

ADULTS ¹					
CLINICAL CHEMISTRY		LOW LIMIT		HIGH LIMIT	
Test	Units	Mean (SD)	Range	Mean (SD)	Range
Glucose	mmol/L	2.6 (0.4)	1.7-3.9	26.9 (8.0)	6.1-55.5
	mg/dL	46 (7)	30-70	484 (144)	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	1.65 (0.17)	1.25-2.15	3.22 (0.22)	2.62-3.49
	mg/dL	6.6 (0.7)	5.0-8.6	12.9 (0.9)	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	0.41 (0.16)	0.21-0.74	2.02 (0.82)	1.03-5.02
	mg/dL	1.0 (0.4)	0.5-1.8	4.9 (2.0)	2.5-12.2
Phosphorus	mmol/L	0.39 (0.10)	0.26-0.65	2.87 (0.48)	2.26-3.23
	mg/dL	1.2 (0.3)	0.8-2.0	8.9 (1.5)	7.0-10.0
Bilirubin	μmol/L	—	—	257 (86)	86-513
	mg/dL	—	—	15 (5)	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	—	—	37.1 (21.1)	14.3-107.1
	mg/dL	—	—	104 (59)	40-300
Uric acid	μmol/L	—	—	773 (119)	595-892
	mg/dL	—	—	13 (2)	10-15
CSF glucose	mmol/L	2.1 (0.6)	1.1-2.8	24.3 (11.4)	13.9-38.9
	mg/dL	37 (10)	20-50	438 (206)	250-700
Creatinine	μmol/L	—	—	654 (380)	177-1326
	mg/dL	—	—	7.4 (4.3)	2.0-15.0
Ionized calcium ⁴	mmol/L	0.82 (0.14)	0.50-1.07	1.55 (0.19)	1.30-2.00
	mg/dL	3.29 (0.56)	2.00-4.29	6.21 (0.76)	5.21-8.02
Lactate	mmol/L	—	—	3.4 (1.3)	2.3-5.0
	mg/dL	—	—	30.6 (11.7)	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
pH		7.21 (0.06)	7.00-7.35	7.59 (0.03)	7.50-7.65
pO ₂	mm Hg	43 (6)	30-55	—	—
	kPa	5.7 (0.8)	4.0-7.3	—	—

1. 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.

2. 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.

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.

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 Dr. Kost and Kristin N. Hale investigate trends in critical values practices including improving preanalytical processing; streamlining urgent notification; assuring effective critical limits; assessing decision levels; and using visual logistics. Special considerations for pediatrics are addressed since newborns/neonates 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 laboratories 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 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 will be difficult to explain to a jury.

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CHILDREN ²						
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	×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	
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 ²						
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