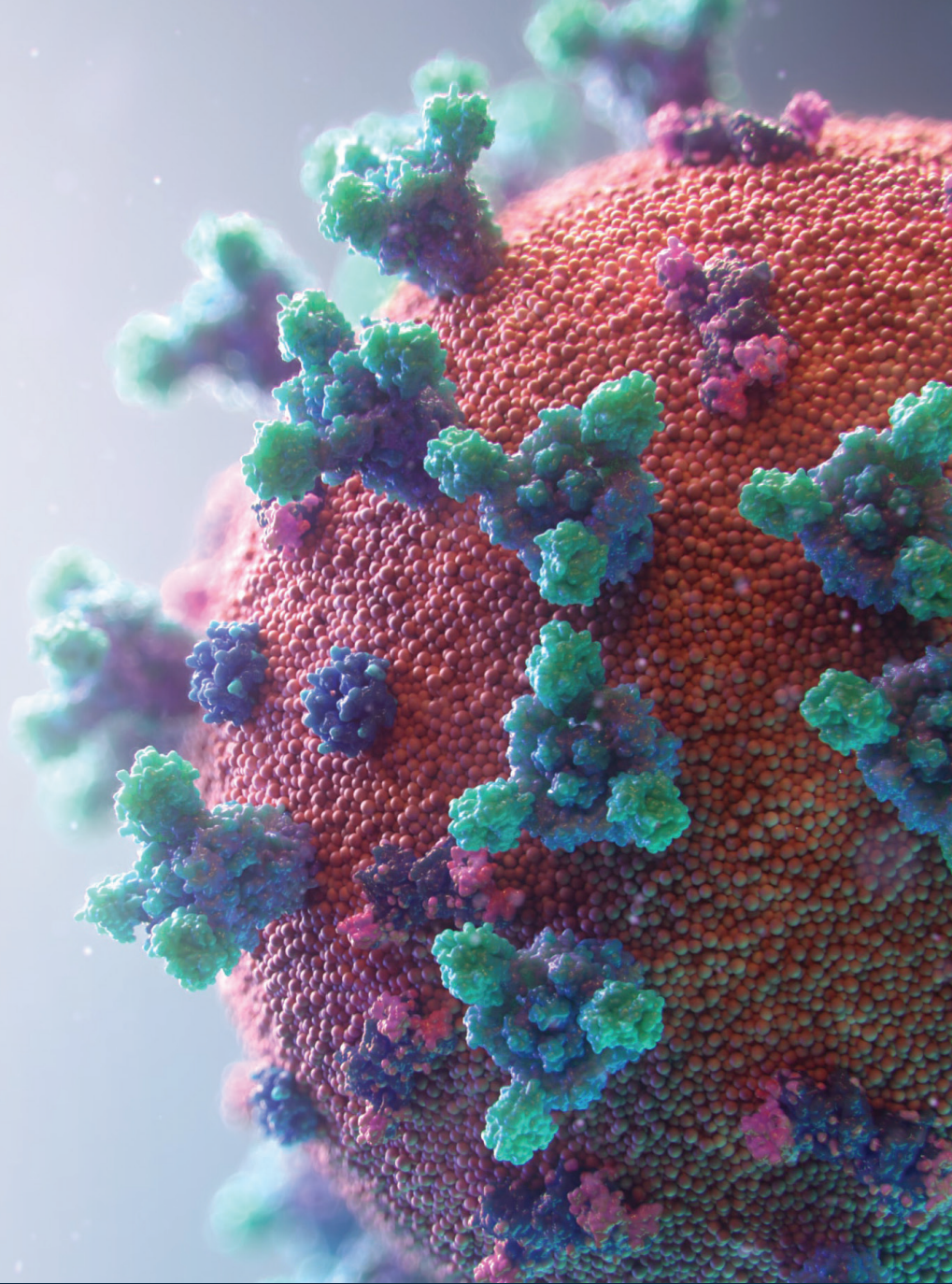


COVID-19 Testing in the United States



DIAGNOSTICS INDUSTRY MOBILIZATION

*Analysis of 800M+
COVID-19 Molecular Tests
from the AdvaMed Registry*



AdvaMed
Advanced Medical Technology Association



AdvaMedDx
Vital Insights | Transforming Care

MAY 2022



Diagnostic testing is an essential part of the U.S. COVID-19 response

In the fight against COVID-19, diagnostic tests are critical front-line tools used to screen for and diagnose infections, guide treatment decisions, conduct contact tracing, inform public health decisions, and understand disease epidemiology. Testing has also been instrumental to the development of COVID-19 vaccines.

Over the course of the pandemic, the diagnostics industry has dramatically mobilized in an unprecedented effort to develop and manufacture hundreds of millions of COVID-19 molecular¹, antigen², serology/antibody³ and T-cell tests⁴ and has rapidly augmented instruments used by laboratories to run tests, supporting patient care and public health in the U.S.

The Advanced Medical Technology Association (AdvaMed), and diagnostics division, AdvaMedDx, represent leading manufacturers of diagnostic tests for SARS-CoV-2 (the virus that causes COVID-19) in the U.S. and abroad.

To support U.S. federal and state governments' responses, 13 leading diagnostic companies joined forces with the association in July 2020 to establish the AdvaMed COVID-19 Diagnostics Supply Registry. Together, tests made by these companies currently represent ~80% of total molecular testing in the U.S. The Registry publishes weekly reports on molecular and serology test shipments and utilization of molecular COVID-19 testing at the state and national levels. These reports leverage data from the Registry to illuminate the diagnostics industry's commitment to our collective response. Registry participants include:



AdvaMed thanks Linden Capital Partners for their extensive support in developing this Registry and Water Street Healthcare Partners for additional support.

- Molecular tests** detect active SARS-CoV-2 infection. Highly accurate and generally lab-based. Point-of-care testing is available. Can be used for screening, diagnostic, or surveillance testing. Polymerase chain reaction (PCR), sequencing, isothermal, and microarray technologies are among molecular testing technologies.
- Antigen tests** detect active SARS-CoV-2 infection. High through-put lab testing available but most often performed at the point of care. Can be used for diagnostic, screening, and surveillance testing.
- Serology tests** measure an immune response generated against SARS-CoV-2. Can be used to identify past infection with SARS-CoV-2 where an immune response was triggered or measure vaccine response.
- T-cell tests** aid in identifying individuals with an adaptive T-cell immune response to SARS-CoV-2 indicating recent or prior infection with SARS-CoV-2.



PHOTO: QIAGEN

Diagnostics companies develop and manufacture, for the commercial market, advanced diagnostic tests and platforms/instruments on which tests are performed in laboratories, physician offices, other health care settings and in the home.

The Food and Drug Administration (FDA) regulates the validation, manufacturing, and distribution of IVDs as medical devices, while also regulating the manufacturing processes of IVDs, quality management systems, and the analytical and clinical validity of IVDs, along with certain requirements after tests are on the market. During a public health emergency, the FDA uses the Emergency Use Authorization (EUA) process.

Diagnostics companies have rapidly developed, and manufactured at scale, molecular COVID-19 tests

As the pandemic reached the U.S., **diagnostics companies rapidly mobilized and developed quality COVID-19 tests, beginning with laboratory-based molecular tests used to detect active infection.** Molecular tests use various technologies, including PCR (polymerase chain reaction), to achieve results.

Typically, it takes three to five years from development to commercialization for a new diagnostic test to become available on the commercial market. Given the nature of the public health emergency, this timeline was greatly accelerated and supported by the FDA, which granted the first authorization under EUA for a laboratory-based molecular test on March 12, 2020. As additional commercial tests quickly came online, the diagnostics industry's capacity to manufacture tests at scale dramatically increased test availability.

While the first molecular tests were manufactured to be performed in laboratories, later, point-of-care⁵ molecular and antigen tests become available. These tests may be performed using small, desk-top instruments or even without instruments, delivering flexibility in where these tests can be used and providing results in minutes.

The scope of the diagnostics industry response to the pandemic has been unprecedented. Figure 1 illustrates the growth in manufacturing in molecular testing from pre-pandemic 2019 to the first year of the pandemic (March 2020 – February 2021) and the second year of the pandemic (March 2021 – February 2022). **The manufacturing of molecular tests increased by 208% to address the extraordinary need for testing nationwide.**

⁵ **Point of Care:** Near-patient settings, such as provider offices, urgent cares, and retail clinics. Generally simple tests that provide results in less than 30 minutes. Some point-of-care tests are authorized for use over-the-counter.

FIGURE 1: Molecular test shipments during first two years of the COVID-19 pandemic exceeded all 2019 molecular tests

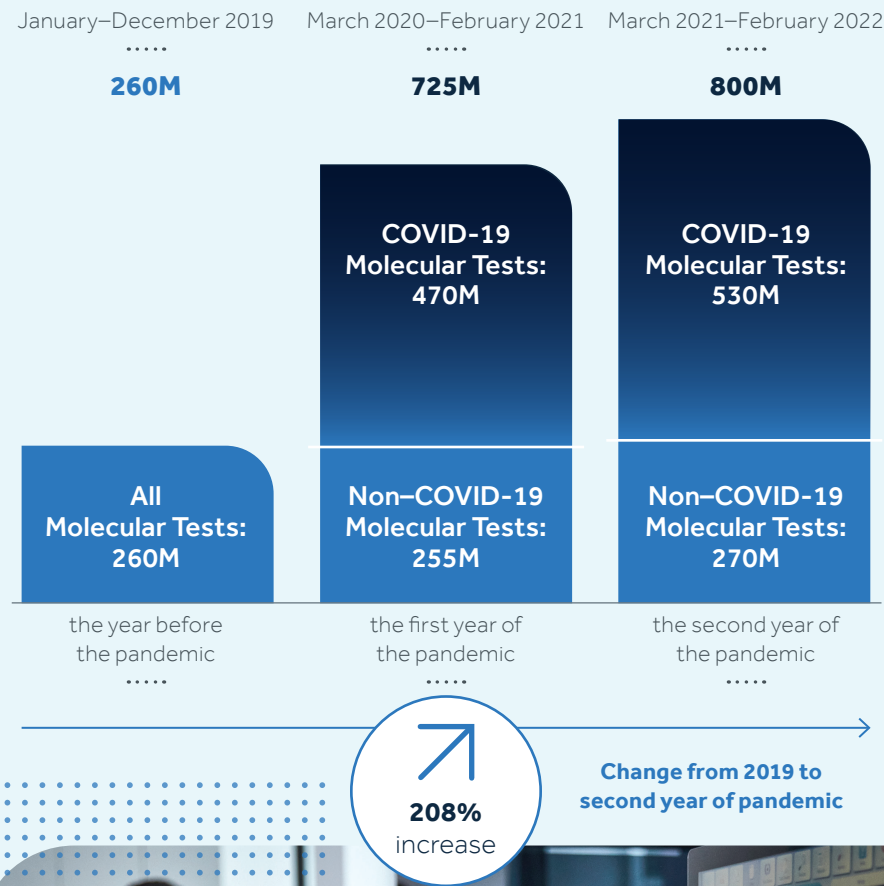


PHOTO: HOLOGIC



Diagnostics companies have expanded U.S. laboratory infrastructure by increasing the number of testing instruments that automate and allow for high-throughput testing

The diagnostics industry's swift mobilization expanded molecular testing infrastructure across the U.S. by increasing the number of instruments available to perform testing. This increase in critical equipment allowed laboratories to run more tests than they were previously able to do.

Especially critical to COVID-19 testing efforts was the increase in **high-throughput** (e.g. highly automated) platforms—most often used in large **hospital laboratories⁶**, **reference laboratories⁷** and **increasingly in public health laboratories⁸**—that can process hundreds of tests in a single shift.

This increased laboratory capacity has been able to analyze millions of patient samples per week, which, during the pandemic, have been gathered at sample-collection sites such as drive-through testing centers, schools, workplaces, skilled nursing facilities, and pharmacies.

Figure 2 shows from March 2020 to January 2022, the number of molecular instruments manufactured by Registry participants—and placed in laboratories across the U.S.—increased from ~11,700 to ~24,600 instruments. **Diagnostics companies increased molecular laboratory instruments in the U.S. by 110% over the first 22 months of the pandemic.**

- 6 **Hospital Lab:** Clinical laboratory located within a hospital that usually accepts inpatient and outpatient samples. Performs testing for many conditions including COVID-19.
- 7 **Reference Lab:** Commercial laboratory that accepts samples from hospitals, physician offices, urgent cares, and patients directly. Performs testing for many conditions including COVID-19.
- 8 **Public Health Lab:** Laboratories that perform diagnostic testing, reference testing, and disease surveillance. They also provide emergency response support, provide laboratory trainings, and perform research.

FIGURE 2: Increase in number of testing instruments, March 2020 – January 2022

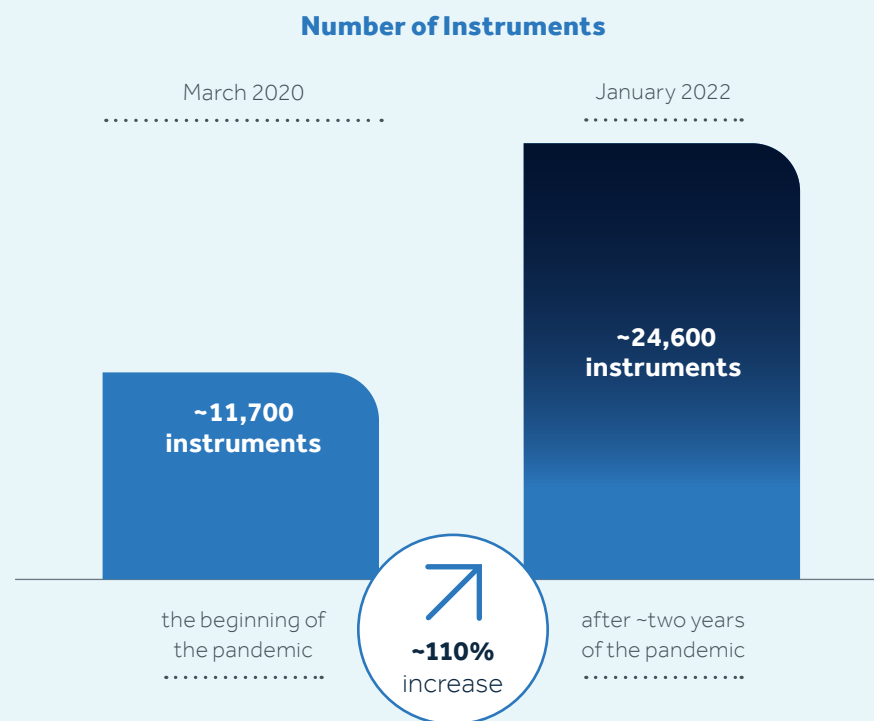


PHOTO: ROCHE

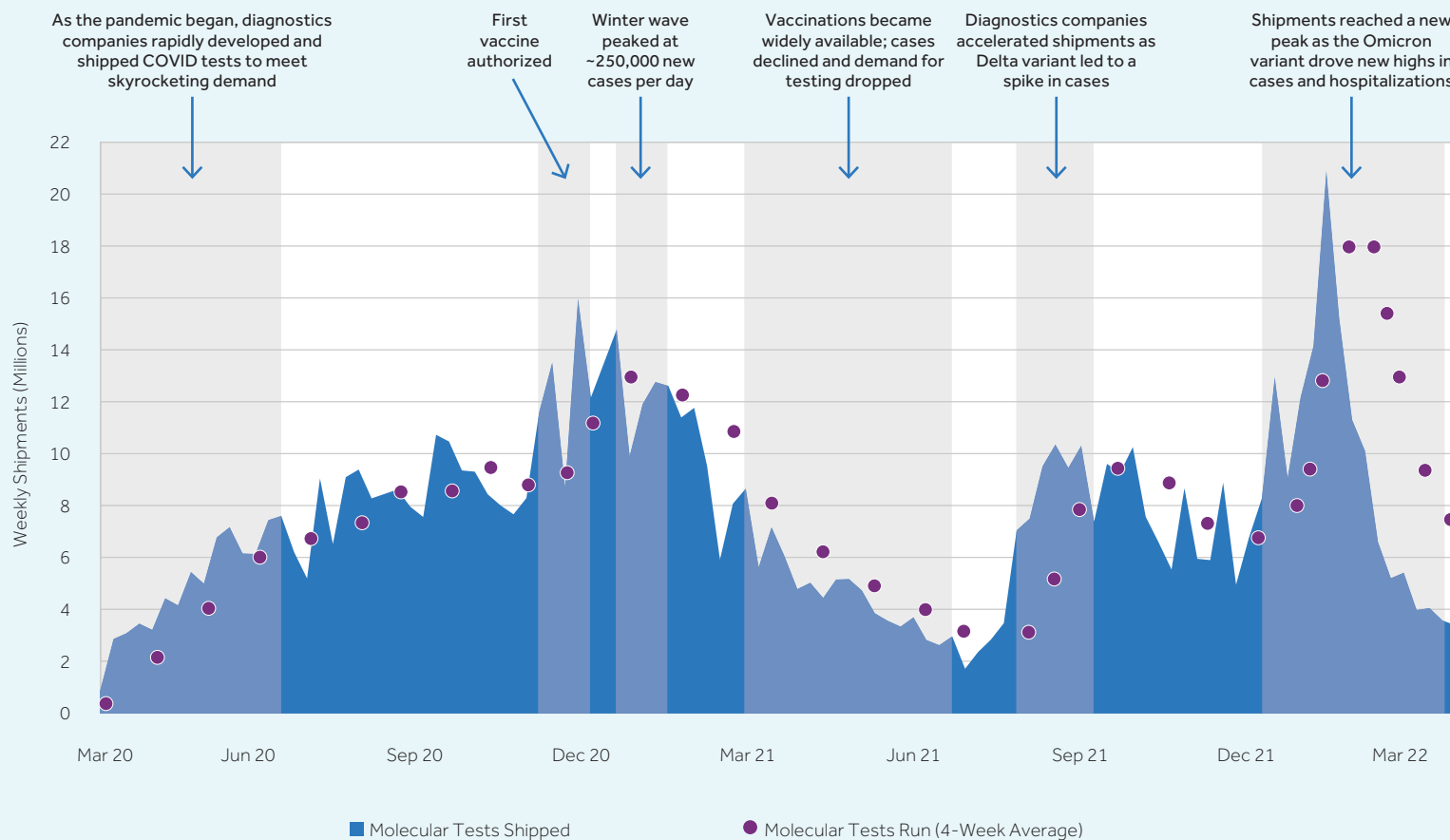


The AdvaMed COVID-19 Diagnostics Supply Registry data illustrates the mobilization of the diagnostics industry to meet the unprecedented need for COVID-19 testing

Figure 3 shows Registry companies' molecular tests shipped throughout the pandemic along with state-reported tests run at key points in time. Registry companies manufacture ~80% of molecular tests in the U.S.

The diagnostics industry dramatically mobilized at the start of the pandemic and then surged manufacturing and shipments throughout each distinct wave of the pandemic. When industry received orders for tests, it flexed manufacturing capacity to meet demand. Note in the chart below—as vaccinations increased in the first half of 2021, new cases decreased and there was a reduction in orders for new tests. When the Delta variant became dominant in July 2021, the demand for testing increased again, and industry rapidly met orders for molecular tests. This continued as the Omicron variant took hold.

FIGURE 3: Registry participant molecular test shipments facilitated unprecedented levels of testing



**805 million
molecular tests
have been
shipped as of
March 26, 2022**

The role of serology and antigen testing in the COVID-19 pandemic

While this report focuses on the scale-up and shipments of molecular tests for COVID-19, there are additional types of tests that are also critical to managing the COVID-19 pandemic:

Serology (antibody) tests are used to identify people with antibodies to SARS-CoV-2 in their blood, indicating a previous infection. They can also be used to measure a vaccine response. Early in the pandemic, diagnostics manufacturers secured EUAs for serology tests. There is currently robust instrumentation and test supply nationwide. As of mid-October 2021, 70 million serology tests have been shipped by Registry participants.

Antigen tests are used to detect active infections and can be performed in a laboratory or at the point of care. The Registry does *not* track shipments of antigen tests. Some point-of-care antigen tests are available over-the-counter and have been tremendously beneficial given their ease-of-use and flexibility to be used anywhere, including at home. To date, hundreds of millions of antigen tests have been shipped throughout the U.S., according to public releases from the federal government and industry. In late September 2021, the federal government took action to support increased manufacturing of antigen tests so antigen tests are more widely available.



PHOTO: BECKMAN COULTER

The mobilization of the testing industry during COVID-19 should be maximized, sustained, and leveraged beyond this pandemic

The ongoing experience of diagnostic test manufacturers during the COVID-19 pandemic provides critical insight into the capability of industry, when faced with a new pathogen, to rapidly develop and manufacture at scale quality laboratory and point-of-care tests (including those sold over-the-counter) that are essential front-line tools in the fight against the pathogen, while also augmenting the availability of instruments used in laboratories and at point-of-care facilities to run tests.

As a result of COVID-19, diagnostics manufacturers have greatly increased their capacity to produce tests and laboratories now have substantially more molecular instrumentation, produced by diagnostics companies, to be able to run more tests in less time. This increased manufacturing and laboratory capacity should be sustained and leveraged beyond this pandemic, enabling greater testing capacity for all types of diseases and conditions. This hard-fought increase in testing can be leveraged to make access to testing equitable across all communities to reduce disparities in patient care and outcomes, and to better equip us for future public health emergencies.

Maintaining increased manufacturing capacity for diagnostic tests and instrumentation will require policy that fosters and sustains public-private collaboration between the federal government and the diagnostics industry to ensure testing will continue to be available when needed in order to support patient care and public health.

AdvaMed continues to encourage the federal government to enter enduring public-private partnerships to plan now for public health emergencies beyond COVID-19. Critical to a robust response is regular, meaningful communication and collaboration between the federal government and industry at all stages of a public health emergency and beyond. Continuing that collaboration is essential.

RECOMMENDATIONS

AdvaMed has a set of recommendations on how the federal government may leverage the increased testing capacity that has resulted from this pandemic in order to prepare for the next. Those recommendations include:

1. Expand the Strategic National Stockpile to include a robust supply of diagnostic testing equipment and consumables in the stockpile, enabling “vendor managed inventory” of the stockpile to ensure that critical, up-to-date diagnostics are available and rapidly deployed during any public health emergency.
2. Execute warm-base contracting with diagnostics companies to sustain manufacturing lines and to ensure the ability to rapidly scale up again when needed.
3. Increase funding and expand the authorities of the National Institutes of Health’s Rapid Acceleration of Diagnostics (RADx Program), and HHS’s Biomedical Advanced Research and Development Authority (BARDA) to continue successful work cultivating innovation in diagnostic testing development.
4. De-risk the diagnostic test market to provide a meaningful incentive for industry to develop and manufacture products for which a viable market may not exist.
5. Establish a permanent public-private forum for frequent, real time and meaningful communication and collaboration between the Administration, diagnostics manufacturers, and laboratories.
6. Improve test developer access to government-held patient samples to facilitate rapid development of tests and streamline the FDA Emergency Use Authorization pathway.
7. Support wide availability of diagnostic testing by ensuring timely CMS coding, coverage, and reimbursement.

About AdvaMed and AdvaMedDx

The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed’s membership has reached over 400 members.

AdvaMedDx, a division of AdvaMed, represents over 75 manufacturers of innovative in vitro diagnostic (IVD) tests in the U.S. and abroad, seeking to advance policy to promote innovation and expand access to quality testing.



AdvaMedDx
Vital Insights | Transforming Care



PHOTO: BD