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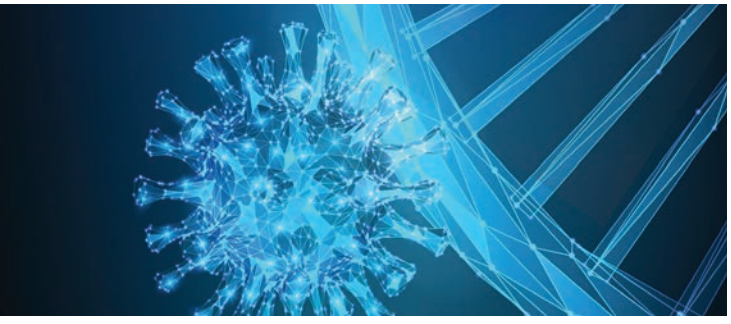

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The product information section includes company descriptions, their essential laboratory products, and contact information for pricing and ordering.

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Publishing information to help guide patient care

Medical Laboratory Observer (MLO) has been committed to producing clinical reference tables for laboratories since 1972.

We continue that tradition with the 2021-22 edition of CLR.

Critical limits and reference intervals help laboratorians interpret test results. Critical limits establish 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 provide clues about test results that may require clinical follow-up to determine if a patient has a disease. It is hard to think of many decision aids that are more important to patients' health and well-being.

As is the case every year, the editors at *MLO* would not have been able to produce this year's CLR issue without help from a roster of external experts.

For CLR's core reference tables, all of which have been updated this year, we thank the following experts:

- 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.

In addition, the author of last year's special feature on pediatric reference intervals updated the accompanying charts, which we have published again in the 2021-22 edition. For this work, we thank Maj. Matthew Raines, MD, DABP, Director and Pathologist in the U.S. Air Force. The tables were developed initially to help providers at Joint Base Elmendorf-Richardson Hospital care for their youngest patients.

This year's special feature is on a topic that has consumed us all since early 2020: COVID-19. In the article, the authors from Baylor Scott & White Medical Center – Temple, TX, discuss the impact of variable sensitivity and specificity in tests to detect SARS-CoV-2 on costs to treat patients with COVID-19. One of the article's authors, Amin A. Mohammad, PhD, DABCC, said they produced the research study originally as a teaching tool for residents and students in the MLS program at Texas A&M Health Science Center. We hope our readers will find the article as enlightening as we did.

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 lwilson@mlo-online.com.

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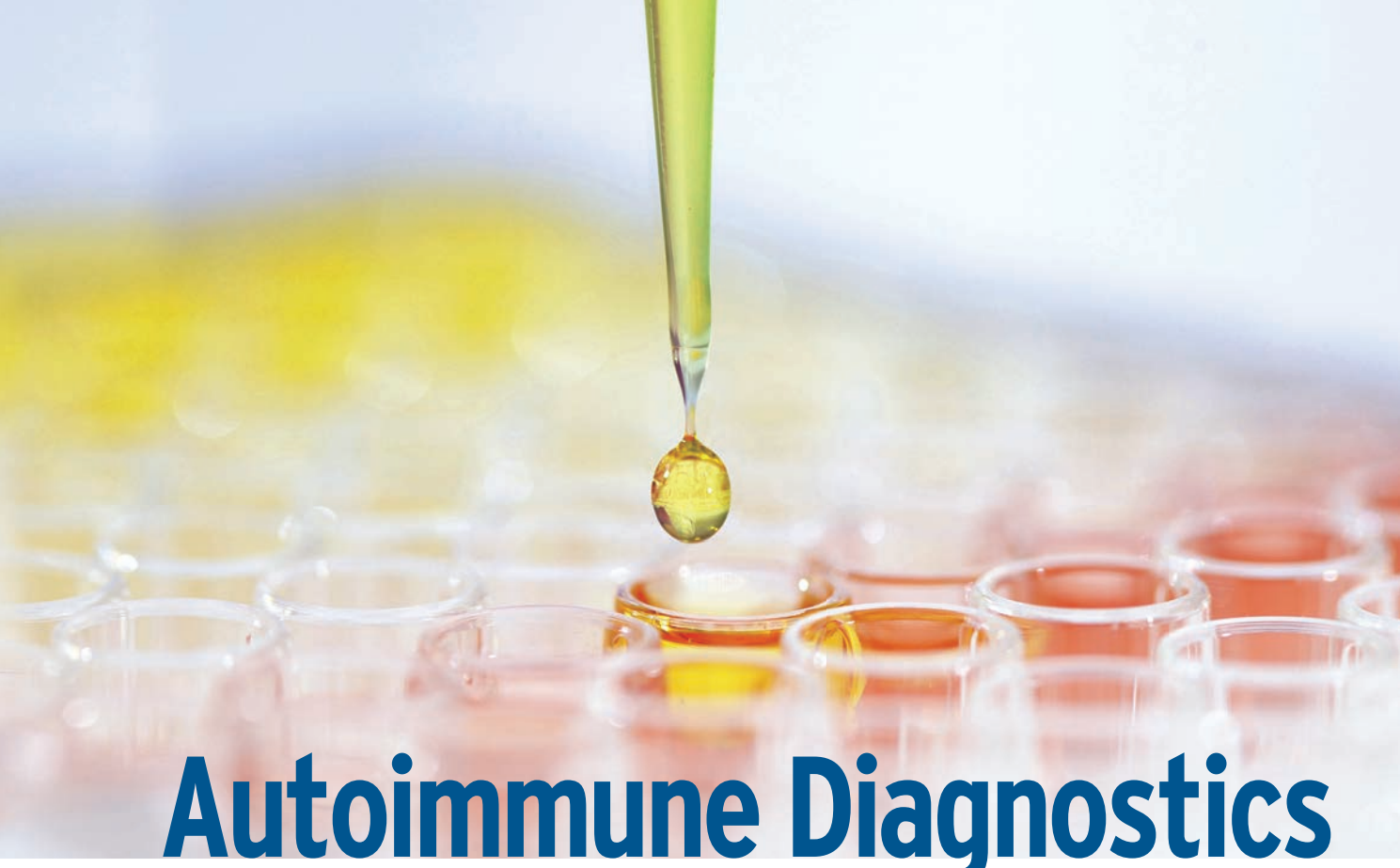

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Test sensitivity and specificity influence cost of pandemic

Impact of SARS-COV-2 test on total charges for treating suspected COVID-19 patients in a tertiary academic medical center in Central Texas.

By Arundhati Rao, MD, PhD; Briget M da Graca, JD, MS; Nguyen Nguyen, PhD; Alejandro C. Arroliga, MD; William Koss, MD; Eduardo Castro, MD, MPH; Shekhar Ghamande, MD; Alita Risinger; Manohar Mutnal, PhD; and Amin. A. Mohammad, PhD.

Introduction

A major concern of the COVID-19 pandemic is the financial burden imposed on the U.S. healthcare system, which has been expressed by elected officials, healthcare economists and health professionals.[1,2,3]

Monte Carlo simulation analysis suggests that if 20% of the U.S. population were to be infected, there could be a median of 11.2 million hospitalizations, 2.7 million ICU admissions, 1.6 million patients requiring a ventilator, 62.3 million hospital bed days, and $163.4 billion in direct medical costs over the course of the pandemic.[4] An analysis performed by Kaiser Family Foundation estimated the average cost of COVID-19 treatment for a patient with employer-based insurance and without complications at $9,763, and this could double or more with complications.[5]

Laboratory tests help diagnosis multiple diseases, including COVID-19, such as a positive reverse-transcriptase polymerase chain reaction (rtPCR) to confirm diagnosis. Based on symptom severity, a patient may go home to self-quarantine for 14 days or may be admitted to a COVID-19 care unit. The rtPCR test results could be true positive (TP), true negative (TN), false positive (FP) or false negative (FN). The probability of each is determined by the test sensitivity and specificity, which has a huge impact on how a patient is treated, a fact often overlooked. The most routinely used rtPCR test has a sensitivity ranging from 60–90%, depending on numerous pre-analytic and analytic variables, including when the patient is tested after symptom onset.[6]

Sensitivity defines the proportion of patients with the disease who will have a positive result, which is useful in ruling out a disease with a negative test. On the other hand, the specificity of a test is the proportion of people without the disease who will have a negative result, which is useful for ruling in a disease if a person tests positive.[7] From a clinician's perspective, positive and negative predictive values for a given test are the most important parameter. The positive predictive value (PPV) of a test is the proportion of people with a positive test result who actually have the disease. The negative predictive value (NPV) of a test is the proportion of people with a negative test result who do not have the disease. Both PPV and NPV are highly dependent on the prevalence of a disease in the population. A test with good sensitivity will have moderate to low PPV if it is used in locales with low disease prevalence.

Responding to the pandemic, the U.S. Food and Drug Administration (FDA) started issuing emergency use authorizations (EUAs) on February 4, 2020,[8] resulting in a plethora of rtPCR and serological tests flooding the marketplace.[9] Since laboratory tests play a pivotal role in triaging patient care, the PPV of the test has a significant impact on overall cost burden. With such a wide range of tests available for COVID-19, the varying sensitivities and specificities of these tests will affect the overall cost for treating patients in emergency departments suspected of having COVID-19. While many publications discuss the diagnostic impact of test characteristics on a patient's outcome, the impact of test sensitivity and specificity on overall treatment cost for COVID-19 patients has not yet been addressed.[10,11,12]

The emergency department (ED) at our tertiary academic medical center (Baylor Scott & White Medical Center – Temple, TX) annually treats 102,000 patients, and approximately 40% (40,800) of these patients have symptoms, per guidelines from the Centers for Disease Control and Prevention (CDC), suspicious for COVID-19. We found

Exhibit 1: Assumptions used for deterministic simulation analysis

Number of Patients seen in Emergency Department annually	102,000
Number of Patients with CDC defined symptoms for COVID-19	40,800
Average Charge for True Positive COVID-19 patient per day	$7,815
Average Charge for False Positive COVID-19 patient per day	$7,815
Average Charge for True Negative COVID-19 patient	$3,208
Average Initial Charge of False Negative COVID-19 patient	$3,208
Length of Stay for True Positive COVID-19	3.4 days
Length of Stay for False Positive COVID-19	2 days
ED room Length of Stay for True and False Negative patient	1 day
Infectivity of False Negative Patient i.e. R0	1

Exhibit 2: Comparing LOS and charges/LOS for COVID-19 and non-COVID-19 patients

	COVID-19 patients Discharged From ED N = 151		COVID-19 Patients Admitted N = 17	
	Median	**95% CI**	**Median**	**95% CI**
Length of Stay	3.3 h	1.3 – 12 h	3.4 d	2.2 – 4.6 d
Charges / LOS ($)	3208	364.0 - 10130.0	7815	4596.0 – 8446.0

CI = confidence interval; ED = emergency department; LOS = length of stay

the simulated impact of differing test sensitivities and specificities on hospital charges for suspected COVID-19 patients in the population.

Exhibit 1 lists the assumptions that were used to perform deterministic simulation analysis and calculate predicted charge estimates.

Cost analysis of COVID-19 patients

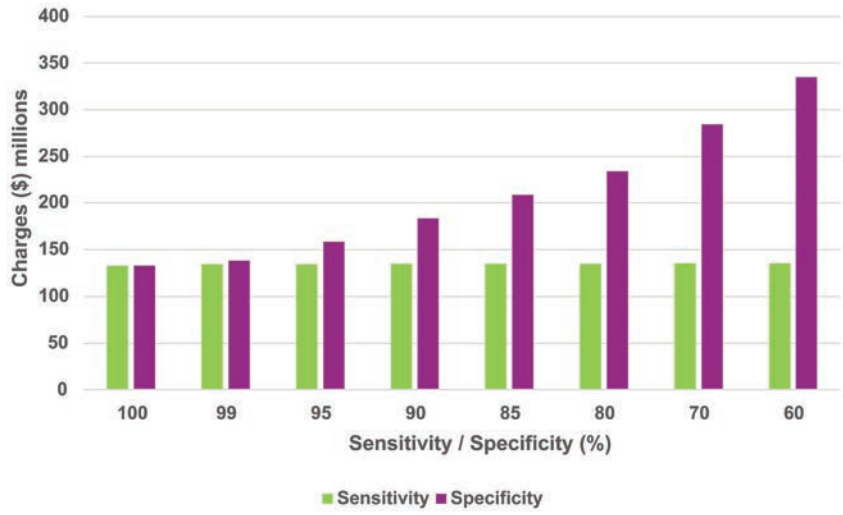
Between the months of April 1st–June 30th, 2020, 170 patients treated in the ED had the ICD-10 code for COVID-19 (U07.1). Of the 170 patients, 153 were discharged from an ED within 24 hours after a negative test result, and the remaining 17 were admitted for observation or treatment after being confirmed positive for COVID-19 by rtPCR. **Exhibit 2** compares the charges/LOS and LOS for COVID-19 patients treated in the ED and discharged with those admitted as inpatients. The charges for the 153 patients discharged from the ED ranged from $364 - $10,130, with a median of $3,208. Expectedly, charges for patients admitted to COVID-19 wards were significantly higher, with a median of $7,815 per day of hospitalization, ranging from $4,596 - $8,446. Median LOS for a COVID-19 patient was found to be 3.4 days with a minimum and maximum of 2 and 10 days. Based on these median LOS and charges, estimated charges for a TP, FP, TN and FN patient were $26,571 (3.4 days x $7,815.0), $ 15,630 (2 days x $7,815.0), $3,208 and $29,779 (charge for TP + charge for TN).

Exhibit 3 graphs that with an ideal test at a sensitivity and specificity of 100%, the total financial burden of hospital charges would be $132.8 million dollars per annum if disease prevalence was maintained at 0.2%. However, if the prevalence increased to 10%, there would be a 68% increase in charges to $226.9 million dollars.

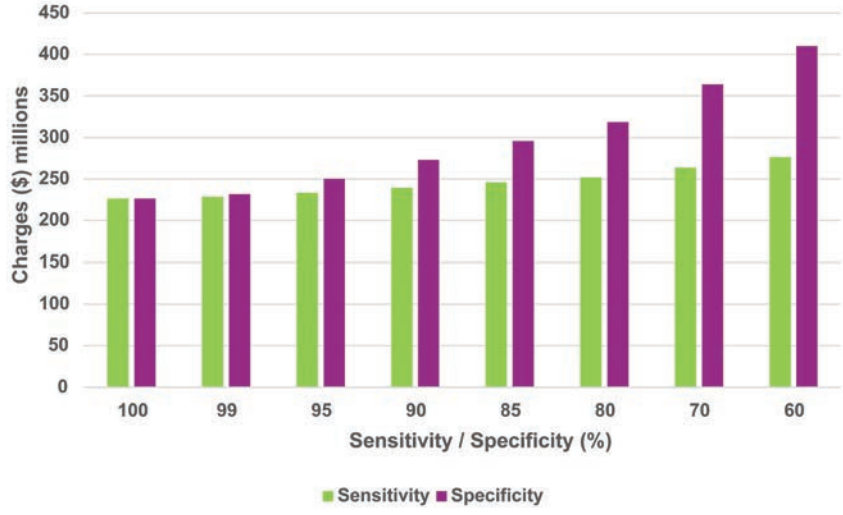
False negative and false positive impacts

For a diagnostic test to accurately identify a patient as having, or not having, a disease is clinically important. A false positive result can cause anxiety and result in patients undergoing treatment for a condition they do not have, incurring all the risks and expenses involved. Alternatively, a false negative can result in timely intervention being missed, worsening disease, requiring more resource intense intervention, disability or even death. In the pandemic, test results drive not only patient treatment decisions but also isolation and quarantine requirements of patients and their contacts. False negatives carry the additional burden of individuals remaining in the community and infecting others who will then require treatment.

Exhibit 3: Effect of test sensitivity and specificity on total charges for COVID-19.



A. Assuming low disease prevalence (0.2%)



B. Assuming high disease prevalence (10%)

Results demonstrate that, even at a single healthcare system, the hospital charges for a declining positive predictive value are substantial —whether driven by charges associated with treating false positives (such as declining specificity in high or low disease prevalence), or by the costs of later patient admissions with false negative results, plus the people they infected (as in the case of declining sensitivity in high disease prevalence). To maximize patient benefit and avoid unnecessary spending, test characteristics, as well as disease prevalence, need to be considered when choosing an appropriate test and/or when interpreting results and deciding whether a patient should be considered as having COVID-19 for contact tracing and disease containment purposes.

Current rtPCR test sensitivity ranges from 60% to 90% and specificity of 99.0 - 99.7%. Improving test sensitivity from 60% to 99% would result in savings of $0.96 and $47.38 million dollars for low- and high-prevalence scenarios in one year at this single tertiary-care medical center. However, improving test specificity from 60% - 99.7% would result in bigger savings of

$202.34 and $183.67 million dollars for low- and high-prevalence instances. A test with low specificity will result in higher numbers of false positive results for patients, who would be hospitalized for 1-2 days, before being confirmed as COVID-19 negative and discharged.

Previous research examined costs associated with false positives in mammograms;[13] prostate, lung, and ovarian cancer screenings;[14] and radiographic interpretations in the pediatric emergency department.[15] Costs of false negatives have been estimated, for example, for human epidermal growth factor receptor 2 (HER2) testing in patients with breast cancer.[16] These studies report increased costs associated with inaccurate results, but differ considerably in terms of context from the examination of COVID-19 testing. Most importantly, they examined the diagnosis of conditions with relatively stable prevalence, creating a stable positive predictive value for a diagnostic procedure with a given sensitivity and specificity and in conditions not involving contagious pathogen; meaning, there is no risk of people with false negative results then unknowingly infecting others.

In contrast, COVID-19 is highly contagious, with an unstable prevalence, differing geographically and over time, creating challenges as localized "hot spots" develop and are controlled through various non-pharmaceutical interventions. A test with a particular specificity and sensitivity may provide adequate diagnostic accuracy to successfully identify and control an outbreak in one community without incurring excessive unnecessary costs. However, in another community with a different disease prevalence, it is woefully inadequate and results in unnecessary treatment costs associated with false-positive patients — or releases so many false negatives into the population that "test and trace" containment fails.

Conclusion

Test selection in the United States is based largely on the availability of tests and supplies needed to run them.[17] This is likely to continue when there are shortages or disruptions in the supply chain. Results demonstrate that failing to take local disease prevalence into account when choosing a test or interpreting results can incur substantial, unnecessary charges.

Analysis shows that when disease prevalence is low (≤ 0.2%), it is reasonable to have a test with high specificity (≥ 99.5 %), while allowing some flexibility in sensitivity (ranging from 95.0% - 60.0%). However, when disease prevalence increases to ≥ 10%, the best option is to have tests with both sensitivity and specificity as close to 100% as possible. Healthcare providers and public health officials should consider strategies to mitigate the risks of inaccurate results, such as repeat testing and giving greater weight to symptoms and epidemiologic risk factors.

The authors are executives, directors, managers, physicians, and laboratorians at Baylor Scott & White Medical Center – Temple, TX.

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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		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[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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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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The **LumiraDx RNA STAR Complete SARS-CoV-2 Test** has not been FDA cleared or approved but has been authorized by FDA for emergency use under an EUA for use by authorized laboratories; this test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and the emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The **LumiraDx SARS-CoV-2 Ag Test** has not been cleared or approved by FDA. The **LumiraDx SARS-CoV-2 Ag Test** has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid protein. The test has not been authorized for use to detect any other viruses or pathogens. The test is authorized in the United States for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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 2021-2022 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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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

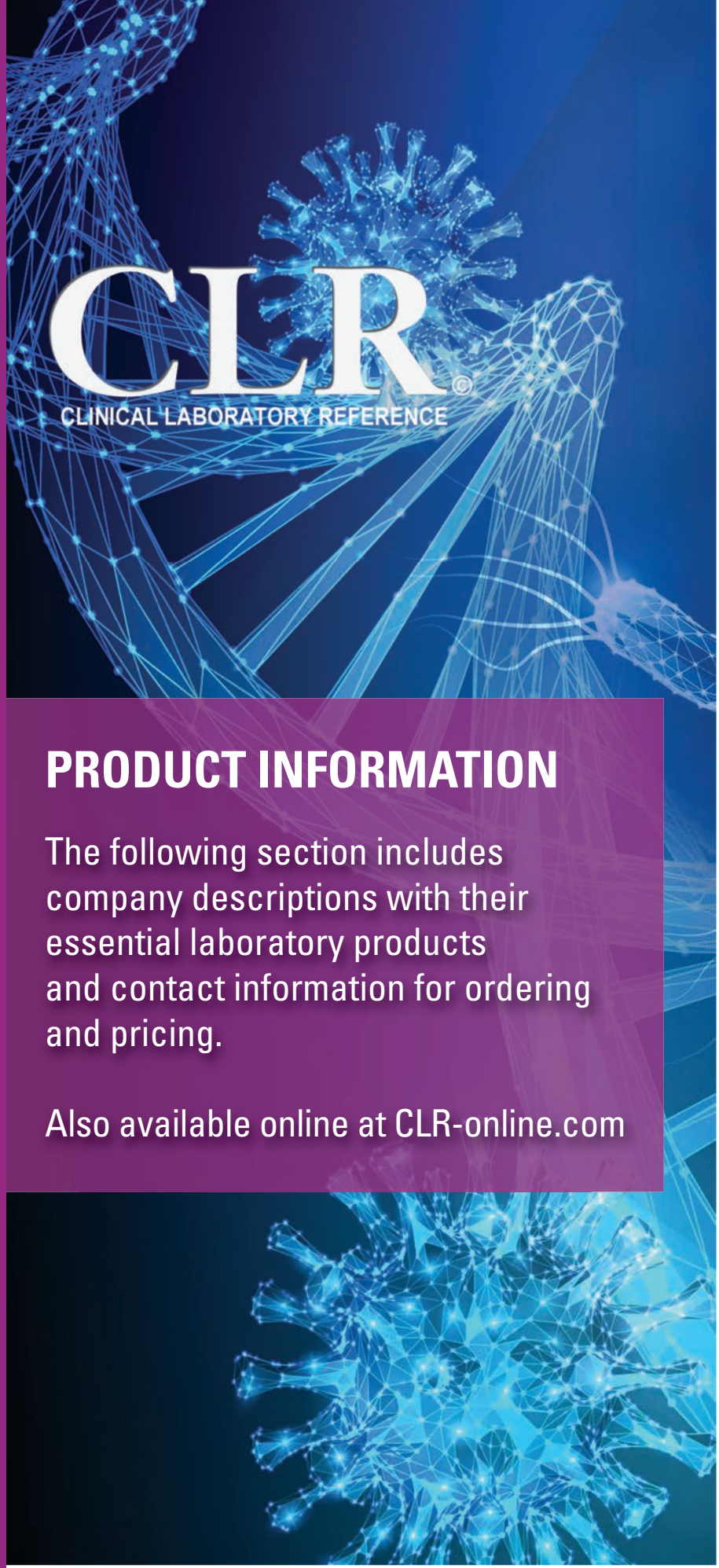
**Values given in this table were obtained from published studies performed on the Stago STA-R, the precursor to the current analytical platform in use at JBER. Flanders MM, et al. Pediatric reference intervals for ten coagulation assays. Blood 2004;104:2988.

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)

Company Name	Last Updated (and Original Date EUA Issued)	Name of Test	Type of Test	Authorized Settings
Abbott Molecular Inc.	6/10/2021 (3/4/2021)	Alinity m Resp-4-Plex	Real-time RT-PCR, Multi-analyte	H, M
Abbott Molecular Inc.	12/23/2020 (5/11/2020)	Alinity m SARS-CoV-2 assay	Real-time RT-PCR, Pooling, Screening	H, M
Access Bio, Inc.	2/5/2021 (7/7/2020)	CareStart COVID-19 MDx RT-PCR	Real-time RT-PCR	H
Agena Bioscience, Inc.	5/4/2021 (10/26/2020)	MassARRAY SARS-CoV-2 Panel	RT-PCR, chip array and MALDI-TOF Mass Spec.	H
Applied BioCode, Inc.	6/8/2021 (6/15/2020)	BioCode SARS-CoV-2 Assay	RT-PCR, Pooling	H
Atila BioSystems, Inc.	12/28/2020 (4/10/2020)	iAMP COVID-19 Detection Kit	RT, Isothermal amplification	H
BayCare Laboratories, LLC	1/28/2021 (8/31/2020)	BayCare SARS-CoV-2 RT PCR Assay	Real-time RT-PCR, Pooling	H
Becton, Dickinson and Company (BD)	4/29/2021 (4/8/2020)	BD SARS-CoV-2 Reagents for BD MAX System	Real-time RT-PCR, Serial Screening	H, M
Becton, Dickinson and Company (BD)	4/29/2021 (2/10/2021)	BD SARS-CoV-2/Flu for BD MAX System	Real-time RT-PCR, Multi-analyte	H, M
BioCore Co., Ltd.	12/18/2020 (5/21/2020)	BioCore 2019-nCoV Real Time PCR Kit	Real-time RT-PCR	H
BioFire Defense, LLC	6/17/2021 (3/23/2020)	BioFire COVID-19 Test	RT, Nested multiplex PCR, Pooling	H, M
BioFire Diagnostics, LLC	4/27/2021 (10/2/2020)	BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)	RT, Nested multiplex PCR, Multi-analyte	H, M, W
Bio-Rad Laboratories, Inc	12/9/2020 (5/1/2020)	Bio-Rad SARS-CoV-2 ddPCR Test	RT-droplet PCR	H
Bio-Rad Laboratories, Inc.	5/6/2021 (1/15/2021)	Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit	Real-time RT-PCR	H
Bio-Rad Laboratories, Inc.	2/11/2021 (2/11/2021)	Bio-Rad Reliance SARS-CoV-2/FluA/FluB RT-PCR Assay Kit	Real-time RT-PCR, Multi-analyte	H
Centers for Disease Control and Prevention (CDC)	1/8/2021 (7/2/2020)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay	Real-time RT-PCR, Multi-analyte	H
Cepheid	4/20/2021 (11/27/2020)	Xpert Omni SARS-CoV-2	Real-time RT-PCR	H, M, W
Cepheid	1/27/2021 (9/24/2020)	Xpert Xpress SARS-CoV-2/Flu/RSV	Real-time RT-PCR, Multi-analyte	H, M, W
Cepheid	1/7/2021 (3/20/2020)	Xpert Xpress SARS-CoV-2 test	Real-time RT-PCR	H, M, W
Cepheid	12/23/2020 (12/23/2020)	Xpert Xpress SARS-CoV-2 DoD	Real-time RT-PCR, Pooling	H, M, W
Cue Health Inc.	3/26/2021 (6/10/2020)	Cue COVID-19 Test	RT, Isothermal amplification, Screening	H, M, W
DiaCarta, Inc	2/3/2021 (4/8/2020)	QuantiVirus SARS-CoV-2 Test kit	Real-time RT-PCR	H
DiaCarta, Inc.	12/28/2020 (7/21/2020)	QuantiVirus SARS-CoV-2 Multiplex Test Kit	Real-time RT-PCR	H
DiaSorin Molecular LLC	4/1/2021 (3/19/2020)	Simplexa COVID-19 Direct assay	Real-time RT-PCR	H, M
Enzo Life Sciences, Inc.	12/30/2020 (7/7/2020)	AMPIPROBE SARS-CoV-2 Test System	Real-time RT-PCR, Pooling	H
Euroimmun US, Inc.	4/22/2021 (6/8/2020)	EURORealTime SARS-Cov-2	Real-time RT-PCR	H
Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	4/7/2021 (5/5/2020)	FTD SARS-CoV-2	Real-time RT-PCR	H
Fluidigm Corporation	2/26/2021	Advanta Dx SARS-CoV-2 RT-PCR Assay	Real-time RT-PCR, Saliva, Home Collection	H
Fosun Pharma USA Inc.	12/28/2020 (4/17/2020)	Fosun COVID-19 RT-PCR Detection Kit	Real-time RT-PCR	H
Gencurix, Inc.	12/28/2020 (6/23/2020)	GenePro SARS-CoV-2 Test	Real-time RT-PCR	H
Grifols Diagnostic Solutions Inc.	2/10/2021 (2/10/2021)	Procleix SARS-CoV-2 Assay	TMA	H
Guardant Health, Inc.	12/28/2020 (8/21/2020)	Guardant-19	Sequencing	H
Hologic, Inc.	5/24/2021	Aptima SARS-CoV-2 assay	TMA, chemiluminescent, Pooling, Screening	H
Hologic, Inc.	5/6/2021 (12/16/2020)	Aptima SARS-CoV-2/Flu assay	Real-time TMA, chemiluminescent, Multi-analyte	H
Hologic, Inc.	1/22/2021 (3/16/2020)	Panther Fusion SARS-CoV-2 Assay	Real-time RT-PCR, Pooling, Screening	H
Illumina, Inc.	4/22/2021 (6/9/2020)	Illumina COVIDSeq Test	Sequencing	H
Laboratory Corporation of America (Labcorp)	5/11/2021 (3/16/2020)	COVID-19 RT-PCR Test	Real-time RT-PCR, Home Collection, Pooling, Screening	H
Laboratory Corporation of America (LabCorp)	5/11/2021 (12/9/2020)	Pixel by LabCorp COVID-19 Test Home Collection Kit	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Pooling, Screening	H
LGC, Biosearch Technologies	5/18/2021 (4/15/2021)	Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test	Real-Time and End-Point RT-PCR	H
Luminex Molecular Diagnostics, Inc.	3/3/2021	NxTAG Respiratory Pathogen Panel + SARS-CoV-2	RT-PCR, Multi-analyte	H
LumiraDx UK Ltd.	3/29/2021 (10/14/2020)	LumiraDx SARS-CoV-2 RNA STAR Complete	RT, qSTAR amplification	H

LumiraDx UK Ltd.	12/28/2020 (8/11/2020)	LumiraDx SARS-CoV-2 RNA STAR	RT, non-isothermal nucleic acid amplification qSTAR	H
Maccura Biotechnology (USA) LLC	12/28/2020 (4/15/2020)	SARS-CoV-2 Fluorescent PCR Kit	Real-time RT-PCR	H
Mesa Biotech Inc.	2/3/2021 (3/23/2020)	Accula SARS-Cov-2 Test	RT and amplification	H, M, W
MobileDetect Bio Inc.	6/17/2021 (9/1/2020)	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit	RT-LAMP	H, M
NeuMoDx Molecular, Inc.	4/23/2021 (3/25/2021)	NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay	Real-time RT-PCR, Multi-analyte	H, M
NeuMoDx Molecular, Inc.	1/22/2021 (3/30/2020)	NeuMoDx SARS-CoV-2 Assay	RT-PCR, Collection Kit, Saliva	H, M
OPTI Medical Systems, Inc.	4/20/2021 (5/6/2020)	OPTI SARS-CoV-2 RT PCR Test	Real-time RT-PCR, Screening, Pooling	H
PathogenDx, Inc.	4/20/2021	DetectX-Rv	RT-PCR, DNA Microarray Hybridization	H
PerkinElmer Genomics	4/12/2021	PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit	Real-time RT-PCR, Home Collection	H
PerkinElmer, Inc.	4/1/2021 (3/24/2020)	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Real-time RT-PCR, Pooling, Screening	H
PlexBio Co., Ltd.	2/3/2021 (6/25/2020)	IntelliPlex SARS-CoV-2 Detection Kit	RT-PCR	H
Primerdesign Ltd.	1/5/2021 (3/20/2020)	Primerdesign Ltd COVID-19 genesig Real-Time PCR assay	Real-time RT-PCR	H
Quadrant Biosciences Inc.	5/6/2021 (9/22/2020)	Clarifi COVID-19 Test Kit	Real-time RT-PCR, Saliva, Pooling	H
Quidel Corporation	5/25/2021 (5/18/2020)	Lyra Direct SARS-CoV-2 Assay	Real-time RT-PCR	H
Quidel Corporation	4/21/2021 (3/17/2020)	Lyra SARS-CoV-2 Assay	Real-time RT-PCR	H
Quidel Corporation	3/25/2021 (12/23/2020)	Solana SARS-CoV-2 Assay	Isothermal Reverse Transcriptase – Helicase-Dependent Amplification (RT-HDA)	H, M
Roche Molecular Systems	6/17/2021	cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat System (cobas SARS-CoV-2)	Real-time RT-PCR, Screening	H, M, W
Roche Molecular Systems, Inc.	6/8/2021 (9/3/2020)	cobas SARS-CoV-2 & Influenza A/B	Real-time RT-PCR, Multi-analyte	H, M
Roche Molecular Systems, Inc.	12/10/2020 (9/14/2020)	cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System	Real-time RT-PCR, Multi-analyte	H, M, W
Roche Molecular Systems, Inc. (RMS)	5/14/2021 (3/12/2020)	cobas SARS-CoV-2	Real-time RT-PCR, Pooling, Screening	H, M, H-Pooling
SEASUN BIOMATERIALS	2/9/2021 (4/27/2020)	U-TOP COVID-19 Detection Kit	Real-time RT-PCR	H
SEASUN BIOMATERIALS, Inc.	4/29/2021 (10/5/2020)	AQ-TOP COVID-19 Rapid Detection Kit PLUS	RT-LAMP	H
Seasun Biomaterials, Inc.	2/23/2021 (5/21/2020)	AQ-TOP COVID-19 Rapid Detection Kit	RT-LAMP	H
Seegene, Inc.	4/15/2021 (4/21/2020)	Allplex 2019-nCoV Assay	Real-time RT-PCR	H
Sherlock BioSciences, Inc.	1/14/2021 (5/6/2020)	Sherlock CRISPR SARS-CoV-2 Kit	RT-LAMP, CRISPR	H
SML GENETREE Co., Ltd.	4/30/2021 (1/13/2021)	Ezplex SARS-CoV-2 G Kit	Real-time RT-PCR, Pooling	H
SolGent Co., Ltd	12/28/2020 (5/21/2020)	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit	Real-time RT-PCR	H
T2 Biosystems, Inc.	12/28/2020 (8/31/2020)	T2SARS-CoV-2 Panel	RT, amplification, T2 Magnetic resonance	RT, amplification, T2 Magnetic resonance
TBG Biotechnology Corp.	1/6/2021 (6/10/2020)	ExProbe SARS-CoV-2 Testing Kit	Real-time RT-PCR	H
Thermo Fisher Scientific	4/9/2021	Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit	Real-time RT-PCR	H
Thermo Fisher Scientific	2/10/2021 (2/10/2021)	TaqPath COVID-19, FluA, FluB Combo Kit	Real-time RT-PCR, Multi-analyte	H
Thermo Fisher Scientific Inc.	5/25/2021 (5/25/2021)	TaqPath COVID-19 Pooling Kit	Real-time RT-PCR, Pooling	H
Thermo Fisher Scientific, Inc.	2/23/2021 (3/13/2020)	TaqPath COVID-19 Combo Kit	Real-time RT-PCR, Home Collection	H
Trax Management Services Inc.	4/7/2021 (7/13/2020)	PhoenixDx SARS-CoV-2 Multiplex	Real-time RT-PCR	H
Twist Bioscience Corporation	3/23/2021 (3/23/2021)	SARS-CoV-2 NGS Assay	Sequencing	H
Visby Medical, Inc.	2/8/2021 (2/8/2021)	Visby Medical COVID-19 Point of Care Test	RT-PCR	H, M, W
Visby Medical, Inc.	12/28/2020 (9/16/2020)	Visby Medical COVID-19	RT-PCR	H, M
Zymo Research Corporation	12/30/2020 (5/7/2020)	Quick SARS-CoV-2rRT-PCR Kit	Real-time RT-PCR	H
De Novo Authorized Test				
BioFire	3/17/2021 De Novo Authorized	Respiratory 2.1 (RP2.1) Panel	RT-PCR, Multi-analyte	H, M

Source: U.S. Food and Drug Administration



PRODUCT INFORMATION

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

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Arlington Scientific, Inc® (ASI) is a USA based, FDA registered, industry leading global medical technology company that develops, manufactures, and sells in-vitro diagnostics, diagnostic analyzers for syphilis screening, face shields, medical donor lounges for Apheresis and Blood Donor Collection, and nasal curettes for uniform mucosal samples.

Arlington Scientific's expertise and emphasis are in diagnostic syphilis reagents and serological test kits. Arlington Scientific developed the ASI Evolution, the only automated nontreponemal (RPR) syphilis analyzer FDA cleared for diagnostic, blood donor screening and cadaveric (Non-heart beating) donor screening.

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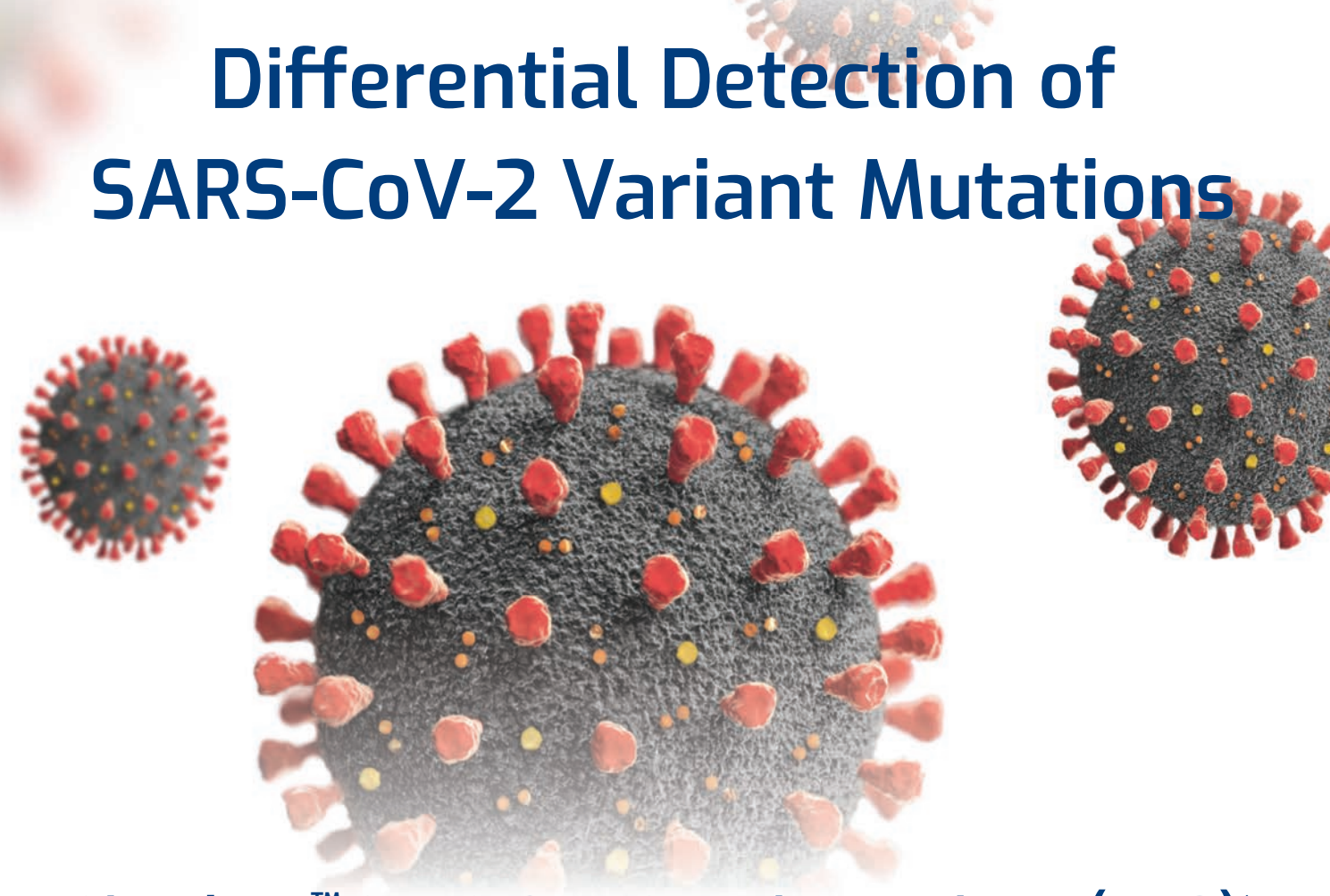

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