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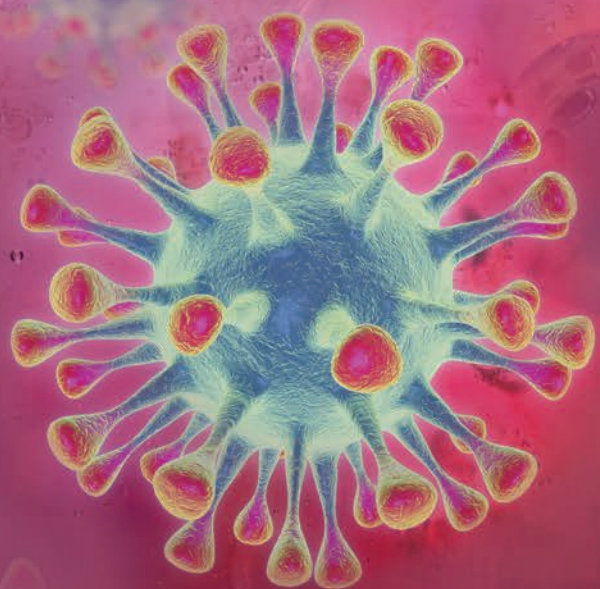

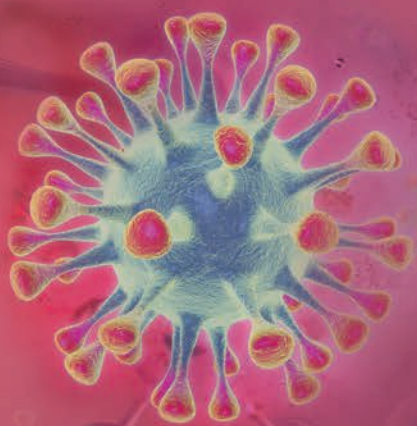

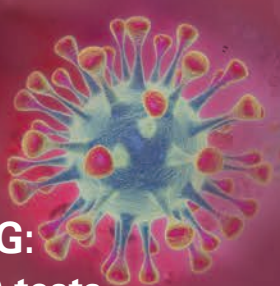

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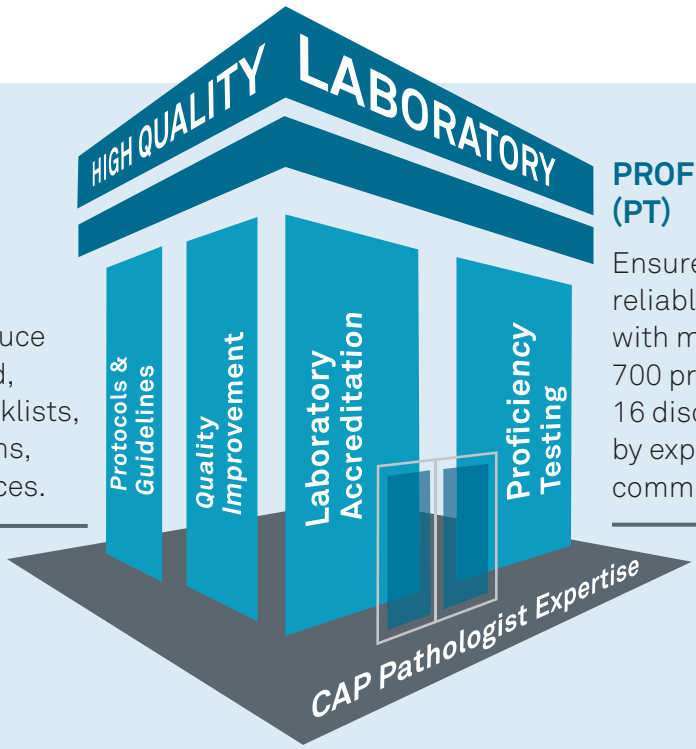

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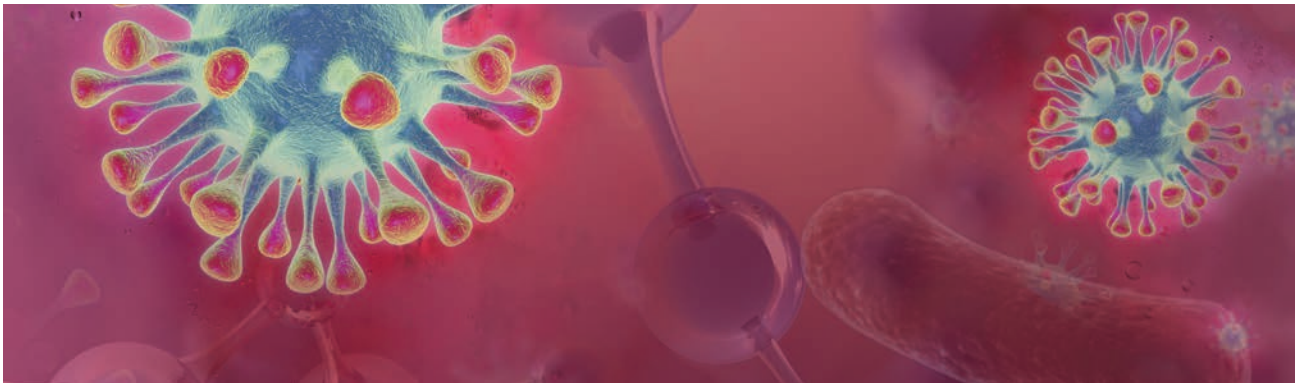

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FEATURES

CLINICAL LABORATORY REFERENCE GUIDES

PRODUCT LISTINGS AND TESTS

DEPARTMENTS

HOW TO USE CLR

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

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

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MLO's annual reference guide

Medical Laboratory Observer has published its annual reference guide, *Clinical Laboratory Reference (CLR)*, since 1972. *CLR* provides a guide to tests, equipment, and services for the clinical lab market, in addition to tables of critical limits, reference intervals, and critical values. It is the industry's only complete resource guide.

The *CLR* product guide includes company descriptions, their essential laboratory products, and contact information for ordering and pricing. This is a "Yellow Pages" service for our readers.

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

Also in this issue, MLO editors pulled together summaries of some of the biggest diagnostic updates from the U.S. Food and Drug Administration and National Institutes of Health so far in 2023. One of these updates is deeper insight into long COVID — the post-infection set of conditions that can affect nearly every tissue and organ in the body. Researchers, funded by the National Institutes of Health, have identified more than 200 symptoms associated with long COVID. Clinical symptoms vary but include fatigue, brain fog, dizziness, loss of taste and smell, and they can last for months or years after a person has had COVID-19. The research team also found that long COVID was more common and severe in study participants infected before the 2021 Omicron variant. To date, more than 100 million Americans have been infected with SARS-CoV-2, the virus that causes COVID-19. It is estimated that about 10% of adults infected with the virus continue to experience and suffer from the many symptoms termed together as long COVID.

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

- Gerald J. Kost, MD, PhD, MS, FAACC, Emeritus Professor, University of California, Davis for the Table of Critical Limits.
- Sean Campbell, PhD, DABCC, FAACC, Director of Chemistry, Montefiore Medical Center, Bronx, NY for the Table of Reference Intervals.
- Rajasri Chandra, MS, MBA for the Critical Values for Therapeutic Drug Values.

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

For comments or feedback on *CLR*, please feel free to reach out to me at cwichmann@mlo-online.com.

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2023 diagnostic updates

By MLO staff

Medical Laboratory Observer connects laboratory professionals with industry trends every year. There have been important diagnostic updates for laboratories from the U.S. Food and Drug Administration and the National Institutes of Health in 2023 — MLO staff put this article together to summarize those updates for its readers.

With this new research, medical experts are closer to identifying better cancer treatments, determining blood donor eligibility, having a deeper understanding of long COVID, and diagnosing severe COVID-19 in pediatric patients.

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FDA launches pilot program to help reduce risks associated with using laboratory developed tests to identify cancer biomarkers

The U.S. Food and Drug Administration announced a new voluntary pilot program for certain oncology drug products used with certain corresponding in vitro diagnostic tests to help clinicians select appropriate cancer treatments for patients.

Through the pilot program, the FDA will request, from drug manufacturers, performance information for the tests used to enroll patients into the clinical trials that support drug approval. Based on an assessment of that information, the FDA will post to the FDA website the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug. Laboratories may use this information to guide their development of LDTs to identify specific biomarkers used for selecting cancer treatment. This transparency aims to help facilitate better and more consistent performance of these tests, resulting in better drug selection and improved care for patients with cancer.

As discussed in the guidance, the initial phase of the pilot program is anticipated to last up to one year, during which the FDA will evaluate no more than nine drug sponsors for possible acceptance into the pilot. The minimum recommended performance characteristics for in vitro diagnostic tests used with each approved drug product under the pilot, based on the clinical trial assays, will be made publicly available on the FDA's website following drug approval.[1]

FDA finalizes move to recommend individual risk assessment to determine eligibility for blood donations

The U.S. Food and Drug Administration finalized recommendations for assessing blood donor eligibility using a set of individual risk-based questions to reduce the risk of transfusion-transmitted HIV. These questions will be the same for every donor, regardless of sexual orientation, sex, or gender. Blood establishments may now implement these recommendations by revising their donor history questionnaires and procedures.

These final recommendations are consistent with the policy initially proposed in January 2023.

This policy eliminates time-based deferrals and screening questions specific to men who have sex with men (MSM) and women who have sex with MSM. Under the final guidance issued, all prospective blood donors will answer a series of individual, risk-based questions to determine eligibility. All prospective donors who report having a new sexual partner, or more than one sexual partner in the past three months, and anal sex in the past three months, would be deferred to reduce the likelihood of donations by individuals with new or recent HIV infection who may be in the window period for detection of HIV by nucleic acid testing.

Additionally, under these final recommendations, those taking medications to treat or prevent HIV infection (e.g., antiretroviral therapy (ART), pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)), will also be deferred. Though these antiretroviral drugs are safe, effective, and an important public health tool, the available data demonstrate that their use may delay detection of HIV by currently licensed screening tests for blood donations, which may potentially give false negative results. Although HIV is not transmitted sexually by individuals with undetectable viral levels, this does not apply to transfusion transmission of HIV because a blood transfusion is administered intravenously, and a transfusion involves a large volume of blood compared to exposure with sexual contact. As stated in the guidance, individuals should not stop taking their prescribed medications, including PrEP, or PEP, in order to donate blood.[2]

Large study provides scientists with deeper insight into long COVID symptoms

Initial findings from a study of nearly 10,000 Americans, many of whom had COVID-19, have uncovered new details about long COVID, the post-infection set of conditions that can affect nearly every tissue and organ in the body. Clinical symptoms can vary and include fatigue, brain fog, and dizziness, and last for months or years after a person has COVID-19. The research team, funded by the National Institutes of Health, also found that long COVID was more common and severe in study participants infected before the 2021 Omicron variant.

The study, published in *JAMA*, is coordinated through the NIH's Researching COVID to Enhance Recovery (RECOVER) initiative, a nationwide effort dedicated to understanding why some people develop long-term symptoms following COVID-19, and most importantly, how to detect, treat, and prevent long COVID. The researchers hope this study is the next step toward

potential treatments for long COVID, which affects the health and wellbeing of millions of Americans.

Researchers examined data from 9,764 adults, including 8,646 who had COVID-19 and 1,118 who did not have COVID-19. They assessed more than 30 symptoms across multiple body areas and organs and applied statistical analyses that identified 12 symptoms that most set apart those with and without long COVID: post-exertional malaise, fatigue, brain fog, dizziness, gastrointestinal symptoms, heart palpitations, issues with sexual desire or capacity, loss of smell or taste, thirst, chronic cough, chest pain, and abnormal movements.

They then established a scoring system based on patient-reported symptoms. By assigning points to each of the 12 symptoms, the team gave each patient a score based on symptom combinations. With these scores in hand, researchers identified a meaningful threshold for identifying participants with long COVID. They also found that certain symptoms occurred together and defined four subgroups or "clusters" with a range of impacts on health.

Based on a subset of 2,231 patients in this analysis who had a first COVID-19 infection on or after Dec. 1, 2021, when the Omicron variant was circulating, about 10% experienced long-term symptoms or long COVID after six months. The results are based on a survey of a highly diverse set of patients and are not final. Survey results will next be compared for accuracy against an array of lab tests and imaging.

The researchers explain studying the underlying biological mechanisms of long COVID is central to advancing informed interventions and identifying effective treatment strategies.

In addition to establishing the scoring system, the researchers found that participants who were unvaccinated or who had COVID-19 before the Omicron strain emerged in 2021 were more likely to have long COVID and more severe cases of long COVID. Further, reinfections were also linked to higher long COVID frequency and severity, compared to people who only had COVID-19 once.[3]

NIH funds eight studies to advance rapid diagnosis of COVID-19–related inflammatory syndrome in children

The National Institutes of Health has awarded eight research grants to refine new technologies for early diagnosis of severe illnesses resulting from SARS-CoV-2 infection in children. The new awards follow grants issued in 2020 to foster methods for diagnosing children at high risk for Multisystem Inflammatory Syndrome in Children (MIS-C), a rare, severe and sometimes fatal after-effect of SARS-CoV-2 infection or exposure in children.

The awards are from NIH's Predicting Viral-Associated Inflammatory Disease Severity in Children with Laboratory Diagnostics and Artificial Intelligence (PreVAIL kIds) initiative. They are part of the Rapid Acceleration of Diagnostics Radical (RADx-rad) program to support new, non-traditional approaches and reimagined uses of existing tools to address gaps in COVID-19 testing and surveillance.

Although some children develop mild or no symptoms from COVID-19, others will develop more severe effects, including MIS-C, which results in inflammation of one or more organs, including the heart, lungs, kidneys, brain, skin, eyes and gastrointestinal tract.

The 2020 awards supported studies involving more than 7,400 research participants in four countries and yielded prototype methods and techniques for potential use in clinics, emergency departments and for hospital inpatients. These PreVAIL kIds studies were supported through NIH's RADx-rad initiative and were part of an NIH collaborative research effort called CARING for Children with COVID. Results from these studies include a laboratory technique for detecting specific immune cells associated with MIS-C; databases that help diagnose children at risk for MIS-C and severe COVID-19, based on certain blood proteins and genetic biomarkers; and a database that can distinguish between MIS-C, Kawasaki disease (which has similar symptoms) and fever-causing viral and bacterial infections.

The new awards will allow researchers to continue their efforts to develop ways to rapidly diagnose MIS-C and identify those at risk for serious and long-term effects of SARS-CoV-2. Earlier identification of those most at risk will allow for earlier interventions to prevent severe health effects.

Awardees

- Jane C. Burns, University of California, San Diego Diagnosing and predicting risk in children with SARS-CoV-2-related illness
- Cedric Manlhiot, Johns Hopkins University, Baltimore Data science approach to MIS-C identification and management associated with SARS
- Ananth V. Annapragada, Baylor College of Medicine, Houston-AICORE-kids: Artificial intelligence COVID-19 risk assessment for kids
- Audrey R. Odom John, Children's Hospital of Philadelphia Diagnosis of MIS-C in febrile children
- Usha Sethuraman, Central Michigan University, Mount Pleasant Severity predictors integrating salivary transcriptomics and proteomics with multineural network intelligence in SARS-CoV2 infection in children
- Juan C. Salazar, Connecticut Children's Medical Center, Hartford Identifying biomarker signatures of prognostic value for MIS-C
- Charles Yen Chiu, University of California, San Francisco Discovery and clinical validation of host biomarkers of disease severity and MIS-C with COVID-19
- Lawrence Kleinman, Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey COVID-19 network of networks expanding clinical and translational approaches to predict severe illness in children[4]

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2. FDA finalizes move to recommend individual risk assessment to determine eligibility for blood donations. U.S. Food and Drug Administration. Published May 11, 2023. Accessed June 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-finalizes-move-recommend-individual-risk-assessment-determine-eligibility-blood-donations.

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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. This table was updated by Dr. Gerald Kost in 2023. 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 the boundaries of life-threatening diagnostic test results. Critical results falling outside high and low critical limits must be reported to clinicians without delay, so the patient can be treated promptly if necessary. Critical value reporting was first implemented by George Lundberg, MD, and published in MLO in 1972. These tables are based on three national surveys by Gerald Kost, MD, PhD, MS, of UC Davis Health. Adapted with permission from his articles,[1-3] they summarize critical limits used by 92 responding U.S. medical centers, including 20 trauma centers, and by 39 children's hospitals.

Mean low and mean high figures may be considered critical limits for each test listed. The frequency with which critical limits were listed can be found in the original articles. Dr. Kost conducted an independent national survey to determine ionized calcium critical limits.[3] His overview of critical limits and patient outcomes appeared in MLO[4] followed by calls for national harmonization and standards of care for critical value practices.[5,6]

The Joint Commission identifies critical values and the need to report critical results timely in National Patient Safety Goals.[7] Elements of performance comprise: (a) define critical values and develop written procedures for managing critical results, by whom and to whom they are reported, and acceptable lengths of time between resulting and reporting; (b) implement procedures for managing critical results; and (3) evaluate the timeliness of reporting. Laboratories should carefully monitor failed clinician notifications and strive for none.

Surveys and practice reviews are advancing harmonization[8] of critical values and notification practices in Australia,[9] Canada,[10] China,[11-16] Croatia,[17] Iran,[18-20] Italy,[21,22] Kuwait,[23] Turkey,[24] Spain,[25] South Africa,[26] and the U.S.[27-28] Understanding quantitative critical limits, qualitative critical values, alternate nomenclature (e.g., "critical-risk results, significant-risk results, and alert thresholds"[27]), and national norms will be necessary to enable a global standard. Special considerations for newborn and pediatric critical values are necessary because of rapid adaption to the extrauterine demands for physiological changes.

Studies address critical values for cytology,[29,30] cytogenetics and molecular genetics,[31] point-of-care glucose,[32] virology,[33] and anatomic and surgical pathology.[34] One US study addressed false positive critical value results.[35] If institutions list COVID-19 tests, then both false positive and false negatives should be of concern, the former for triggering unnecessary isolation and the latter, for spreading disease by those unaware of infection.[36] Repeat testing will improve the performance of COVID-19 testing[37] but may not be indicated for other critical results.[19,24,38,39]

Lifesaving diagnostic speed and accurately informed decision-making lead to appropriate therapy in times of human crises.[40] Clinical laboratories and point-of-care specialists can assign critical values and develop notification practices collaboratively with emergency physicians, hospitalists, and other clinical colleagues to achieve optimal outcomes for patients.

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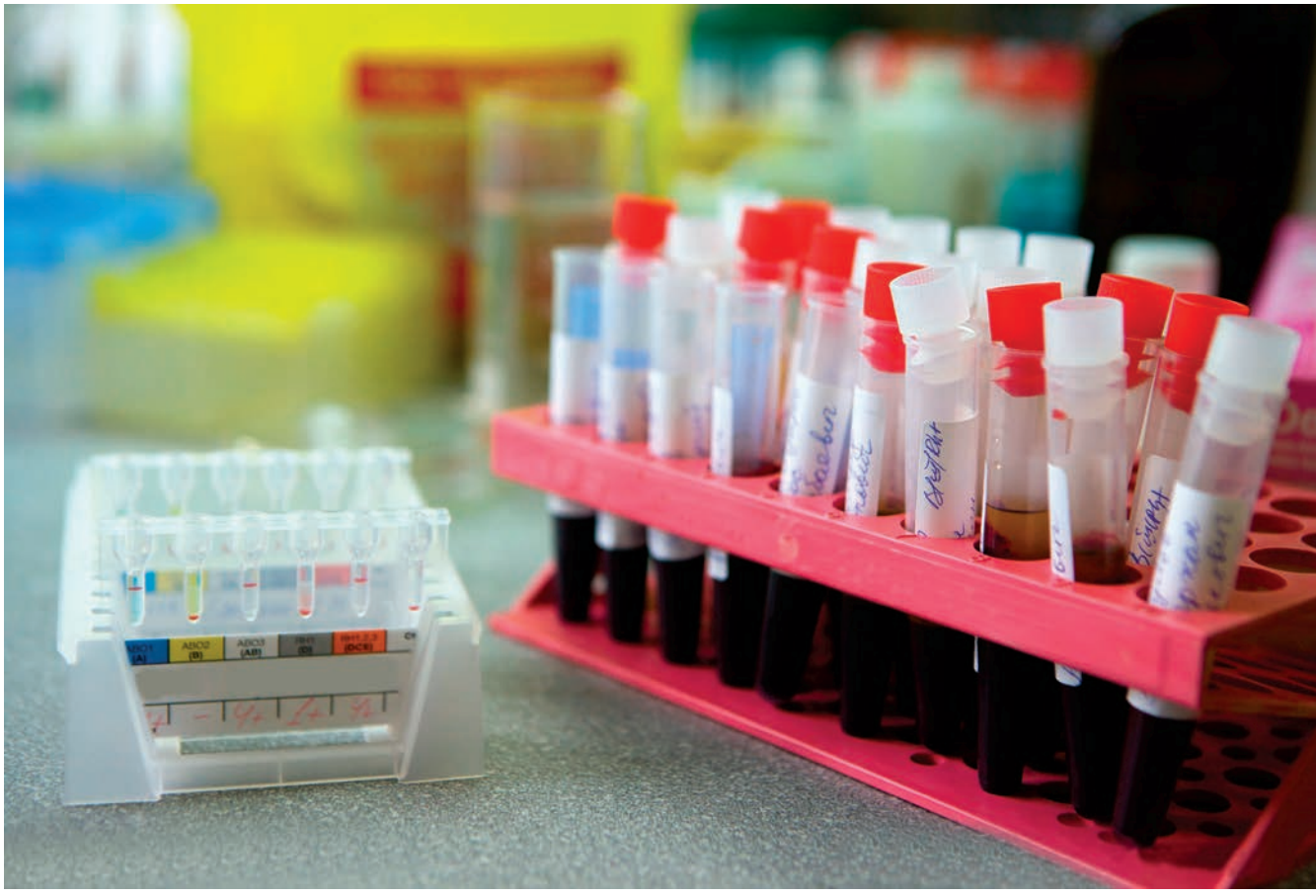

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This table was put together by MLO staff referring to federal regulations at 49 CFR part 40, Section 40.87 and information from Thermo Fisher. Section 40.87 states that:

a. As a laboratory, you must use the cutoff concentrations displayed in the following table for initial and confirmatory drug tests. All cutoff concentrations are expressed in nanograms per milliliter (ng/mL).
b. On an initial drug test, you must report a result below the cutoff concentration as negative. If the result is at or above the cutoff concentration, you must conduct a confirmation test.
c. On a confirmation drug test, you must report a result below the cutoff concentration as negative and a result at or above the cutoff concentration as confirmed positive.
d. You must report quantitative values for morphine or codeine at 15,000 ng/mL or above.[1]

The table follows:

INITIAL TEST ANALYTE	COMMON STREET NAME(S)	INITIAL TEST CUTOFF[A]	CONFIRMATORY TEST ANALYTE	CONFIRMATORY TEST CUTOFF CONCENTRATION
Marijuana metabolites (THCA)[B]	Marijuana (Pot)	50 ng/mL[C]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine)	Cocaine (Coke)	150 ng/mL[C]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	Opiates	2000 ng/mL	Codeine Morphine	2000 ng/mL. 2000 ng/mL.
Hydrocodone/Hydromorphone	Vicodin/Dilaudid	300 ng/mL	Hydrocodone Hydromorphone	100 ng/mL. 100 ng/mL.
Oxycodone/Oxymorphone	OxyContin/Opana	100 ng/mL	Oxycodone Oxymorphone	100 ng/mL. 100 ng/mL.
6-Acetylmorphine	Heroin	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	PCP (Angel Dust)	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	Meth	500 ng/mL	Amphetamine Methamphetamine	250 ng/mL. 250 ng/mL.
MDMA[D]/MDA[E]	Ecstasy	500 ng/mL	MDMA MDA	250 ng/mL. 250 ng/mL.

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2. SAMHSA guidelines - US. Accessed June 1, 2023. https://www.thermofisher.com/us/en/home/clinical/diagnostic-testing/clinical-chemistry-drug-toxicology-testing/drugs-abuse-testing/drug-testing-overview/samhsa.html.

A. For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
B. An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
C. *Alternate technology (THCA and Benzoylecgonine):* When using an alternate technology initial test for the specific target analytes of THCA and Benzoylecgonine, the laboratory must use the same cutoff for the initial and confirmatory tests (i.e., 15 ng/mL for THCA and 100ng/mL for Benzoylecgonine).
D. Methylenedioxymethamphetamine (MDMA).
E. Methylenedioxyamphetamine (MDA).

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*	<0.3 mg/dL	17.1	<5 µmol/L
S	Bilirubin, total*	0.1-1.2 mg/dL	17.1	2.0-19.9 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	Iron, total	20-168 µg/dL	0.179	3.5-30.0 µmol/L
S	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	0.56-1.39 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 g/dL	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)*	218-459 µmol/L	59.48	0.22-0.46 mmol/L
S	Uric acid (women)*	147-366 µmol/L	59.48	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, 6th 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 2023 by S.T. Campbell, PhD, DABCC, FAACC, Director of Chemistry, Montefiore Medical Center, Bronx, NY.

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 lists the critical values for common therapeutic drugs updated in 2023 by Rajasri Chandra, MS, MBA.

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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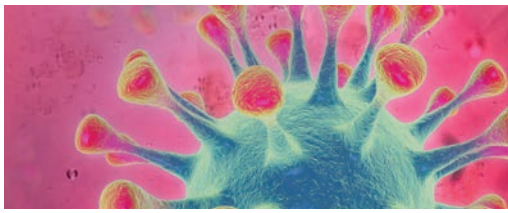

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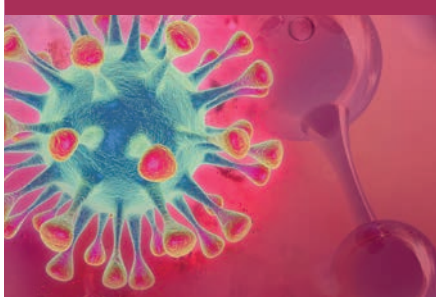

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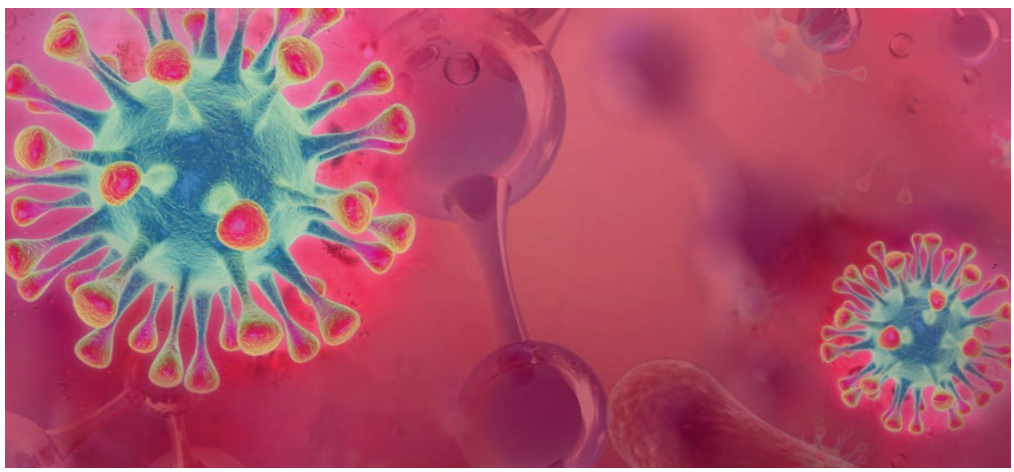

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