mmol/L
S/P	Bilirubin, conjugated*	0.0-0.2 mg/dL	17.1	0.0-3.4 µmol/L
S/P	Bilirubin, total*	0.0-2.0 mg/dL	17.1	0.0-34 µmol/L
S/P	Calcium, total	8.6-10.3 mg/dL	0.25	2.15-2.57 mmol/L
S/P	CO_2 content, venous	22-26 mmol/L	1	23-26 mmol/L
P	Chloride*	98-107 mEq/L	1	98-107 mmol/L
S/P	Cholesterol (NCEP recommendation)	140-200 mg/dL	0.0259	3.6-5.2 mmol/L
S	Cortisol (a.m.)*	5-23 µg/dL	27.6	138-635 nmol/L
S	Creatinine (Jaffe, men)*	0.9-1.3 mg/dL	88.4	80-115 µmol/L
S	Creatinine (Jaffe, women)*	0.6-1.1 mg/dL	88.4	53-97 µmol/L
S	Ferritin (men)*	20-250 ng/mL	1	20-250 µg/L
S	Ferritin (women)*	10-120 ng/mL	1	10-120 µg/L
P	Fibrinogen	200-400 mg/dL	0.01	2-4 g/L
S	Folate	2.6-12.2 ng/mL	2.265	6.0-28.0 nmol/L
S	Glucose, fasting*	74-100 mg/dL	0.0555	4.1-5.6 mmol/L
S	Haptoglobin*	30-200 mg/dL	0.01	0.3-2.0 g/L
B	Hematocrit (men)*	40.0-52.0 %	0.01	0.40-0.52 Vol fraction
B	Hematocrit (women)*	35.0-47.0 %	0.01	0.35-0.47 Vol fraction
B	Hemoglobin (men)*	14-18 g/dL	10	140-180 g/L
B	Hemoglobin (women)*	12-16 g/dL	10	120-160 g/L
S/P	Iron, total	60-150 µg/dL	0.179	10.7-26.9 µmol/L
S/P	Iron binding capacity	250-400 µg/dL	0.179	44.8-71.6 µmol/L
B	Lactate (venous)	5-12 mg/dL	0.111	0.36-0.75 mmol/L
B	Lead	<5 µg/dL	0.048	<0.24 µmol/L
S/P	Lithium, therapeutic	0.5-1.2 mEq/L	1	0.5-1.2 mmol/L
S	Magnesium*	1.7-2.4 mEq/L	0.4114	0.70-0.99 mmol/L
B	MCH (RBC index)	28.0-32.0 pg/cell	1	28.0-32.0 pg/cell
B	MCHC (RBC index)	32.0-36.0 %	10	0.32-0.36 g/L
B	MCV (RBC index)	83.0-95.0 fL	1	83.0-95.0 fL
S/P	Osmolality	270-295 m0sm/kg	1	270-295 mmol/kg
B	pCO_2 (arterial) (men)	35-48 mm Hg	0.133	4.7-6.4 kPa
B	pCO_2 (arterial) (women)	32-45 mm Hg	0.133	4.3-6.0 kPa
B	pH (arterial)*	7.35-7.45	1	7.35-7.45
S/P	Phosphate (as P)*	2.5-4.5 mg/dL	0.323	0.81-1.45 mmol/L
B	pO_2 (arterial)	83-108 mm Hg	0.133	11.0-14.4 kPa
B	Platelet count	150-450 $10^3/mm^3$	1	150-450 $10^9/L$
P	Potassium (men)*	3.5-4.5 mEq/L	1	3.5-4.5 mmol/L
P	Potassium (women)*	3.4-4.4 mEq/L	1	3.4-4.4 mmol/L
S	Protein, total (recumbent)	6.0-7.8 g/dL	10	60-78 g/L
B	RBC count (men)*	4.6-6.2 $10^6/mm^3$	1	4.6-6.2 $10^{12}/L$
B	RBC count (women)*	4.2-5.2 $10^6/mm^3$	1	4.2-5.2 $10^{12}/L$
S	Sodium	136-145 mEq/L	1	136-145 mmol/L
S	Thyroxine, free*	0.8-2.7 ng/dL	12.9	10.3-34.7 pmol/L
S	Thyroxine (T4), total (men)*	4.6-10.5 µg/dL	12.9	59-135 nmol/L
S	Thyroxine (T4), total (women)*	5.5-11 µg/dL	12.9	65-138 nmol/L
S	Triglyceride (NCEP recommendation)	10-150 mg/dL	0.0113	0.11-1.7 mmol/L
S	Urea nitrogen (BUN)*	6-20 mg/dL	0.357	2.1-7.1 mmol/L
S	Uric acid (men)*	4.4-7.6 mg/dL	0.059	0.26-0.45 mmol/L
S	Uric acid (women)*	2.3-6.6 mg/dL	0.059	0.13-0.39 mmol/L
S	Vitamin B_{12}	206-678 pg/mL	0.733	151-497 pmol/L
S	Vitamin D (25-OH)	10-65 ng/ml	2.50	25-162 nmol/L
B	WBC count	4-11 $10^3/mm^3$	1	4-11 $10^9/L$
S	Zinc	80-120 µg/dL	0.153	12-18 µmol/L

Specimens: B, whole blood; P, plasma; S, serum. Reference intervals depend on test method and the demographics of the normal population used.
*Adult intervals (18Y-60Y). Age specific ranges apply for pediatric and/or geriatric populations.
Source: Burtis CA, Bruns DE. *Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics.* 7th ed. St. Louis, MO; Elsevier; 2015 and McPherson RA, Pincus MR. *Henry's Clinical Diagnosis and Management by Laboratory Methods.* 22nd ed. Philadelphia, PA: Elsevier Saunders; 22nd ed; 2011. Revised 2019 by S.T. Campbell, PhD, Department of Pathology, Montefiore Medical Center, Bronx, NY.

The concept of critical values for drug levels was originally developed by the late Daniel M. Baer, MD, and first published in the April 1982 issue of *MLO*. This table is an expanded version of that publication and newly revised for 2019-2020 by Steven W. Cotten PhD, DABCC, FAACC, Assistant Professor in Pathology and Laboratory Medicine, University of North Carolina at Chapel Hill.

Drug	Indication	Therapeutic Range	Critical Value	Comments
Acetaminophen	Analgesic	5-20 µg/mL	>200 µg/mL *drawn 4 hours after ingestion	*Determination if a concentration is toxic is dependent upon when it is drawn in relation to the time of ingestion of the dose. Multiple serum concentrations will be needed to monitor improvement and removal of drug.
Amikacin	Antimicrobial	Peak: 15-30 µg/mL Trough: 4-8 µg/mL	>10 µg/mL	Peak: 30 minutes after end of infusion. Trough: before next dose. Conventional dosing protocol.
Amiodarone	Antiarrhythmic	0.5-2 µg/mL	>2.5 µg/mL	Trough concentration. Serum amiodarone levels >2.5 µg/mL had a positive predictive value of 76% for adverse drug events.
Amitriptyline	Antidepressant/ analgesic (neuropathic pain)	125-250 ng/mL	>500 ng/mL	Trough concentration. Life threatening cardiac toxicity and/or seizures with concentration >1000 ng/mL.
Busulfan (IV)	Anti-leukemic, Hematopoietic cell transplantation conditioning	900-1350 µmol/min	>1500 µmol/min	Area Under the Curve (AUC) calculations based on post-infusion sampling and dosing protocols vary by institution.
Carbamazepine	Antiepileptic/ mood stabilizer	4-12 µg/mL	>20 µg/mL	Trough concentrations. Correlate serum concentration with clinical presentation.
Cyclosporine	Immunosuppressant	100-400 ng/mL	>500 ng/mL	Specific concentration goal dependent upon clinical situation. For concentrations drawn with intravenous therapy, blood should be drawn from site other than that where drug is infusing. (Cyclosporine adheres to plastic.) TDM levels are dependent on transplant type. Blood concentrations can be method (immunoassay or mass spectrometry) dependent.
Digoxin	Inotrope, AV node blocker	0.5-2.0 ng/mL*	>2.5 ng/mL	Samples should be drawn >8 hours after last dose. *Concentrations >1.5 ng/mL may be associated with higher mortality.
Doxepin	Antidepressant	110-250 ng/mL	>500 ng/mL	Trough concentration.
Ethosuximide	Antiepileptic	40-100 µg/mL	>200 µg/mL	Trough concentration.
Everolimus	Immunosuppressant	3-8 ng/mL	>15 ng/mL	Trough concentration. Varies by transplant protocol.
Flecainide	Antiarrhythmic	0.2-1.0 µg/mL	>1.0 µg/mL	Midpoint or trough concentration. Monitoring recommended when given concurrently with medications that may decrease metabolism (increase concentrations).
Fluconazole	Antifungal	4.0-20.0 µg/mL	None established	Limited TDM utility except in patients receiving hemodialysis.
Flucytosine	Antifungal	25-50 µg/mL	>100-200 µg/mL	Concentration should be a peak drawn 2 hours post dose.
Gentamicin	Antimicrobial	Peak: 5-10 µg/mL Trough: <2 µg/mL	Peak: >12 µg/mL Trough: >2 µg/mL	Peak: 1 hour after infusion. Trough: before next dose. Conventional dosing protocol.
Hydroxyl itraconazole	Antifungal	Not established	None established	Active metabolite of itraconazole.
Imipramine	Antidepressant	>180-240 ng/mL	>500 ng/mL	Concentration = imipramine + desipramine (metabolite).
Itraconazole	Antifungal	>0.5 ug/mL (localized) >1.0 ug/mL (systemic)	None established	Large PK variability. Should be measured within 5-7 after initiation of therapy.
Lamotrigine	Antiepileptic/mood stabilizer	1-15 µg/mL	>20 µg/mL	Trough concentration. High concentrations generally associated with increased somnolence/confusion.
Lidocaine	Antiarrhythmic	1.5-5 µg/mL	>6 µg/mL	Concentration can be drawn at any point (from separate IV line).
Lithium	Mood stabilizer	Acute: 1-1.6 mmol/L Chronic: 0.6-1.2 mmol/L	>2.0 mmol/L >5 mmol/L potentially fatal	Serum concentrations may increase in presence of hyponatremia. Concentration: 12 hours after dose.
Nortriptyline	Antidepressant/ analgesic (neuropathic pain)	50-150 ng/mL	>500 ng/mL	Trough concentration.
Phenobarbital	Antiepileptic	15-40 µg/mL	>60 µg/mL	Trough concentration. Do not collect before steady state achieved.
Phenytoin	Antiepileptic	10-20 µg/mL	>20 µg/mL	Trough concentrations. Toxic >20 µg/mL (lateral nystagmus), >40 µg/mL (decreased mentation). Toxicity may occur at lower concentrations in presence of hypoalbuminemia. Consider free phenytoin.
Posaconazole	Antifungal	>0.7 µg/mL	None established	Should be measured within 7 days of initiation therapy.
Primidone	Antiepileptic	5-12 µg/mL	>15 µg/mL	Metabolized to phenobarbital.
Procainamide (PA) (metabolite: NAPA)	Antiarrhythmic	PA: 4-8 µg/mL NAPA: 10-20 µg/mL	>10 µg/mL >40 µg/mL	Mid-point or trough concentration. Procainamide monitoring is particularly important in patients who might be fast acetylators (60% to 70% of northern Europeans, and 50% of black and white Americans) and in patients with renal impairment. Procainamide and N-acetylprocainamide levels should always be measured on the same sample.
Protriptyline	Antidepressant	50-170 ng/mL	>500 ng/mL	Trough concentration.
Quinidine	Antiarrhythmic	2-5 µg/mL	>6 µg/mL	Midpoint or trough concentration.
Salicylate	Analgesic, antipyresis Anti-inflammatory	20-100 µg/mL 100-200 µg/mL	Vertigo, tinnitus 150-300 µg/mL Nausea, vomiting, hyper-ventilation 250-400 µg/mL Toxicity >500 µg/mL	Serum concentration should be used in conjunction with clinical presentation to make decision on therapy. Multiple serum concentrations will be necessary to monitor improvement and removal of drug.
Sirolimus	Immunosuppressant	4-20 ng/mL	>25 µg/mL	Trough concentration. Whole blood samples. Therapeutic levels can be lower when used in combination with other immunosuppresants. Blood concentrations can be method (immunoassay or mass spectrometry) dependent. Therapeutic levels depend on type of transplant, time post transplant, and other concomitant drug therapy.
Tacrolimus	Immunosuppressant	5-20 ng/mL	>25 ng/mL	Whole blood samples collected as trough. Therapeutic levels can be lower when used in combination with other immunosuppressants. Bias may be present between immunoassay and LC/MS methods.
Theophylline	Bronchodilator	10-20 µg/mL	>25 µg/mL	Pulmonary literature suggest that concentrations 5-15 mg/L may be as efficacious with less toxicity. Trough concentration dependent upon drug formulation.
Tobramycin	Antibacterial	Peak: 4-8 µg/mL Trough: <1.0 µg/mL	>12 µg/mL >2 µg/mL	Peak: 1 hour after end of infusion. Trough: before next dose. Conventional dosing protocol.
Valproic acid	Antiepileptic/mood stabilizer	50-125 µg/mL	>200 µg/mL	Toxicity may occur at lower concentrations in presence of hypoalbuminemia. Consider free valproic acid. Trough concentration preferred.
Vancomycin	Antimicrobial	Trough concentrations: General: 5-15 µg/mL Pneumonia: 15-20 µg/mL	Trough: >30 µg/mL	Monitoring of peaks no longer recommended. Goal trough concentration dependent upon indication. Trough: before next dose.
Voriconazole	Antifungal	1.0-5.5 µg/mL	>6 µg/mL	Should be measured within 7 days of initiation therapy.

Ranges are approximate and may vary with laboratory and/or assay. Proper interpretation of therapeutic drug concentrations requires that the specimen be drawn at an appropriate time in relation to drug administration.

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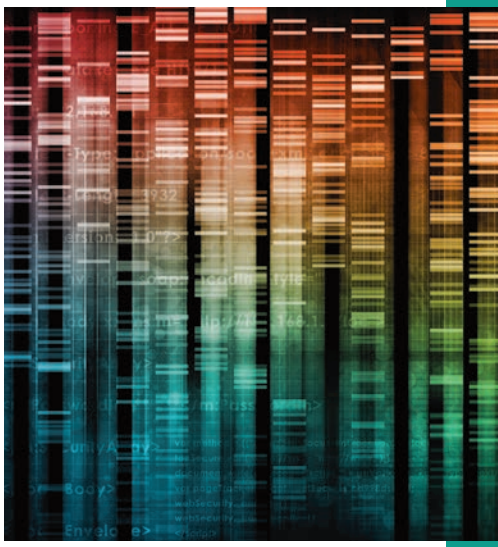

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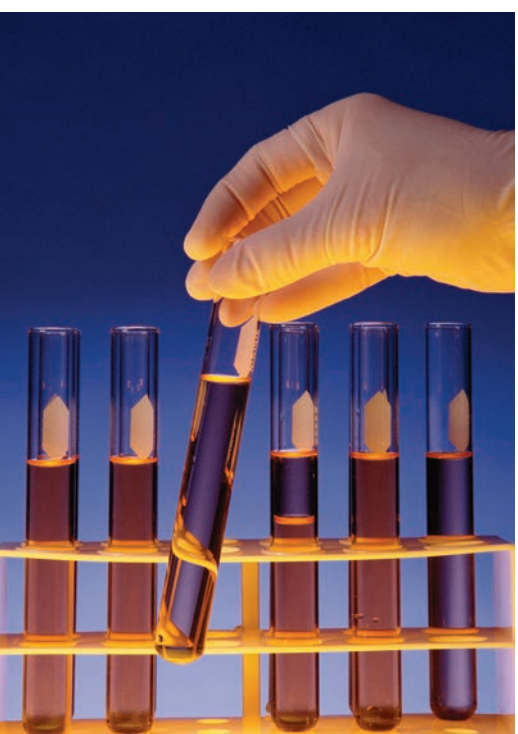

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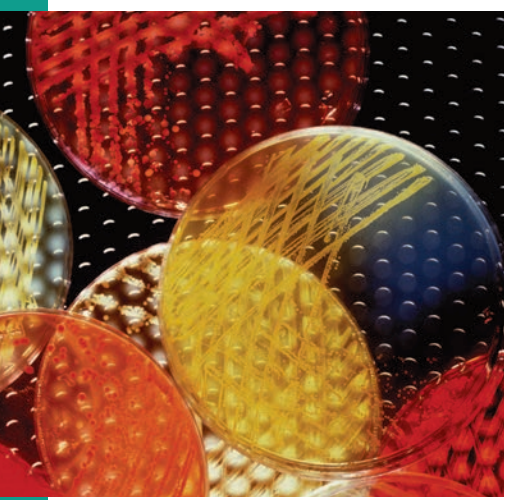

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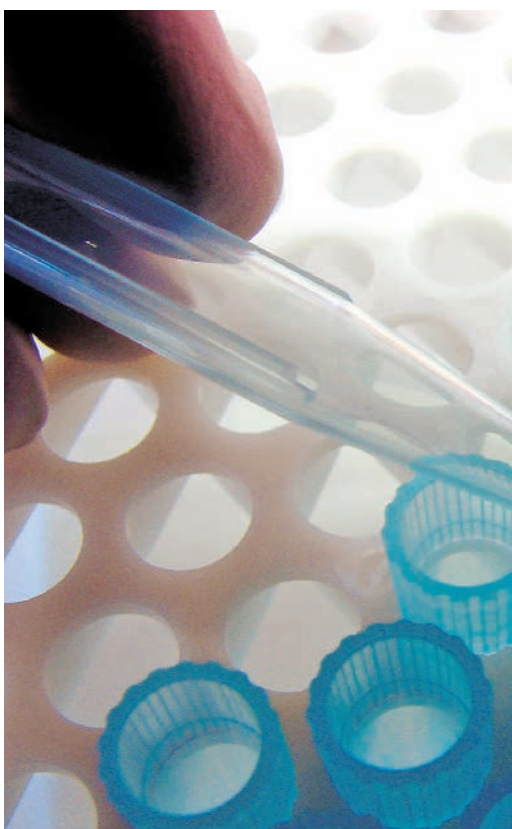

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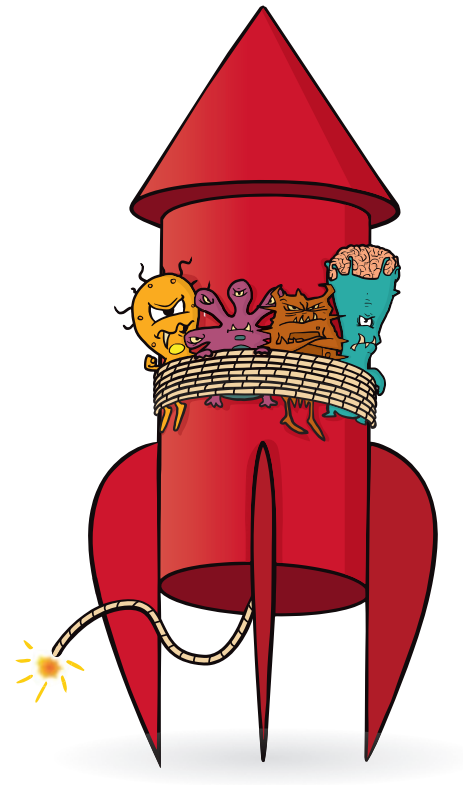

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