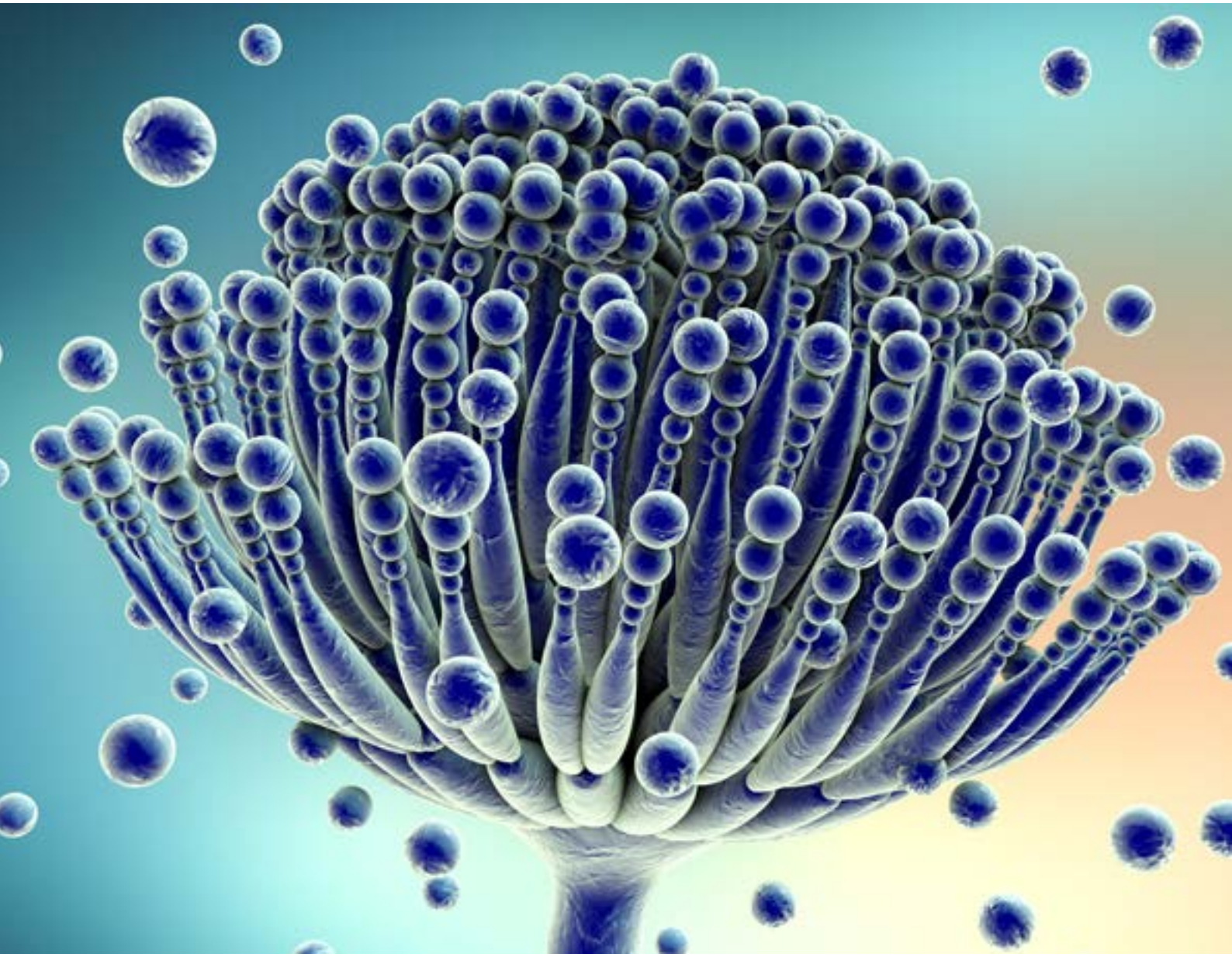
FUNGAL INFECTION Dx

BIOMEDICA



Global Technology.
Local **Solutions.**

2022
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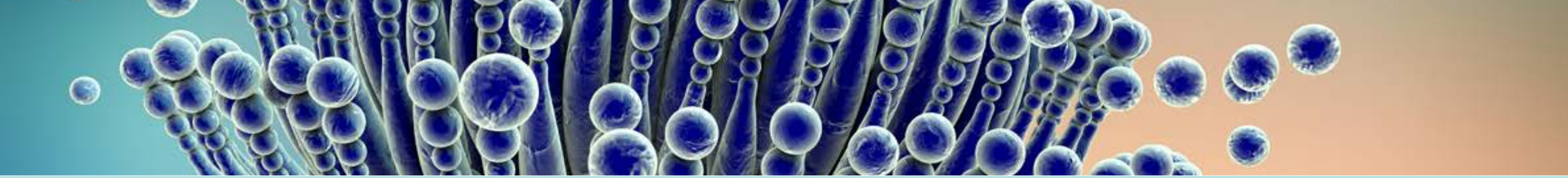


BIOMEDICA - YOUR PARTNER IN MYCOLOGY

BIOMEDICA – YOUR PARTNER IN MYCOLOGY

BIOMEDICA has been on the forefront as a distributor of in vitro diagnostics for **more than 40 years**. BIOMEDICA has established **13 local offices**, distributed **across Central Eastern Europe (CEE)**, employing a **team of 280 professionals**. The reliability of BIOMEDICA's business performance and quality of products are evidenced in our daily work and our daily efforts with and for our customers.

We supply customers in the fields of health care and research with **flexible solutions, quality products, technical services and ongoing support.**

The **ISO 9001:2015 certification** throughout the entire group of companies ensures constant improvement in quality of products and services.

Map showing BIOMEDICA local offices.

Fungal infections affect approximately one quarter of the global population. They **kill** at least **1,350,000** patients with or following AIDS, cancer, TB and asthma globally each year. An observed increase in incidence of **drug resistant** and previously rare fungal species is additional public health concern. Despite high clinical and economic burden public awareness of invasive fungal diseases is still low.

An **early diagnosis** and correct treatment have direct impact of patient survival. Therefore, there is an urgent need for improved diagnostic options to provide a rational basis for antifungal therapy. The introduction of **non-culture tests for early detection** of infection with a rapid assessment of drug susceptibility is an important step in this direction.

Biomedica has a comprehensive portfolio of diagnostics, including molecular assays, dedicated to rapid detection and differentiation of fungal pathogens and assessment of potential drug resistance.

Our Partners:

ELITechGroup MOLECULAR DIAGNOSTICS

IMMY

ademtech MycoGENIE®

FUJIFILM Value from Innovation

Wako

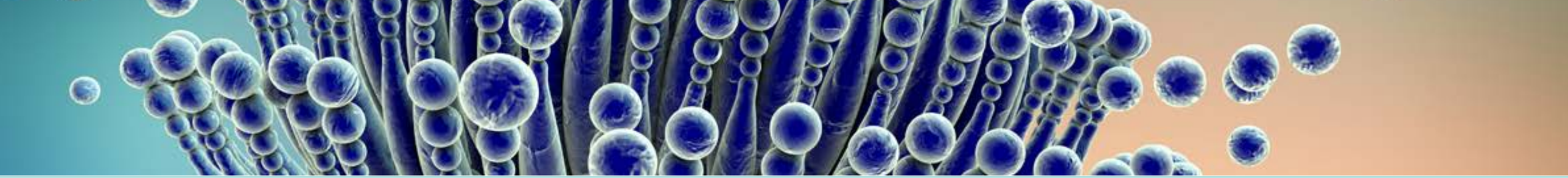
MERLIN A Bruker Company

vircell MICROBIOLOGISTS

ingenetix

MycoReal assays

T2Biosystems



(1—›3)-ß-D-glucan Monotest

FUJIFILM Value from Innovation

Wako

The Toxinometer MT-6500 based ß-Glucan Test is an in vitro diagnostic test for the quantitative determination of (1->3)-ß-D-glucan in serum or plasma.
In most pathogenic fungi, (1->3)-ß-D-glucan is an integral component of the cell wall. Small quantities are released into the blood during infection.
The Limulus reagent (LAL: Limulus amebocyte lysate), made from the extract of blood cells of horseshoe crabs, has drawn attention as an in vitro diagnostic reagent for mycosis.
It reacts with (1->3)-ß-D-glucan as well as with endotoxin. The ß-Glucan Test exclusively measures the (1->3)-ß-D-glucan concentration through a kinetic turbidimetric assay in a sample pretreated with a solution which inactivates endotoxin by the use of a non-ionic detergent and polymyxin B.

- FJ-997-04101 ß-Glucan Test (50 tests)

Additional reagents and consumables needed:
- FJ-993-04201 ß-Glucan Sample Pretreatment Solution (50 0,9 ml)
- FJ-999-04301 ß-Glucan Sample Dilution Buffer (10 x 0,9 ml)
- FJ-995-04901 Aluminium Caps, sterile (10 x 10 caps)
- FJ-995-04401 LAL Control Wako (10 x 0,5 ml)
- FJ-995-05001 BC Tip Wako EXT (100 pcs)
- FJ-991-05101 BC Tip Wako 1000-R (100 pcs)

Key features:
- Monotest reagents
- Calibration by QR Code Scan
- Quality control available
- Simple procedure
- Ready to use reagents
- Intuitive Software
- Quantitative ß-D-glucan measurement
- Measurement range: 6 to 600 pg/mL
- Cut-off value: 11 pg/mL
- High precision and no significant interference observed due to bilirubin, hemolysis or antifungal drugs

PanReal Kit Fungi & Bacteria

ingenetix

MycoReal assays

PanReal Kit Fungi & Bacteria is a multiplex-PCR real-time PCR test for universal detection of fungi and bacteria in samples purified from bronchoalveolar lavages (BAL), aspirates, cerebrospinal fluid, tissue, paraffin embedded tissue and fungal/bacterial colonies. The kit is suitable only to a limited extent for the detection of fungi in blood samples.

IG-DHUFB0153 PanReal Fungi & Bacteria kit is used for amplification and detection of ITS2 region of fungi and 16S rDNA of bacteria. It includes Internal Positive Control System to exclude false-negative results and it is optimized to handle PCR inhibitors. It runs on all established standard real-time PCR- platforms and its harmonized thermal profiles enable running RNA and DNA samples simultaneously.

Over 30 million people are at risk of invasive aspergillosis each year because of corticosteroid use or other therapies, and over 300,000 patients develop it annually.

The disease is common in high risk patients with:
- Hematological malignancies
- Chemotherapy-induced neutropenia
- Allogeneic HSCT (stem cell transplant)
- Solid organ transplant (primarily lung)

Aspergillus as a pathogen plays a big role in terms of post-transplant infections. In solid organ transplantation, invasive aspergillosis occurs mainly from week 2-5 after transplantation, whereas for hematopoietic stem cells transplantation infections with *Aspergillus* have a broader time-range of 1-6 weeks after transplantation.

Aspergillus Galactomannan Lateral Flow

IMMY

Invasive aspergillosis is associated with significant morbidity and mortality in immunocompromised populations, including haematology, solid organ transplantation, and critical care patients.

- YI-AF2003 sõna *Aspergillus* Galactomannan Antigen Lateral Flow Assay (50 tests)

Key Advantages of the sõna AGM LFA:
- 30 Minute test time
- on demand testing possible
- Simplified procedure
- High sensitivity and specificity
- Serum & BAL specimens
- Test more frequently/Eliminate batch testing

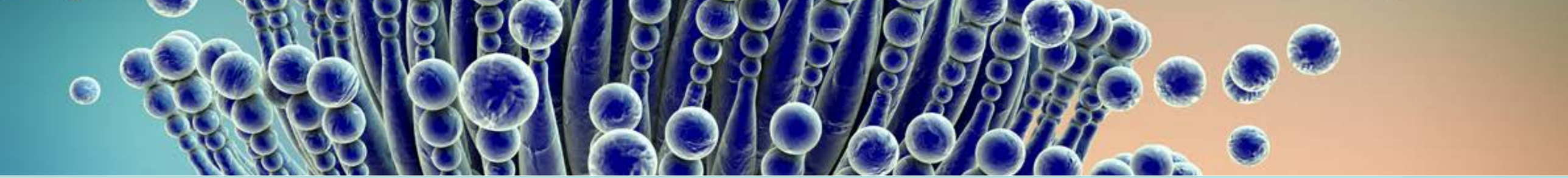
Aspergillus Galactomannan Ag VIRCLIA

vircell MICROBIOLOGISTS

VC-VCM073 *Aspergillus* Galactomannan Antigen VIRCLIA® IgG MONOTEST (24 tests)

Sandwich Chemiluminescent Immunoassay (CLIA) for the detection of Aspergillus galactomannan antigen in serum, plasma and human bronchoalveolar lavage (BAL) samples.

Aspergillus Galactomannan Antigen VIRCLIA® IgG MONOTEST is compatible with the entire VIRCLIA® panel.



ASPERGILLUS

Aspergillus spp. MolDx

MycoGENIE® product line (Ademtech) comprises fungal DNA extraction kits as well as multiplex qPCR kits for detection of fungal pathogens and antifungal drug resistance.

Extraction of high quality fungal DNA from a complex sample matrix, which is also fungal DNA contamination free, is made possible with MycoGENIE® DNA extraction kits.
Those are magnetic beads based kits (manual and automated).

All MycoGENIE® fungal pathogen detection kits use UDG technology for cross-contamination prevention:

- DD-60308 MycoGENIE® *Aspergillus* spp. offers a robust detection of clinically relevant *Aspergillus* species within a large dynamic range.
- DD-60303 MycoGENIE® *Aspergillus fumigatus* kit not only efficiently detects the pathogen, but also tests for pan-azole resistance in the same tube.

Aspergillus spp. MolDx

Detection of a wide range of *Aspergillus* species – the kit detects the five clinically most relevant species:

- *Aspergillus fumigatus*
- *Aspergillus flavus*
- *Aspergillus terreus*
- *Aspergillus niger*
- *Aspergillus nidulans*

as well as some other closely related Aspergillus/Emericella species belonging to *Aspergillus* section *Fumigati, Flavi, Terrei, Nigri, Nidulantes, Usti* and *Versicolori*.

It is validated with blood samples and as such enables early diagnosis of invasive aspergillosis. Discrimination of *A. flavus, A. terreus* and *A. fumigatus* helps in prescribing specific antifungal therapy.
IG-DHUF00253 is used for amplification and detection: ITS2-region of Aspergillus. It includes Internal Positive Control System to exclude false-negative results and it is optimized to handle PCR inhibitors. It runs on all established standard real-time PCR-platforms.

Aspergillus spp. fully automated MolDx

Aspergillus infections are occurring with an increasing frequency in transplant recipients with an unacceptable high mortality rate (up to 92%). Elitech offers a fully automated sample-to-result solution for detection and quantification of the DNA of the *Aspergillus* genus (*Aspergillus* spp.). The assay can detect and quantify the DNA of the following species:

- *Aspergillus fumigatus*
- *Aspergillus niger*
- *Aspergillus nidulans*
- *Aspergillus glaucus*
- *Aspergillus terreus*
- *Aspergillus flavus*
- *Aspergillus versicolor*

EG-RTS110PLD is automated assay validated for bronchoalveolar lavage (BAL), bronchial aspirate (BA) and EDTA plasma samples.

CANDIDA

Invasive candidiasis is a disease of fungal etiology with an increasing incidence, especially in immunosuppressed patients (graft receivers, neutropenic and AIDS patients, etc), long-stay hospitalized and catheterized patients, as well as those subjected to extensive surgery or receiving broad spectrum antibiotic therapy. The diagnosis of invasive candidiasis is especially difficult due to the absence of pathognomonic symptoms specific of the disease and the low recovery of the microorganism in culture.

Invasive Candidiasis (CAGTA) VIRCLIA

VC-VCM094 INVASIVE CANDIDIASIS (CAGTA) VIRCLIA® IgG MONOTEST (24 tests)

This test is based upon the detection of specific IgG antibodies against antigens located on the cell wall surface of the mycelium of *Candida albicans* (CAGTA *Candida albicans* germ tube antibody). These antibodies are normally present in sera from patients with invasive candidiasis caused by *C. albicans* and other species of this genus.

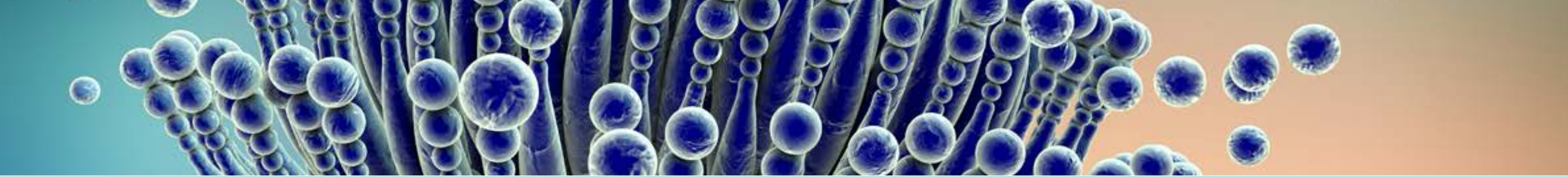
Indirect chemiluminescent immunoassay (CLIA) using human serum and plasma.

Candida & *Aspergillus fumigatus* MolDx

MycoReal Kit Candida & A. fumigatus is an in vitro diagnostic test based on real-time PCR, for the qualitative detection of specific DNA of *C. albicans, C. dubliniensis, C. glabrata, C. krusei (= Pichia kudriavzevii, Issatchenkia orientalis), C. parapsilosis group, C. tropicalis and Aspergillus fumigatus.*

Starting material is DNA purified from blood, biopsies, aspirates, punctates, cerebrospinal fluid (CSF) or samples of the respiratory tract. The kit supports the detection of a Candida or A. fumigatus infection of patients with a suspected sepsis or fungal infection. The species are detected with two different assay mixes which have to be analyzed in parallel. With this approach, C. glabrata, C. krusei, C. parapsilosis and A. fumigatus can be differentiated from other Candida species, which enables specific antifungal therapy. Since MycoReal Kits and PanReal Kit use identical temperature/time profiles, they can be combined in the same real-time PCR run. This allows the detection of a wide panel of pathogenic fungi within only a few hours.

IG-DHUF00153 is used for amplification and detection ITS2- Region of Candida and A. fumigatus.



CANDIDA

Candida Sepsis Dx from whole blood

Run on the fully automated T2Dx Instrument, the T2Candida Panel identifies the five clinically relevant species of *Candida* directly from whole blood. This enables physicians to initiate appropriate therapy within hours of the blood draw. This is especially important given that research has shown that the mortality rate for sepsis rises 8% every hour treatment is delayed. Today, all other FDA-cleared *Candida* diagnostics rely on blood culture, which is hampered by a sensitivity of 50% and a lag time of up to 2 to 6 days for species identification or negative result. When up to half of infections are missed, even the most accurate blood-culture-reliant diagnostic cannot detect what blood culture missed.

- T2*Candida* Panel detects the following species of *Candida* directly from whole blood: *C. albicans, C. tropicalis, C. parapsilosis, C. krusei* and *C. glabrata*.
  - 91,1% sensitivity & 99,4% specificity
  - Limits of detection as low as 1 CFU/mL
  - Species-specific results in an average of 3 to 5 hours directly from whole blood
  - Accuracy even in the presence of antimicrobials

CRYPTOCOCCI

Cryptococcosis, a fungal disease caused by both species of the *Cryptococcus* species complex (*Cryptococcus* neoformans and *Cryptococcus* gattii). Individuals with impaired cell-mediated immunity are at greatest risk of infection. Cryptococcosis is one of the most common opportunistic infections in AIDS patients. Every year, approximately 1,000,000 cases of cryptococcal meningitis occur globally resulting in more than 1,700 deaths every day.
Cryptococcosis is most commonly diagnosed by detection of cryptococcal antigen (CrAg) using one of several methods.

Cryptococcal Antigen Lateral Flow

The IMMY CrAg® LFA (Cryptococcal Antigen Lateral Flow Assay) is the first and only immunochromatographic dipstick assay for the qualitative and semi-quantitative detection of cryptococcal antigen.
This lateral flow assay is revolutionizing cryptococcal antigen testing, by delivering analytical sensitivity that is up to 200x more sensitive than other commercial assays. The CrAg® LFA is empowering health care providers in all clinical settings with rapid, reliable and robust diagnostic results.

YI-CR2003 Cryptococcal Antigen Lateral Flow Assay (50 tests)

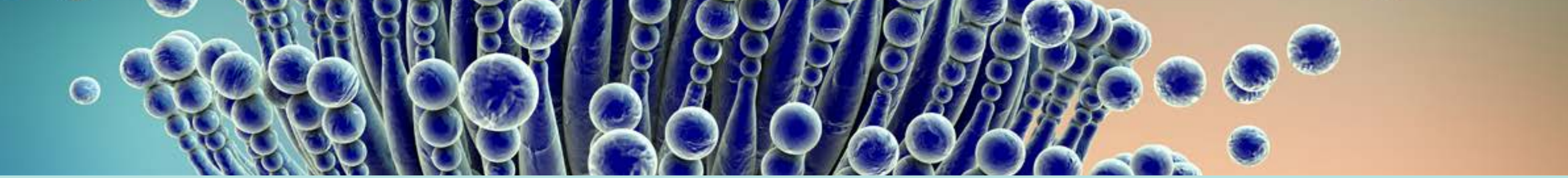
- No Pronase Treatment
- Qualitative & Semi-Quantitative Results
- 2-Year Shelf Life
- Most Sensitive Assay on the Market
- Cleared for CSF & Serum

Latex Agglutination / Immunodiffusion

YI-CR1003 *Cryptococcus* Antigen Latex Agglutination Test (50 tests)
YI-CR1004 *Cryptococcus* Antigen Latex Agglutination Test (120 tests)
The *Cryptococcus* Antigen Latex Agglutination Test System has proven to be a valuable aid in establishing diagnosis of cryptococcosis. This assay is a simple, sensitive test system that can be used on serum and CSF and can give qualitative and semi-quantitative results.

Enzyme Immuno Assays (EIA)

YI-CRY101 CrAg EIA (192 tests)
The ALPHA Cryptococcal Antigen enzyme immunoassay (CrAg EIA) is a qualitative or semi-quantitative (titration) test system for the detection of capsular polysaccharide antigens of *Cryptococcus* species complex (*Cryptococcus neoformans* and *Cryptococcus gattii*) in serum and cerebrospinal fluid (CSF). It is a direct immunoenzymatic sandwich microplate assay and has been considered the most sensitive and specific EIA for the detection of cryptococcal antigen.



COCCIDIOIDES

Coccidioides species are dimorphic fungi that exist as either mycelia (saprobic growth) or spherules (parasitic growth) which cause respiratory diseases and occasionally diseases affecting other systems.

Coccidioides Antigen Lateral Flow

The sōna *Coccidioides* Antibody Lateral Flow Assay (LFA) is used for the qualitative detection of serum antibodies directed against TP and CF antigens from *Coccidioides* species as an aid in the diagnosis of coccidioidomycosis. The sōna *Coccidioides* Antibody LFA utilizes a proprietary mixture of recombinant and native *Coccidioides* antigens, including the CF and TP antigens, adsorbed to nitrocellulose. Antibodies against TP antigens form early in the course of disease (typically IgM), followed by antibodies against CF (typically IgG).

YI-CTA2003 sōna *Coccidioides* Ab LFA (50 tests)

- Results in only 30 minutes
- Fewer Send-outs
- High negative Predictive Value
- Reduce Hands-on Time
- Run On All Shifts

Latex Agglutination / Immunodiffusion

YI-CL1001 *Coccidioides* Antibody Latex Agglutination Test System (80 tests)
YI-CI1001 *Coccidioides* Antibody Latex Agglutination and Immunodiffusion Combination Kit (60 tests)
The *Coccidioides* Antibody Latex Agglutination Test System is a sensitive and rapid screening test. This assay does have a false-positive rate, so the results of this test should be confirmed by EIA, Complement Fixation and/or Immunodiffusion.

Enzyme Immuno Assays (EIA)

YI-CAB102 *Coccidioides* Ab EIA (96 tests)
The *Coccidioides* Antibody EIA is a very useful tool to aid in the diagnosis of coccidiodomycosis. This assay is a sensitive, specific, and rapid test for the qualitative detection of serum antibodies against TP and CF antigens from *Coccidioides*.

PNEUMOCYSTIS

Pneumocystis jiroveci is a yeast-like fungus which can be found worldwide. *Pneumocystis jiroveci* is a distinct species that only infects humans, while the related species *P. carinii* can be found in rodents and other mammals. Airborne transmission of Pneumocystis from host to host has been demonstrated in rodent models and several observations suggest that interindividual transmission occurs in humans. Both healthy and immunocompromised people can be colonised with *P. jiroveci*. While it does not affect healthy people, *P. jiroveci* can cause an interstitial Pneumocystis-pneumonia (PCP) in HIV-patients, persons with primary immune deficiencies, including hypogammaglobulinemia and severe combined immunodeficiency (SCID), patients receiving long-term immunosuppressive regimens for connective-tissue disorders, vasculitides, or solid-organ transplantation, patients with hematologic and nonhematologic malignancies, including solid tumors and lymphomas, and persons with severe malnutrition. Currently the diagnosis of PCP relies on microscopic methods or PCR, as *P. jiroveci* cannot be cultured in routine microbiology laboratories.

Pneumocystis jirovecii MolDx

DD-60307 MycoGENIE® *Pneumocystis jirovecii* is a one tube duplex qPCR assay includes Quantification Standards for the quantitative detection of P. jirovecii.

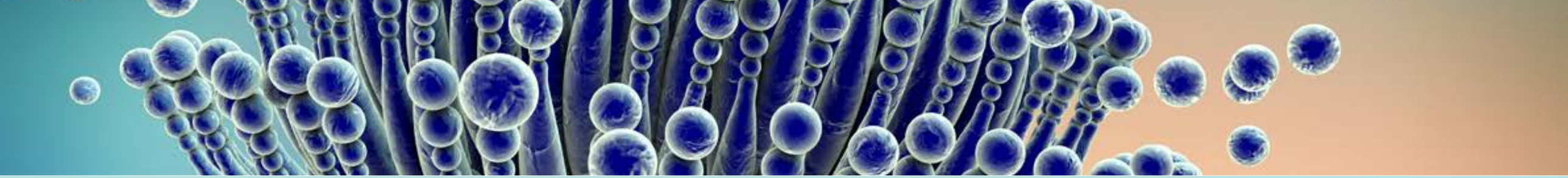
MycoReal Kit Pneumocystis uses real-time PCR for the detection of the mitochondrial large subunit rRNA gene (mt LSU) of *P. jiroveci.* Carefully designed primers and probe ensure highest sensitivity and specificity. To minimize PCR cross-contamination, the reaction mix included contains dUTP and uracil-N glycosylase (UNG).

IG-DHUF00353 is used for amplification and detection of mt LSU of *Pneumocystis jiroveci*.

Pneumocystis jirovecii fully automated MolDx

Automated sample-to-result assay to detect and quantify the DNA of *Pneumocystis jirovecii* (PJ).

EG-RTS150ING is automated assay validated for bronchoalveolar lavage (BAL) and liquefied Sputum samples.



Blastomyces

YI-BTA101 *Blastomyces* Antibody EIA (96 tests)
The *Blastomyces* Antibody EIA is used for the qualitative detection of serum antibodies directed against yeast-phase antigens from *Blastomyces*. This assay is a sensitive, specific, and rapid test, which can help consolidate the workload of immunodiffusion and complement fixation testing.

Histoplasma

YI-HL1001 *Histoplasma* Antibody Latex Agglutination Test System (80 tests)
The *Histoplasma* Antibody Latex Agglutination Test System can aid in the diagnosis of histoplasmosis; however, cross-reactions with other fungal organisms may occur. Results should be interpreted with caution, particularly if the titer is low and only one specimen has been examined. It is recommended to confirm the LA test result with ID and/or CF.

YI-HAG102 *Histoplasma* Ag EIA (96 tests)
The *Histoplasma* Antigen EIA is the first and only commercially available diagnostic kit for *Histoplasma* antigen detection. This diagnostic kit is a cost-effective alternative for hospitals and labs that no longer wish to send specimens off to service laboratories.

Sporothrix

YI-SL1001 *Sporothrix* Antibody Latex Agglutination Test System (80 tests)
The *Sporothrix* Antibody Latex Agglutination Test System can aid in the diagnosis of sporotichosis.
Sporothrix is generally endemic to the tropical and subtropical regions of the Americas.

Antimicrobial Susceptibility Test (AST)

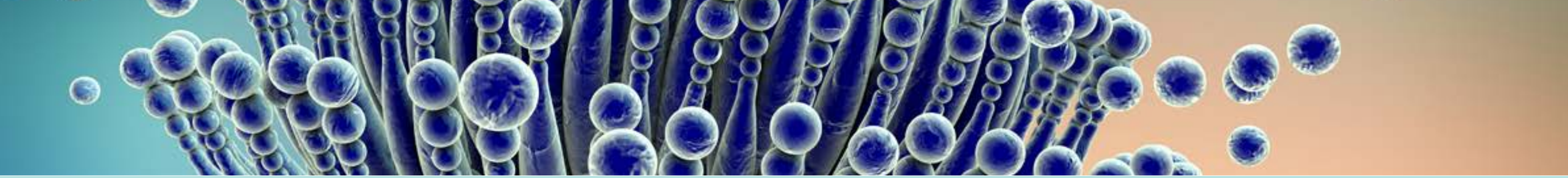
The testing principle of MICRONAUT antimicrobial susceptibility test (AST) is based on phenotypical resistance detection by the growth of the microorganisms in the presence of the antifungal agents tested. Because of a special vacuum drying process, the plates can be stored at a room temperature of 15-25°C. MICRONAUT test plates have a shelf life of 24 months at date of production.

MICRONAUT-AM for the susceptibility testing of *Candida* and *Cryptococci*

- Indicator for easy visual reading
- Reading via photometer possible
- Results after 22 – 48 hours of incubation
- Individual configuration of the antifungal agents is feasible
- Standard plates available as 1- or 2-Test plate

MycoGENIE® DNA extraction kits

Extraction of high quality fungal DNA from a complex sample matrix, is made possible with MycoGENIE® DNA extraction kits. Those are magnetic beads-based kits suitable for manual and automated (AutoMag One or AutoMag Prime) DNA extraction. The kits have been developed to purify high quality contamination free fungal DNA from serum, plasma, sputum, BAL, fresh and frozen tissues.



INSTRUMENTATION

AutoMag One
It is easy-to-use automated extraction workstation for low throughput.
The instrument purifies 1-8 samples simulant in less than 1 hour using pre-sealed cartridges.
The extraction automate is very robust, has integrated UV lamp for contamination protection and very attractive price.

AutoMag PRIME
This compact instrument with a small footprint is ideal for laboratories with middle sample throughput (up to 24 samples). It is based on the KingFisher Duo Prime system and is using magnetic rods covered with a disposable, specially designed tip comb and plates. The instrument functions without any dispensing or aspiration parts or devices. It is therefore very fast and is able to purify NA from 1-12 samples in 30 minutes. Prefilled plates are pre-sealed and incor¬porate all reagents needed for purification process of 12 samples.
Optional bar-code reader enhances functionality.

MICRONAUT Skan + MICRONAUT Software
For a fast and standardized reading of all MICRONAUT systems several photometers have been qualified.
MICRONAUT Software offers rapid and standardized reading, calculation, and interpretation of identification and susceptibility testing by using MICRONAUT systems.
All patient data (specimen number, name, data of birth) and test types can be manually administered or imported from the mainframe.

The MICRONAUT software generates work lists defining an optimized inoculation procedure considering an economic use of test plates.
Subsequently to evaluate the identification result is attached the corresponding susceptibility pattern.
The expert module of the MICROANUT software checks the plausibility of the susceptibility test results.
Identification results are compared with typical resistance profiles. In case of discrepancies to the typical profiles, additional tests are recommended for the corresponding isolates. Exceptional and impossible phenotypes can be detected.

T2Dx
The fully automated T2Dx is a benchtop analyser for running the T2Candida and the T2Bacteria Panel on it.

- Random access workflow – 7 drawers
- "Sample in – result out"
- Minimal specimen handling
- Cartridge based
- Direct from whole blood

Elite InGenius
The Elite InGenius is a fully automated, cassette-based sample-to-result real-time PCR instrument, that can perform automated universal extraction and up to 4 PCR reactions from just one extracted sample (with 25 validated sample matrices).
Primary sample loading from whole blood and plasma is possible. With its MGB® Technology, the Elite InGenius is a highly flexible and reliable instrument with minimal hands-on-time, and possibility to run 12 samples simultaniously with approx. time of 2h30min from sample to result.
Elitech with its Elite InGenius offers a wide portfolio from transplant pathogen monitoring, respiratory, gastrointestinal, sexually transmitted infections, healthcare associated infections and meningitis & encephalitis diagnosis.

VIRCLIA
Walk-away processing of any EIA or Chemiluminescence assay. The ThunderBolt® for ELISA + CLIA offers automation features previously reserved for instruments many times the price and size. Streamline your workflow with easy loading, and fully automated processing, reading and reporting of results. Experience the difference ThunderBolt® automation will bring to your laboratory.

- Fully automated – load and walk away
- High capacity – 192 sample capacity
- Open architecture – program an EIA or CLIA protocol
- Up to 8 different protocols in a single batch
- High precision micro-syringe: aspirate 1µl with less than 3% CV
- Convection incubator: Eliminate „Edge Effect" by evenly heating each well
- Orbital shaker: No-spill design, up to 900 RPM
- Built-in reader: Ultra compact and fully-automated reader
- Intelligent racks: Reduce errors with Positive Patient Identification
- On board camera: Remote diagnostics for maximum uptime
- Intuitive, open, flexible software: Powerful test designer, custom report generator, LIS compatible, bi-directional interface

Wako Toxinometer und Thermostation
The Toxinometer MT-6500 and the related equipment are proprietary devices developed by FUJIFILM Wako Pure Chemical Corporation. These devices are used for the quantitative measurement of (1->3)-ß-D-glucan by a kinetic turbidimetric assay.
The MT-6500 Extension Module is used to enlarge the measurement capacity by 16 samples per unit. The pretreatment of samples at 70°C is done using the Thermostation TS-70/16. The operation of all devices is very simple.

- 16 sample positions; can be expanded up to 64 by adding up to 3 MT-6500 Extension Modules
- Automatic measurement starts after sample is inserted
- Touchscreen display
- Calibration by barcode-driven reading of calibration card
- LIS integration capability
- Maximum 90 minutes measurement time

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