



PORTFOLIO

Products in favor of life



Ministério da Saúde

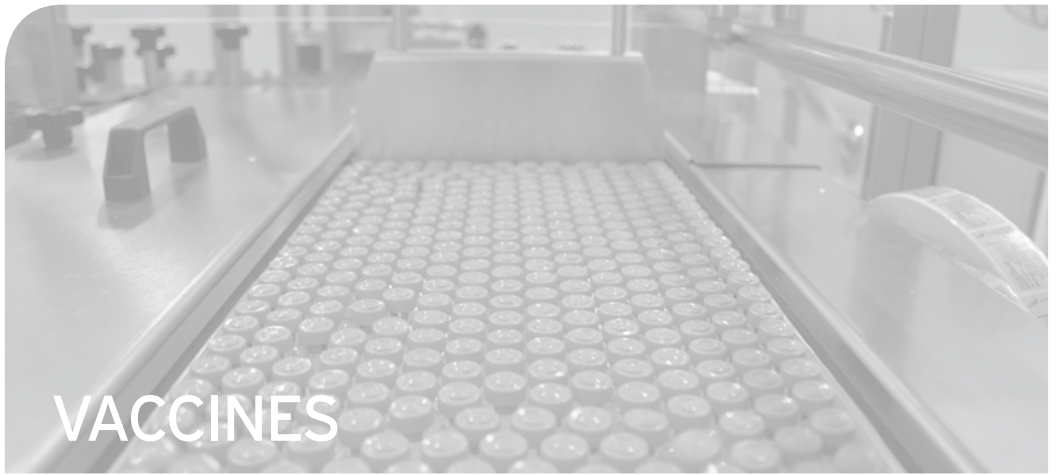
FIUCRUZ
Fundação Oswaldo Cruz



Instituto de Tecnologia
em Imunobiológicos
Bio-Manguinhos



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VACCINES



IN VITRO DIAGNOSTICS (IVDS)



BIOPHARMACEUTICALS



VACCINES

Population's increased access to biopharmaceuticals also includes the introduction of products in the portfolio, and consequently in the public health system, through internal development, partnerships or new technologies acquisition agreements with companies and national and international institutes.

The vaccines supply to the National Immunization Program (NIP) is part of the Bio-Manguinhos trajectory. The Institute has incorporated new products to its

portfolio to meet quickly and efficiently the public health system demands. Bio-Manguinhos exports yellow fever and meningococcal ACW vaccines, mainly to Latin American and African countries, via UN agencies. The vaccines portfolio consists of ten products, among viral and bacterial vaccines.



BACTERIAL VACCINES

***Haemophilus influenzae* type b (Hib) - (conjugated)**

Haemophilus influenzae b vaccine is indicated for active immunization of children against invasive disease caused by *Haemophilus influenzae* type b, such as meningitis, epiglottitis, blood infections, arthritis and pneumonia.

Presentations: 1 and 5 doses.

Diphtheria, tetanus and pertussis (DTP) and Hib

DTP and Hib vaccine is indicated for active immunization of children against diphtheria, tetanus, whooping cough and diseases caused by *Haemophilus influenzae* type b. The vaccine is produced in partnership with the Butantan Institute.

Presentation: 5 doses.

Meningococcal ACW

The meningococcal ACW vaccine is indicated for active immunization against meningococcal disease caused by *Neisseria meningitidis* infection of serogroups A, C and W-135. This vaccine is exported to developing countries, through UN agencies such as UNICEF and the Pan American Health Organization (PAHO).

Presentation: 10 doses.

10-valent pneumococcal

10-valent pneumococcal vaccine protects children under age 2 against invasive disease and acute otitis media caused by *Streptococcus pneumoniae*.

Presentation: 1 dose.



VIRAL VACCINES

Yellow fever (attenuated)

Yellow fever vaccine (attenuated) is used in the prevention of yellow fever disease caused by an arbovirus of *Flaviviridae* family.

Presentation: 5, 10 and 50 doses.

Human rotavirus

The oral rotavirus vaccine is indicated to avoid the complications caused by this virus, which can lead to vomiting, diarrhea and fever. These symptoms occur mainly between six months and two years of age.

Presentation: 1 dose.

Measles, mumps and rubella (MMR)

The vaccine is indicated for immunization against measles, mumps and rubella as well as for the prevention of its complications.

Presentation: 10 doses.

Measles, mumps, rubella and varicella (tetraivalent viral)

The tetraivalent vaccine is indicated for immunization against measles, mumps, rubella and chickenpox, as well as for the prevention of its complications.

Presentation: 1 dose.



Poliomyelitis 1, 2 and 3 (inactivated)

The vaccine is indicated for immunization against polio, which is a viral disease that can affect nerves and lead to partial or total paralysis. At two and four months of age, babies should get inactivated polio vaccine (IPV), which is injectable.

Presentation: 10 doses.

Poliomyelitis 1, 3 (attenuated)

The oral polio vaccine is indicated for active immunization against this disease. The drops, which are offered during an annual vaccination campaign against polio, should be given at 15 months and four years of age.

Presentation: 25 doses.



IN VITRO DIAGNOSTICS (IVDS)

Bio-Manguinhos develops and produces 12 in vitro diagnostics (IVDs) that are part of public programs of the General Coordination of Public Health Laboratories (CGLAB) of the STD, AIDS and Viral Hepatitis Department; besides others programs of epidemiological surveillance, through the Control of Endemic Diseases and Aggravations of Health Surveillance Secretariat of the Ministry of Health (SVS / MS) and programs of the Blood and Hemoderivatives General Coordination (CGSH).

They are tests used in the detection of antigens or antibodies to obtain a diagnosis for a given disease. These products have advantages such as simple execution method, automation possibility, good sensitivity and specificity. Currently, the Institute distributes the following kits, segmented into different platforms:

Molecular Test

National NAT method, multiplex for HIV, HCV and HBV, is based on the Real Time Polymerase Chain Reaction (PCR) platform. NAT tests were developed for viral nucleic acid detection during the preceding period of the systemic antibody production, which is the early stage of infection called the window period for AIDS, hepatitis B and hepatitis C viruses. It increases the transfusion safety.

- Kit NAT HIV/HCV/HBV (96 reactions)

Rapid Tests (RTs)

Dual Path Platform (DPP®) is a chromatographic immunoassay technology for rapid diagnostic tests from 15 to 20 minutes, adaptable to different types of body fluids: blood, serum, plasma and saliva, among others, which has a wide variety pathologies application and allows the diagnosis in hard reaching places or with no laboratory infrastructure. The

DPP® technology expands considerably the potential application of rapid tests, which provides accurate results with agility. It also allows the application in the field, the conduction of multitests essays and the use of minimum sample volumes.

- DPP® HIV-1/2 SSP or oral fluid (10 and 20 reactions)
- DPP® HIV-1/2 oral fluid
- Imunoblot rapid DPP® HIV-1/2 (20 reactions)
- DPP® HIV / Syphilis Combo (10 and 20 reactions)
- DPP® Syphilis Duo (20 reactions)
- DPP® Syphilis (10 and 20 reactions)
- DPP® Canine Leishmaniasis (20 reactions)
- DPP® Leptospirosis (20 reactions)
- DPP® Zika IgG IgM (20 reactions)



Indirect immunofluorescence test (IFI)

It consists in the reaction of antibodies present in human sera or plasmas infected with parasites, previously fixed on microscope slides for fluorescence. The reading is performed under microscope using incidence of blue and ultraviolet light.

- IFI Chagas disease (600 reactions)
- IFI Human Leishmaniasis (600 reactions)

Elisa tests

It consists in the reaction of antibody present in the sera or plasmas with solubled and purified antigens derived from in vitro culture, previously absorbed onto microplate wells. To highlight the reaction, a chromogen substance is used that, by the action of peroxidase, forms a turquoise blue compound that, when added the sulfuric acid, interrupts and characterizes the reaction.

- EIE Canine Leishmaniasis (384 reactions)

Kato Katz Technique

It is a qualitative and quantitative test for parasitological stool detection. The test is based on Kato method technology, modified by Katz et al. This method allows to reveal all helminth eggs that are found in the faeces: Ascaris, Shistosoma, Hookworms, whipworms, Taenia and more rarely the Enterobius and Strongyloides. The reading is performed under microscope.

- Test Helm (100 reactions)





BIOPHARMACEUTICALS

The production of biopharmaceuticals requires high investments in technology and is receiving increased attention from the pharmaceutical industry. This type of drug, derived from living organisms, has been pointed out as the solution to several chronic and rare diseases.

Since 2004, Bio-Manguinhos operates in development and production of biopharmaceuticals, in order to meet the Pharmaceutical Assistance Department, under the Ministry of Health. Thus, in addition to working in the technological development

of biological medicines, the Institute participates decisively in large achievements of public health by reducing the high social and economic impact of autoimmune diseases, such as cancer, diabetes, sclerosis, arthritis, among others. In 2015, more than 12 million biopharmaceuticals vials were supplied to the government.

Interferon alfa-2b

Indicated for the treatment of chronic hepatitis caused by viruses B or C and hematopoietic tissue neoplasms such as chronic myelogenous leukemia.

Presentations: 3 MUI, 5 MUI and 10 MUI.

Epoetin alfa

Indicated for the treatment of anemia in patients with chronic renal failure, anemia in AIDS patients undergoing treatment with zidovudine (AZT) and cancer patients in chemotherapy treatment.

Presentations: 2,000 UI, 4,000 UI and 10,000 UI.

Alfataglicerase

It is indicated for long-term enzyme replacement therapy in adult patients with Gaucher disease type I. The disease symptoms may include: enlarged spleen (splenomegaly), enlarged liver (hepatomegaly), anemia, decreasing in the number of clotting Blood cells (thrombocytopenia), bone disease.

Presentation: 200 units.

Infliximab

This drug is used to treat pediatric and adult patients with Crohn's disease, fistulizing Crohn's disease, adult patients with colitis or ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis. It aims to reduce inflammatory activity.

Presentation: 100 mg.



Beta interferon 1a

The biopharmaceutical is indicated primarily for treatment of multiple sclerosis, according to the international standards of treatment. Multiple sclerosis is a degenerative and incurable disease, which affects seriously the life quality of patients. While it is not lethal, it can result in paralysis of limbs or loss of vision in more severe cases.

Presentations: 22 mcg and 44 mcg.



There is a little of Bio
in each Brazilian.



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