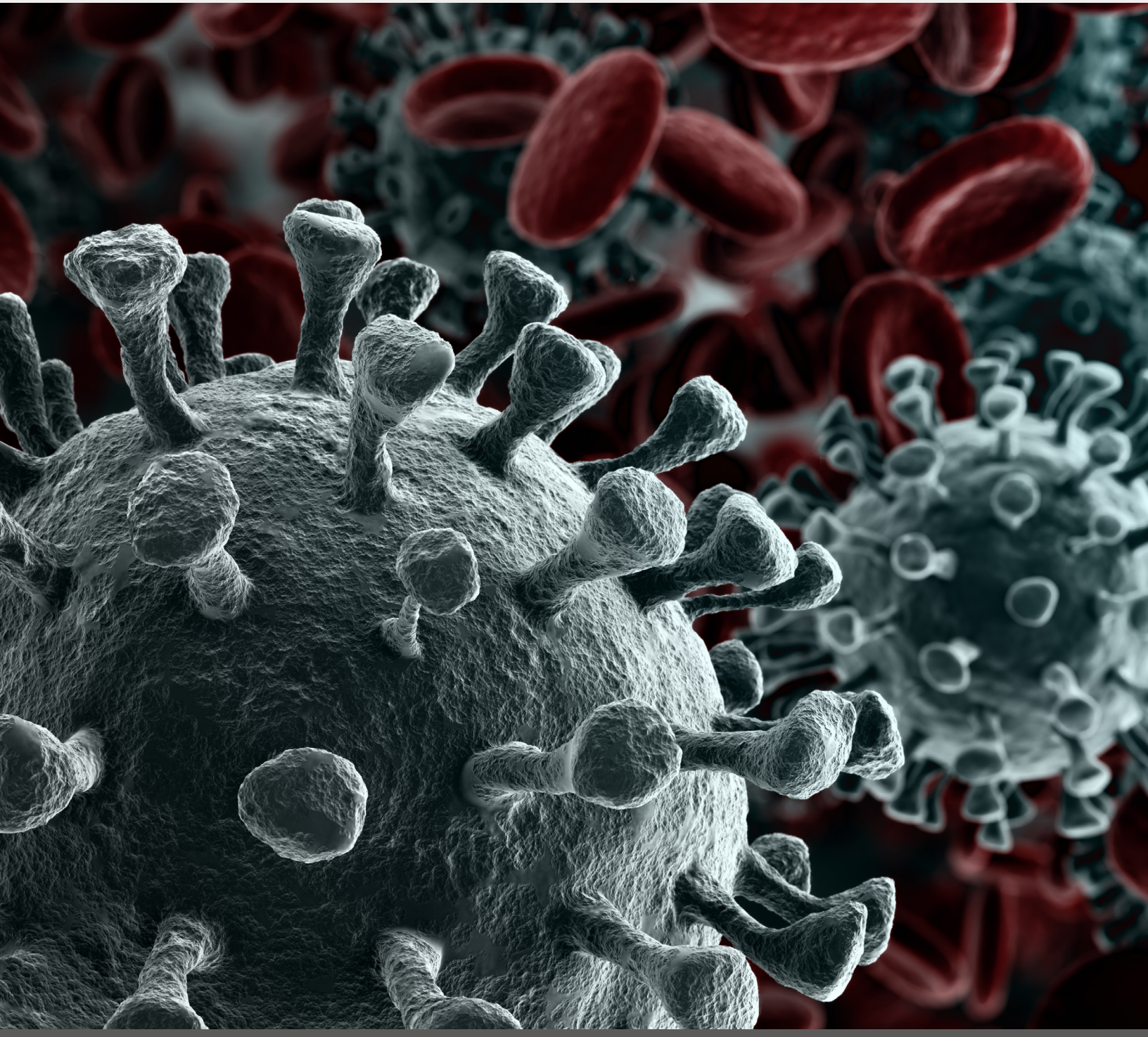
COVID-19

Combating the Global Health Crisis Together



enzolifesciences.com

Enzo continues to use its expertise to develop and deliver innovative solutions to address today's global healthcare challenges.

Enzo is helping those on the frontlines of the crisis by offering the scientific and healthcare communities tools and support to tackle the disease from different angles across research, diagnostics, therapeutics, and clinical services.

The current global health crisis shines a light on the systemic issues inherent in our healthcare system. From chasms within the supply chain to lack of readiness, staff, and capacity, the coronavirus pandemic has brought to light numerous inadequacies.

One of the most commonly reported challenge throughout the pandemic is the inability to keep up with the testing demands because of the lack of complete kits and/or individual components and supplies needed for testing, such as nasal swabs, viral transport media, and detection reagents. Manufacturers may exacerbate the issue with their closed systems, which can lack flexibility for laboratories to add third-party reagents and design their own protocol.

These underlying problems have manifested themselves in the current COVID-19 crisis. Laboratories and hospitals are unable to effectively test patients and have delays in testing and results, thus making it more difficult for providers to deliver appropriate care and impeding the efforts to limit the transmission of COVID-19.

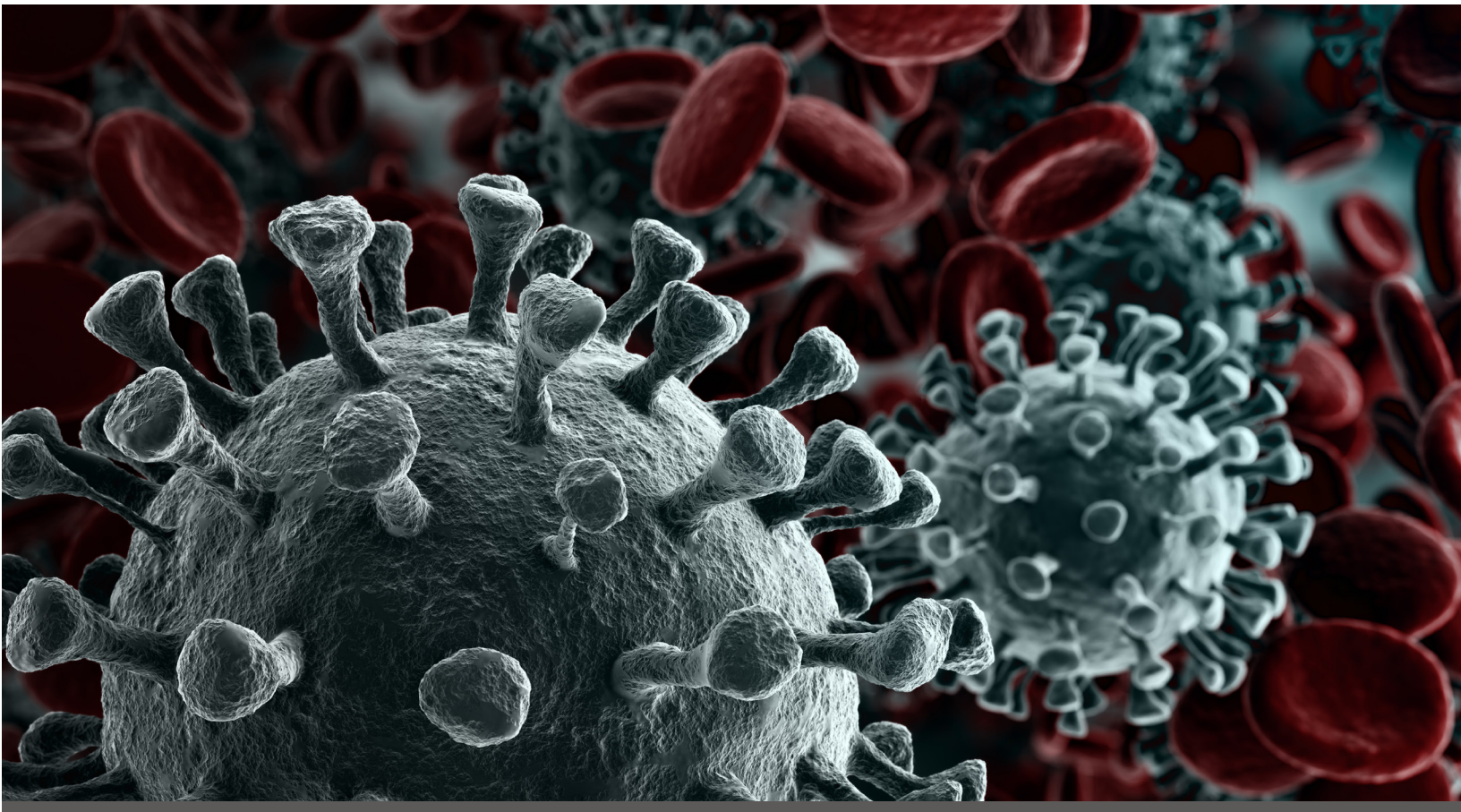
What are Coronaviruses?

Coronavirus is a family of viruses that can live and reproduce in mammals and birds. In humans, they can cause mild to severe diseases in the respiratory system. There are no vaccines or anti-viral drugs currently available to prevent or treat coronavirus infections.

Coronaviruses are RNA viruses with a positive sense single-stranded RNA genome. When the infectious agent is looked at under a microscope, the outer part of the viral particle is reminiscent of the solar corona or crown that appears around the sun. This comes from the club-shaped proteins that cover the virion's capsid.

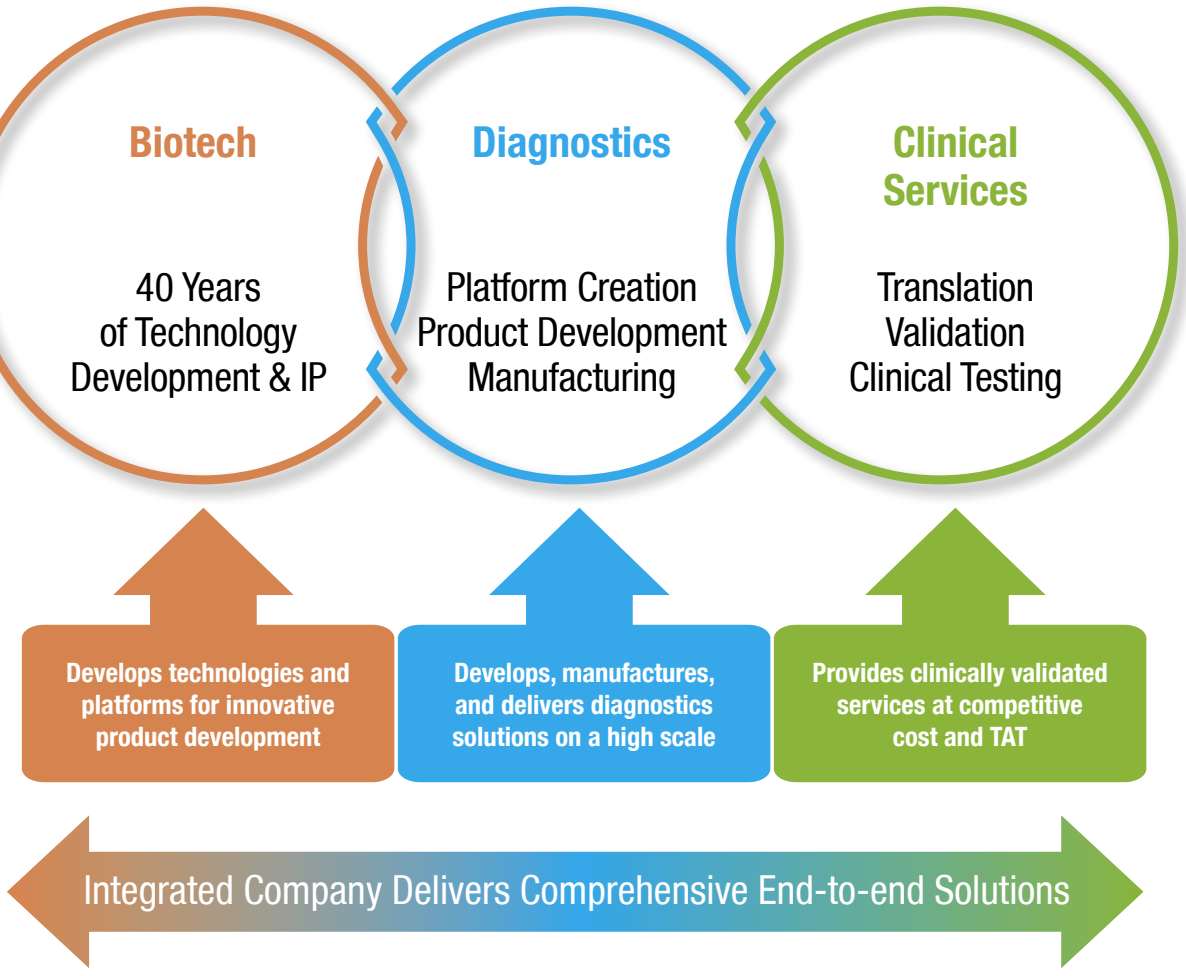
These viruses were discovered in the late 1960s in the infected bronchioles of chickens and in humans that were exhibiting symptoms similar to the common cold. Other members of this virus family include: SARS-CoV which emerged in 2003, HCoV NL63 in 2004, HKU1 in 2005, MERS-CoV in 2012, and most recently, SARS-CoV-2 in 2019.

www.enzolifesciences.com/coronavirus



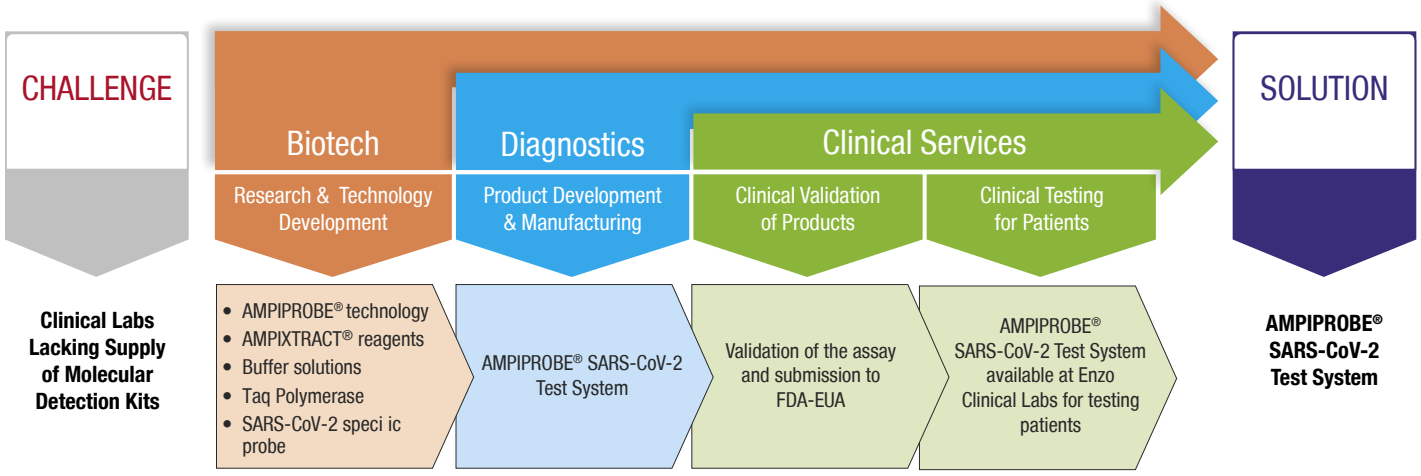
Our Unique Structure

Enzo is one of few companies to incorporate a biotech entity, a diagnostic division, and a CLIA certified clinical laboratory within the same company. Enzo develops products that address gaps in performance, cost, obtainability and safety through its technological capabilities, manufacturing infrastructure, and clinical diagnostic knowledge. To address the COVID-19 global crisis, Enzo has relied on its capabilities and integrated structure by manufacturing reagents and assay workflows in-house.



A Case Study on the SARS-CoV-2 Molecular Test

The high demand of molecular tests and the inability of diagnostics companies to provide enough extraction and detection kits to clinical laboratories and hospitals created one of the biggest challenges of the COVID-19 pandemic. In only six weeks we have been able to develop, manufacture, and validate the AMPIPROBE® SARS-CoV-2 Test System under FDA Emergency Use Authorization (EUA) guidelines*. This test utilizes our proprietary AMPIPROBE® technology, as well as our buffer solutions, Taq Polymerase and SARS-CoV-2 specific primers, and represents a cost-effective, high performance, and adaptable solution for the clinical diagnostics market.



*FDA issued an EUA for the AMPIPROBE SARS-CoV-2 Test System on July 7, 2020.

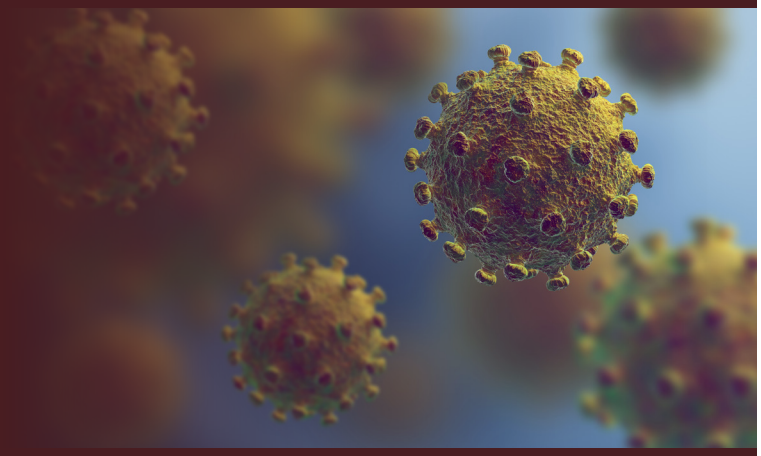
Our Comprehensive Approach to Combat COVID-19 Disease

We are offering a comprehensive approach that tackles the disease from different angles. This includes molecular assays for the detection of nucleic acid from SARS-CoV-2, serological (antibody) assays for the detection of antibodies to SARS-CoV-2, tools for COVID-19 research and therapeutics, and clinical services to assist in the scalable testing of as many COVID-19 patients as possible.

Molecular detection of the virus is the first line of defense to identify infection. Our AMPIPROBE® SARS-CoV-2 Test System allows for the molecular detection of SARS-CoV-2 viral RNA using the GENFLEX® platform and its interlocking modules including: AMPIXTRACT® SARS-CoV-2 Extraction Kit and AMPIPROBE® SARS-CoV-2 Assay and Control Kits. We complemented our molecular test with the SARS-CoV-2 IgG ELISA Kit, a serological test for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, and intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, including recent or prior infection.

Finally we offer a full service CLIA certified laboratory featuring a drive-through pop-up specimen collection tent that is in full operation and supports COVID-19 testing for patients.

COVID-19 DETECTION



There are two main types of tests to detect COVID-19 in patients: molecular detection of the virus and serological detection of antibodies.

The molecular detection of the SARS-CoV-2 virus determines if a patient has COVID-19. The serological detection of antibodies determines if a patient has been exposed to SARS-CoV-2 infection even if asymptomatic.

Molecular Testing

AMPIPROBE® SARS-CoV-2 Test System

The AMPIPROBE® SARS-CoV-2 Test System, which is comprised of the AMPIXTRACT® SARS-CoV-2 Extraction Kit, the AMPIPROBE® SARS-CoV-2 Assay kit and the AMPIPROBE® SARS-CoV-2 Controls Kit, is a multiplex assay system based on real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate specimens) collected from individuals suspected of COVID-19 by their healthcare provider. The AMPIPROBE® SARS-CoV-2 Test System has been authorized by FDA under an Emergency Use Authorization (EUA) and it is adaptable to different extraction methodologies and throughput including our proprietary GENFLEX® platform, QIAsymphony® SP, and manual workflow.

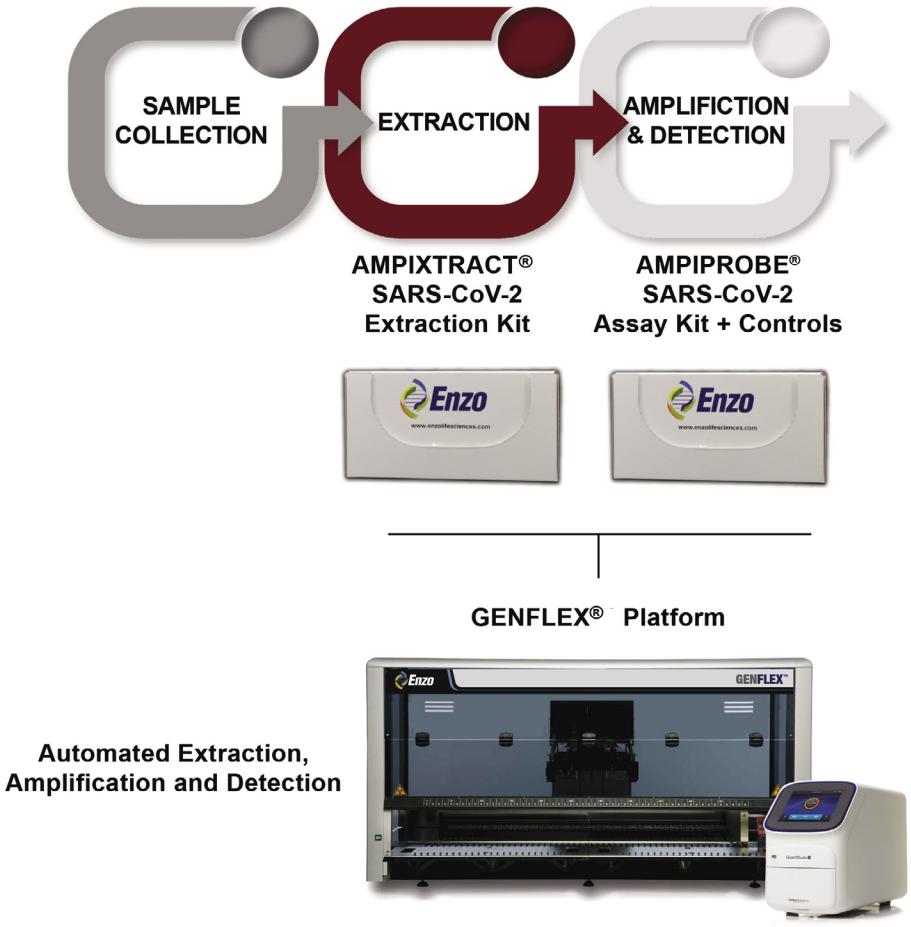


Figure 1. AMPIPROBE® SARS-CoV-2 Test System on the GENFLEX® platform

Our Solutions for SARS-CoV-2 Molecular Testing

Our SARS-CoV-2 Test System is designed to also be used in modular settings according to customer needs, consistent with the FDA EUA-approved directions for use. Each of the workflow components can be combined with any equipment specifically listed in the directions for use or used in manual settings. For more detailed information, please refer to the product-related flyers.

AMPIXTRACT® SARS-CoV-2 Extraction Kit

- Magnetic bead separation technology with proprietary buffer systems to enable isolation of RNA
- Adaptable to automated and manual processing

PRODUCT NAME	PRODUCT # EUA	PRODUCT # RUO
AMPIXTRACT® SARS-CoV-2 Extraction Kit	ENZ-GEN216	ENZ-GEN225

AMPIPROBE® SARS-CoV-2 Assay and Control Kits

- RT-PCR assay intended for the qualitative detection of human coronavirus SARS-CoV-2 from viral RNA extracted from upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, oropharyngeal swab specimens and nasopharyngeal wash/aspirate or nasal aspirate specimens)
- Multiplex assay containing two primer/probe sets specific to different SARS-CoV-2 genomic regions
- 96 samples in one hour qPCR assay TAT or four hours including sample preparation on the GENFLEX® platform
- Full set of controls, including both negative and positive, as well as an internal control
- Designed for automated process of small, medium, and high-throughput samples, as well as for manual workflow

PRODUCT NAME	PRODUCT # EUA	PRODUCT # RUO
AMPIPROBE® SARS-CoV-2 Assay Kit	ENZ-GEN215	ENZ-GEN230
AMPIPROBE® SARS-CoV-2 Contols	ENZ-GEN218	ENZ-GEN231

Emergency Authorization Use Only
In Vitro Diagnostic (IVD) Use Only
Prescription/Rx Use Only

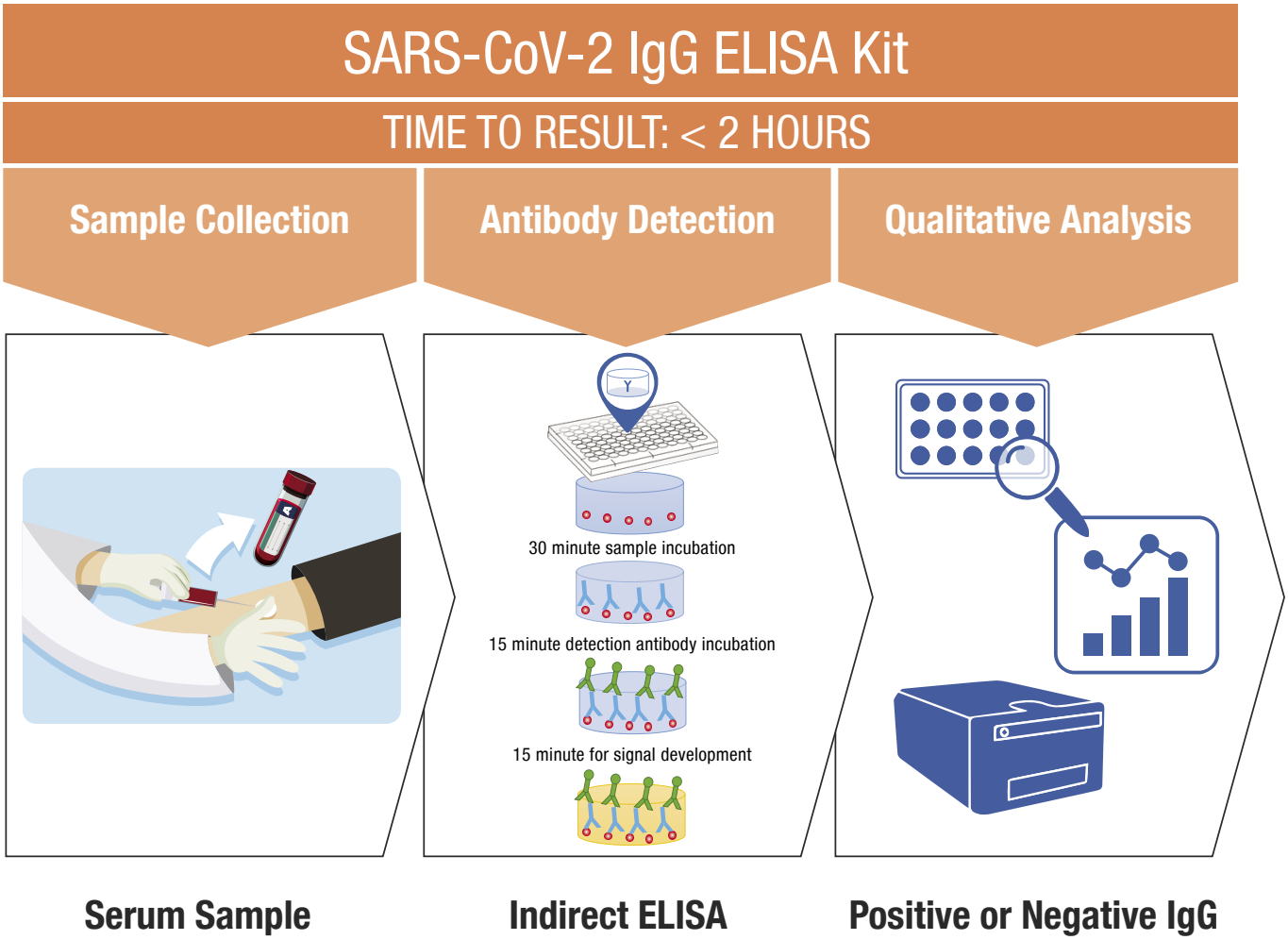
The AMPIPROBE® SARS-CoV-2 Test System has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, to perform high complexity tests.
The AMPIPROBE® SARS-CoV-2 Test System has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
The AMPIPROBE® SARS-CoV-2 Test System is only authorized 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.

Serological Antibody Test

SARS-CoV-2 IgG ELISA

Our SARS-CoV-2 IgG ELISA Kit is an Enzyme-Linked Immunosorbent Assay (ELISA) intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum. The kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

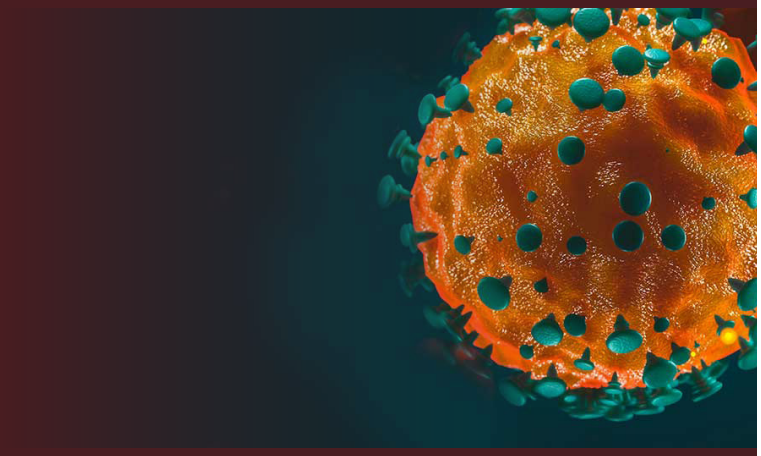
- Formatted in 96-well microplate
- Adaptable to automated open platforms and manual workflows
- Cost-effective



PRODUCT NAME	PRODUCT # EUA/IVD Pending	PRODUCT # RUO
SARS-CoV-2 IgG ELISA Kit	ENZ-GEN170	ENZ-GEN190

This test has been validated but FDA's independent review of this validation is pending. This test is provided in compliance with FDA policy "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)." Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

COVID-19 CHARACTERIZATION



The characterization of the SARS-CoV-2 virus is critical for understanding the mechanisms of action of the virus, including the viral entry into the host cells, the replication cycle and the viral spread into the human body. A better understanding of these biological processes is key for a better diagnosis and treatment of the disease. Here we provide a list of tools including antibodies, antigens and assay kits that may help investigating different aspects of the biology of the SARS-CoV-2 virus.

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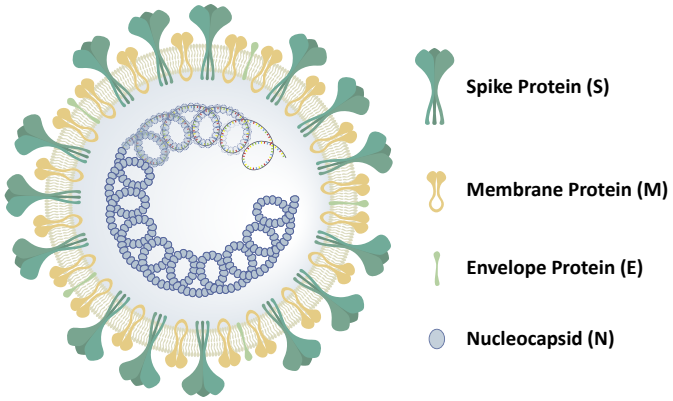
Antibodies and Antigens Related to SARS-CoV-2 Biology



Our variety of antibodies and antigens are suitable to investigate the mechanism of viral entry of the virus into host cells and at the same time to identify potential targets for the development of specific treatment or vaccine.

See Our List of Antibodies and Antigens

Monitoring of T-cell Exhaustion

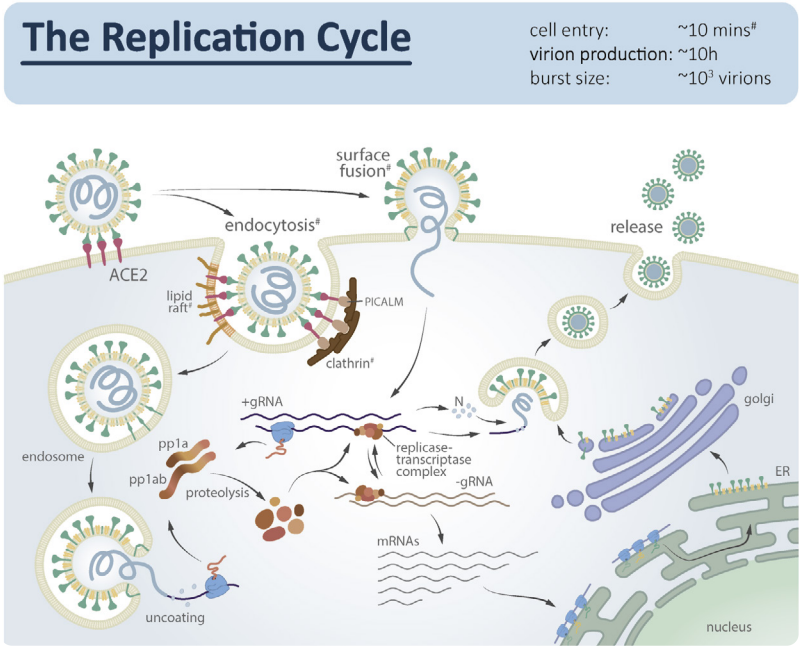
T cells play a critical role in antiviral immunity, and their exhaustion has been recently correlated with the progression of the COVID-19 disease. However, it still remains unclear how the viral infection affects the exhaustion of T cells and if it impairs their functional state[1]. We provide a variety of markers to quantify T cells and assess their functional state.

[1]Chen, Z., John Wherry, E. T cell responses in patients with COVID-19. Nat Rev Immunol (2020)

Monitoring of Virion Endocytosis/Lysis

The Endo-/Lysosomal pathway is a key player in viral entry into host cells. We offer a number of antibody markers to monitor this process.

See Our List of Antibody Markers



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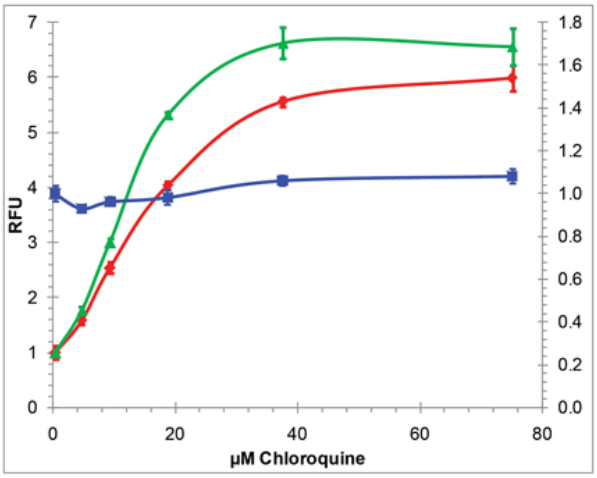
LYSO-ID® Red Cytotoxicity Kit (GFP-CERTIFIED®)

Our LYSO-ID® Red cytotoxicity kit (GFP-CERTIFIED) is the tool to study lysosomal processes and viral biology in fluorescent live microscopy. It monitors dysfunction of lysosomal degradation using a drug-like cationic amphiphilic tracer (CAT) dye that rapidly and selectively stains acidic organelles and is suitable for monitoring accumulation of lysosomes and lysosome-like structures in live cells.

- Assay includes unique drug-like dye that rapidly partitions into cells and labels acidic organelles
- Allows for long term cell monitoring of cytotoxic effects
- Multi-well, high-throughput with rapid 10-15 minute dye incubation
- No co-incubation with artificial phospholipid analogs required for detection, eliminating the potential for confounding dye-associated artifacts
- Monitors lysosome accumulation
- Quantitative results in as little as 3 hours



Eliminate Confounding Dye-associated Artifacts. The short 15-minute LYSO-ID® Red dye incubation eliminates the potential for confounding dye-associated artifacts. Relative fluorescent intensity of U-2 OS cells treated with chloroquine at different concentrations for 24 hours. Cells stained with LipidTox dye (green line) were incubated in the presence of the fluorescent lipid for 24 hours during treatment with the drugs. Cells stained with LYSO-ID® Red dye (red line) or Hoechst 33342 (blue line) were stained for 15 minutes after drug incubation. Internal data from Enzo Life Sciences.

See Our List of Endocytosis/Lysis Related Assays

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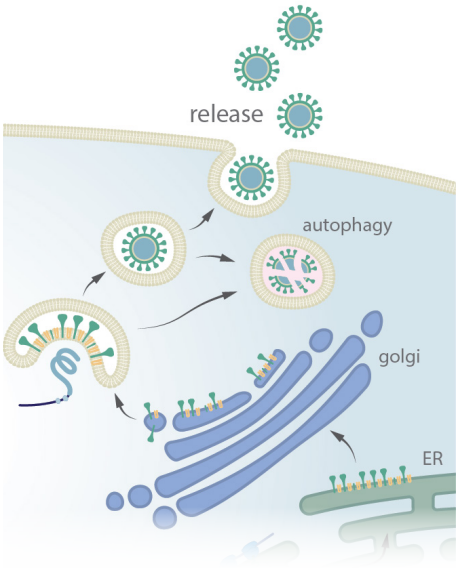
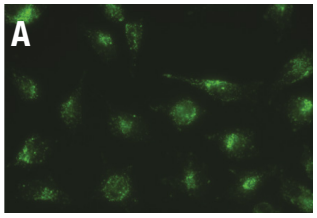
Monitoring of Autophagy

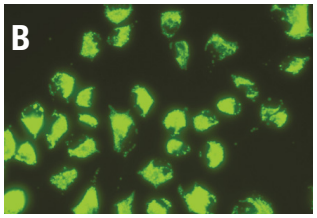


Autophagy is a self-degradative process that cells use to recycle damaged proteins and destroy pathogens. Together with the endocytic pathway it plays a role in the process of viral entry and replication into host cells.

CYTO-ID® Autophagy Detection Kit 2.0

Our CYTO-ID® Autophagy detection kit 2.0 is a tool to measure autophagy in live cells. Specifically, it measures autophagic vacuoles and monitors autophagic flux in lysosomally inhibited live cells using a novel dye that selectively labels accumulated autophagic vacuoles. The dye has been optimized through the identification of titratable functional moieties that allow for minimal staining of lysosomes while exhibiting bright fluorescence upon incorporation into pre-autophagosomes, autophagosomes, and autolysosomes (autophagolysosomes). The assay offers a rapid and quantitative approach to monitoring autophagy in live cells without the need for cell transfection.





- No transfection assay eliminates need for transfection efficiency validation
- Brighter, more photostable dye specifically stains autophagic vesicles
- Negligible staining of lysosomes reduces background seen with other dyes
- Rapidly quantifies autophagy in native heterogeneous cell populations
- Facilitates high-throughput screening of activators and inhibitors of autophagy

HeLa cells were stained with CYTO-ID® Green Detection Reagent 2 after being cultured in (A) full media or (B) starvation media (EBSS) with 40µM Chloroquine for 4h. Cells starved in EBSS in the presence of Chloroquine showed very bright green fluorescent signals and punctate structures.
Internal data from Enzo Life Sciences.

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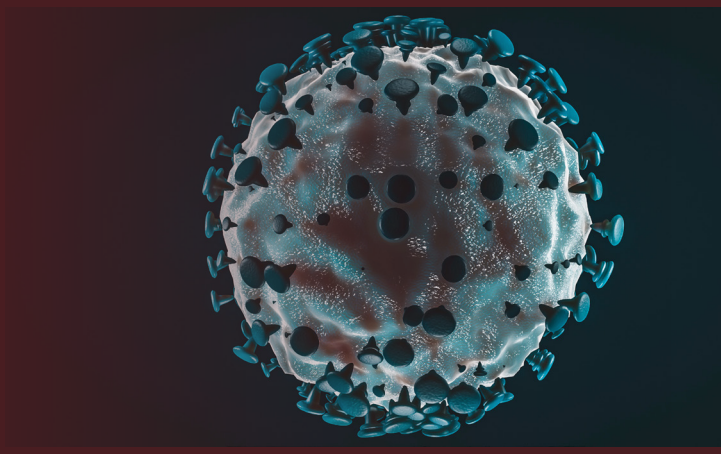
COVID-19 THERAPEUTIC DEVELOPMENT



The COVID-19 pandemic has challenged the scientific communities around the globe to develop a cure. Current investigation is focused on three different approaches including drug discovery, immunotherapy and vaccine production. Here we highlight some of the key products that can help with tackling this challenge.

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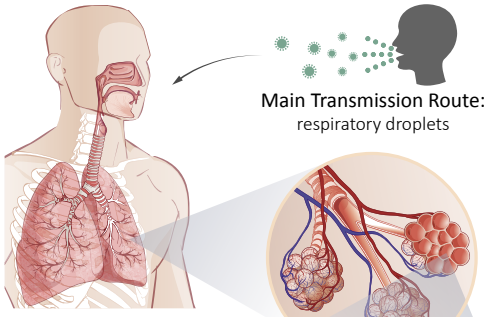
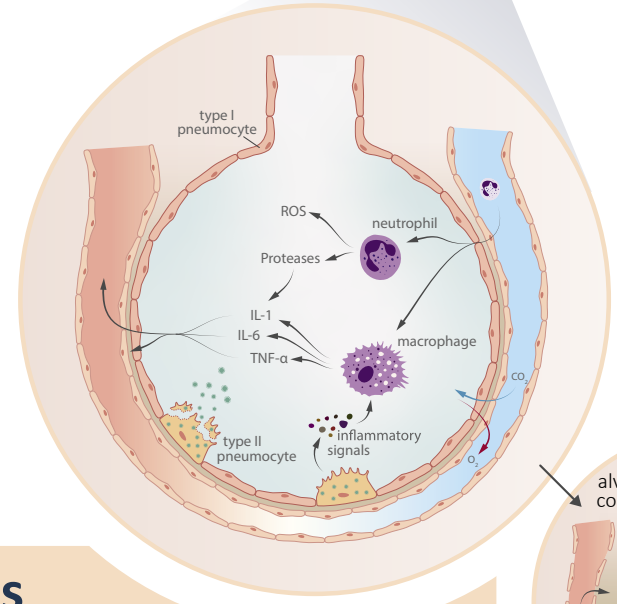
Drug Discovery

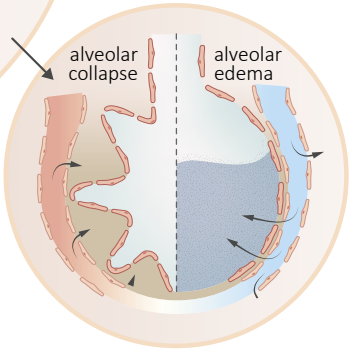
Drug repurposing can be an important part of any drug discovery program and has led to several blockbuster drugs. High-content screens and high throughput biomarker monitoring have created new opportunities for pursuing new therapeutic applications.

COVID-19

R_0: 2-4
S_I: 5-7.5 days
case fatality rate: 0.8-10%







Viral Load

Nasopharynx:
10^6-10^9 RNAs/swab
early peak
live virus: ++

Throat:
10^4-10^8 RNAs/swab
early peak
live virus: ++

Sputum:
10^6-10^{11} RNAs/mL
prolonged
live virus: +++

Stool:
10^4-10^8 RNAs/g
late peak
live virus: rare

Viral Progression

Upper Respiratory Tract:
symptoms mild to none
↓
Type II Pneumocytes:
productive cough
fever
increased heart rate
increased respiratory rate
↓
Entire Lung Epithelium:
pneumonia
hypoxemia
ARS / SIRS

Symptomatic Cascades

↓ pO2↓	IL-1, IL-6, TNF-α	pulmonary cell debris	alveolar edema
↓	↓	↓	↓
chemoreceptors	hypothalamus	consolidation	↑ surface tension ↑
↓	↓	↓	↓
sensory nervous system	↑ body temperature ↑	sputum	alveolar collapse
↓	↓	↓	↓
↑ heart rate ↑ ↑ respir. rate ↑	fever	productive cough	shortness of breath

pneumonia → **ARS** (acute respiratory sndrome) → **SIRS** (systemic inflammatory response) → **MSOF** (multi-system organ failure)

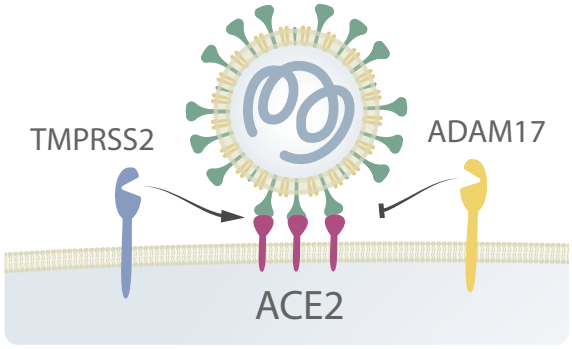
SCREEN-WELL® FDA Approved Drug Library V2

Our SCREEN-WELL® FDA v. 2.0 Approved Drug Library has known and well-characterized bioactivity, safety, bioavailability and properties which may accelerate drug development and optimization.

- Unique collection of 786 FDA-approved compounds that are part of FDA-approved products, including inhibitors for endocytosis, viral entry, viral replication, receptor ligands, and more
- 96-well plate and ready-to-screen format in biocompatible solvent (DMSO/water), no reconstitution needed
- 100% known bioactivity
- Comprehensive documentation with compound list, structure, compound category, mechanism of action, side-effects

ADAM17 Fluorometric Drug Discovery Kit

Our disintegrin and metalloproteinase domain-containing protein 17 (ADAM17) Drug Discovery Kit analyzes pharmacologic modulation of ADAM 17 (also known as TNF-alpha converting enzyme (TACE)) enzymatic activity.



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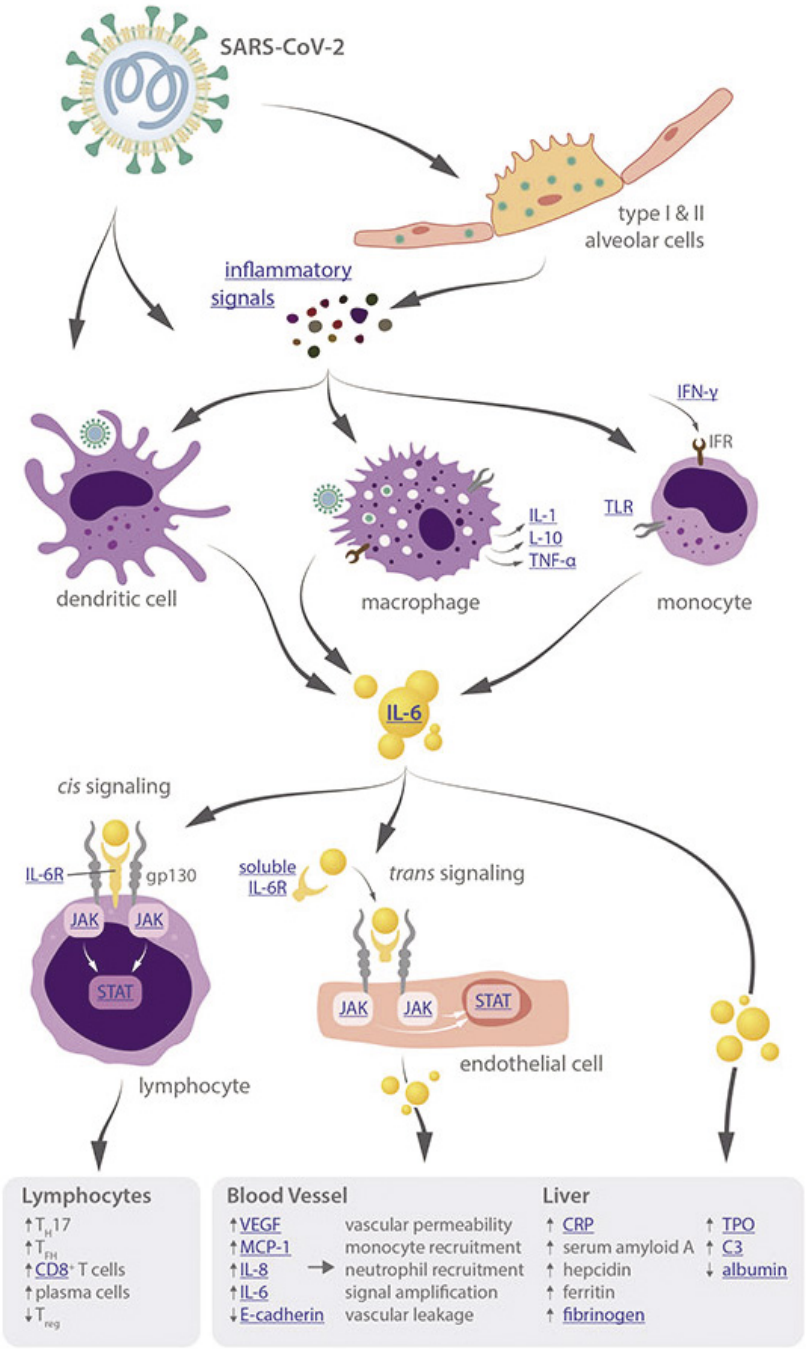
Cytokine Storm Monitoring

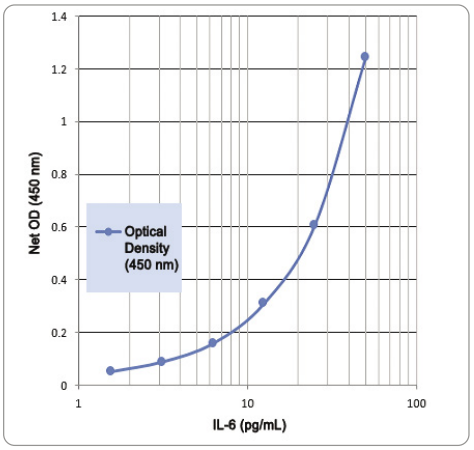
Influenza and diseases such as COVID-19 can be fatal due to an overreaction of the body's immune system called a cytokine storm. Enzo is in the early stage of development of a test for inflammation that may include IL-1 β, IL-6, IL-8, TNF-α, and INF-γ. This test is not available for use and is not FDA-cleared.



IL-6 (human) High Sensitivity ELISA Kit

Interleukin-6 (IL-6) is a key pro-inflammatory cytokine and research studies have shown that it is one of the major citokines activated during the cytokine storm triggered by SARS-CoV-2 viral infection[2]. We offer one for the most sensitive IL-6 ELISA kit on the research market.

- Ultrasensitive – Allows you to quantify low interleukin amounts
- Highly Specific – Negligible reactivity with other family members
- Strict Quality Control – Ensures reproducible results, lot-after-lot
- Scientist Trusted – Regularly cited in peer-reviewed publications for over four decades



Standard Curve for IL-6 High-Sensitivity ELISA Kit

[2]John B Moore, Carl H June. Cytokine release syndrome in severe COVID-19. Science (2020)

See Our List of Cytokines ELISA Assays

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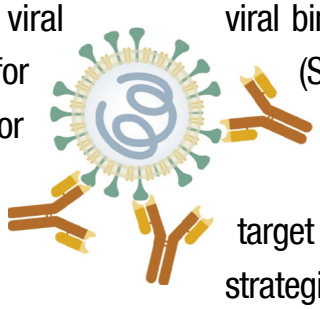
Immunotherapy and Vaccine Development

Whether you are looking for antigen candidates in host immunity and vaccination efficacy studies, developing virus blocking peptides or antibodies, studying protein-protein interaction, or need positive controls, reliable and robust antigens and antibodies are key to your research. Enzo offers a wide selection of both coronavirus antigens and antibodies.

Recombinant COVID-19 Antigens

The spike protein (S) of SARS-CoV-2 is the most prominent structure on the outside of the viral particles and the most promising target for blocking of viral entry. It is responsible for binding of the ACE2 host receptor and viral entry[3]. Because of this feature, the spike protein is a potential candidate for immunotherapy and vaccine development.



See Our List of COVID-19 Antigens

COVID-19 Antibodies

Angiotensin converting enzyme 2 (ACE2) is the main viral binding target of the SARS-CoV-2 spike protein (S1). ACE2-S1 interaction is an essential promoter of viral cell entry. Blocking binding of S1 to ACE2 with antibodies against either target is one of the most promising immunotherapy strategies[3]. This may prevent infection of host cells by SARS-CoV-2 and may decrease the disease progression. We offer highly specific, antibodies for ACE2 and SARS-CoV-2 spike protein.

See Our List of COVID-19 Antibodies

[3]Markus Hoffmann *et al.* SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor. Cell (2020).

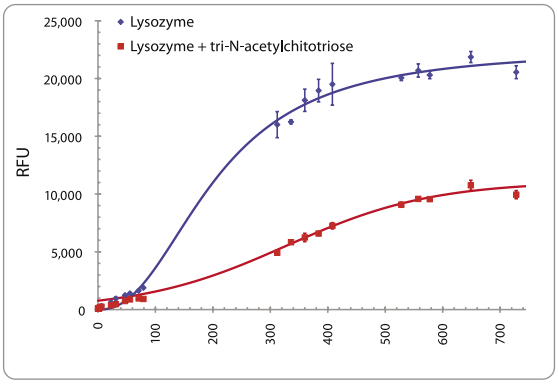
Scale Up Manufacturing and Quality Control

Efficient large scale production of recombinant proteins requires careful handling during isolation and purification. This will prevent protein aggregation and contamination issues that can arise during processing. We offer a variety of products to facilitate an effective biotherapeutic scale up production.

Protein Aggregation Monitoring

PROTEOSTAT® Protein aggregation assay provides a simple, homogenous assay format for monitoring peptide and protein aggregation in solution. This assay offers you a sub-micromolar range sensitivity and will allow you to detect as little as 1-5% protein aggregate in a concentrated protein solution. The assay is capable of providing quantitative analysis of protein aggregation in a robust and high-throughput fashion (Z' factor score >0.5).

- A simple, sensitive, homogenous fluorescent assay
- Validated for use with microplate or flow cytometry platform
- Extensively benchmarked with IgG
- Optimize buffers and excipients for protein formulation
- Performs with a wide pH and ionic strength range
- Use with PROTEOSTAT® Protein Aggregation Standards for accurate quantification of aggregated protein in solution



Monitor the ability of an excipient to inhibit protein aggregation. Lysozyme was incubated in the presence or absence of N,N',N"-triacetyl-chitotriose (inhibitor of lysozyme aggregation). Aggregation was induced and monitored for several weeks at room temperature. Internal data from Enzo Life Sciences.

For Research Use Only. Not for use in diagnostic procedures.

Protein A Contamination Monitoring

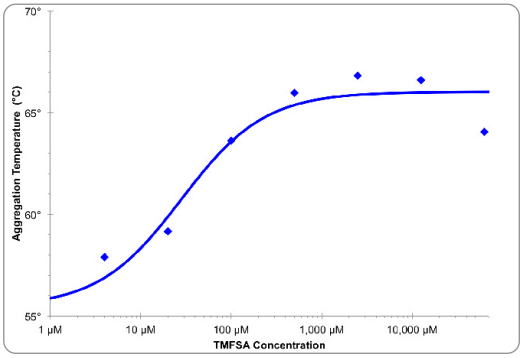
The Protein A ELISA kit is a sensitive and reproducible sandwich assay to quantify Protein A residuals in protein preparations. This ELISA kit enables you to efficiently detect natural and recombinant Protein A constructs with up to 100% recovery.

- Detects 1ppm of Protein A residuals in human IgG
- Recognizes 4 different Protein A variants
- Useful for contamination analysis and measurement of Protein A variants in monoclonal antibody preparations
- Produces results in less than 3 hours with low cost per test

Accelerated Protein Stability Assay

The PROTEOSTAT® Thermal Shift Stability Assay is a rapid, simple screening method based on a novel molecular rotor dye which detects protein aggregation. The assay does not require any prior knowledge of protein structure, sequence or ligand binding activity, and is performed on a thermally regulated fluorimeter or RT-PCR instrument.

- Performs accelerated screening for protein stability as a function of pH, ionic strength, and concentration
- Screens for ligand binding to proteins of unknown function
- Screens protein variants to determine their relative stabilities or excipients to determine optimal protein storage conditions
- Identifies protein-protein interaction inhibitors
- PROTEOSTAT® dye is tolerant of detergents and hydrophobic compounds



Carbonic anhydrase I (1 µM) was incubated with 0 to 62.5 mM of TFMSA (trifluoromethane sulfonamide) in 25 mM MES, 50 mM NaCl, pH 6.1. The ProteoStat Thermal Shift Stability Assay demonstrates that ligand binding increases protein thermal stability by an amount proportional to the concentration of the ligand. Internal data from Enzo Life Sciences.

See Our List of Products for Scale Up Production

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Enzo Clinical Laboratories

Enzo Clinical Labs is a full service clinical reference laboratory and one of the leading regional labs in the country. It combines the extensive testing capabilities of a large laboratory with the convenience and personalized service of a local one. It was one of the area's first laboratories to be awarded the prestigious College of American Pathologists (CAP) accreditation. This award indicates that Enzo has passed a rigorous series of inspections.

As a leading reference laboratory, integrated with an innovative diagnostics company, we understand the challenges other laboratories are facing in today's market. With increasing cost pressures and declining reimbursements, we decided to develop our own technology platforms. We offer those technology platforms in formats, thereby enabling clinical laboratories to integrate them into their current workflows.

Enzo Clinical labs has immediately responded to the COVID-19 outbreak in the USA. We have been accepting specimens for COVID-19 testing since March 9, and on March 23, we took one step further by offering patient testing services through a drive-through pop-up. This pop-up specimen collection tent serves individuals that have made an appointment to get tested after being pre-screened by their physician. We run our in-house developed COVID-19 molecular and antibody tests as we continue to rely on our own technologies and products with quality service.

cap ACCREDITED™

Clinical Laboratory Improvement Amendments

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Put our experience to work for you!

Our broad range of scientific expertise and industry-proven manufacturing capabilities enables us to provide a comprehensive set of solutions for COVID-19 research.

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