November/December 2023

CLN Clinical Laboratory News

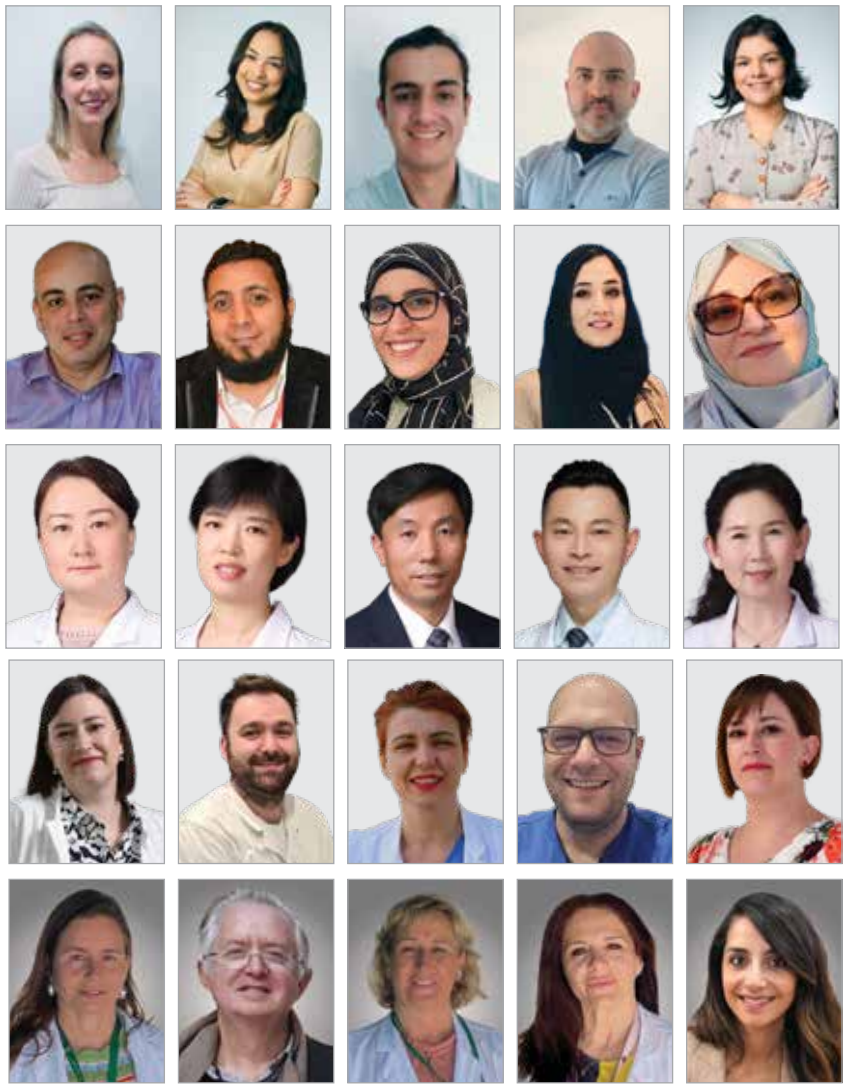
An ADLM Publication | Special Supplement

ENHANCED COVID-19 TESTING STRATEGY

81%

Test results returned within 6 hours

PAGE 6



UNIVANTS Teams of Achievement Demonstrate Excellence in Improving Patient Care

BY KIMBERLY SCOTT

Clinical laboratories across the globe are demonstrating the important role they play in helping improve patient care through streamlined and rapid testing, particularly in emergency departments, where efficient patient flow and quick diagnosis can be a matter of life and death. The five initiatives highlighted below have been recognized by the UNIVANTS of Healthcare Excellence Awards as the 2022 "Teams of Achievement."

These prestigious awards were created by Abbott in partnership with the Association for Diagnostics & Laboratory Medicine (ADLM, formerly AACC) and other leading healthcare organizations to recognize teams that collaborate across disciplines to transform healthcare delivery. In addition to demonstrating the critical role of clinical laboratories, the winning teams

demonstrate how working together with other specialties as part of an interdisciplinary team can have a significant impact on improving patient outcomes.

This supplement explores the outstanding accomplishments of the Teams of Achievement, which include using a noninvasive serological model to diagnose liver cancer, optimizing direct quantitative PCR (qPCR) during the COVID-19 pandemic, accelerating a diagnostic pathway for patients with suspected mild traumatic brain injury, strategic laboratory stewardship in the emergency department (ED), and enhanced staff support and resource utilization during the pandemic.

USING A NONINVASIVE SEROLOGIC MODEL TO DIAGNOSE LIVER CANCER

Primary liver cancer, or hepatocellular carcinoma (HCC), is currently the fourth most common malignant tumor in China, with a 5-year survival rate of only 12.1%. The key means to improving the overall survival rate of HCC patients is the early identification and early diagnosis of high-risk groups of HCC.

Ideally, diagnosis of early HCC at an asymptomatic stage allows more patients to receive potentially curative treatments, such as lobectomy, interventional therapy, and liver transplantation to maximize patient outcomes and reduce mortality associated with liver cancer, noted Yinlong Zhao, MD, professor and director of nuclear medicine at The Second Hospital of Jilin University in Changchun, China. Regular surveillance of patients with chronic liver disease to identify high-risk groups and the application of imaging tests to identify early HCC or precancerous lesions are effective means of detecting potential liver cancer, she said.

In terms of early diagnosis of liver cancer, ultrasound is currently recognized as an important screening method. However, ultrasound has limitations and is easily affected by the personal experience and skill of the operator. At the same time, patients with nodular cirrhosis are prone to misdiagnosis. Serum biomarkers such as alpha-fetoprotein (AFP) are commonly used, but AFP detection is insufficient in the diagnosis of liver cancer, Zhao said.

In clinical practice, more than 30% of patients with liver cancer have normal or only mildly elevated AFP levels, especially in patients with early or small liver cancer. Zhao believes that significant opportunities exist to ensure patient safety through routine and effective use of clinical risk models, which are also recommended by the latest clinical guidelines.

An integrated clinical care team at The Second Hospital of Jilin University recognized an opportunity to provide education to the population at risk and detect liver cancer through a new diagnostic pathway known as ASAP, which they believed could improve patient safety and reduce unnecessary invasive examinations. The hospital began experimenting with the new pathway on June 1, 2020.

ASAP is a risk-stratification model based on serological tests, developed by a Chinese multicenter,

Stigur Már Karlsson /Heimsmyndir / iStock

Using a Noninvasive Serologic Model to Diagnose Liver Cancer

17.4% Increase in number of patients identified as having primary hepatocellular carcinoma using ASAP versus AFP alone.

8,000 Yuan ($1,200) Average savings per patient due to reduction of the number of unnecessary imaging examinations.

19.3% Increase in added clinical confidence using ASAP model.

large-sample cohort study in 2019. The ASAP model is comprised of four key elements: age, sex, AFP, and PIVKA-II. It is convenient, relatively noninvasive, and easily available, and has been shown to accurately predict the presence of HCC, Zhao said.

For patients suspected of having HCC, use of ASAP versus AFP alone identified an additional 17.4% (from 54.4% –71.8%) of patients with liver cancer. Implementation of the ASAP model also resulted in a reduction in the number of unnecessary imaging examinations, invasive procedures, and surgeries for patients, saving approximately 8,000 yuan ($1,200) per patient. A reduction of about 14,000 ultrasounds per year is equivalent to savings of 2.1 million yuan ($290,000).

With the support of a multidisciplinary team, high-risk patients underwent further examinations to confirm the diagnosis. Medium-risk patients were monitored while high-risk patients were regularly screened and followed to reduce unnecessary examinations and patient anxiety.

The use of biomarker panels for diagnosis is widely accepted, Zhao noted. However, in this case, the ASAP biomarker panel was specifically validated in a Chinese population. "Our multidisciplinary approach has enabled cross-functional utility, implementation, and endorsement of the risk model across specialties for liver cancer diagnosis and intervention," she said.

Clinicians at the hospital also appreciated that the ASAP model was validated in the Chinese population. "In a field of evidence-driven medicine, where ethnic diversities can have an impact on patient care, I am pleased to have an actionable, real-time model that has not only been developed but also validated in the population I serve," said Yongshen Yang, MD, director of the Hapatobiliary and Pancreatic Surgery Department.

Implementing the ASAP model can be straightforward and simple for most healthcare systems, Zhao said, provided they already have the main components of the model available, including a core laboratory that can run the AFP and PIVKA-II-biomarker panel and an intelligent information solution (such as AlinIQ AMS) for calculating the score.

Optimizing Direct qPCR During COVID Pandemic

15 hours to 3 hours Average reduction in wait time for results for SARS-CoV-2 testing.

480,000 Euros ($508,000) Savings from isolation reagents no longer required for PCR testing.

3% Identified false negative rate for rapid antigen testing identified by POC dqPCR testing.

OPTIMIZING DIRECT QPCR DURING THE COVID-19 PANDEMIC

During the COVID-19 public health emergency, rapid testing was key to minimizing the spread of SARS-CoV-2. However, many parts of the world struggled to achieve fast result turnaround. Clinical Hospital Center in Rijeka, Croatia, found that due to lack of supplies and the expense of patient testing, rapid testing for SARS-CoV-2 was seriously restricted early in the pandemic.

Although most hospitals have specialized laboratories capable of performing quantitative qPCR testing for SARS-CoV-2, the collection of samples at various sites within hospitals and their transport to dedicated laboratories increases the time from sample acquisition to result.

Given that several different commercially available qPCR reagents demonstrated the feasibility of direct qPCR (dqPCR) detection without an RNA isolation phase, the hospital chose to adapt an existing assay into a point-of-care (POC)-style direct qPCR process and introduce it into the ED, explained Martina Pavletic, PhD, a specialist in intensive care medicine in the ED.

The Seegene Allplex SARS-CoV-2 diagnostic test was modified by the clinical laboratory team into a POC dqPCR test that could be performed by clinicians and technicians with little prior experience with qPCR testing and implemented in the hospital ED. The hospital partnered with the Center for Proteomics at the University of Rijeka in modifying the test.

"At that time, there were not any CE-IVD/Food and Drug Administration approved kits that we could use out of the box, so on top of organizing the logistics of setting up the lab, we needed to make sure the results were comparable to the classic test, which was a lot of work," said Mate Lerga, MD, an emergency medicine specialist. "Besides validating the test, we also needed to validate our performance of the test since we are primarily clinicians and the other personnel we sourced later were from various fields—biochemistry, transfusion medicine,

biotechnology, and sanitary engineering."

Emergency specialists and physicians were trained in PCR technique analysis during the POC-PCR laboratory implementation, noted Vanda Juranic Lisnic, PhD, a university professor and researcher in the Center for Proteomics. "The development and validation of direct qPCR was mainly performed by clinicians with no previous experience in techniques employed in a molecular biology lab in collaboration with the Center for Proteomics," she said. "Over 10 clinicians, both experienced specialists and just-graduated MDs, successfully learned how to analyze and interpret qPCR data."

Once they implemented the POC dqPCR method, the waiting period for the results decreased from an average of 15 hours (maximum of 44 hours) to 3 hours (maximum of 6 hours). What's more, the POC dqPCR testing revealed a 3% false negative rate from rapid antigen testing. Hence, use of the POC dqPCR method for SARS-CoV-2 testing both increased patient safety and reduced intrahospital virus transmission, Pavletic said.

This approach also saved money, with the cost of testing for one patient declining from 30 euros to 20 euros as a result of isolation reagents that were not used. This saved an average of 40,000 euros monthly ($42,000), or 480,000 ($508,000) euros per year. Altogether, the hospital's molecular diagnostics expenses were reduced by 33%.

Clinical Hospital Center Rijeka was the first hospital in the region to create and implement direct quantitative PCR, significantly improving the flow of patients through the hospital system, Pavletic said. The design of the dqPCR test for SARS-CoV-2 is transferable to different molecular detection techniques, both established and emerging, she added.

"The Laboratory for Rapid Molecular Diagnostics in the Emergency Department at the Rijeka Clinical Hospital Center was established with the intention of continuing to develop molecular diagnostics methods based on the point-of-care principle for the purpose of rapid diagnosis and application of therapeutic agents in emergency procedures," Pavletic said. "The automated transfer of PCR test results from the SARS-CoV-2 viewer software to the hospital information system allows for quicker results validation and increased lab processivity."

Development of the Laboratory for Rapid Molecular Diagnostics and the dqPCR test has since led to development of other POC tests, including assays for respiratory syncytial virus and other infectious diseases, Lerga said.

"When the European Centre for Disease Prevention and Control issued a Mpox advisory, we were ready in literally a few days, and for any future needs, we would need only a short amount of time to be ready to provide a huge number of tests per day," he said. "At this point in time, we have unlimited options to provide patients with some sort of individually tailored tests any time we see fit."

ACCELERATED DIAGNOSTIC PATHWAY FOR PATIENTS WITH SUSPECTED MILD TBI

Traumatic brain injury (TBI) is the greatest contributor to death and disability among all trauma-related injuries. TBI can also increase the risk of developing a neurodegenerative syndrome, like dementia, later in life. The gold standard to assess TBI in the ED is through the use of computed tomography (CT), a technology that uses radiation, which has been linked to increased risk of developing cancer over the long term. TBI has also been associated with high costs to individual patients and society at large.

Mild TBI (mTBI) can be difficult and costly to diagnose. An interdisciplinary team at Hospital Universitario Virgen de Las Nieves in Granada, Spain, implemented a new TBI panel in routine practice, which not only resulted in fewer CT scans, but also shorter waiting times in the ED, according to Gemma Álvarez Corral, a clinical laboratory specialist in laboratory medicine. The hospital uses the new panel in conjunction with other clinical information to aid in the evaluation of patients 18 years of age and older who present with suspected mTBI within 12 hours of injury. The panel assists in determining the need for

Accelerated Diagnostic Pathway for Patients with Suspected Mild TBI

10% Reduction in CT scans in first three months of implementation.

2-Fold Reduction in wait times for patients who have been ruled out for TBI, from 8.63 hours to 4.3 hours.

4,568 Euros ($4,837) Total mitigated costs from not performing unnecessary CT scan in first nine months.

a CT scan of the head by enabling semiquantitative interpretations of GFAP (glial fibrillary acidic protein) and UCH-L1 (ubiquitin C-terminal hydrolase L1) as found in human plasma and serum.

Since implementing the TBI clinical care initiative, 33 patients who would previously have been unnecessarily exposed to radiation did not require a CT scan to rule out mild TBI. Overall, there was a 10% reduction in CT scans, enabling a reallocation of skilled resources to other functional areas. In addition, there has been a more than two-fold reduction in average wait times for patients who have been ruled out for TBI, from 8.63 hours to 4.3 hours, saving a total of 132 patient hours over 9 months, according to Corral.

Clinicians also found the panel useful. In a survey conducted among ED doctors and nurses, 77.8% indicated that the added insights from the panel helped reduce the uncertainty related to the absence of brain lesions, particularly in the elderly.

"Working in emergency departments involves high pressure. Equally high are the expectations of patients and their families," commented Jose Franciso Vargas Rivas, MD, head of the ED. "By reducing patient wait times associated with diagnostic tests, we minimize the added pressures associated with unfortunate delays directly, or indirectly, related to emergency services."

Use of the mTBI panel is estimated to have saved almost 250 euros ($264) per patient with suspected mild TBI, according to Corral. Total mitigated costs through reduction in unnecessary CT scans has exceeded 4,568 euros ($4,837) since the hospital implemented the initiative.

"The introduction of the TBI panel has made it possible to reduce the number of patients staying in the emergency room," she explained. "The price of a simple emergency consultation (medications and analytics) is 144.24 euros ($152.75). The price of assistance if it requires more complex tests (such as the TAC) and longer waiting time, is 392.03 euros ($415.15). Avoiding these costs can be significant."

This clinical initiative is unique in that there are few hospitals in Europe that have begun using the mTBI marker panel. The Hospital Universitario Virgen de Las Nieves in Granada is the only hospital in Spain to have implemented this panel, according to Corral. The process is very easy and does not require any changes in the infrastructure, she added, noting the markers are as easy to measure as glucose.

STRATEGIC LABORATORY STEWARDSHIP IN THE EMERGENCY DEPARTMENT

ED overcrowding is a global challenge that can lead to delays in patient management, increased patient length of stay, and increased healthcare costs. Key to patient triage is understanding the clinical conditions and need for hospital admissions. Laboratory tests have long played an essential role in those decisions. Increased testing can have a dramatic impact on already constrained human and economic resources, particularly if requests do not follow evidence-based criteria. By contrast, inappropriate laboratory testing could trigger additional, unnecessary, and even invasive investigations.

To reduce overcrowding in the ED, a team at Ain-Shams University Emergency Hospital in Cairo, Egypt, in 2021 designed a novel testing approach for optimization of urgent testing, according to Wessam ELSayed, MD, a professor of clinical pathology and emergency lab director at the hospital.

ED physicians now have the choice to order from a panel of

Strategic Laboratory Stewardship in the ED

15.2% Increase in patients who were low-risk for adverse events being confidently sent home, without the need for unnecessary serial lab testing.

12% Increase in workflow capacity in the ED, allowing more than 10,000 more patients to be seen each year.

270 EGP ($13) Average savings per patient in reduction in unnecessary testing.

peakSTOCK / iStock

10 tests, with individual recommendations related to evidence-based ordering. Based on the results, ED physicians make the decision to admit for more testing. The test panel is based on a consensus between internal medicine, surgeons, and laboratory medicine professionals.

The test menu includes the most informative tests across the most common emergency conditions, with the ability to be performed within 1 hour. Selection is based on patients' clinical conditions. For example, amylase testing is ordered for patients with acute abdominal pain.

The 10-test-panel includes the following assays: arterial blood gas, complete blood count, prothrombin time, random blood glucose, creatinine, total bilirubin, direct bilirubin, amylase, high-sensitive (hs) troponin II, and beta human chorionic gonadotropin. A cardiologist must request the hs-troponin test.

If additional testing is needed, the patient is admitted to the hospital and further testing is selected from a 20-test panel. In addition to the tests included in the 10-test panel, the 20-test panel also includes the following: sodium, potassium, creatine kinase, CK-MB, albumin, alanine aminotransferase, aspartate aminotransferase, hepatitis B surface antigen, hepatitis C antibodies, and HIV Ag-Ab.

"The new process has substantially and positively improved workflow, as well as the patient experience, enabling expedited care and enhancing our hospital's ability to maximize the number of patients who are seen, admitted, or safely discharged home from the ED," ELSayed said.

As a result of the new testing initiative, 15.2% more patients who were low risk for adverse outcomes (from 49%–64.2% of ED patients) were confidently sent home, without the need for unnecessary serial lab testing. Test turnaround times improved in every testing category, with improvements of 21 minutes in chemistry, 6 minutes in hematology, 30 minutes in virology, and 14 minutes in hormone testing.

In addition, length-of-stay in the ED declined from 10 hours to 6 hours, thus accelerating ED patient flow to internal departments for earlier management and helping to decrease overcrowding.

"In an area where health resources are scarce and minimal alternatives exist, patients are at the mercy of the capacity of our emergency department," said Abdall Hamed Ibrahim, MD, deputy manager of the emergency hospital. "With our new process, we've witnessed a substantial reduction in patient wait times, saving up to four hours from arrival to discharge or admission."

In addition, workflow capacity in the ED increased by 12%, enabling more than 10,000 more patients to be seen each year since (14,978 in 2020/2021 and 12,515 in 2021/2022). Admissions from the ED to internal medicine and surgery also increased by 14% and 19%, respectively, according to Essam Fakhery, MD, manager of the ED.

What's more, unnecessary lab tests performed in the ED are reduced from 20 tests to 10 tests per patient, leading to a savings of 270 EGP (about $13) per patient.

"In our institute, the ED services are free of charge," ELSayed said. "That means poor patients can receive the healthcare services without paying. The university hospital offers the resources needed for care in the ED; thus, these resources should be optimized to help in patient management in the emergency setting."

The clinical care initiative is unique, ELSayed added, noting that the use of only 10 common tests with clinical evidence instead of ordering additional tests in the ED is challenging. The initiative is also highly scalable. "Any ED-setting or institute could implement the 10-lab-test panel in the ED," she noted. "However, the choice of tests should be of clinical significance according to each institute and the common patient clinical settings."

Enhanced Staff Support and Resource Utilization During COVID

6 Newly established sample collection points allowing collection of more than 3,500 specimens during peak time of COVID pandemic.

81% Test results returned within six hours of sample collection.

1,881 Number of staff who became aware of their COVID-19 status.

ENHANCED STAFF SUPPORT AND RESOURCE UTILIZATION DURING COVID

Early in the COVID-19 pandemic, a multidisciplinary team with the Associação Fundo de Incentivo a Pesquisa (AFIP) in Brazil convened to devise a strategy on how to deal with

COVID. AFIP is a private, non-profit, and philanthropic institution with a wide range of health services in eight Brazilian states. The AFIP has more than 3,000 employees and performs about 6 million laboratory tests monthly, of which about 80% are assigned to the Sistema Únicoe Saúde (SUS) in Brazil. The SUS is the largest public health system in the world, serving nearly 190 million people.

The Cuidando de Quem Cuida (CQC), a program that aims to promote employee healthcare, was used by the committee to implement a comprehensive COVID-19 testing strategy for employees and their families. The AFIP laboratory performed real-time PCR tests on more than 3,500 samples from employees and their families; tests were free for employees and provided at a cost for family members. Six new sample collection points were established, with two points with the highest number of collections located 1.2 miles from the facility to facilitate home pickups and drive-through services. These strategic collection points accounted for more than 3,500 samples during peak times of the COVID pandemic.

"With 81% of test results released within 6 hours and 19% released within 12 hours, we were able to provide early guidance to most employees in relation to symptom control, warning signs, and isolation procedures to reduce on-site transmission of work and in the family," said Josue Augusto do Amaral Rocha, MD, a family physician with the CQC program. "As a result, we had excellent indicators regarding the number of serious cases (16 hospitalizations in 1,959 confirmed cases) and mortality (two deaths) among all healthcare workers with positive tests."

What's more, AI predictive data for human analytics enabled staff changes that equated to the savings of one full-time employee who was deployed in times of need to support areas of business need during different waves of the COVID-19 pandemic, said Gabriel Costa de Carvalho, PhD, a researcher with the AFIP.

The process is highly scalable, not only for viral pandemic outbreaks, but also for other testing situations that require some complexity and responsibility.

"Caring for employee fragility is a unique initiative in terms of quick turnaround times for laboratory results and family uncertainties," said de Carvalho. "This specific look can be replicated and introduced to other organizations as new pandemic outbreaks occur."

CLINICAL LABORATORIES HELP OPTIMIZE PATIENT CARE

The initiatives highlighted above are just a few of the many projects in which laboratories are playing a critical role in transforming healthcare delivery.

Whether identifying liver cancer through noninvasive methods or diagnosing mild traumatic brain injury faster and more efficiently, clinical laboratories around the world are making a real difference in improving patient outcomes and quality of life. Beyond simply providing test results, these labs are actively improving care in emergency departments, reducing wait time for test results, and optimizing test ordering.

To learn more about UNIVANTS and past award recipients, go to www.univantshce.com.

UNIVANTS 2022 Teams Recognized in This Issue

A Noninvasive Serologic Model Using an Intelligent Informatic Solution to Enhance Clinical Decision-Making and Improve Patient Safety

The Second Norman Bethune Hospital of Jilin University

Yinlong Zhao, Zhenjing Jin, Yongsheng Yang, Chunmei Hu, Yan Zhao

Improving Emergency Department Flow and Decreasing Risk Through Development and Implementation of Molecular Diagnostics Guided Triage

Clinical Hospital Center Rijeka

Martina Pavletić, Vanda Juranic Lisnic, Mate Lerga, Mario Franic, Jennifer Babic

Improved and Accelerated Diagnostic Pathway for Patients That Present to the Emergency Department With Suspected Mild Traumatic Brain Injury

Hospital Universitario Virgen de las Nieves

Gemma Alvarez Corral, Maria Molina Zayas, Francisco Ruiz-Cabello Osuna, Maria Isabel Romero Manjon, Eva Gutierrez Pérez

Enhancing Resource Utilization and Improving Patient Experience Through Strategic Laboratory Stewardship

Ain-Shams University - Emergency Hospital

Wessam EL Sayed Saad, Esam Fakhery Ebied, Rawan Mahmoud Mohamed, Ashraf Hassan Abdelmobdy, Nouran Mahmoud Bahig

Enhanced Staff Satisfaction and Resource Utilization During the Covid-19 Pandemic

Associação Fundo de Incentivo a Pesquisa

Debora Ribeiro Ramadan, Tatiane Rodrigues dos Santos, Josué Augusto do Amaral Rocha, Cristiane Franca Ferreira, Paulo Eduardo de Andrade Souza

UNIFY FOR SOMETHING GREATER

UNIVANTS™
OF HEALTHCARE EXCELLENCE

The **UNIVANTS** of Healthcare Excellence Award program celebrates teams who have achieved measurably better outcomes in healthcare.

If you are a team of **UNIFIERS** who have applied **AVANT-GARDE** approaches to achieve better healthcare outcomes, learn more and apply at **UnivantsHCE.com**.

IN PARTNERSHIP WITH

Abbott | IFCC International Federation of Clinical Chemistry and Laboratory Medicine | ADLM | EHMA European Health Management Association | Modern Healthcare | HIMSS | NAHQ National Association for Healthcare Quality | IHE | INSTITUTE OF HEALTH ECONOMICS