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Passing the test on the importance of testing

Testing plays a central – and often unsung – role in treating acute and chronic diseases. Without data to determine a diagnosis, providers cannot treat a disease. But because of the COVID-19 pandemic, the public is getting a rare look at how important testing is in the fields of medicine and public health.

At a virtual conference hosted by the American Society for Clinical Laboratory Science (ASCLS) and the Association of Genetic Technologists (AGT) in late June, attendees expressed frustration about the perceived lack of respect and financial support for lab operations among other healthcare professionals, politicians, and the public. But despite their exasperation, they also voiced optimism. They noted how important it is for lab professionals to turn the public's focus on testing for SARS-CoV-2 into a teachable moment.

As one attendee noted, "We need to seize this opportunity to get the attention of regulators, legislative officials (state and local) and the general public about the woeful state of clinical laboratory funding. Time for training dollars and reimbursement relief – not to mention RESPECT."

In hospitals, labs garner a small chunk of the total budget – roughly 2.5 percent, by some estimates.

The financial pressures on laboratory services has become even greater in recent years. The Protecting Access to Medicare Act of 2014 (PAMA), which bases Medicare pricing for lab tests on rates that private insurers pay, has impacted budgets. Since the new payment system became effective on January 1, 2018, labs have seen as much as a 20 percent reduction in Medicare payments, according to COLA estimates in 2019.

Value-based care, which bases payment on patient outcomes and resource utilization, is also a factor, as some value-based programs, such as bundling, lump costs for lab tests with other medical services necessary to treat patients for an episode of care.

Meanwhile, at public health labs, budgets have been shrinking as part of the cutbacks in overall funding for public health. Spending on public health is less than 3 percent of all healthcare expenditures, and its share of total funds has been declining since 2000, according to the Trust for America's Health. Given those dwindling budgets, the public health workforce has lost 56,000 positions over the last decade, the trust also said.

The demand for testing created by SARS-CoV-2 has only intensified the financial pressure on laboratories. Breaking even on molecular testing for SARS-CoV-2 is challenging. The Centers for Medicare & Medicaid Services (CMS) reimburses labs $100 per test run on high-throughput analyzers and $51 per test run on other equipment. However, lab managers told me that those rates do not cover their costs, which include capital expenditures, testing supplies and kits, personal protective equipment (PPE), staff salaries, and more.

To offer testing in their communities, lab managers also have had to combat continuing shortages of PPE, test kits, reagents, and swabs. In a survey of 100 of its members in June, for example, Premier found that 40 percent of them do not have enough testing swabs and test kits. At the ASCLS-AGT virtual conference, attendees also talked about not having access to enough basic materials to make transport media in-house.

But they persevere because they know testing is key in the fight against SARS-CoV-2. They are not the only ones who understand this. The public recognizes it, too.

That is the why this is an opportunity for lab professionals to talk about the important role their field plays in keeping the public safe and healthy and why adequate funding is necessary. I encourage you to talk about it everywhere – from the halls in the hospitals to the socially distanced chats in the neighborhoods – until these conversations produce viable, actionable solutions for everyone.

I welcome your comments, questions, and opinions — please send them to me at lwilson@mlo-online.com.

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The quality of treatment starts with diagnosis.

Pediatric reference intervals in routine laboratory practice

By Maj. Matthew Raines, MD, DABP

Maj. Matthew Raines, MD, DABP, director and pathologist in the U.S. Air Force.

In order to establish a diagnosis of wellness or disease, checklists – like that of the College of American Pathologists' (CAP) All Common checklist for the chemistry section – require all patient results to be reported with reference ranges. This ensures that healthcare providers can review results compared to the (usually) normal population, as measured on the same analytical platform.

The process for establishing or adopting reference ranges for adult populations is well-documented elsewhere. Pediatric reference ranges, on the other hand, are more complicated. Pediatric and adult physiology differ, and results can vary with age, analyte, and sometimes sex. Instead of establishing a single reference range per analyte (as with adults), up to 18 total ranges may be established for a single analyte when considering incremental age ranges (up to 18) and sex. However, many laboratories do not receive enough pediatric samples within each age interval to statistically power each reference range. As part of standard medical practice, clinicians want to prevent multiple unnecessary blood draws from children, further adding to the complexity of determining pediatric reference ranges.

In pediatrics, test results can vary with age, analyte and sometimes sex.

When it is not feasible to establish reference ranges in-house due to limitations in the number of samples, it may be acceptable to adopt reference ranges from studies performed by the manufacturer or otherwise published in the literature. But searching the literature for each analyte, one by one, and comparing the analytical platform to that employed in one's own lab can be laborious.

To address this issue, the American Association for Clinical Chemistry (AACC) published *Pediatric Reference Intervals* (previously *Pediatric Reference Ranges*),[1] which provides tables of analytes with pediatric reference ranges, platforms utilized, and study references.

In an attempt to provide the most relevant information to providers at Joint Base Elmendorf-Richardson Hospital (JBER Hospital), we queried our laboratory information system (LIS) to create a report identifying the tests most frequently ordered for pediatric patients at our institution. I also reviewed LIS test files to identify which pediatric reference ranges were reported with lab results.

The next task was to compile missing reference ranges. Our laboratory utilizes a Siemens Vista for chemistry and a Stago STA Compact for coagulation studies. A search of reagent inserts and the published literature revealed few, if any, pediatric reference ranges established on these models. The above-mentioned text, however, provided extensive tables of reference ranges performed on precursor instruments (Dimension RxL and STA-R, respectively). A review of manufacturer reagent inserts was performed to insure uniformity between previous and current platforms.

Following these steps, I consolidated previously established reference ranges into a more provider-friendly and accessible chart form, based on commonly ordered tests at our institution. This handout for providers includes a comprehensive chemistry panel, a coagulation panel, a lipid panel, and an iron panel. The handout was distributed to clinics and published in our lab guide.

A useful (and even more verifiable) future step for the laboratory industry would be the publication of reference ranges by large-volume pediatric facilities on the most current analytical platforms.

(Please see Pediatric reference tables on page 8)

REFERENCES:

1. Wong E, Brugnara C, Straseski, Kellogg M, Adeli K. *Pediatric Reference Intervals.* New York: Elsevier; 2011.

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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

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)

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 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 (Ultram, Tramal Ultracet)	Ultra T	6 hours to 2 days	200 ng/mL	Not established	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 (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	>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, 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	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 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

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*	0.1-0.4 mg/dL	17.1	1.7-6.8 µmol/L
S/P	Bilirubin, total*	0.1-1.2 mg/dL	17.1	1.7-20.5 µmol/L
S/P	Calcium, total	8.6-10.3 mg/dL	0.25	2.15-2.57 mmol/L
B	CO2 content (venous)	22-26 mEq/L	1	22-26 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)*	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 (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 mg/dL	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	Osmolality	270-295 mOsm/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)*	8-24 mg/dL	0.357	2.7-8.6 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 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 McPherson RA, Pincus MR. Henry's Clinical Diagnosis and Management by Laboratory Methods. 22nd ed. Philadelphia, PA: Elsevier Saunders; 22nd ed; 2011. Revised 2020 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 2020-2021 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.

Company Name	Website	Name of Test	Type of Test	Platform/Application	Time to Results
1drop	http://www.1drop.co.kr/sp.php?p=63	1copy COVID-19 qPCR Multi Kit	qPCR Multi Kit	N/A	2 hours
A. Menarini/ Credo Diagnostics Biomedical	https://www.menarini.com/Home/Menarini-News/News/News-details/ArticleId/2664/COVID-19-Menarini-Diagnostics-kit-for-diagnosis-in-20-minutes	SARS-CoV-2 Assay Kit	POC molecular test	VitaPCR molecular testing platform	20 minutes
Abbott Diagnostics	https://www.alere.com/en/home/product-details/id-now-covid-19.html	ID NOW COVID-19	POC molecular test	Abbott ID NOW instrument	5 minutes
Abbott Molecular		Alinity m SARS-CoV-2 Assay	Real-time RT-PCR Test	Alinity m System	2 hours
Abbott Molecular	https://www.molecular.abbott/us/en/products/infectious-disease/RealTime-SARS-CoV-2-Assay	Abbott RealTime SARS-CoV-2 Assay	Real-time RT-PCR test	Abbott m2000 RealTime System	470 tests/24 hours
altona Diagnostics	https://altona-diagnostics.com/en/products/reagents-140/reagents/realstar-real-time-pcr-reagents/realstar-sars-cov-2-rt-pcr-kit.html	RealStar SARS-CoV-2 RT-PCR Kit	RT-PCR Kits	Mx 3005P QPCR System, VERSANT kPCR Molecular System AD, ABI Prism 7500 SDS, ABI Prism 7500 Fast SDS, LightCycler 480 Instrument II, Rotor-Gene 6000, Rotor-Gene Q 5/6 plex Platform, CFX96 Deep Well Real-Time PCR Detection System, CFX96 Real-Time PCR Detection System	N/A
Applied BioCode	http://www.apbiocode.com/sars-cov-2.htm	BioCode SARS-CoV-2 Assay	Molecular Assay Kit	BioCode MDx 3000	N/A
Applied DNA Sciences	https://adnas.com/dxcovid/	Linea COVID-19 Assay Kit	Real-time RT-PCR Test	N/A	1 hour
Atila BioSystems	https://atilabiosystems.com/our-products/covid-19/	iAMP COVID-19 Detection Kit	Real-time reverse transcription isothermal amplification test	Compatible with Atila Power-Gene 9600 Plus, Bio-Rad CFX96, ABI7500, and other commonly used RT-qPCR instruments with FAM and HEX fluorescent channels.	1 hour
Avellino Lab USA	https://www.avellinocoronatest.com/	AvellinoCoV2 test	Real-Time RT-PCR test	Applied Biosystems 7500 Fast Real-Time PCR System with software version 2.3.	6-24 hours
BD/BioGX	https://www.bd.com/en-us/company/news-and-media/press-releases/bd-biogx-announce-fda-emergency-use-authorization-submissions-for-new-covid-19-diagnostics-for-use-in-us	SARS-CoV-2 test	Rapid diagnostic test	BD MAX system	3 hours
BGI Americas (A subdivision of BGI Genomics)	https://www.bgi.com/us/2019-ncov-real-time-fluorescent-rt-pcr-kit-ivd/	Real-Time Fluorescent RT-PCR for Detecting SARS-2019-nCoV	Real-Time RT-PCR test	QIAamp Virus RNA Mini Kit and the Applied Biosystems Real time PCR system 7500 with software v2.0.5	3 hours
BioCore	http://www.bio-core.com/biocore/kr/common/Brochure_(ENG).pdf	BioCore 2019-nCoV Real-Time PCR Kit	RT-PCR Kit	N/A	2 hours
BioFire Defense (A subdivision of BioMerieux)	https://www.biofiredx.com/covid-19/	BioFire COVID-19 test	Real-time RT-PCR test	FILMARRAY 2.0 and FILMARRAY TORCH	45 minutes
BioFire Diagnostics	https://www.biofiredx.com/products/the-filmarray-panels/filmarrayrp/	BioFire Respiratory Panel 2.1 (RP2.1)	Respiratory Panel	BioFire FilmArray 1.5, BioFire 2.0, and the BioFire Torch	45 minutes
BioMérieux	https://www.biomerieux-diagnostics.com/sars-cov-2-r-gene	SARS-CoV-2 R-GENE	Real-time PCR Kit	N/A	4-5 hours
Bio-Rad Laboratories	https://www.bio-rad.com/featured/en/sars-cov-2-covid-19-testing-solutions.html	Bio-Rad SARS-CoV-2 ddPCR Test	RT-PCR Test	Bio-Rad QX200 or QXDx AutoDG Droplet Digital PCR Systems	45 minutes
Cepheid	https://www.cepheid.com/coronavirus	Xpert Xpress SARS-CoV-2 test	Real-time RT-PCR test	GeneXpert Systems	45 minutes
ChromaCode	https://chromacode.com/products/hdpcr-sars-cov-2-assay/#/sars-cov-2	HDPCR SARS-CoV-2 Assay	Real-time qPCR Assay	ABI 7500 Fast, ABI QuantStudio 7, ABI QuantStudio 12K Flex	Less than 1.5 hours
Co-Diagnostics	http://codiagnostics.com/products/diagnostic-solutions/logix-smart-covid19/	Logix Smart Coronavirus Disease 2019 (COVID-19) Kit	Real-Time RT-PCR test	Designed for the CoDx Box and compatible with other open systems, using the FAM and HEX channels	1 hour
Cue Health	https://www.cuehealth.com/news-listing/2020/6/11/1vhtsyzexgjv5kfa314fvisiy2elw5	Cue COVID-19 Test	POC Molecular Test	M/A	25 minutes
DiaCarta	https://diacarta.com/products/coronavirus-test	QuantiVirus SARS-CoV-2 Test kit	Real-time RT-PCR test	Thermo Fisher (ABI) QuantStudio 5, Thermo Fisher (ABI) 7500 Fast Dx, and Bio-Rad CFX 384	2 hours
DiaSorin Molecular	https://molecular.diasorin.com/us/kit/simplexa-covid-19-direct-kit/	Simplexa COVID-19 Direct Assay	Real-time RT-PCR test	Liaison MDX real-time PCR instrument	1 hour
Emperical Bioscience	https://empiricalbioscience.com/quantiscript-one-step-rt-qpcr-kit/	QuanTASE and QuanTASE Plus One Step RT-qPCR kit	RT-qPCR kit	N/A	4 hours
EUROIMMUN	https://www.coronavirus-diagnostics.com/documents/Indications/Infections/Coronavirus/MP_2606_D_UK_A.pdf	EURORealTime SARS-CoV-2	Real-time RT-PCR Test	LightCycler 480 (Roche), ABI 7500 Fast, CFX 96 (Bio-Rad)	90 minutes
Fast Track Diagnostics Luxembourg (A Siemens Healthineers company)	http://www.fast-trackdiagnostics.com/human-line/products/ftd-sars-cov-2/	FTD SARS-CoV-2	Multiplex PCR Test	Applied Biosystems® 7500 Real-Time PCR System (ThermoFisher Scientific) and the NucliSENS® easyMAG® (bioMérieux).	N/A
Fulgent Therapeutics	https://www.fulgentgenetics.com/covid19	Fulgent COVID-19 by RT-PCR Test	RT-PCR Test	N/A	1-2 days
Gencurix	http://www.gencurix.com/ENG_GenePro_COVID19_Brochure.pdf	GenePro SARS-CoV-2 Test	Real-time RT-PCR Test	ABI 7500 and CFX96	Less than 1.5 hours
GeneMatrix	https://www.buykorea.org/bk/byr/product/GOODS_DETAIL-3218179.do	NeoPlex COVID-19 Detection Kit	Multiplex RT-PCR Assay	ABI 7500 and CFX96	3 hours

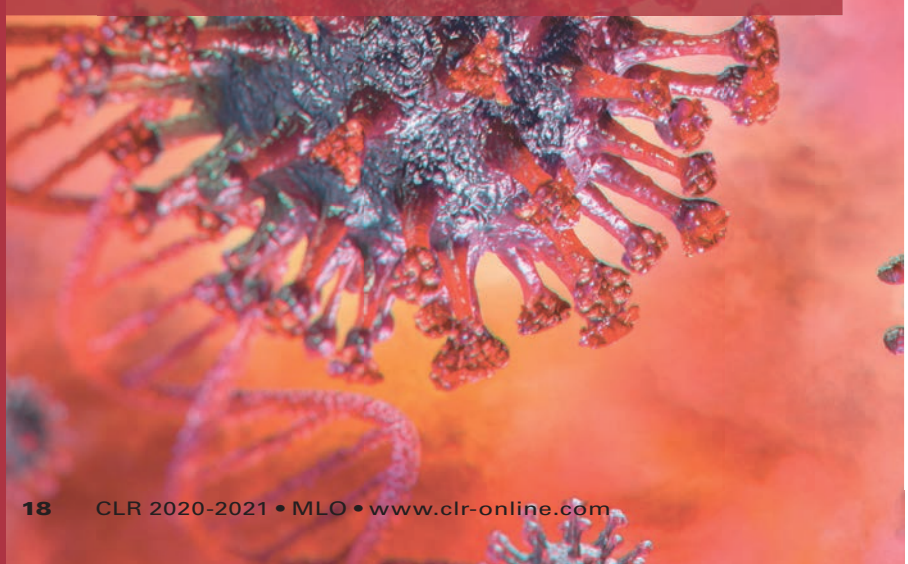
Company Name	Website	Name of Test	Type of Test	Platform/Application	Time to Results
Genetron Health	https://www.fda.gov/media/138685/download	Genetron SARS-CoV-2 RNA Test	Real-time RT-PCR Test	Applied Biosystems 7500 Real-Time PCR System	Less than 2.5 hours
GenMark Diagnostics	https://www.genmarkdx.com/solutions/panels/eplex-panels/eplex-sars-cov-2-test/	ePlex SARS-CoV-2 Test	Nucleic Acid Multiplex assay	GenMark ePlex System	Less than 2 hours
GenoSensor	https://www.genosensorcorp.com/COVID19%20Kit.html	GS COVID-19 RT-PCR Kit	RT-PCR Test	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument	Less than 90 minutes
Gnomegen	https://gnomegendx.com/	Gnomegen COVID-19 RT-qPCR Detection Kit	RT-qPCR Detection Kit	QuantStudio 3D Digital PCR System	3 hours
Gnomegen	https://gnomegendx.com/	Gnomegen COVID-19 RT-Digital PCR Detection Kit	RT-Digital PCR Detection Kit	Applied Biosystems QuantStudio 3D Digital PCR system	N/A
Hologic	http://hologic.com/hologic-products/diagnostic-solutions/hologic-sars-cov-2-assays	Aptima SARS-CoV-2 Assay	In vitro Assay	Panther and Panther Fusion Systems	3.5 hours or less
Hologic	https://www.hologic.com/coronavirus-test	Panther Fusion SARS-CoV-2	Real-time RT-PCR test	Panther Fusion	3 hours
Illumina	https://www.illumina.com/products/by-type/ivd-products/covidseq.html	Illumina COVIDSeq Test	NGS In Vitro Test	NovaSeq 6000 Sequencing System	N/A
InBios International	https://inbios.com/smart-detecttm-sars-cov-2-rrt-pcr-kit/	Smart Detect SARS-CoV-2 rRT-PCR Kit	Real-time RT-PCR kit	7500 Fast Dx Real-Time PCR Instrument by Applied Biosystems CFX96 Touch Real-Time PCR Detection System (Bio-Rad) and CFX Maestro Software (Bio-Rad)	4 hours
Ipsum Diagnostics	https://www.ipsumdiagnostics.com/for-physicians/supply-order-form-covid-19/	COV-19 IDx assay	Real-Time RT-PCR test	Applied Biosystems QuantStudio12 Flex (QS12) instrument with software version 1.2.2	24 hours
Jiangsu Bioperfectus Technologies	http://en.s-sbio.com/product/420.html	COVID-19 Coronavirus Real Time PCR Kit	RT-PCR Kit	N/A	72 minutes
LabCorp	https://www.labcorp.com/coronavirus-disease-covid-19	COVID-19 RT-PCR Test	Real-time RT-PCR test	N/A	Up to 4 days
LabGenomics	http://www.labgenomics.co.kr/eng/invest/news.php?act=view&encData=aWR4PTI3MA==	LabGun COVID-19 RT-PCR Kit	rRT-PCR Test	CFX96 DX System, ABI 7500 RT-PCR	1 hour
Luminex	https://www.luminexcorp.com/aries/	ARIES SARS-CoV-2 Assay	Qualitative Assay	ARIES Systems	2 hours
Luminex Molecular Diagnostics	https://investor.luminexcorp.com/news-releases/news-release-details/luminex-receives-fda-emergency-use-authorization-nxtagr-cov	NxTAG CoV Extended Panel Assay	Multiplex PCR test	MAGPIX system	96 samples/4 hours
Maccura Biotechnology	https://www.maccura.com/en/product/vAMA7UmFXAE-.html	SARS-CoV-2 Fluorescent PCR Kit	NA Fluorescent PCR Test	N/A	2 hours
Mesa Biotech	https://www.mesabiotech.com/coronavirus	Accula SARS-CoV-2 test	Real-time PCR test	Accula Dock and Silaris Dock	30 minutes
MicroGenDx Laboratories	https://microgendx.com/covid19/	SARS-CoV-2 Molecular Diagnostic Assay	Real-Time RT-PCR test	N/A	24 hours
NeuMoDx Molecular	https://www.neumodx.com	NeuMoDx SARS-CoV-2 Assay	Real-Time RT-PCR test	NeuMoDx 288 Molecular and NeuMoDx 96 Molecular Systems	1 hour
Novacyt/ Primerdesign	http://www.primerdesign.co.uk/home	Primerdesign COVID-19 genesig Real-Time PCR assay	Real-time PCR test	Applied Biosystem 7500 Real-Time PCR System Bio-Rad CFX96 Roche LightCycler 480 II	1 hour
OPTI Medical Systems	https://www.optimedical.com/en/products-and-services/kits/opti-sars-cov-2-rt-pcr-test-kit/	OPTI SARS-CoV-2 RT PCR Test	Multiplex RT-PCR Diagnostic Kit	N/A	2-3.5 hours
OSANG Healthcare	http://www.osanghc.com/en/products_en/molecular-diagnosis/#	GeneFinder COVID-19 Plus RealAmp Kit	Reverse Transcription Real-Time PCR Kit	Applied Biosystems 7500/7500FAST (Thermo Fisher) and CFX96 (Bio-Rad)	2 hours
PerkinElmer	https://perkinelmer-appliedgenomics.com/home/products/new-coronavirus-2019-ncov-nucleic-acid-detection-kit/	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Real-Time RT-PCR test	Applied Biosystems 7500 Real-Time PCR System	96 samples/4 hours
QIAGEN	https://www.qiagen.com/us/products/diagnostics-and-clinical-research/infectious-disease/qiastat-dx-syndromic-testing/qiastat-dx-eua-us/#orderinginformation	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Multiplexed nucleic acid test	QIAstat-Dx instrument	1 hour
Quest Diagnostics	https://testdirectory.questdiagnostics.com/test/test-detail/39433/sars-cov-2-rna-qualitative-real-time-rt-pcr?q=39433&cc=MASTER	Quest SARS-CoV-2 rRT-PCR	Real-time RT-PCR test	N/A	4-5 days
Quidel	https://www.quidel.com/molecular-diagnostics/lyra-direct-sars-cov-2-assay	Lyra Direct SARS-CoV-2 Assay	Real-time RT-PCT Assay	Applied Biosystems 7500 Fast Dx, Applied Biosystems 7500 Standard, Roche LightCycler 480 Instrument II, Roche cobas z 480, Qiagen Rotor-Gene Q, Bio-Rad CFX96 Touch, Thermo Fisher QuantStudio 7 Pro.	Less than 70 minutes
Quidel	https://www.quidel.com/molecular-diagnostics/lyra-sars-cov-2-assay	Lyra SARS-CoV-2 Assay	Real-time RT-PCR test	Applied Biosystems 7500 Fast Dx, Applied Biosystems 7500 Standard, Roche LightCycler 480, Qiagen Rotor-Gene Q.	Less than 75 minutes
Rheonix	https://rheonix.com/covid-19/	Rheonix COVID-19 MDx Assay	MDx Assay	Rheonix Encompass MDx workstation	Same-day results
Roche Molecular Systems	https://diagnostics.roche.com/us/en/products/params/cobas-sars-cov-2-test.html	cobas SARS-CoV-2	Real-Time RT-PCR test	cobas 6800/8800 Systems	96 results/3 hours

COVID-19 Test Updates continued on page 32

PRODUCT INFORMATION

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

Also available online at CLR-online.com



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Biocare Medical is a global leader in solutions for cancer research and diagnostics. We provide world-class reagents and a comprehensive suite of advanced instrumentation for IHC, molecular, and histology testing. Biocare's reagent portfolio includes primary antibodies, Multiplex IHC, and FISH probes for target indications. We also offer a unique line of polymer detections for clinical, human, and animal research that delivers high sensitivity and minimal background. Our advanced platforms of semi and fully-automated instrumentation, including the intelliPATH FLX® and VALENT® are designed to meet every need from high throughput clinical diagnostics to flexible research requirements. Biocare has received multiple awards for product quality, service, and support.

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COVID-19 Test Updates continued from page 17

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SD Biosensor	http://sdbiosensor.com/xe/product/7653	STANDARD M nCoV Real-Time Detection Kit	Real-time RT-PCR Test	LightCycler 480, CFX96 DX System, ABI 7500 RT-PCR	90 minutes
Seasun Biomaterials	http://www.seasunbio.com/english/etc.html#tab01	U-TOP COVID-19 Detection Kit	Real-time RT-PCR test	CFX96 DX System, ABI 7500 RT-PCR	15-30 minutes
Seasun Biomaterials	http://www.seasunbio.com/english/etc.html#tab01	AQ-TOP COVID-19 Rapid Detection Kit	Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) test	CFX96 DX System, ABI 7500 RT-PCR	15-30 minutes
Seegene	http://www.seegene.com/assays/allplex_2019_ncov_assay	Allplex 2019-nCoV Assay	Multiplex real-time PCR assay	Seegene NIMBUS & STARlet only	2 hours
Sherlock BioSciences	https://www.idtdna.com/pages/landing/coronavirus-research-reagents/sherlock-kits	Sherlock CRISPR SARS-CoV-2 Kit	CRISPR-based Assay	N/A	1 hour
TBG Biotechnology	http://www.tbgbio.com/en/product/product_detail/51	ExProbe SARS-CoV-2 Testing Kit	Real-time RT-PCR Assay	ABI7500 and TBG Q6000 real time PCR systems	N/A
Thermo Fisher Scientific	https://www.thermofisher.com/us/en/home/clinical/clinical-genomics/pathogen-detection-solutions/coronavirus-2019-ncov/genetic-analysis/taqpath-rt-pcr-covid-19-kit.html	TaqPath COVID-19 Combo Kit	Real-time RT-PCR test	Applied Biosystems 7500 Fast Dx Real-Time PCR instrument	4 hours

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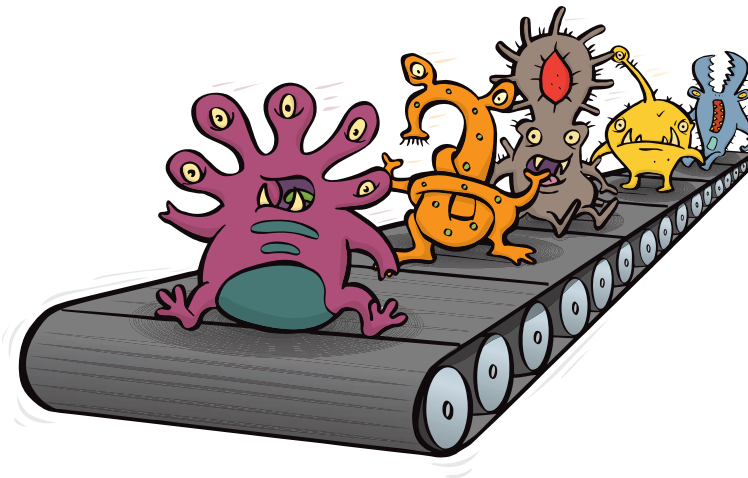

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1. Riddle MS, et al. ACG clinical guideline: diagnosis, treatment, and prevention of acute diarrheal infections in adults. Am J Gastroenterol. 2016 April. 11(5):602. **2.** Beal S, et al. A gastrointestinal PCR panel improves clinical management and lowers healthcare costs. J Clin Microbiol. 2018 Jan. 56:1 e01457-17. **3.** Cybulski R, et al. Clinical impact of a multiplex gastrointestinal PCR panel in patients with acute gastroenteritis. Clin Infect Dis. 2018 Nov. 13; 67 (11):1688-1696. **4.** Axelrad J, et al. Impact of gastrointestinal panel implementation on health care utilization and outcomes. J Clin Microbiol. 2019 Feb. 57(3) e01775-18. **5.** Spina A, et al. Spectrum of enteropathogens detected by the FilmArray GI Panel in a multicenter study of community-acquired gastroenteritis. Clin Microbiol Infect. 2015 Aug. 21(8):719-28.

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