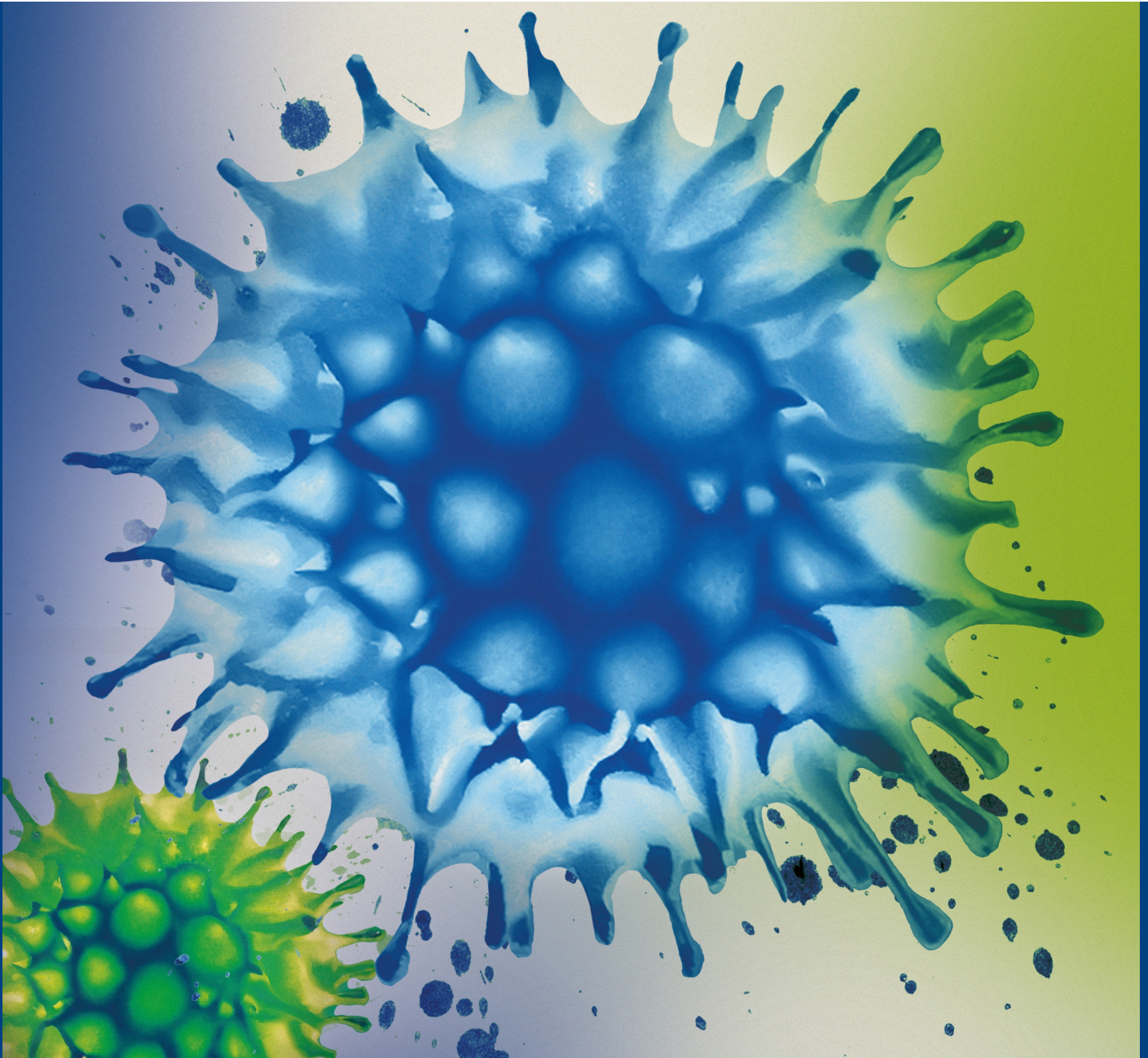




## **Infectious Diseases**

Antibodies and antigens



# Introduction

During the last decade, the number of deaths caused by infectious diseases has decreased, thanks to considerable progress having been made in diagnostics, therapy and prevention. However, infectious diseases remain the second highest cause of death in the world. And in low and middle income countries, infectious diseases continue to be the main cause of death. WHO estimated in 2021, lower respiratory infections remained the world's deadliest communicable disease other than COVID-19. Historically, diarrhoeal diseases and HIV/AIDS were also among the leading infectious causes of death worldwide.

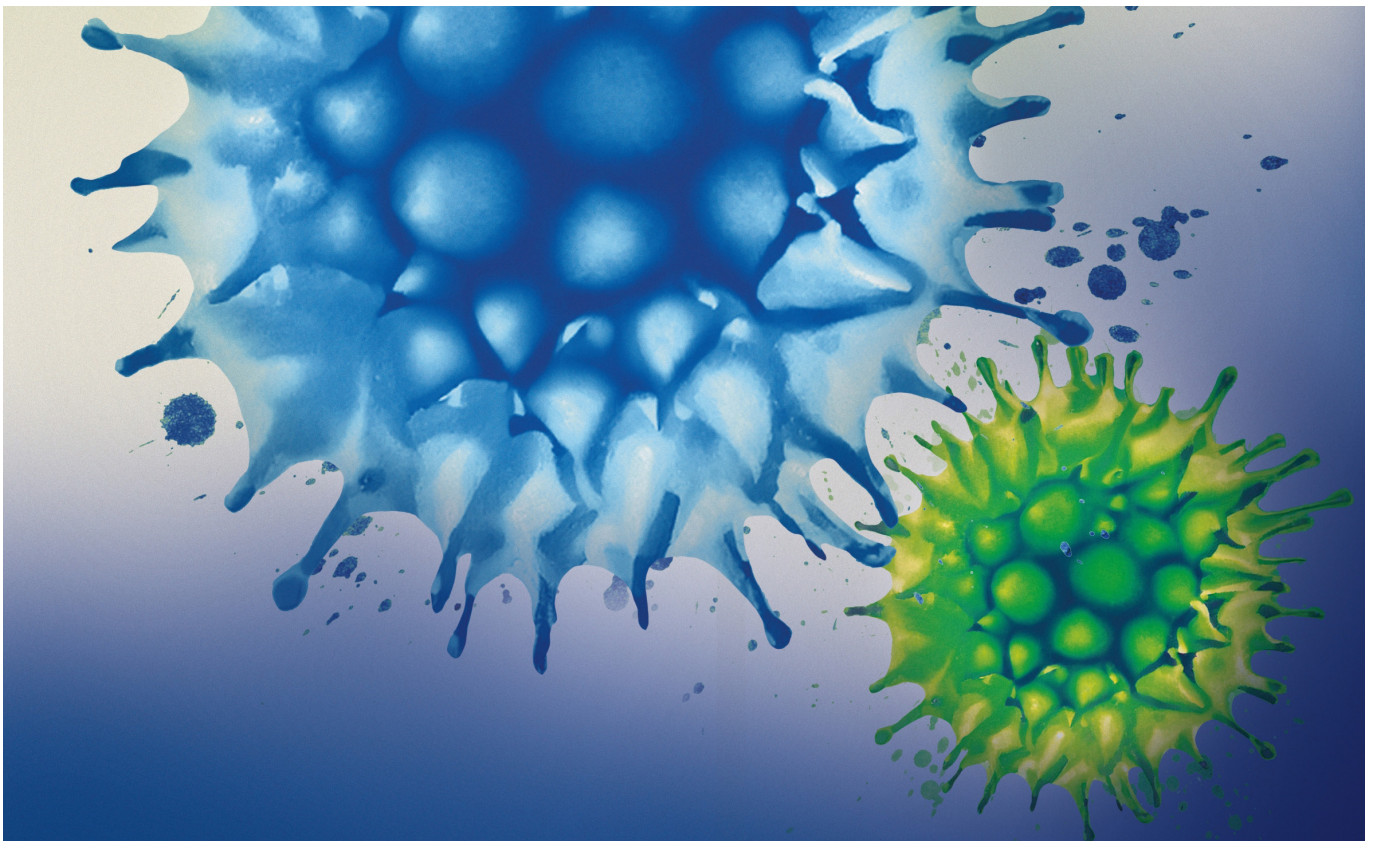
Since 1994, Hytest has developed and supplied immunological reagents for infectious disease diagnostics. We currently offer antibodies and antigens that cover a wide range of diseases causing acute respiratory infections and diarrhea. These include reagents for detecting the influenza A and B viruses, adenovirus, respiratory syncytial virus, rotavirus and salmonella. In addition, we have antibodies and antigens that enable, for example, the detection of some sexually transmitted diseases including HIV, tuberculosis, hepatitis B and C

Note that in this brochure the monoclonal antibodies (MAbs) are listed only according to the analyte they recognize. In most cases there are several different MAbs available under one catalogue number.

**More detailed information regarding the performance of our products, a full list of individual MAbs and recommendations for capture-detection antibody pairs (when available) can be found on our website — [www.hytest.fi](http://www.hytest.fi).**

**You are also most welcome to contact our Sales Team directly by writing to [hytest@hytest.fi](mailto:hytest@hytest.fi).**

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SARS-CoV-2		Human papilloma virus	
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Rotavirus		Staphylococcus aureus endotoxins	
Calicivirus (norovirus)		Diphtheria toxin	
Salmonella		Cholera toxin	
Listeria monocytogenes			



# Influenza and other acute respiratory diseases

## Influenza A

Each year, the influenza A and B viruses cause seasonal disease in human beings. Seasonal influenzas range from mild to severe and the viruses evolve quickly, limiting the effectiveness of vaccines developed to protect against influenza. In addition to seasonal influenza, new influenza A viruses can also cause pandemics and the last 100 years has seen a number of these occur. The most recent one was caused by the influenza A strain H1N1 in 2009. This strain has now established itself as a seasonal influenza virus.

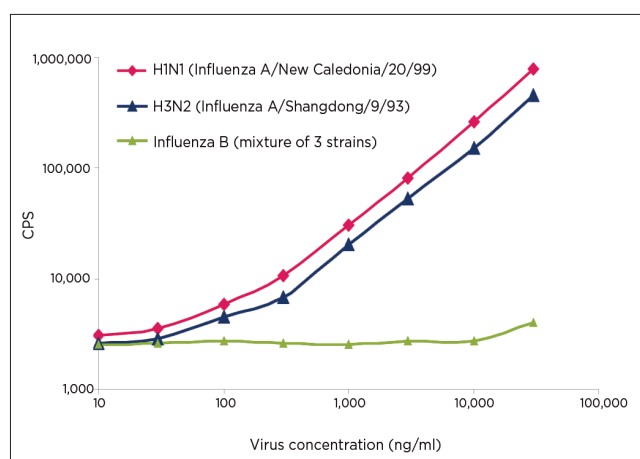
Influenza A viruses are divided into subtypes based on the variations in the hemagglutinin (HA) and neuraminidase (NA) proteins on the surface of the virus. There are 18 known types of hemagglutinin and 11 known types of neuraminidases.

Influenza A viruses infect both human beings and animals.

### Antibodies specific to different influenza A proteins

We have developed a broad selection of MAbs with different specificities that enable the detection of influenza A from clinical samples. For example, MAbs against the influenza A nucleoprotein (NP) detect different influenza A strains with high specificity and show no cross-reactivity to the NP of the influenza B virus (see Figure 1). On the other hand, some of these antibodies are specific to single HA subtypes, H1, H3 or H7. MAbs specific to H1 do not cross-react with the influenza A H3 subtype and vice versa, or with a mixture of influenza B viruses.

Our anti-influenza A MAbs have been tested in different types of immunoassays including direct or sandwich ELISA and Western blotting.



**Figure 1.**

A calibration curve for the influenza A sandwich fluoroimmunoassay using MAbs specific to the nucleoprotein of influenza A. Capture-detection pair: InA108-InA245 (Cat.# 3IN5). Please refer to our datasheets for more information

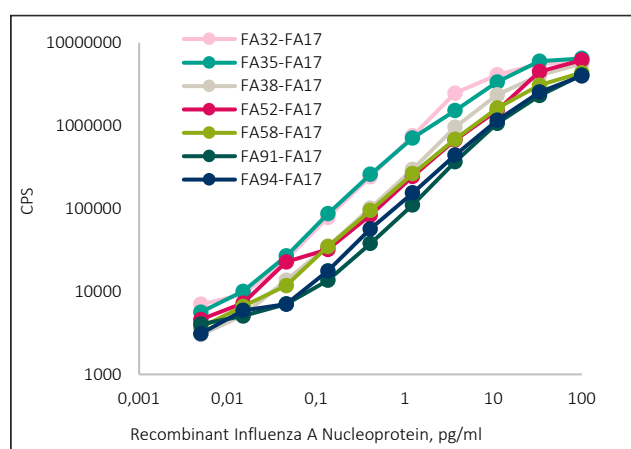
## Latest MABs specific to influenza A NP (Cat.# 3IN5)

The latest influenza A group virus antibodies were derived from several animal species including mice, rabbits, rat, and sheep. Rat and sheep antibodies were transferred into the recombinant chimeric format with human IgG constant domains. MABs are suitable for the LF assay format with sensitivity of 0.5-1 ng/ml recombinant NP of influenza A. The calibration curves for the recommended MAB pairs are shown in Figure 2.

All of the latest antibodies were developed to provide broad specificity to influenza A group virus and are capable of recognizing the native antigen which was tested on the viral lysates samples. Antibodies FA17, FA32, FA35, FA38, FA52, FA58, FA91, FA94 can recognize various strains of influenza A virus.

All influenza A antibodies of this group were developed to provide lowest possible cross-reaction with influenza B virus. All antibodies are not cross-reactive to influenza B virus.

Antibodies FA17, FA32, FA35, FA38, FA52, FA58, FA91, FA94 were also tested in indirect ELISA with preabsorbed 100 ng/well SARS-CoV-2 Nucleoprotein and demonstrated no cross-reaction (<0.05%).



**Figure 2.** Calibration curve for the recommended MAB pairs in plate-sandwich CLIA format. Recombinant Nucleoprotein of Influenza A/California/07/2009(H1N1) has been used as a calibrator. Detection MABs were biotinylated. Streptavidin-polyHRP was used for detection. Incubation time with the antigen is 30 minutes.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3IN5*	Monoclonal mouse anti-influenza virus type A (nucleoprotein)	Enzyme immunoassays Immunohistochemistry Western blotting Lateral Flow Chemiluminescence immunoassay
3AH1*	Monoclonal mouse anti-Influenza A hemagglutinin H1	Enzyme immunoassays Western blotting
3HG3*	Monoclonal mouse anti-Influenza A hemagglutinin H3	Enzyme immunoassays Western blotting
3HI7*	Monoclonal mouse anti-influenza A hemagglutinin H7	Enzyme immunoassays
3IH4*	Monoclonal mouse anti-influenza virus type A (hemagglutinin)	Enzyme immunoassays Hemagglutinin inhibition test Immunofluorescence Immunohistochemistry

\* Several MABs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

# Influenza B

Similarly to influenza A, influenza B also circulates as a seasonal disease among human beings. Although influenza B viruses evolve more slowly than influenza A viruses, a vaccination will not provide long-term immunity against the virus. Influenza B viruses are not divided into subtypes. Instead they are named after the areas where they were first identified. The influenza B virus only infects human beings.

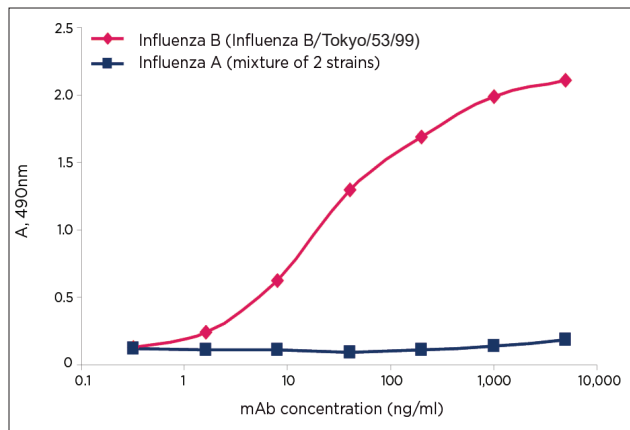
## MABs suitable for assay development

Hytest offers a panel of MABs specific to NP, hemagglutinin (HA) and the matrix protein M1 of the influenza B virus. These MABs work with high affinity and specificity in different immunoassays including direct or indirect ELISA, sandwich immunodetection systems and in Western blotting.

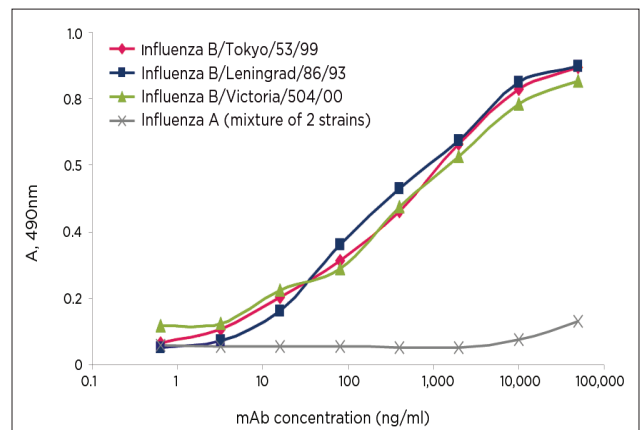
Anti-NP MABs are highly specific to influenza B nucleoprotein and do not bind to the NP of the influenza A virus or to any

other viral proteins that we have tested (see Figure 3). The low detection limit of these MABs allows the detection of the Influenza B virus in samples with low influenza B titer. Due to the high specificity and affinity they are recommended to be used in rapid influenza B immunodetection systems.

Anti-HA MABs are specific to the Influenza B haemagglutinin HA2 and equally detect different strains of the influenza B virus (see Figure 4). Anti-matrix protein MABs are highly sensitive to the M1 matrix protein of influenza B viruses and detect the M1 of different influenza B strains in EIA and Western blotting.



**Figure 3.**  
Titration curve of MAB InB114 (Cat.# 3IF18) specific to the NP of the influenza B virus.



**Figure 4.**  
Titration curve of MAB InB190 (Cat.# 3BH9) specific to the HA of the influenza B virus.

## Latest MAbs specific to influenza B NP (Cat. # 3IF18)

The latest antibodies were derived from several kinds of animals, specifically mice, rats, and sheep. All of them except the mouse MAbs are transferred into the recombinant chimeric format with human IgG constant domains. MAbs are suitable for the lateral flow (LF) assay format with sensitivity against the recombinant antigen below 0,5 ng/ml. All of the latest antibodies are capable of recognizing the native antigen which was tested on the viral lysates samples; the viral lysates titration graph of MAb pair IB44-IB91 is shown in Figure 5. Finally, the cross-reactivity of new MAb pairs is below the level of 0.15% (typically 0.06-0.04%) when comparing the signals for the 10 µg/ml of influenza A NP and influenza B NP.

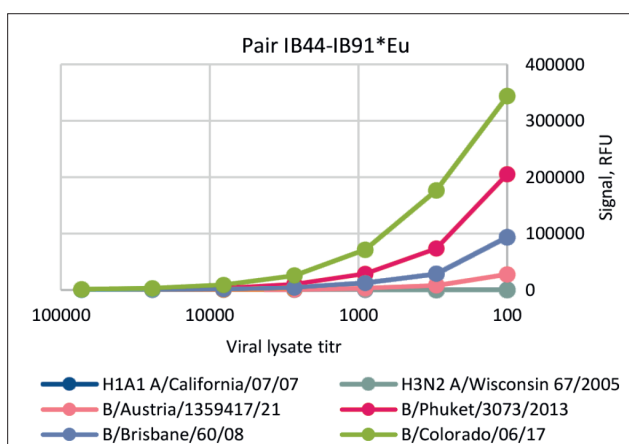


Figure 5.

### Titration curves of the viral lysate samples of different strains of influenza A and influenza B viruses, obtained in sandwich immunoassay.

For the MAb pair IB44-IB91, detection MAbs are conjugated with Eu<sup>3+</sup>-chelates. Diluted samples of viral lysates were added together with the detection MAbs in the wells with preabsorbed capture MAbs. Incubation time with the antigen is 30 min.

## In vitro produced monoclonal mouse anti-influenza virus B group antigen (Cat.# RIF17)

We provide an *in vitro*-produced MAb that is specific to the influenza B virus. This antibody detects the nucleoprotein of the virus and has been tested with several influenza B strains (see Figure 6). No cross-reactivity was detected when it was tested with nine influenza A strains, three parainfluenza strains, adenovirus (type 6) or respiratory syncytial virus.

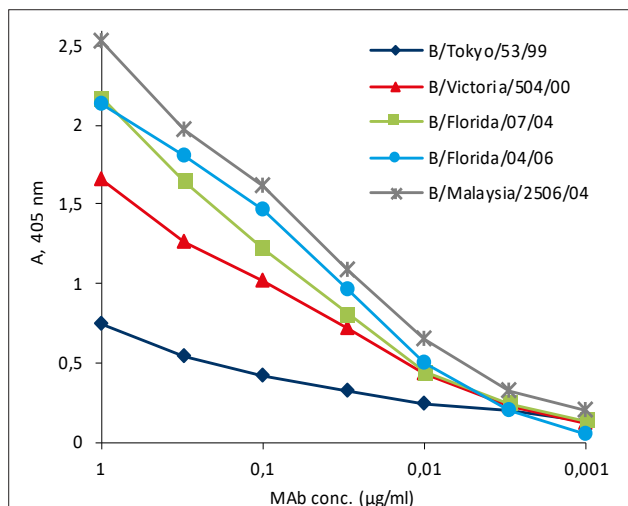


Figure 6.

A direct ELISA analysis of the anti-influenza B group antigen (Cat.# RIF17) with different influenza B strains. Antigens were absorbed to the plate in 5 µg/ml concentration and antibody binding was tested using a dilution series of the antibody from 1 µg/ml to 1 ng/ml concentration.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3IF18*	Monoclonal mouse anti-influenza virus B group antigen	Enzyme immunoassays Immunofluorescence Western blotting Lateral Flow Chemiluminescence immunoassay
3BH9*	Monoclonal mouse anti-influenza B haemagglutinin	Enzyme immunoassays Western blotting
3BM17*	Monoclonal mouse anti-influenza B Matrix protein M1	Enzyme immunoassays Western blotting
RIF17	Monoclonal mouse anti-influenza virus B group antigen	Enzyme immunoassays Western blotting

\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

# SARS-COV-2

SARS-CoV-2 belongs to a large family of single-stranded RNA viruses (+ssRNA). Betacoronaviruses such as SARS-CoVs can cross species barriers and cause in human beings illness ranging from a common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).

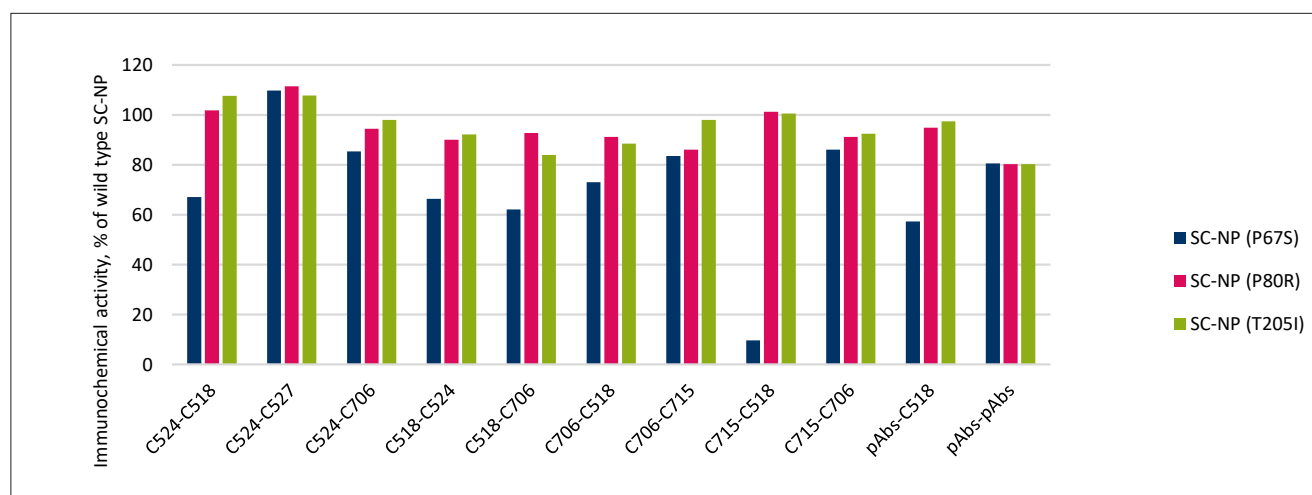
## COVID-19 antigen tests

COVID-19 antigen tests are used for detecting the presence of viral antigens in clinical specimens. Whilst antigen tests are generally less sensitive than PCR tests, it has been shown that rapid antigen tests can reach the same efficiency when used for serial testing.

## COVID-19 serology tests

Serology (antibody) tests are used for monitoring the presence of antibodies specific to SARS-CoV-2 in a clinical sample. During the course of a typical infection, B-cells produce antibodies of different classes. Usually, IgM antibodies can be detected first, whereas IgG class antibodies appear only later. IgM and IgG antibodies are the most common targets in COVID-19 antibody tests, however, recent studies suggest that measuring the presence of IgA class antibodies could increase the sensitivity of the tests (1,2).

We provide several antibodies specific to nucleoprotein or the RBD domain of spike protein. Key antibody combinations are continuously characterised with emerging variants to ensure our products are able to recognize the circulating variants (see Figure 7).



**Figure 7.** Specificity of anti-SC-NP MAbs sandwich antibody pairs to different point mutations. Signal from recombinant wild type NP (Cat.# 8COV3) was considered as 100%.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3CV2*	Monoclonal anti-SARS-CoV-2 Spike	Enzyme immunoassays Lateral flow
3CV4*	Monoclonal anti-SARS-CoV-2 Nucleoprotein	Enzyme immunoassays Lateral flow

\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

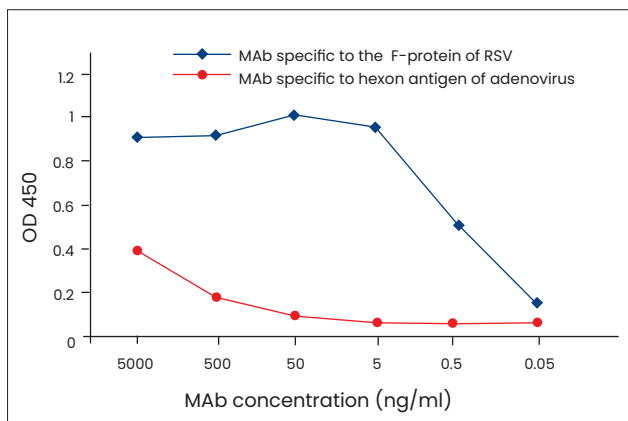
## ANTIGENS

Cat.#	Product	Source	Purity
8COV1	SARS-CoV-2 Spike RBD, recombinant	Recombinant	>95%
8COV3	SARS-CoV-2 Nucleoprotein, recombinant	Recombinant	>95%

# Respiratory syncytial virus (RSV)

Respiratory syncytial virus is one of the most important respiratory pathogens in infants and young children and it provokes considerable morbidity and often requires bed care. In older children and adults the symptoms are usually milder. The more severe diseases caused by the respiratory syncytial virus are most common among infants during the first six months of life and patients with immunodeficiency. Repeated infections are common and result in neutralizing antibody formation.

We offer *in vitro*-produced MAbs and an inactivated virus as an antigen for the development of immunoassays. As shown in Figure 8, the RSV antigen demonstrates strong specific reactivity with RSV-specific MAbs and low cross-reactivity with adenovirus-specific MAbs.



**Figure 8.** Control of specific activity and cross-reactivity of respiratory syncytial virus in ELISA with MAbs specific to different viruses.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3ReS2lcc 3ReS2l	Monoclonal mouse anti-respiratory syncytial virus (RSV)	Enzyme immunoassays Western blotting

## ANTIGENS

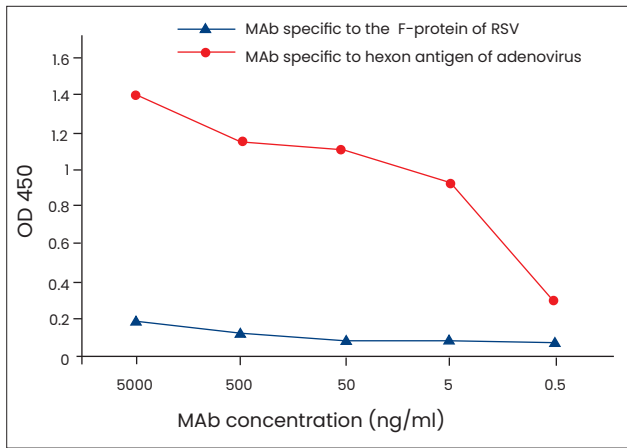
Cat.#	Product	Strain	Purity
8RSV79	Respiratory syncytial virus	Long	>90%

# Adenovirus

Adenoviruses are common viruses that infect both human beings and animals. They cause respiratory illnesses but the symptoms can also include diarrhea, fever and conjunctivitis. Most adenovirus infections are mild although some adenoviruses (for example type 6) are endemic and at least one infection is usually acquired during childhood. Approximately 10% of the acute respiratory diseases (ARDs) during childhood are caused by adenoviruses.

Some virus types spread in military units cause ARDs among recruits and a considerable proportion of these diseases result in hospitalization. A few adenovirus types are known as causative agents of epidemic keratoconjunctivitis while others provoke outbreaks of gastroenteritis.

Hytest offers MAbs that are specific to the hexon antigen of adenovirus. These antibodies react with the hexon antigen of (at the very least) human, dog, cow, monkey and rat adenoviruses and can be used in various enzymatic immunoassays including ELISA, immunodiffusion and immunohistochemistry. We also offer an inactivated adenovirus type 6 that could be used in serological assays. As shown in Figure 9, the inactivated adenovirus type 6 antigen demonstrated strong specific reactivity with adenovirus-specific MAbs and low cross-reactivity with RSV-specific MAbs.



**Figure 9.**  
Control of specific activity and cross-reactivity of adenovirus in ELISA with MAbs specific to different viruses.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3AV13	Monoclonal mouse anti-adenovirus hexon	Enzyme immunoassays Immunodiffusion Immunohistochemistry

## ANTIGENS

Cat.#	Product	Strain	Purity
8AV13	Adenovirus, type 6	Tonsil 99	>90%

# Foodborne pathogens

## Rotavirus

By the age of five, almost every child will have suffered from a diarrhea caused by a rotavirus. Rotavirus is the number one cause of severe diarrhea in young children worldwide. It has been estimated that the rotavirus infection leads to approximately 500,000 deaths each year, most of which occur in developing countries.

Our anti-rotavirus MAbs have been shown to detect numerous human rotavirus field strains. In addition, they cross-react well with rotaviruses that are infecting animals.

### MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3R10	Monoclonal mouse anti-rotavirus A	Enzyme immunoassays Immunohistochemistry Western blotting



# Calicivirus (norovirus)

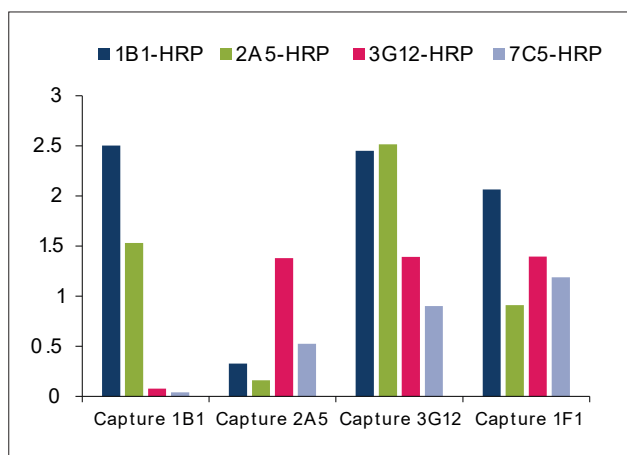
Noroviruses are highly contagious viruses that cause vomiting and diarrhea. In fact, most nonbacterial gastroenteritis infections are caused by noroviruses. These viruses are transmitted by the fecal-oral route and the source of infection is often contaminated food or water. The virus also spreads easily when one comes into contact with infected individuals and from surfaces that they have touched. This means that the virus easily spreads among groups of people, for example in schools, in hospitals or even at home.

Calicivirus infects also cats. Approximately half of the upper respiratory infections found in cats are caused by feline calicivirus (FCV). Infecting virus strains differ in their virulence and pathogenicity, and the symptoms also vary from mild to severe. Despite vaccines having been available for decades and a systematic vaccination program, the virus remains a common cause of infection. The prevalence of FCV is higher in facilities that house several cats, such as catteries and shelters, although the virus can also be found in approximately 10% of cats that are kept as pets.

We provide five different MABs that detect caliciviruses. The antibodies were developed using the FCV and rabbit hemorrhagic disease virus (RHDV) as immunogens in order to obtain antibodies that would detect the most common epitopes of different caliciviruses. All MABs detect human norovirus, feline calicivirus and the rabbit hemorrhagic disease virus.

## Immunological activity of MABs

The antibodies were tested for their ability to detect a field strain of human norovirus in a sandwich ELISA (see Figure 10).



**Figure 10**  
Immunological activity of several antibody pairs (capture-detection) in a sandwich immunoassay. A native human norovirus was used as the antigen.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3CNV1*	Monoclonal mouse anti-Caliciviridae (norovirus)	Enzyme immunoassays Western blotting Hemagglutinin inhibition test

\* Several MABs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

# Salmonella

Salmonella is an enteric pathogen which — depending on the bacterium serotype — can cause salmonellosis or typhoid fever. Salmonellosis is one of the most common foodborne gastroenteritis and it affects tens of millions of human beings every year. The infection typically lasts for a few days and requires no treatment. However, the more severe forms of the disease can be life threatening and must be attended to accordingly. Young children, the elderly and people with a compromised immune system are more at risk of developing the severe form of the infection.

The infection is often contracted through the consumption of contaminated poultry or meat. Salmonella is a robust pathogen and it can survive for several weeks in a dry environment and several months in water.

For the development of MAbs against *Salmonella* Typhimurium, we used the lipopolysaccharides of *S. Typhimurium* as an immunogen. This antibody has a broad reactivity range recognizing *E. coli* 1234 and *Listeria monocytogenes* (ATCC 7644) species as well, which means that it is a potential positive control antibody for a variety of assays.

## MONOCLONAL ANTIBODIES

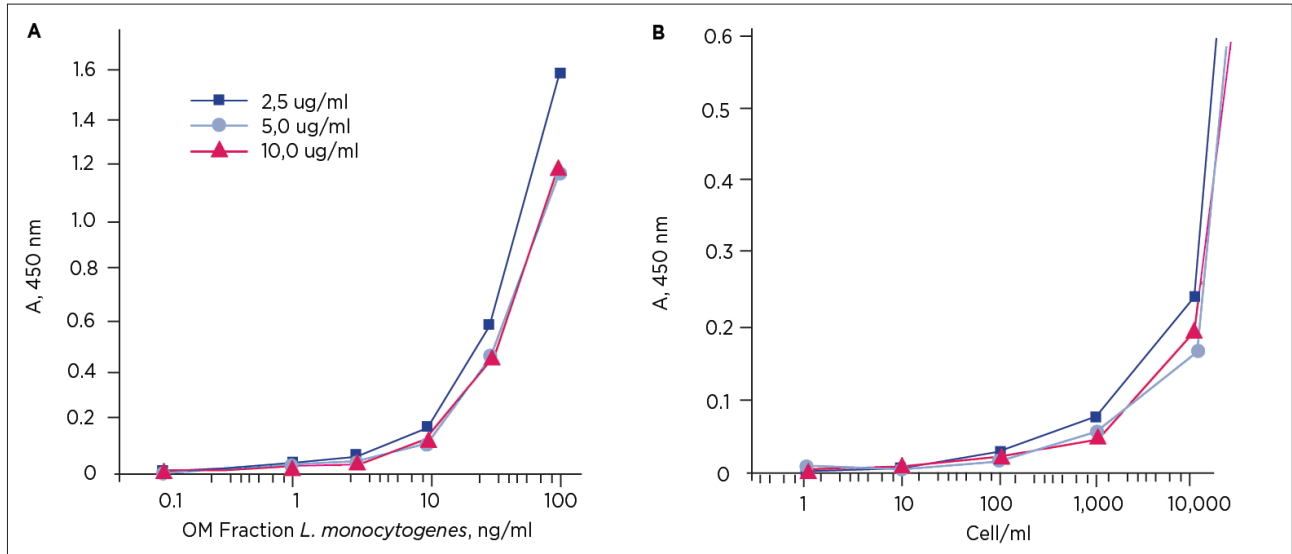
Cat.#	Product	Tested applications
3S9	Monoclonal mouse anti-Salmonella Typhimurium	Enzyme immunoassays

# Listeria monocytogenes

*Listeria monocytogenes* is a bacterium that is normally found in the environment but it is also one of the organisms that can cause severe foodborne diseases. Listeriosis is among the leading causes of death from foodborne illness. In addition to the severe, invasive form of the illness that causes septicemia and meningitis, the *L. monocytogenes* infection can result in a milder, non-invasive gastroenteritis. Risk groups for the severe, life-threatening form of this illness are people with impaired

immune systems, the elderly, pregnant women and newborn babies.

Our anti-*L. monocytogenes* MAbs show high immunoreactivity against the outer membrane (OM) fraction of *L. monocytogenes* as well as against the whole cells (see Figure 11).



**Figure 11.**  
**Calibration curves for the detection of the OM fraction of *L. monocytogenes* (A) or whole cells (B).**  
 Capture-detection pair: LZH1-LZF7 (Cat.# 3L1).

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3L1*	Monoclonal mouse anti-Listeria monocytogenes	Enzyme immunoassays Western blotting

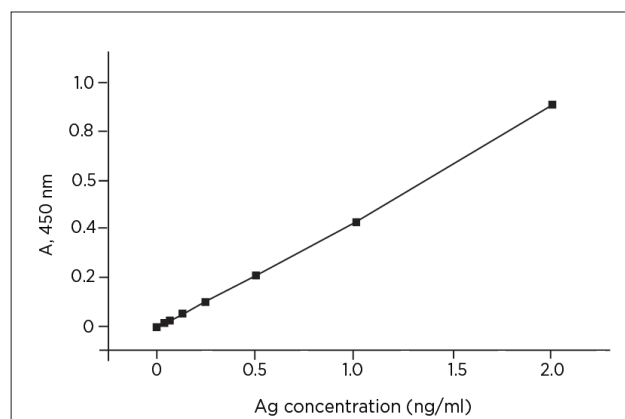
\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

# Other infectious diseases

## Hepatitis B virus

The hepatitis B virus (HBV) can cause acute or chronic hepatitis B. The hepatitis B infection affects the liver and in a subset of cases may lead to the development of cirrhosis and liver cancer. Hepatitis B is a major global health problem and according to WHO the consequences of this illness result in the death of more than 780,000 people every year.

We offer three hepatitis B virus surface antigens (HBsAgs). These can be used, for example, in developing hepatitis B serological tests. In addition, we have developed a panel of MAbs. These MAbs are specific to the HBsAg and the hepatitis core antigen HBcAg. An example of a calibration curve for the hepatitis B virus is given in Figure 12.



**Figure 12.** Calibration curve for the hepatitis B virus sandwich ELISA. Capture-detection pair: Hs33-Hs41 (Cat.# 3HB12).

### MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3HB12*	Monoclonal mouse anti-hepatitis B virus surface antigen (HBsAg)	Enzyme immunoassays
3HB17*	Monoclonal mouse anti-hepatitis B virus core antigen (HBcAg)	Enzyme immunoassays Western blotting

\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

### ANTIGENS

Cat.#	Product	Source	Purity
8HS7ay	HBsAg, ayw subtype	Recombinant	>98%
8HS7-2ad	HBsAg, adw subtype	Recombinant	>98%
8HS15	HBsAg, adw, A, m, rec	Recombinant	≥95%

# Hepatitis C virus

Hepatitis C is a liver infection caused by the hepatitis C virus (HCV), which can lead to inflammation of the liver. The virus can cause both acute and chronic hepatitis, with severity ranging from mild illness to serious, lifelong conditions such as liver cirrhosis or liver cancer. Testing is a critical first step in enabling access to hepatitis C prevention, care, and treatment services. According to WHO guidance, HCV testing is recommended for people who may be at increased risk of infection, including individuals from populations with high HCV prevalence and those with a history of risk exposures or behaviours associated with HCV transmission.

Hytest offer a panel of recombinant HCV antigen products for the development of serological test to detect anti-HCV antibodies. See Table 1.

**Table 1.**  
Recombinant HCV antigens.

Product	Immunodominant fragment	Theoretical pI	Theoretical MW	Purity	Expression system
Cat. # 8HC51	NS4	5.9	19.2	>90%	bacterial cells
Cat. # 8HC52	NS4	5.9	86.7	>90%	mammalian cells
Cat. # 8HC53	NS3	6.2	29	≥92%	bacterial cells
Cat. # 8HC55	Core	11.8	18	≥90%	bacterial cells
Cat. # 8HC56	Core	5.7	36	≥90%	mammalian cells

## ANTIGENS

Cat. #	Product	Source	Purity
8HC51	HCV, NS4 p, rec	Recombinant	≥90%
8HC52	HCV, NS4 m, rec	Recombinant	≥90%
8HC53	HCV, NS3 p, rec	Recombinant	≥92%
8HC55	HCV core p, C-Cys, rec	Recombinant	≥90%
8HC56	HCV, core m, rec	Recombinant	≥90%

# Human Immunodeficiency Virus (HIV)

Human Immunodeficiency Virus (HIV) belongs to the genus *Lentivirus* within the *Retroviridae* family. It primarily targets CD4+ T lymphocytes. If left untreated, HIV infection can progress to AIDS (Acquired Immunodeficiency Syndrome), the most advanced stage of the disease.

According to the 2018 Quick Reference Guide from the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL), initial laboratory testing for HIV should be performed using an FDA-approved combo antigen/antibody immunoassay. This assay is designed to detect both HIV-1 and HIV-2 antibodies, as well as the HIV-1 p24 antigen, which enables the identification of both established.

## MAbs for HIV immunoassay development

Hyttest offers several MAbs specific to HIV p24, which can be used for the development of HIV p24 antigen immunoassays or HIV Ag/Ab combo assays based on a two-site sandwich format.

Sensitivity analysis on the CLIA platform using the WHO HIV-1 p24 international standard (NIBSC code: 90/636) indicates that the recommended pairs are able to achieve an analytical sensitivity of 0.5–0.64 IU/mL, which exceeds the requirements set by the EU IVDR Class D regulations.

Details of the recommended antibody pairs and their corresponding limit of detection (LoD) data are summarized in Table 2. All of the recommended HIV p24 antibody pairs are capable of recognizing the WHO HIV-1 p24 international standard material (NIBSC code: 90/636), as well as the following HIV-1 subtypes: A1, B, C, D, F1/CRF12\_BF/BFrec, G, CRF20\_BG, CRF01\_AE, CRF02\_AG,

H, and Group O (NIBSC code: 16/210). It's worth mentioning that the recommended pairs exhibited a greater detection capacity for HIV-1 p24 and HIV-2 p26 reagents than antibodies used in Abbott and Roche's assays. In addition, external clinical sample testing shows that the specificity of the recommended pairs exceeds 99.95%, which meets clinical standards.

## Recombinant proteins for HIV-1/HIV-2 IgM/IgG detection

Hyttest also offers a panel of recombinant proteins for HIV-1/2 IgM/IgG detection (see Table 3 on page 18). All proteins were evaluated on a CLIA platform using a two-site sandwich format.

Two selected HIV-1 antibody assay prototypes and four HIV-2 antibody assay prototypes were tested with their respective positive sample panels, each containing 11 samples, and demonstrated 100% sensitivity.

Analytical specificity was assessed using various interference samples and clinical specimens. The two Hyttest HIV-1 antibody assay prototypes met the performance requirement defined in Commission Implementing Regulation (EU) 2022/1107, with specificity >99.5%. Using the same specificity assessment approach, all four Hyttest HIV-2 antibody assay prototypes also met the EU 2022/1107 performance requirement, with specificity >99.5%. See Table 4 on page 18.

**Table 2.**

LoDs for HIV p24 antigen assay prototypes.

Sample preparation: WHO HIV-1 p24 international standard material (NIBSC code: 90/636), HIV-1 p24 (group M) antigen, HIV-1 p24 (group O) antigen and HIV-2 p26 antigen.

Detection method: all of the samples were detected using sandwich-chemiluminescent immunoassay (alkaline phosphatase labelling).

The recommended assay prototypes exhibited a higher analytical sensitivity for HIV-1 p24 and HIV-2 p26 proteins than Abbott and Roche assays.

Capture MAb	Detection MAb	LoD of WHO international standard p24, IU/ml	LoD of HIV1 p24_M, pg/ml	LoD of HIV1 p24_O, pg/ml	LoD of HIV-2 p26, pg/ml
GA17	GA54	0.55	4	1.5	15
GA17	GA12	0.64	2	2	8
GA17	GA38	0.55	1.5	1.5	8
GA34	GA54	0.5	2	1.5	20
GA38	GA54	0.55	4	1.5	20
Abbott Alinity HIV Ag/Ab combo reagent kit		1.0	5	4	n/d when HIV-2 p26 is 1 ng/ml
Roche CombiPT HIV reagent kit		1.3	5	6	20

## Hytest HIV Ag/Ab Combo Assay Prototype Evaluation

Using the above-described combinations of p24 antigen and HIV antibody assay prototypes, two HIV combo assay prototypes were constructed and evaluated on a CLIA platform. Both developed combo assay prototypes were able to detect the following tested genotypes: A, B, C, C/CRF\_BC, C/CRF08\_

BC, C/CRF31\_BC, CRF\_BG, CRF01\_AE, CRF02\_AG, CRF03\_AB, CRF22\_01A1, D, F2, G. For total of 4272 clinical samples with a variety of disease status, including interference samples, HIV combo assay prototype 1 showed a specificity of 99.93% and HIV combo assay prototype 2 showed 99.91% specificity. See Table 5.

**Table 3.**

### Recombinant HIV-1/2 antigens

Proteins	Description	Theoretical pI	Theoretical molecule weight (kDa)	Purity	Expression system
Cat. # 8H11	HIV-1 V3 domains of gp120 from groups M and O, ectodomain of gp41 from group M and ectodomain fragment of gp41 from group O	5.93	56.98	≥80 %	bacterial cells
Cat. # 8H12	HIV-1 ectodomain fragments of gp41 from groups M and O and V3 domains of gp120 from groups M and O	6.55	65.75	>80 %	mammalian cells
Cat. # 8H13	HIV-1 ectodomain fragment of gp41 from group M	6.39	87.09	>85 %	mammalian cells
Cat. # 8H16	HIV-1 V3 domains of gp120 from groups M and O	8.34	33.3	≥90%	mammalian cells
Cat. # 8H24	HIV-2 ectodomain fragment of gp36	6.5	86.6	>90%	mammalian cells
Cat.# 8H25	HIV-2 ectodomain fragment of gp36	4.7	37.6	≥90%	mammalian cells

**Table 4.**

Specificity evaluation of two HIV-1 and four HIV-2 antibody assay prototypes.

	HIV-1 antibody assay prototype		HIV-2 antibody assay prototype			
	8H11	8H13	8H24	8H25	8H24	8H25
Particle Antigen, Cat.#	8H11	8H13	8H24	8H25	8H24	8H25
Conjugate Antigen, Cat.#	8H12	8H13	8H24	8H25	8H24	8H25
Interference sample number	305	305	78	268	78	78
False reactive	1	4	0	0	0	0
Clinical sample number	2957	5901	2652	6683	1638	750
False reactive	4	10	0	0	0	1
Total clinical samples specificity, %	99.85	99.77	100	100	100	99.88

**Table 5.**

Specificity evaluation of HIV Ag/Ab assay prototypes.

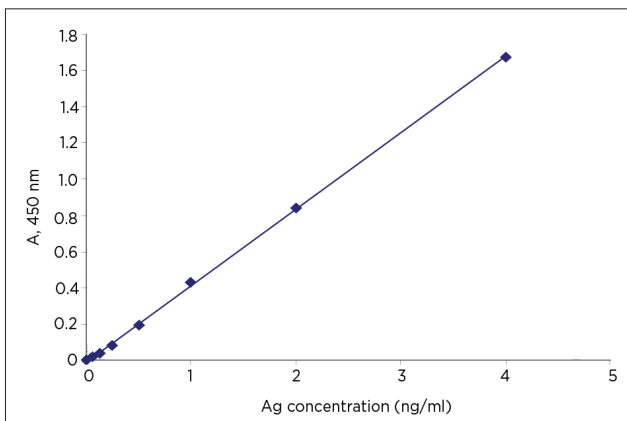
Assay	HIV Combo assay 1	HIV Combo assay 2
HIV-1 antibody assay	8H11 - 8H13	8H11 - 8H12
HIV-2 antibody assay	8H24 - 8H25	8H24 - 8H25
p24 antigen assay	GA17- GA12	GA17- GA54
Sample number	4272	4272
Number of false reactive	3	4
Specificity	99.93%	99.91%

## ANTIGENS

Cat. #	Product	Source	Purity
8H11	Human Immunodeficiency Virus 1 Antigen (HIV-1, gp120-gp41 N-Trx), recombinant	5.93	≥80 %
8H12	Human Immunodeficiency Virus 1 Antigen (HIV-1, gp41-gp120 N-Fc), recombinant	6.55	>80 %
8H13	Human Immunodeficiency Virus 1 Antigen (HIV-1, gp41 N-HSA), recombinant	6.39	>85 %
8H16	Human Immunodeficiency Virus 1 Antigen (HIV-1, gp120 C-Fc), recombinant	8.34	≥90%
8H24	Human Immunodeficiency Virus 2 Antigen (HIV-2, gp36 N-HSA), recombinant	6.5	>90%
8H25	Human Immunodeficiency Virus 2 Antigen (HIV-2, gp36 C-TnC), recombinant	4.7	≥90%

# Human papilloma virus

Hytest offers a wide spectrum of MAbs specific to oncoprotein E7 of HPV types 16 and 18. These MAbs can be used in routine immunoassays including ELISA and Western blotting. Some MAbs display high specificity to a single type of HPV while others can be used for the determination of E7 proteins of all four types of viruses. An example of a calibration curve for E7 HPV type 16 is given in Figure 13. (The performance data presented here were obtained using the earlier in vivo-produced version of the antibody. Hytest currently offers the corresponding in vitro-produced version.) We also provide recombinant L1 proteins



**Figure 13.**  
**Calibration curve for the E7 HPV type 16 sandwich immunoassay.**  
 Capture-detection pair. 716-D1 – 716-332 (Cat.# 3HP16).

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3HP16*	Monoclonal mouse anti-human papilloma virus (HPV), type 16, oncoprotein E7	Enzyme immunoassays Western blotting
3HP18*	Monoclonal mouse anti-human papilloma virus (HPV), type 18, oncoprotein E7	Enzyme immunoassays Western blotting

\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

## ANTIGENS

Cat.#	Product	Source	Purity
8HPV16	Human Papillomavirus L1 protein (HPVL1), type 16, recombinant	Recombinant	>90%
8HPV18	Human Papillomavirus L1 protein (HPVL1), type 18, recombinant	Recombinant	>90%

# Mycobacterium tuberculosis

Approximately one-third of the world population is infected with *Mycobacterium tuberculosis*. This bacterium spreads through the air and causes tuberculosis (TB), which mainly affects the lungs. TB infection can remain latent; it is estimated that about 10% of the infections lead to the disease. According to WHO, over one million people die from TB each year. These

people mainly come from low-income and middle-income countries.

We provide a broad selection of MAbs specific to different *M. tuberculosis* proteins.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3CFP1*	Monoclonal mouse anti-Mycobacterium tuberculosis CFP10	Enzyme immunoassays

\* A few MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

# Helicobacter pylori

*Helicobacter pylori* is a gram-negative bacterium that can inhabit various areas of the stomach, in particular the antrum. It can cause a chronic, low-level inflammation of the stomach lining and is strongly linked to the development of duodenal and gastric ulcers and stomach cancer. *H. pylori* is a very common bacterium of the stomach, although over 80% of individuals infected are asymptomatic.

CagA encoded by the cytotoxine-associated gene A is found in a subset of *H. pylori* strains. It is associated with the severe disease outcomes, most notably gastric carcinoma.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3HE70cc	Monoclonal mouse anti-Helicobacter pylori CagA-protein	Enzyme immunoassays Immunoprecipitation Western blotting

# Toxoplasma gondii

Toxoplasmosis is a disease that is caused by *Toxoplasma gondii*, which is a very common parasite. Upon infection, healthy people usually show either no or just mild flu-like symptoms. However, if a woman is infected either during or shortly prior to pregnancy this can cause serious injury to the unborn baby. Prenatal infection with the virus is associated with injury to the

developing fetal nervous system. The severity of this condition is related to the stage of pregnancy during which the infection occurs; first trimester infections are associated with a greater degree of neurologic dysfunction. In addition to pregnant women, toxoplasmosis can cause severe illness in people with a compromised immune system.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
3Tx19	Monoclonal mouse anti-Toxoplasma gondii p30 antigen	Enzyme immunoassays Immunofluorescence Western blotting

# Additional products

## Staphylococcus aureus endotoxins

*Staphylococcus aureus* is a bacterium that is commonly found on the skin and noses of both human beings and animals. Up to 25% of healthy people carry this bacterium.

When food is contaminated with *S. aureus*, the growing bacteria secrete different enterotoxins that are responsible for food poisoning. When ingested, enterotoxins usually cause a short-lasting illness with symptoms that are typical of a gastrointestinal disease: nausea, diarrhea and vomiting.

We have developed MAbs that are suitable for the detection of a subset of *S. aureus* enterotoxins. The MAbs are specific to a single enterotoxin (A, B, G or I).

### MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
2S4*	Monoclonal mouse anti-Staphylococcus aureus enterotoxin B	Enzyme immunoassays

\* Several MAbs available under one catalogue number. Please see [www.hytest.fi](http://www.hytest.fi).

## Diphtheria toxin

Diphtheria is an acute disease that is caused by a bacterium called *Corynebacterium diphtheria*. This bacterium produces a toxin that can spread through the bloodstream to various organs. Diphtheria usually infects the throat and nose, causing breathing problems. In more severe cases it can damage the nerves and also result in heart failure, paralysis and even death.

Diphtheria spreads by droplet transmission and it is a highly contagious and potentially life-threatening infection. Nowadays, diphtheria is very rare or has even been eradicated in many

countries as a result of systematic vaccination. However, cases still occur and this is particularly relevant in areas where vaccinations are inadequate.

We provide MAbs against the diphtheria toxin and anatoxin. The antibodies react with different determinants of the toxin and anatoxin or with the free A subunit. They are suitable for the detection of diphtheria toxin using different immunoassays.

### MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
2DT13	Monoclonal mouse anti-Diphtheria toxin	Enzyme immunoassays Western blotting

# Cholera toxin

Cholera toxin is an enterotoxin that is secreted by *V. cholerae*. This toxin induces a massive efflux of water and ions from cells that line the intestine and thereby creates a watery diarrhea characteristic to the cholera.

We offer MAbs that are specific to the B-subunit of cholera toxin.

## MONOCLONAL ANTIBODIES

Cat.#	Product	Tested applications
2C4	Monoclonal mouse anti-cholera toxin, B-subunit	Enzyme immunoassays Western blotting



# Scientific excellence for IVD

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