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DEPARTMENTS

FEATURES

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HOW TO USE CLR

REFERENCE GUIDES

CLR is an annual supplement provided by MLO reflecting peer-reviewed clinical laboratory reference guides, as well as market resources available to clinical laboratorians.

PRODUCT INFORMATION

The product information section includes company descriptions, their essential laboratory products, and contact information for pricing and ordering.

INDEX OF TESTS, EQUIPMENT, AND SERVICES

The alphabetical index conveniently categorizes and cross-references laboratory products by test names, equipment types, and services provided.

READER FEEDBACK

Visit CLR-online.com to access the digital version. Subscribe to receive future CLR supplements here: https://www.mlo-online.com/subscribe/

Publishing information to help guide patient care

Medical Laboratory Observer (MLO) has been committed to producing clinical reference tables for laboratories since 1972. The 2022-23 edition of CLR celebrates 50 years of providing this valuable resource to our readers!

Critical limits and reference intervals help laboratorians interpret test results. Critical limits establish the upper and lower values that indicate when a patient's medical condition may be precarious, requiring the immediate attention of the provider who ordered the test. Reference intervals are the most common decision support tool for interpreting pathology reports, as patients' test results are compared to these ranges to indicate normal results or those that may require clinical follow-up. These decision tools assist in one of the top goals in healthcare: timely communication.

For 15 years, I was a writer and editor of accreditation standards at The Joint Commission. In our Special Feature this month, I summarized the top 10 Joint Commission requirements and top 10 CLIA requirements that were found on laboratory surveys last year. The fifth top-scored requirement by The Joint Commission was a National Patient Safety Goal (NPSG) on improving the effectiveness of communication among healthcare staff. Specifically, this NPSG addresses the reporting of critical results of tests and diagnostic procedures on a timely basis. Having decision support tools readily accesssible is a first step in preventing communication breakdowns that can contribute to missed opportunities for patient care.

As is the case every year, the editors at *MLO* would not have been able to produce this year's CLR issue without the help from experts such as the following:

- Gerald J. Kost, MD, PhD, MS, FACB, of the University of California-Davis Health System, for the Table of Critical Limits.
- Allison B. Chambliss, PhD, DABCC, FAACC, Director of Clinical Chemistry and Point of Care Testing, LAC and USC Medical Center and Assistant Professor of Clinical Pathology, Keck School of Medicine at USC (University of Southern California) for the Cutoff and Toxicity Levels for Drugs-of-Abuse and Toxicology Testing chart.
- S.T. Campbell, PhD, DABCC, FAACC, Department of Pathology, Montefiore Medical Center, Bronx, NY, for the Table of Reference Intervals.
- Steven W. Cotton, PhD, DABCC, FAACC, Assistant Professor in Pathology and Laboratory Medicine at the University of North Carolina, Chapel Hill, for the chart on Critical Values for Therapeutic Drug Levels.

We hope our readers find this resource beneficial. For the online version of CLR, please visit www.clr-online.com

As always, the editors at *MLO* are open to conversations with readers about information or suggestions to improve the charts and other content we publish in CLR. Please feel free to reach out to me at cwichmann@mlo-online.com.

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Top 10 laboratory survey findings

By Christina Wichmann

Before joining MLO, I was the editor of all the accreditation and certification standards published by The Joint Commission. I am probably one of the few people in the world who has read every single Joint Commission standard! I also helped coordinate applications and follow-up activities for deeming approval with the Centers for Medicare & Medicaid Services (CMS); in addition, I kept colleagues apprised of regulation changes such as CLIA. This spring, both The Joint Commission and CMS published their top ten findings on laboratory surveys, which we have summarized for you below.

Table 1 summarizes the 2021 top ten findings on Joint Commission surveys. **Table 2** summarizes the top ten CLIA deficiencies found on CMS surveys. For those who may not be familiar with The Joint Commission's accreditation requirements, the standards are an overarching statement. Under standards are a series of elements of performance, which are called EPs for short. These reflect some kind of action the organization takes and are the scorable part of a standard. CLIA regulations are written pretty broadly. More details on these regulations are on the CMS website in the State Operations Manual (SOM).[1] The SOM provides interpretive guidelines and survey procedures for each regulation.

Table 1. Summary of top ten 2021 Joint Commission survey findings[2]	
1 QSA.01.02.01, EP 2:	The laboratory conducts an investigation, performs corrective action, and maintains records of unacceptable results, late submissions, and lack of consensus in its proficiency testing program.
2 QSA.02.08.01, EP 2:	Every six months, the laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.
3 HR.01.06.01, EP 18:	Staff members' competency assessments include direct observations of them performing routine patient tests, reporting test results, and performing instrument function checks and calibration.
4 QSA.02.11.01, EP 7:	As part of its quality control program, the laboratory reviews records such as equipment records and quality control summaries at least monthly.
5 NPSG.02.03.01, EP 2:	Implement procedures for reporting critical results of tests and diagnostic procedures.
6 HR.01.06.01, EP 20:	Each staff member's competence is assessed on an annual basis.
7 LD.04.05.07, EP 4:	The laboratory director or technical supervisor reviews quality control and proficiency testing data, requires corrective action on unacceptable results, and discusses issues with staff.
8 EC.02.04.03, EP 7:	The laboratory inspects, tests, and maintains all laboratory equipment.
9 HR.01.06.01, EP 3:	A qualified individual assesses a skill for staff competence.
10 QSA.05.18.01, EP 7:	The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events.

Table 2. Summary of top ten 2021 CLIA deficiencies from CMS surveys[3]	
1 **493.1235: Personnel Competency Assessment**	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.
2 **493.1236(c)(1): General Lab Systems**	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented.
3 **493.1236(c)(1): General Lab Systems**	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I or this part.
4 **493.1253(b)(1): Verification of Performance Specifications**	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate that it can obtain performance specifications comparable to those established by the manufacturer.
5 **493.1251(b): Analytic Systems**	The procedure manual must include the requirements for specimen acceptability, microscopic examination, step-by-step performance of the procedure, preparation of materials for testing, etc.
6 **493.1251(a): Procedure Manual**	Written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.
7 **493.1254(a)(1): Analytic Systems**	Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.
8 **493.1252(d): Analytic Systems**	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.
9 **493.1291(c): Post Analytic Systems**	The test report must indicate the following: for positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number, the name and address of the laboratory location where the test was performed, and other requirements specified in 493.1291(c).
10 **493.1407(e) (4)(i): Laboratory Director's Responsibility**	Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that the proficiency testing samples are tested as required under subpart H of this part.

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MEDICAL LABORATORY OBSERVER

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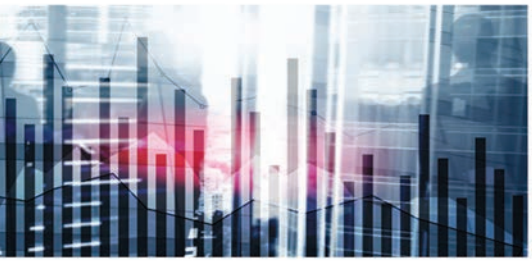
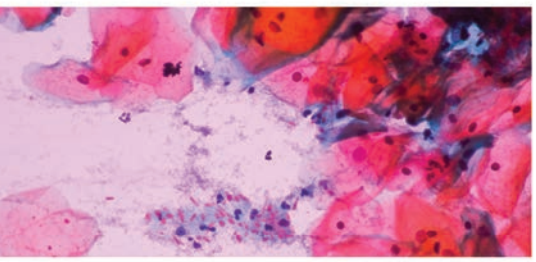


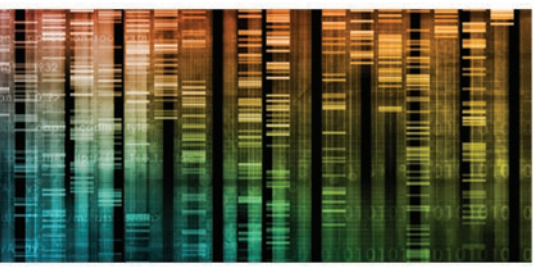
March
"Technology & Trends in the Clinical Lab"

Our editors present findings from our special report on Informatics in the Laboratory, with its focus on using valuable clinical analytics to inform the decision-making process in the lab. The presentation includes additional information on valuable solutions for healthcare laboratories.



June
"Lab Accreditation & MDx Workflow"

MLO presents an overview on maintaining practices that follow accreditation standards. What are the top laboratory deficiencies? How can workflow solutions help you address molecular diagnostic challenges? Do you have sufficient training in place to ensure your staff is confident and competent in their job?



November
"Molecular Diagnostics for the Future Clinical Lab"

Using data gathered from our exclusive State of the Industry report on Molecular Diagnostics published in the November issue of MLO, we will explore the increasing roles of MDx and its solutions use in the clinical laboratory.

https://endeavor.swoogo.com/mlo_forum/about

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 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 mentioning standard of care for reporting times in a table, the CLSI guideline does not adequately address, analyze, or compare standards of care in different countries.

A challenge is the harmonization of actual quantitative and qualitative triggers for emergency notifications, not just terminology. The reader can purchase GP47[8] 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 in recent MLO articles,[10-11] courts may not deem such Q-Probes subscriber data admissible in establishing the standard of care during litigation. Complexities of categories and how individual tests with thresholds are assigned to each of the three categories is 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]

It is recommended that a positive test for COVID-19 be added to critical value for infectious disease.

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CHILDREN

CLINICAL CHEMISTRY	Units	LOW LIMIT Mean (SD)	LOW LIMIT Range	HIGH LIMIT Mean (SD)	HIGH LIMIT 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	Facility	Units	LOW LIMIT Mean (SD)	LOW LIMIT Range	HIGH LIMIT Mean (SD)	HIGH LIMIT 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 AND TOXICOLOGY TESTING

This table summarizes information for the interpretation of drugs-of-abuse toxicology 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, FAACC, 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, Smack, Junk, Brown Sugar, China White, H, Skag, White Horse, Skunk	1-2 days	2000 ng/mL (as morphine) 150 ng/mL (for 6-monoacetylmorphine)	>200 ng/mL	None detected
	Morphine (Duramorph)	M, White stuff, Miss Emma, Monkey	2 days	2000 ng/mL 300 ng/mL	>200 ng/mL	10-80 ng/mL
	Methadone (Dolophine)	Fizzies with MDMA Chocolate Chip Cookies, Amidone	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)	Demmies, Pain Killer	2-3 days	200 ng/mL	>1000 ng/mL	70-500 ng/mL
	Codeine (Analgesics with codeine)	School boy, Captain Cody, Cody, Lean, Sizzurp,	2 days	2000 ng/mL 300 ng/mL	>1000 ng/mL	10-100 ng/mL
	Tramadol[1] (Ultram, Tramal Ultracet)	Ultra T	6 hours to 2 days	200 ng/mL	>1000 ng/mL	100-800 ng/mL, variable by patient and dosing regimen
	Oxycodone (Oxycontin, OxyIR, Percocet, Percodan)	Oxy, Oxycotton, O.C., Oxycet, Hillbilly Heroin, Percs	1-3 days	100 ng/mL 300 ng/mL	>200 ng/mL	10-100 ng/mL
	Hydrocodone (Lorcet, Vicodin, Lortab, Hycodan)	Vikes, Watson-387	1-2 days	300 ng/mL 100 ng/mL 50 ng/mL	>100 ng/mL	10-40 ng/mL
	Hydromorphone (Dilaudid)	Juice, Smack, D, Footballs, Dillies	1-2 days	2000 ng/mL 300 ng/mL	>100 ng/mL	10-30 ng/mL
	Fentanyl[2] (Sublimaze, Duragesic, Actiq, Fentora)	Apache, China girl, China white, Dance fever, Friend, Goodfella, Jackpot,Murder 8, TNT, Tango and Cash	1-2 days	1 ng/mL 2 ng/mL	>3 ng/mL (naïve patients)	0.6-3.0 ng/mL (highly variable; depends on dose and route of administration)
HALLUCINOGENS	Lysergic acid diethylamide (LSD)	Acid, Blotter, Boomers, Cid, Golden Dragon, Looney Tunes, Lucy Mae, Microdots, Tabs, Yellow Sunshine	1-5 days	0.5 ng/mL 100 pg/mL	>2 ng/mL	None detected
	Marijuana and cannabinoids	Weed, Mary Jane, Ganja, Sensemilla, Blunt, Bud, Doobie, Dope, Grass, Pot, Green, Herb, Joint, Smoke, Stinkweed, Trees	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, Hog, Embalming Fluid, Rocket Fuel, Sherms	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	None detected
	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 1000 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 and CAP Proficiency Testing reporting (2020) 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)	Barbs, Dolls, Phennies, Red/BlueBirds, Tooties, Yellows Yellow jackets,	2 days	300 ng/mL 200 ng/mL	>10 µg/mL	1-5 µg/mL
	Secobarbital (Seconal)	barbs, phennies, reds, red birds, yellow, yellow jacketsReds	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	>25 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, phennies, reds, red birds, yellows, yellow jackets	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, Poles, Totem Z-bars, Zannies, Vs, Yellow/ Blue Zs	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, Benzos, Poles, Totem Z-bars, Vs, Zannies, Yellow/Blue Zs.	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, bars, benzos, chill pills,	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, Benzos, Poles, Totem Z-Bars, Vs, Yellow/ Blue Zs, Zannies.	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, Benzos, Poles, Totem Z-bars, Yellow/Blue Zs, Zannies, Vs	Single use: Not detected Prolonged use: 5-7 days	300-600 ng/mL	0.3-0.6ng/mL	50-240 ng/mL
	Flunitrazepam (Rohypnol)	Roofies, Rib, Rope, Date Rape Drug, Mexican Valium,Mind Eraser, Roaches, Roapies, Rophies	72 hours	2 ng/mL	>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, Cat Valium	<72 hours	5-10 ng/mL (GC-MS)	>7-27 µg/mL (highly variable)	0.5-5.0 µg/mL

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1. Morbidity and Mortality Weekly Report (MMWR). Centers for Disease Control and Prevention. https://www.cdc.gov/mmwr/index.html. Published June 15, 2021. Accessed June 28, 2022.
2. TIAFT Guidelines. TIAFT. http://www.tiaft.org/tiaft-guidelines.html?setlang=en. Accessed June 28, 2022.

Specimen	Test	Conventional Units	Conversion Factor (multiply by)	SI Units
S	Albumin*	3.9-5.1 g/dL	10	39-51 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	Bilirubin, conjugated*	0.1-0.4 mg/dL	17.1	1.7-6.8 µmol/L
S	Bilirubin, total*	0.1-1.2 mg/dL	17.1	1.0-19.9 µmol/L
S/P	Calcium, total	9-10.4 mg/dL	0.25	2.24-2.6 mmol/L
B	CO2 content (venous)	22-26 mEq/L	1	22-26 mmol/L
S/P	Chloride*	98-107 mEq/L	1	98-107 mmol/L
S	Cholesterol (NCEP recommendation)	140-200 mg/dL	0.0259	3.6-5.2 mmol/L
S	Cortisol (a.m., total)*	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)*	39-715 ng/mL	1	39-715 µg/L
S	Ferritin (women)*	6-362 ng/mL	1	6-362 µg/L
P	Fibrinogen	200-400 mg/dL	0.01	2-4 g/L
S	Folate	9.5-39.0 ng/mL	2.265	21.5-88.4 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	20-168 µg/dL	0.179	3.5-30.0 µmol/L
S/P	Iron binding capacity	250-400 µg/dL	0.179	44.8-71.6 µmol/L
B	Lactate (at bed rest)	5-12 mg/dL	0.111	0.36-0.75 mmol/L
B	Lead	<25 µg/dL	0.048	<1.21 µmol/L
S	Magnesium (Atomic Absorption)	1.6-2.6 mg/dL	0.4114	0.66-1.07 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	320-360 g/L
B	MCV (RBC index)*	83.0-95.0 fL	1	83.0-95.0 fL
S	Osmolality	280-295 mOsm/kg	1	280-295 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)*	2.8-4.8 mg/dL	0.323	0.89-1.54 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 $10^9/L$
S	Potassium	3.8-4.9 mEq/L	1	3.8-4.9 mmol/L
S	Protein, total (recumbent)	6.0-7.8 g/dL	10	60-78 g/L
B	RBC count (men)*	4.5-5.9 $10^6/mm^3$	1	4.5-5.9 $10^{12}/L$
B	RBC count (women)*	4.5-5.1 $10^6/mm^3$	1	4.5-5.1 $10^{12}/L$
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)*	8-24 mg/dL	0.357	2.8-8.6 mmol/L
S	Uric acid (men)*	3.7-7.7 mg/dL	0.059	0.22-0.46 mmol/L
S	Uric acid (women)*	2.5-6.2 mg/dL	0.059	0.15-0.37 mmol/L
S	Vitamin B12 (WHO Recommendation)	>201 pg/mL	0.733	>147 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 Rifai, N, Horvath AR, Wittwer, CT. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 7th ed. St. Louis, MO; Elsevier; 2018 McPherson RA, Pincus MR. Henry's Clinical Diagnosis and Management by Laboratory Methods. 22nd ed. Philadelphia, PA: Elsevier Saunders; 22nd ed; 2011. Revised 2021 by S.T. Campbell, PhD, DABCC, FAACC, Department of Pathology, Montefiore Medical Center, Bronx, NY.

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CRITICAL VALUES FOR THERAPEUTIC DRUG LEVELS

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 2022-2023 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 MOL/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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[1]Centers for Disease Control and Prevention (CDC). Assessment & Testing.

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Serum Chemistries	Age	Reference Range	
Albumin*		**Male (g/dL)**	**Female (g/dL)**
	1-7 d	2.4 - 3.9	1.9 - 4.0
	8-30 d	2.1 - 4.5	1.9 - 4.4
	31-90 d	2.1 - 4.8	2.0 - 4.2
	91-180 d	2.2 - 4.9	2.3 - 4.4
	181 d - 1 y	2.2 - 4.7	2.3 - 4.7
	1 - 3 y	3.5 - 4.2	3.5 - 4.7
	4 - 6 y	3.6 - 5.2	3.6 - 5.2
	7 - 9 y	3.8 - 5.6	3.8 - 5.6
	10 - 19 y	3.8 - 5.6	3.8 - 5.6
ALT*		**Male (U/L)**	**Female (U/L)**
	1-7 d	20 - 54	21 - 54
	8-30 d	24 - 54	22 - 46
	1 - 3 mo	27 - 54	26 - 61
	4 - 6 mo	26 - 55	26 - 51
	7 - 12 mo	26 - 59	26 - 55
	1 - 3 y	19 - 59	24 - 59
	4 - 6 y	24 - 49	24 - 49
	10 - 11 y	24 - 49	24 - 44
	12 - 13 y	24 - 68	24 - 44
	14 - 15 y	24 - 59	19 - 44
	16 - 19 y	24 - 54	19 - 49
ALK*		**Male (U/L)**	**Female (U/L)**
	1-7 d	121 - 351	107 - 357
	8-30 d	138 - 486	107 - 474
	1 - 3 mo	101 - 467	125 - 547
	4 - 6 mo	94 - 425	125 - 449
	7 - 12 mo	101 - 394	101 - 431
	1 - 3 y	185 - 383	185 - 383
	4 - 6 y	191 - 450	191 - 450
	7 - 9 y	218 - 499	218 - 499
	10 - 11 y	174 - 624	169 - 657
	12 - 13 y	245 - 584	141 - 499
	14 - 15 y	169 - 618	103 - 283
	16 - 19 y	98 - 317	82 - 169
AST*		**Male (U/L)**	**Female (U/L)**
	1-7 d	26 - 98	20 - 93
	8-30 d	16 - 67	20 - 69
	1 - 3 mo	16 - 60	16 - 61
	4 - 6 mo	16 - 62	16 - 60
	7 - 12 mo	16 - 52	16 - 60
	1 - 3 y	16 - 57	16 - 57
	5 - 6 y	10 - 47	10 - 47
	7 - 9 y	10 - 36	5 - 36
	12 - 15 y	10 - 36	5 - 26
	16 - 19 y	10 - 41	0 - 26

Bilirubin, direct*	Age	Male and Female (mg/dL)	
	neonates	< 0.4	
Bilirubin, total*		**Male and Female (mg/dL)**	
	0 - 1 d	< 5.1	
	1 - 2 d	< 7.2	
	3 - 5 d	< 10.3	
	1 mo - adult	< 0.8	
BUN*		**Male and Female (mg/dL)**	
	1-7 d	1 - 13	
	8-30 d	1 - 16	
	1 - 3 mo	1 - 12	
	4 - 12 mo	1 - 14	
	1 - 3 y	4 - 17	
	4 - 13 y	6 - 17	
	14 - 19 y	7 - 21	
Calcium*		**Male (mg/dL)**	**Female (mg/dL)**
	0 - 7 d	7.6 - 11.3	7.8 - 11.2
	8 - 30 d	8.8 - 11.6	8.6 - 11.8
	31 - 90 d	8.7 - 11.2	8.2 - 11.0
	91 - 180 d	8.5 - 11.3	8.0 - 11.4
	181 - 365 d	8.0 - 10.9	8.1 - 11.0
	1 - 3 y	8.9 - 9.9	8.9 - 9.9
	4 - 11 y	9.0 - 10.1	9.0 - 10.1
	12 - 13 y	9.0 - 10.6	9.0 - 10.6
	14 - 15 y	9.3 - 10.7	9.3 - 10.7
	16 - 19 y	9.0 - 10.7	9.0 - 10.7
CO2 (venous)*		**Male and Female (mmol/L)**	
	0-1 wk	13 - 21	
	1 wk - 1 mo	13 - 22	
	1 - 6 mo	13 - 23	
	6 mo - 1 y	14 - 23	
	> 1 y	16 - 25	
Chloride (Cl)*		**Male and Female (mmol/L)**	
	0 d - 6 mo	97 - 108	
	6 mo - 1 y	97 - 106	
	> 1 y	97 - 107	
CRP*		**Male (U/L)**	**Female (U/L)**
	0 - 90 d	0.08 - 1.58	0.09 - 1.58
	91 d - 12 mo	0.08 - 1.12	0.05 - 0.79
	13 - 36 mo	0.08 - 1.12	0.08 - 0.79
	4 - 10 y	0.06 - 0.79	0.05 - 1.00
	11 - 14 y	0.08 - 0.76	0.06 - 0.81
	15 - 18 y	0.04 - 0.79	0.06 - 0.79
CK*		**Male (U/L)**	**Female (U/L)**
	0 - 90 d	29 - 303	43 - 474
	3 - 12 mo	25 - 172	27 - 242
	13 - 24 mo	28 - 162	25 - 177
	2 - 10 y	31 - 152	25 - 177
	11 - 14 y	31 - 152	31 - 172
	15 - 18 y	34 - 147	28 - 142

This chart has been updated and reviewed by Maj. Matthew Raines, MD, DABP, Medical Director and Pathologist in the U.S. Air Force.

Creatinine*		Male (mg/dL)	Female (mg/dL)
	1 - 30 d	0.5 - 1.2	0.5 - 0.9
	31 - 365 d	0.4 - 0.7	0.4 - 0.6
	1 - 3 y	0.4 - 0.7	0.4 - 0.7
	4 - 6 y	0.5 - 0.8	0.5 - 0.8
	7 - 9 y	0.6 - 0.9	0.5 - 0.9
	10 - 12 y	0.6 - 1.0	0.6 - 1.0
	13 - 15 y	0.6 - 1.2	0.7 - 1.1
	16 - 18 y	0.8 - 1.4	0.8 - 1.2
Glucose*		**Male (mg/dL)**	**Female (mg/dL)**
	0 - 1 d	36 - 110	36 - 89
	1 - 7 d	47 - 110	47 - 110
	> 7 d	54 - 117	54 - 117
Magnesium*		**Male (mg/dL)**	**Female (mg/dL)**
	0 - 90 d	1.45 - 2.15	1.49 - 2.05
	91 d - 12 mo	1.59 - 2.49	1.60 - 2.20
	13 - 36 mo	1.59 - 2.20	1.51 - 2.20
	4 - 10 y	1.49 - 2.20	1.60 - 2.50
	11 - 15 y	1.35 - 2.05	1.60 - 2.09
	16 - 18 y	1.55 - 2.10	1.49 - 1.90
Potassium (K)*		**Male and Female (mmol/L)**	
	0 - 1 wk	3.2 - 5.7	
	1 wk - 1 mo	3.4 - 6.2	
	1 - 6 mo	3.5 - 5.8	
	6 mo - 1 y	3.5 - 6.3	
	> 1 y	3.3 - 4.7	
Protein, total*		**Male (g/dL)**	**Female (g/dL)**
	1 - 60 d	40 - 76	3.6 - 7.0
	61 - 180 d	40 - 70	4.0 - 7.6
	181 d - 1 y	42 - 79	4.6 - 7.8
	1 - 6 y	60 - 80	6.0 - 7.8
	7 - 9 y	63 - 81	6.3 - 8.1
	10 - 19 y	64 - 86	6.4 - 8.6
Sodium (Na)*		**Male and Female (mmol/L)**	
	0 - 7 d	131 - 144	
	7 - 31 d	132 - 142	
	1 - 6 mo	132 - 140	
	6 mo - 1 y	131 - 140	
	> 1 y	132 - 141	
Coagulation panel PT**	**Age**	**Male and Female (s)**	
	7 - 9 y	13.1 - 15.4	
	10 - 11 y	12.9 - 15.5	
	12 - 13 y	13.1 - 15.2	
	14 - 15 y	12.9 - 15.4	
	16 - 17 y	12.6 - 15.9	
aPTT**		**Male and Female (s)**	
	7 - 9 y	27 - 38	
	10 - 11 y	27 - 38	
	12 - 13 y	27 - 38	
	14 - 15 y	26 - 35	
	16 - 17 y	26 - 35	

Lipid panel Cholesterol*	Age	Reference Range	
		Male (mg/dL)	Feale (mg/dL)
	1 - 3 y	37 - 178	37 - 178
	4 - 6 y	103 - 184	103 - 184
	7 - 9 y	107 - 245	107 - 245
	10 - 11 y	120 - 228	122 - 242
	12 - 13 y	122 - 228	120 - 211
	14 - 15 y	101 - 222	125 - 211
	16 - 18 y	105 - 218	101 - 215
HDL-C*		**Male (mg/dL)**	**Female (mg/dL)**
	2 - < 7 y	26 - 68	16 - 62
	7 - < 12 y	28 - 76	26 - 77
	12 - < 16 y	22 - 73	28 - 79
	16 - < 19 y	28 - 72	24 - 74
LDL-C*		**Male (mg/dL)**	**Female (mg/dL)**
	13 - 36 mo	35 - 125	35 - 125
	4 - 10 y	45 - 140	35 - 135
	11 - 15 y	45 - 120	50 - 130
	16 - 18 y	55 - 120	70 - 120
Triglyceride*		**Male (mg/dL)**	**Female (mg/dL)**
	1 - 3 y	25 - 119	25 - 119
	4 - 6 y	30 - 110	30 - 110
	7 - 9 y	26 - 123	26 - 123
	10 - 11 y	22 - 131	37 - 134
	12 - 13 y	22 - 138	35 - 124
	14 - 15 y	32 - 158	36 - 129
	16 - 19 y	32 - 134	35 - 134

Iron testing Ferritin*	Age	Reference Range	
		Male (mg/dL)	Feale (mg/dL)
	0 - 90 d	40 - 775	79 - 501
	91 d - 12 mo	25 - 790	25 - 560
	13 - 36 mo	12 - 501	10 - 500
	4 - 10 y	25 - 280	22 - 158
	11 - 14 y	25 - 112	15 - 112
	15 - 18 y	18 - 158	10 - 125

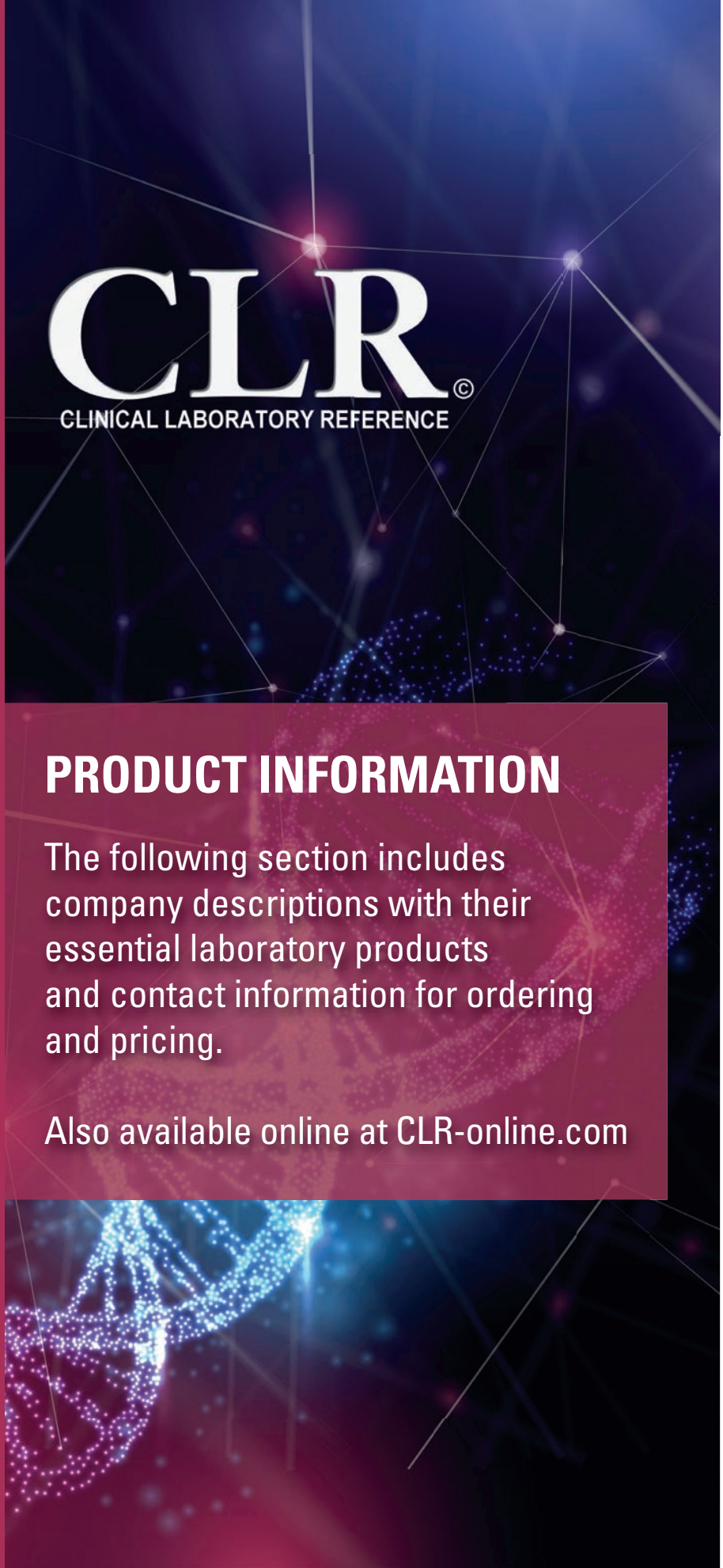
Iron*	Age	5 - 11 am (mcg/dL)	5 - 11 pm (mcg/dL)
	0 - 24 mo	20 - 105	20 - 140
	2 - 9 y	20 - 105	20 - 145
	10 - 14 y	20 - 100	20 - 145
	15 - 18 y	20 - 100	20 - 145

TIBC*	Age	Male (mg/dL)	Female (mg/dL)
	0 - 90 d	155 - 330	165 - 275
	91 d - 12 mo	150 - 380	250 - 455
	13 - 36 mo	215 - 420	160 - 415
	4 - 10 y	185 - 415	260 - 385
	11 - 14 y	265 - 410	250 - 420
	15 - 18 y	270 - 415	285 - 410

*Values given in this table were obtained from published studies performed on the Dimension RxL, the precursor to the current analytical platform in use at JBER Lab. Pediatric Reference Intervals, 7th ed. Washington, DC: AACC Press, 2011

**Values given in this table were obtained from published studies performed on the Stago STA-R, the precursor to the current analytical platform in use at JBER. Flanders MM, et al. Pediatric reference intervals for ten coagulation assays. Blood 2004;104:2988.

Abbreviations: ALK (alkaline phosphatase), ALT (alanine aminotransferase), aPTT (partial thromboplastin time), AST (aspartate aminotransferase), BUN (blood urea nitrogen), CK (creatine kinase), CO2 (carbon dioxide), CRP (C-reactive protein), HDL-C (HDL cholesterol), LDL-C (LDL cholesterol), PT (prothrombin time), TIBC (total iron-binding capacity)



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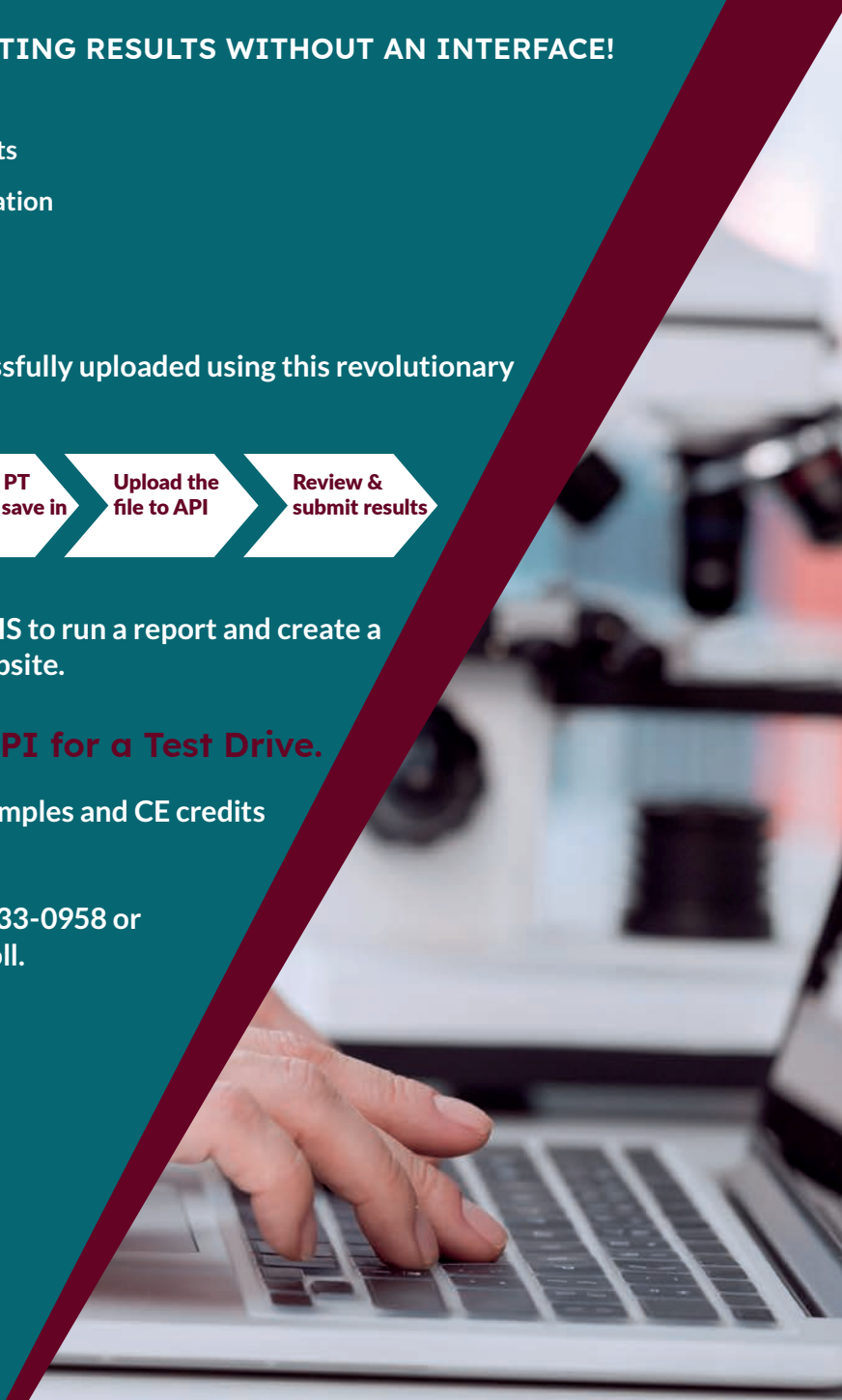

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S

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Individual EUAs for Serology and other Adaptive Immune Response Tests for SARS-CoV-2

Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
Abbott Laboratories Inc.	5/24/2022, 4/26/2020	SARS-CoV-2 IgG assay	IgG, CMIA	H, M
Abbott Laboratories Inc.	4/7/2022, 3/1/2021	AdviseDx SARS-CoV-2 IgG II	IgG, CMIA, Semi-quantitative	H, M
Abbott Laboratories Inc.	10/1/2021	AdviseDx SARS-CoV-2 IgM 10/09/2020	IgM, CMIA	H, M
Access Bio, Inc.	8/12/2021, 7/24/2020	CareStart COVID-19 IgM/IgG	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W
Adaptive Biotechnologies Corporation	9/2/2021, 3/5/2021	T-Detect COVID Test	T-cell receptor beta (TCR β), Sequencing	H
Assure Tech. (Hangzhou Co., Ltd)	1/31/2022, 7/6/2020	Assure COVID-19 IgG/IgM Rapid Test Device	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W
Babson Diagnostics, Inc.	12/15/2021, 6/23/2020	Babson Diagnostics aC19G1	IgG, CLIA	H
Beckman Coulter, Inc.	12/17/2021, 6/26/2020	Access SARS-CoV-2 IgG	IgG, CLIA	H, M
Beckman Coulter, Inc.	12/13/2021, 10/8/2020	Access SARS-CoV-2 IgM	IgM, CLIA	H, M
Beckman Coulter, Inc.	8/18/2021, 3/3/2021	Access SARS-CoV-2 IgG II	IgG, CLIA, Semi-quantitative	H, M
Biohit Healthcare (Hefei) Co. Ltd.	12/16/2021, 6/18/2020	Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit	IgM and IgG Lateral Flow	H, M
Bio-Rad Laboratories, Inc.	2/25/2022, 4/29/2020	Platelia SARS-CoV-2 Total Ab assay	Total Antibody, ELISA	H
Diabetomics, Inc.	8/10/2021, 6/4/2021	CovAb SARS-CoV-2 Ab Test	Total Antibody, Lateral Flow, Oral Fluid	H, M, W
DiaSorin Inc.	10/7/2021, 4/24/2020	LIAISON SARS-CoV-2 S1/S2 IgG	IgG, CLIA	H, M
Diazyme Laboratories, Inc.	1/18/2022, 7/8/2020	Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit	IgG, CLIA, Semi-quantitative	H, M
Diazyme Laboratories, Inc.	1/18/2022, 8/17/2020	Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit	IgM, CLIA	H, M
Emory Medical Laboratories	4/21/2022, 6/15/2020	SARS-CoV-2 RBD IgG test	IgG, ELISA	H
EUROIMMUN US Inc.	2/9/2022, 5/4/2020	Anti-SARS-CoV-2 ELISA (IgG)	IgG, ELISA	H
EUROIMMUN US, Inc.	3/1/2022, 10/4/2021	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)	IgG, ELISA, Semi-quantitative	H, M
Hangzhou Laihe Biotech Co., Ltd.	2/14/2022, 6/19/2020	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	IgM and IgG Lateral Flow	H, M
Healgen Scientific LLC	1/26/2022, 5/29/2020	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	IgM and IgG Lateral Flow	H, M
Immunodiagnostic Systems Ltd.	12/9/2021, 2/10/2021	IDS SARS-CoV-2 IgG	IgG, CLIA	H, M
InBios International, Inc	8/24/2021	SCoV-2 Detect IgG Rapid Test	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W
InBios International, Inc.	10/22/2021	SCoV-2 Detect Neutralizing Ab ELISA	Total Neutralizing Antibodies, ELISA	H
Jiangsu Well Biotech Co., Ltd.	3/1/2022, 9/30/2020	Orawell IgM/IgG Rapid Test	IgM and IgG, Lateral Flow	H, M
LG Chem, Ltd.	5/31/2022	AdvanSure SARS-CoV-2 IgG(RBD) ELISA	IgG, ELISA	H
LG Chem, Ltd.	5/19/2022	AdvanSure SARS-CoV-2 IgG(S1) ELISA	IgG, ELISA	H
Luminex Corporation	3/9/2022, 7/16/2020	xMAP SARS-CoV-2 Multi-Antigen IgG Assay	IgG, FMIA	H
LumiraDx UK Ltd.	8/2/2021	LumiraDx SARS-CoV-2 Ab Test	Total Antibody, Fluorescence Immunoassay, Fingerstick Whole Blood	H, M, W
Megna Health, Inc.	3/9/2022, 7/17/2020	Rapid COVID-19 IgM/IgG Combo Test Kit	IgM and IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W
NanoEntek America, Inc.	12/13/2021, 9/29/2020	FREND COVID-19 total Ab	Total Antibody, FIA	H, M
Nirmidas Biotech, Inc.	11/2/2021, 12/31/2020	MidaSpot COVID-19 Antibody Combo Detection Kit	IgM and IgG, lateral flow, Fingerstick Whole Blood	H, M, W
NOWDiagnostics, Inc.	2/1/2022, 5/4/2021	ADEXUSDx COVID-19 Test	Total Antibody, Lateral Flow, Fingerstick Whole Blood	H, M, W
Ortho-Clinical Diagnostics, Inc.	9/8/2021, 7/9/2021	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Quantitative Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti- SARS-CoV-2 IgG Quantitative Calibrator	IgG, CLIA, Quantitative	H, M
Ortho-Clinical Diagnostics, Inc.	7/22/2021	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Reagent Pack used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total N Antibody Calibrators	Total Antibody, CLIA	H, M
QIAGEN, GmbH	2/28/2022, 5/11/2021	QIAreach Anti-SARS-CoV-2 Total Test	Total Antibody, Digital Lateral Flow	H, M

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Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
Roche Diagnostics, Inc.	2/9/2022, 11/25/2020	Elecsys Anti-SARS-CoV-2 S	Total Antibody, ECLIA, Semi-quantitative	H, M
Shenzhen New Industries Biomedical Engineering Co., Ltd.	12/16/2021, 9/14/2020	MAGLUMI 2019-nCoV IgM/IgG	IgM and IgG, CLIA	H, M
Siemens Healthcare Diagnostics Inc.	3/4/2022, 1/8/2021	Dimension EXL SARS-CoV-2 IgG (CV2G)	IgG, CLIA, Semi-quantitative	H, M
Siemens Healthcare Diagnostics Inc.	3/4/2022, 1/8/2021	Dimension Vista SARS-CoV-2 IgG (COV2G)	IgG, CLIA, Semi-quantitative	H, M
Siemens Healthcare Diagnostics Inc.	1/19/2022, 3/23/2021	Atellica IM SARS-CoV-2 IgG (sCOVG)	IgG, CLIA, Semi-quantitative	H, M
Siemens Healthcare Diagnostics Inc.	1/18/2022, 6/8/2020	Dimension Vista SARS-CoV-2 Total antibody assay (COV2T)	Total Antibody, CLIA	H, M
Siemens Healthcare Diagnostics Inc.	1/18/2022, 6/8/2020	Dimension EXL SARS-CoV-2 Total antibody assay (CV2T)	Total Antibody, CLIA	H, M
Siemens Healthcare Diagnostics Inc.	9/14/2021, 5/29/2020	ADVIA Centaur SARS-CoV-2 Total (COV2T)	Total Antibody, CLIA, Semi-quantitative	H, M
Siemens Healthcare Diagnostics Inc.	8/10/2021, 6/17/2021	ADVIA Centaur SARS-CoV-2 IgG (sCOVG)	IgG, CLIA, Semi-quantitative	H, M
Sugentech, Inc.	11/19/2021, 9/3/2020	SGTi-flex COVID-19 IgG	IgG, Lateral Flow, Fingerstick Whole Blood	H, M, W
ZEUS Scientific, Inc.	12/13/2021, 5/11/2021	ZEUS ELISA SARS-CoV-2 Total Antibody Test System	Total Antibody, ELISA	H, M
ZEUS Scientific, Inc.	12/8/2021, 10/6/2020	ZEUS ELISA SARS-CoV-2 IgG Test System	IgG, ELISA	H, M

Authorized settings include the following:
H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
W - Patient care settings operating under a CLIA Certificate of Waiver.
2 Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.
3 Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay, CMIA = chemiluminescent microparticle immunoassay; ELFA = enzyme-linked fluorescence assay

Source: FDA: In Vitro Diagnostics EUAs - Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2 (Accessed June 29, 2022).

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