TABLE OF CRITICAL LIMITS

ADULT											
CLINICAL CHEMISTRY		LOW L	IMIT	HIGH L	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						
lonized 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	×10 ⁹ /L	37 (18)	10-100	910 (147)	555-1000						
WBC count	×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						
рН		7.21 (0.06)	7.00-7.35	7.59 (0.03)	7.50-7.65						
p0 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 adults¹ 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, *Haemophilus 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.

ritical 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 lifethreatening 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 GP478 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 dis-cussed 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.

 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.

 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		Y	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				
$\rm CO_2$ 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				
lonized 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				
HEMATOLOG	Y									
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		×10 ⁹ /L	53 (25)	20-100	916 (220)	600-1500				
WBC count		×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				
рН		_	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	СН	mmol/L	1.8 (0.4)	1.1-2.8	18.2 (3.6)	16.7-27.8				
Potassium	СН	mmol/L	2.8 (0.4)	2.5-3.7	7.8 (0.5)	6.5-8.0				
Modified potassium	СН	mmol/L	2.8 (0.4)	2.5-3.7	6.5	(See Ref. 3)				
Bilirubin	СН	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				
p0,	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 children² 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.