



Transplant Diagnostics

Transplant Offering

AGENDA

- **Testing Services
@ Eurofins Viracor**

- Overview SOT
- CMV Testing Portfolio
- ImmuKnow
- Fungal Diagnostics



OUR MISSION, VISION, VALUES



OUR VISION

To be a **trusted** healthcare leader **improving patients' lives** through **innovation** solutions, **laboratory services**, and **partnerships**.



OUR MISSION

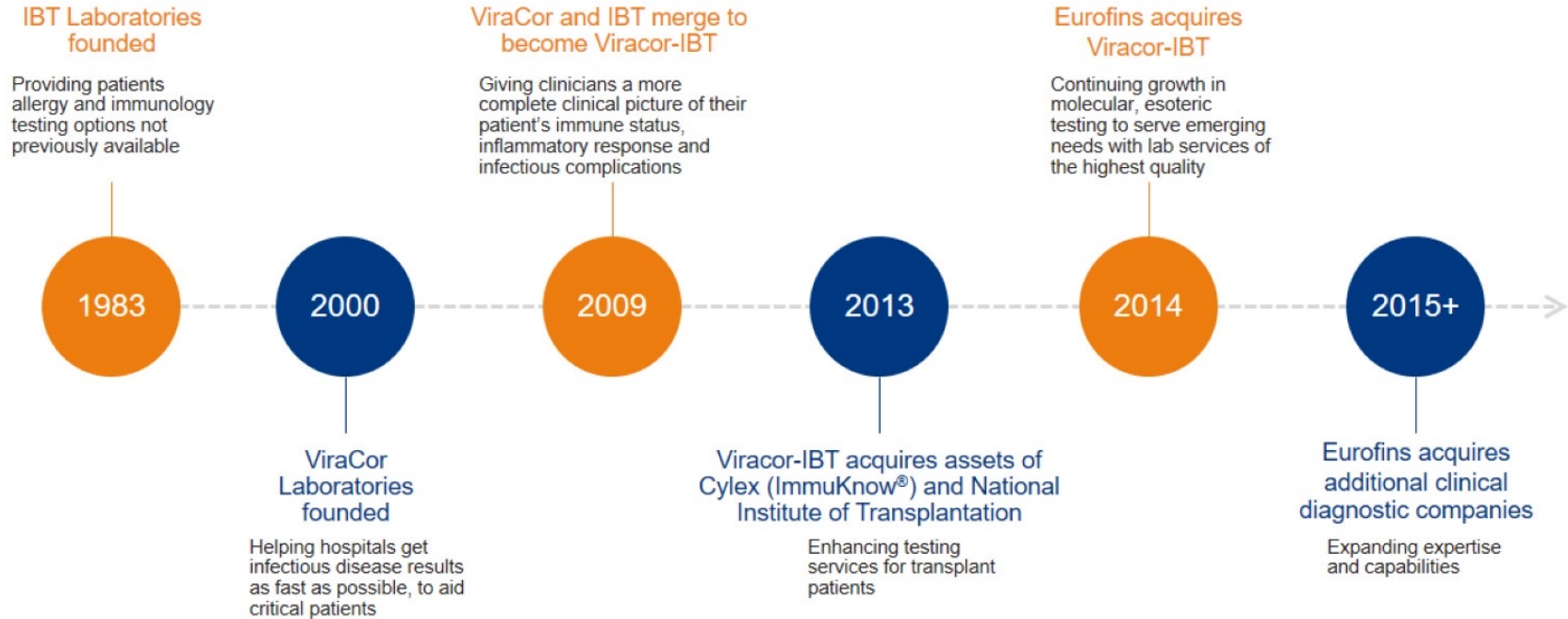
We improve the lives of patients through **timely testing**, **excellence in science**, **innovative solutions** and **exceptional service**.



OUR VALUES

Lead Humbly. Innovate Passionately. Improve Relentlessly. Work Responsibly. Act Honestly. Collaborate Openly. Maximize Talent.

A HISTORY OF HELPING YOU HELP YOUR PATIENTS





We are a trusted specialty laboratory with over **30 years of experience** and **3000+ tests** in infectious disease immunology and allergy testing for your **immunocompromised patients with critical needs.**



WHAT MAKES EUROFINS VIRACOR UNIQUE



Innovation



Accuracy

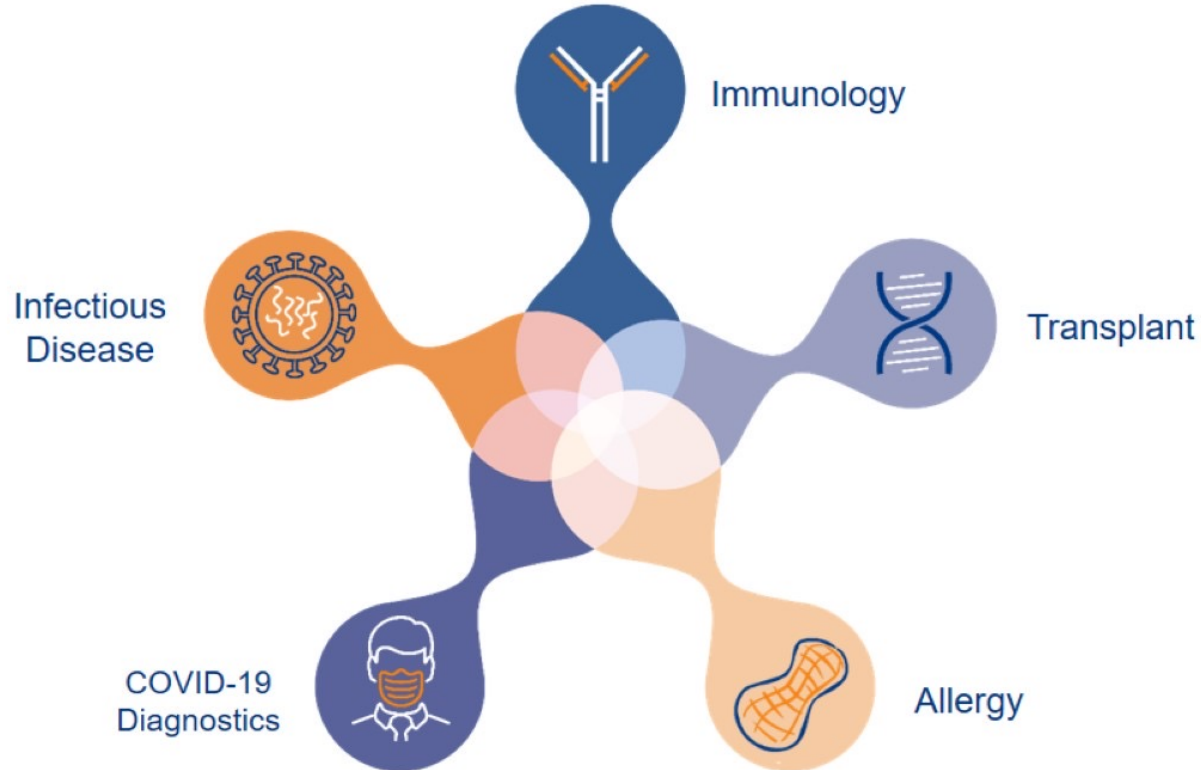


Speed



Expertise

CLINICAL DIAGNOSTIC EXPERTISE



INNOVATION



Among the first commercial laboratories to offer **key tests**

Infectious Disease (Quantitative PCR)

BK Virus

JC Virus

Adenovirus

HHV-7

HHV-8

P. jiroveci (carinii)

T. Gondii

Gastrointestinal PCR Panel

Mucorales PCR

Nocardia PCR

Zika Virus Real-time RT-PCR and IgM

Coronavirus SARS-CoV-2 (COVID-19)

Immune Recognition & Response

MBL Protein, Genotype & Function

Pneumococcal Antibody and Avidity

T-cell Fx

GvHD Biomarkers

aGVHD Algorithm Testing

CMV inSIGHT™ T Cell Immunity
(formerly known as: CMV T Cell Immunity Panel)

Viracor TRAC® (Transplant Rejection Allograft Check)

SARS-CoV-2 inSIGHT™ T Cell Immunity

Allergy & Hypersensitivity

Latex Allergy Testing

BasoFunction

LeukoFunction

Alpha-Gal IgE

Free IgE

Mast Cell Tryptase

Filaggrin

Anti-IgA & Anti-IgE

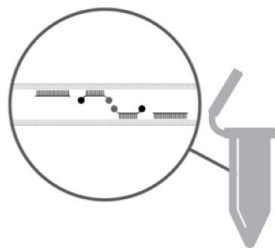
Autoimmune Chronic Urticaria (CU Index)

ACCURACY



Refining our assays to ensure the most accurate results for your patients

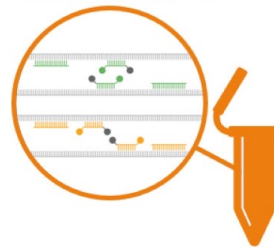
Example: Constant PCR Refinement for Evolving Mutations



TRADITIONAL LAB

Single target, single probe, single reaction

- Risk under-quantification and false negative results



EUROFINS VIRACOR

Dual targets, multiple probes

- Reduces the incidence of under-quantification and false negative results
- Detects other strains that could be missed
- Pathogen surveillance & assay refinement

MANY ACCEPTED SPECIMEN TYPES PROVIDE OPTIONS TO HELP YOUR PATIENTS

*Example: Adenovirus available specimen types featured in **BOLD** print below.*

UPPER RESPIRATORY

nasal aspirated, nasal swab, nasal wash, NP aspirate, NP swab, NP wash, OP swab, saliva swab, **throat gargle**

LOWER RESPIRATORY

BAL, bronch wash, sputum, **trach asp, trach wash**

FLUIDS

abscess fluid, amniotic fluid, aqueous fluid, **CSF pericardial fluid, pleural fluid**, synovial fluid, vitreous fluid

BLOOD/MARROW

bone marrow, plasma, serum, whole blood

OTHER

eye swab, **fecal**, genital swab, mouth swab, skin swab, rectal swab, **tissue, urine**

TESTING FOR KEY SOLID ORGAN TRANSPLANT COMPLICATIONS

REJECTION

Inflammatory Response

- IL-18*
- IL-2*
- IL-6*
- IL-10*
- IL-17*
- IFN γ *
- Pro-inflammatory Cytokines*
- sIL-2R α *
- TNF- α *

Kidney Transplant

- TruGraf® Blood Gene Expression Test*
- Viracor TRAC® Kidney dd-cfDNA*

INFECTIOUS DISEASE

BACTERIAL

- Atypical Pneumonia Panel PCR*
- Bordetella pertussis Plus PCR*
- Legionella Panel PCR*
- Nocardia PCR*
- Respiratory Bacterial Panel

FUNGAL

- Aspergillus Galactomannan EIA*
- Aspergillus Panel PCR*
- Coccidioides Ab EIA*
- Fungal Plus PCR Profile I & II*
- Fungitel® B-D-Glucan*
- Fungitel® with Reflex to Titer*
- Histoplasma Galactomannan EIA*
- Mucorales PCR*
- Pneumocystis jiroveci qPCR*

GASTROINTESTINAL

- Gastrointestinal Pathogen Panel PCR* (15, 14, 11, and 10 results)
- Norovirus RT-PCR*

HEPATITIS

- HBV qPCR*
- HCV Genotyping*
- HCV NS3 Drug Resistance*
- HCV NS5A Drug Resistance*
- HCV NS5B Drug Resistance*
- HCV qRT-PCR*
- HDV IgM*
- HDV RT-PCR*
- HDV Total Ab*
- HEV IgG,* IgM* and Panel*
- HEV qRT-PCR*

PARASITIC

- Toxoplasma gondii qPCR*

VECTOR-BORNE

- C6 Borrelia burgdorferi IgG*, IgM*
- Dengue IgG*, IgM*
- Zika Virus IgM*
- Zika Virus RT-PCR*
- Zika Virus RT-PCR with Reflex to Zika IgM*

VIRAL

- Adenovirus qPCR*
- BKV qPCR*
- BKV IgG Antibody
- CMV Resistance Sequencing*
- CMV qPCR*
- EBV qPCR*
- Enterovirus qRT-PCR*
- HHV-6 IgG,* IgM* and Panel*
- HHV-6 qPCR*
- HHV-7 qPCR*
- HHV-8 qPCR*
- HIV-1 qRT-PCR*
- HIV-1 Genotypic Drug Resistance Sequencing*
- HIV-1 Integrase Genotyping*
- HSV 1 & 2 qPCR*
- HTLV I/II PCR*
- Influenza/RSV Panel
- JC Virus qPCR*
- Parvovirus B19 qPCR*
- Pharyngitis Panel II
- Procalcitonin*
- Respiratory Pathogen Panel
- Respiratory Virus Panel
- Respiratory Supplemental Panel
- cPass™ SARS-CoV-2 Neutralizing Antibody
- SARS-CoV-2 RT-PCR*
- SARS-CoV-2 IgG,* IgM* and Panel*
- SARS-CoV-2 Plus Profiles
- Upper Respiratory Panel
- VZV qPCR*

THERAPEUTIC DRUG LEVEL MONITORING

- Everolimus*
- Isavuconazole*
- Itraconazole*
- Posaconazole*
- Sirolimus*
- Tacrolimus*
- Voriconazole*

IMMUNE ASSESSMENT

T-Cell

- ImmuKnow®*
- T Cell Fx™
- CMV inSIGHT™ T Cell Immunity*
- SARS-CoV-2 inSIGHT™ T Cell Immunity*

Innate Immunity

- NK Cell Function*

* New York Approved

† Some specimen types are not New York approved for this test.

Some qPCR assays report qualitative results for certain specimen types. Visit Viracor-Eurofins.com for complete specimen information.

Fungitel® is a product and registered trademark of Associates of Cape Code, Inc.

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Transplant Diagnostics

Cytomegalovirus (CMV)

THE CMV TEST EXPERTS

- **Cytomegalovirus** (CMV) infection is a frequent cause of complications after transplantation
- **CMV infections** may lead to increased incidence of graft rejection, opportunistic infections and decreased allograft and patient survival
- **Eurofins Viracor** has over 30 years of specialized testing expertise in infectious disease, immunology and allergy testing for immunocompromised and critical patients
- **We are experienced in** and committed to helping medical professionals, transplant teams and reference labs receive accurate, actionable and timely CMV results

COMPREHENSIVE CMV TESTING TO ASSESS, TREAT & MANAGE TRANSPLANT PATIENTS

VIRAL LOAD. RESISTANCE. IMMUNITY.



CMV PCR FOR VIRAL LOAD

Early detection of reactivation
Primary infection
Monitoring response to treatment



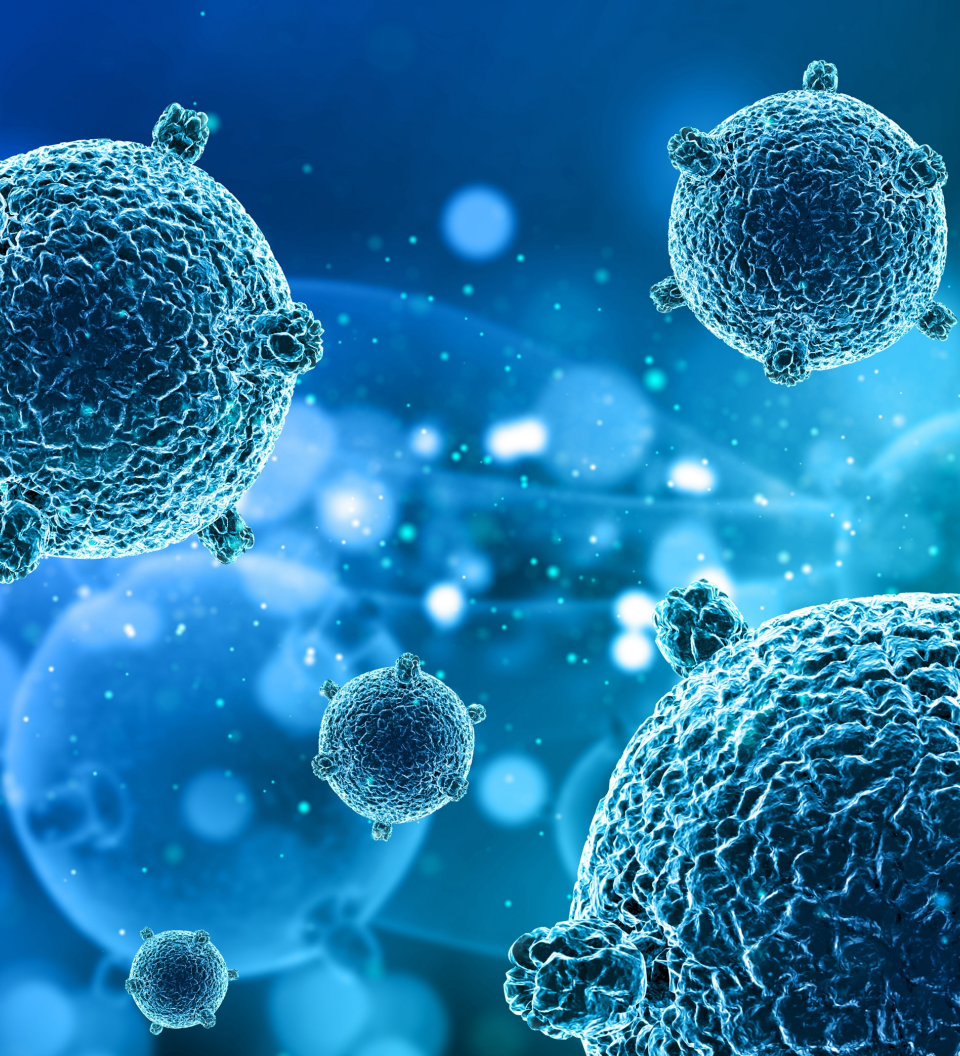
CMV ANTIVIRAL RESISTANCE

Measures drug resistance to Maribavir,
Letermovir, Ganciclovir, Foscarnet,
Cidofovir



CMV inSIGHT™ T CELL IMMUNITY

Measures the strength of T cell responses to
CMV-specific antigens
Reports the activity of CD4 and CD8 T cell
responses independently



Transplant Diagnostics

ImmuKnow®

Immune Cell Function Assay

IMMUKNOW®

ImmuKnow is an **FDA cleared** immune cell function assay that detects cell-mediated immunity in an immunosuppressed population.

The assay detects cell mediated immunity by measuring the concentration of ATP from CD4 cells following stimulation.

ASSAY NAME	SPECIMEN TYPE	TEST CODE	CPT CODE	TURNAROUND TIME
ImmuKnow®*	whole blood	9016	86352	36 – 48 hours from receipt of specimen

KNOW THE FACTS OF IMMUKNOW®

FDA-CLEARED

ImmuKnow's clinical utility has been well characterized and validated:

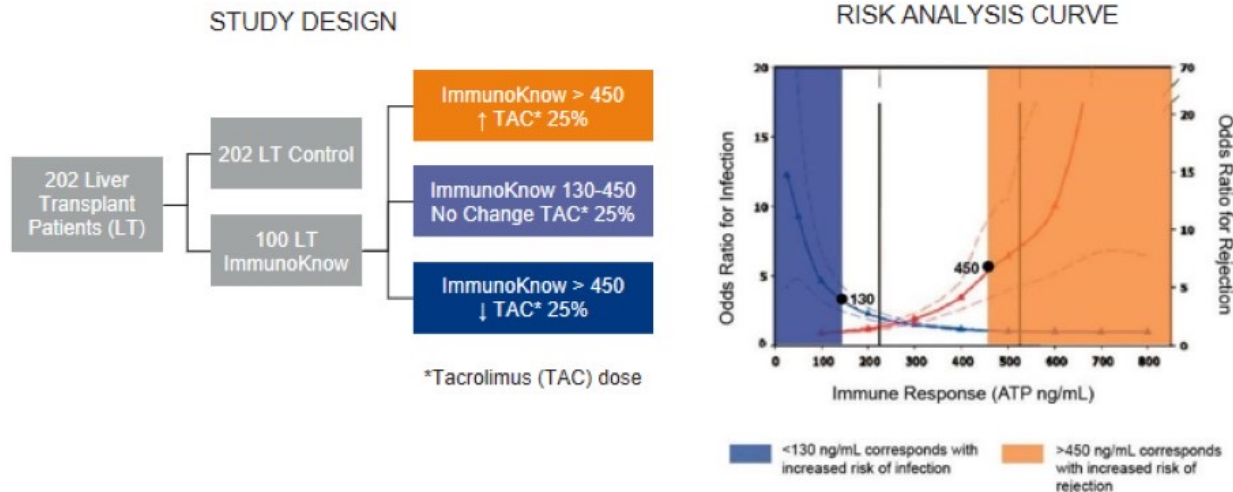
- Over 400,000 assays run
- 25 prospective and interventional studies in 1000+ transplant recipients
- More than 120 clinical studies

Global immune status monitoring has been used to:

- Identify kidney, liver, lung, and heart transplant patients with low immune response, which has the potential to lead to infection
- Define immunologic stability in various solid organ transplant patients
- Longitudinally assess changes in transplant patients' immune status, giving clinicians and additional tool in treatment optimization decisions.

IMMUNOSUPPRESSION MODIFICATIONS BASED ON AN IMMUNE RESPONSE ASSAY: RESULTS OF A RANDOMIZED, CONTROLLED TRIAL

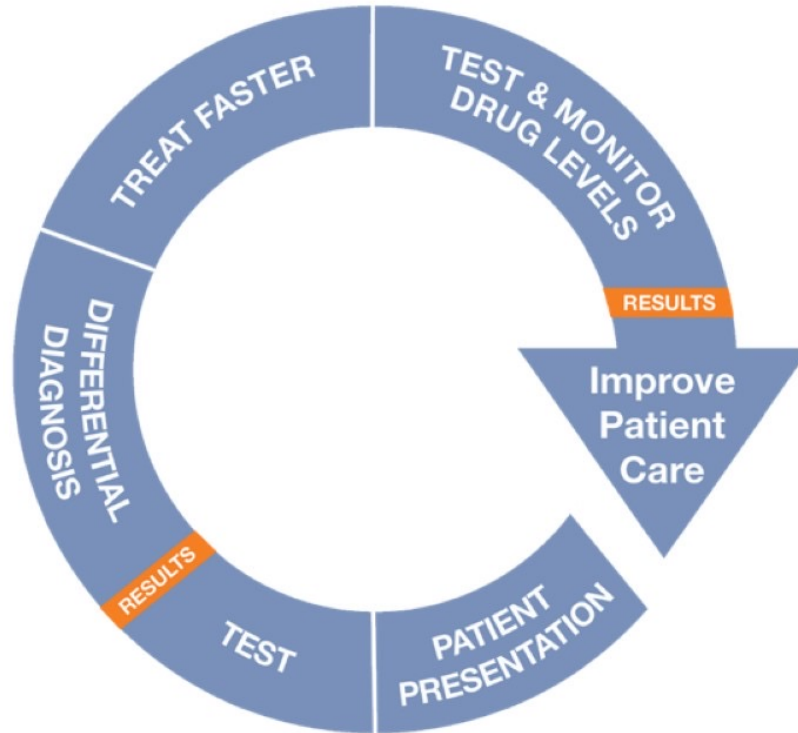
Prospective, randomized, controlled, blinded, interventional trial comparing the outcomes of adult liver transplant recipients whose immunosuppressive therapy was managed by prior standard practice (control group) or by adjusting therapy based on cell-mediated immune responses determined by the ImmuKnow assay (interventional group)



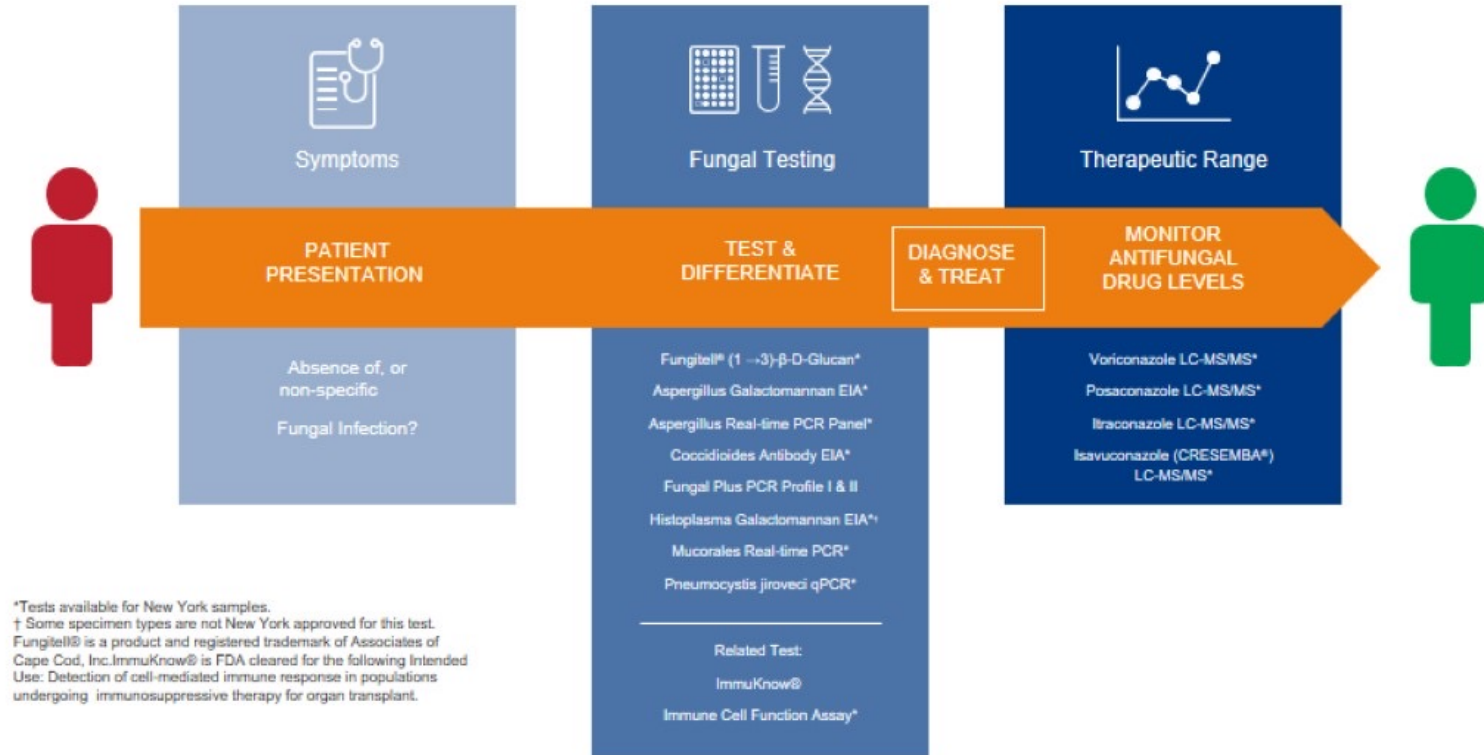


Fungal Infection

FUNGAL TESTING FOR YOUR PATIENT'S CONTINUUM OF CARE



TESTING TO INDIVIDUALIZE YOUR APPROACH TO IFI PATIENTS



RESULTS IN TIME TO MAKE A DIFFERENCE

Treat Faster to Reduce Mortality^{1,2}

Antifungal Treatment Delay in Days	0	1	2	≤3
Mortality	15%	24%	37%	40%
Blood Culture 50% sensitivity	1-5 days for result			
Other Lab's Fungitell® testing >20% failure rate*	2-4 days for result			

1.Assoc of Cape Cod, Fungitell Assay Instructions for Use. 2011 (Feb) Garey et al, Clin Infect Dis. 2006; 43:25-31.
Karageorgopoulos et al. Clin Inf Dis. 2011; 52:750-770

2.Luong ML et al. Clin Inf Dis. 2012; 52 (10):1218-1226. Nguyen ML, Wissel MC et al. Clin Inf Dis. 2012; 54:1240-1248

*Communications from other commercial labs who run Fungitell.

RESULTS IN TIME TO MAKE A DIFFERENCE

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Reduce Mortality^{1,2}

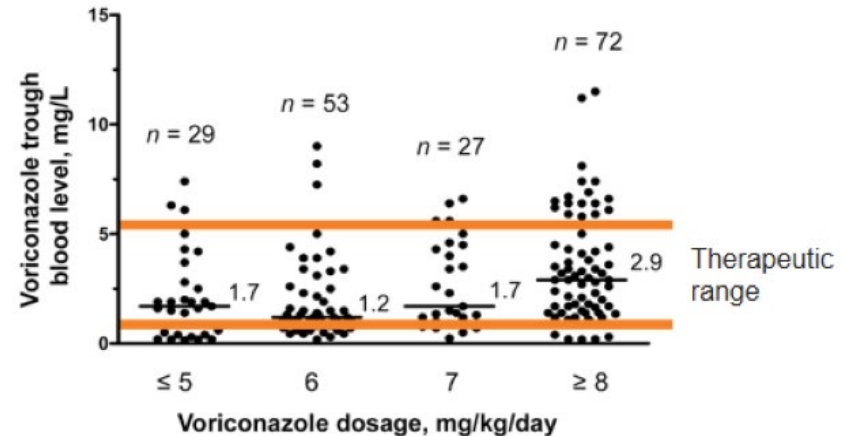
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3.Andres Pascual, Thierry Calandra, Saskia Bolay, Thierry Buclin, Jacques Bille, and Oscar Marchetti, Voriconazole Therapeutic Drug Monitoring in Patients with Invasive Mycoses Improves Efficacy and Safety Outcomes, Clinical Infectious Diseases, 2008;46(2):204 by permission of Infectious Diseases Society of America.

Manage Drug Levels, Keep Patients
in the Therapeutic Range³



Relationship between voriconazole dosage and blood levels. In this study, up to 35% of patient samples were outside the therapeutic range.³

FUNGITELL® (1 > 3, β-D GLUCAN)

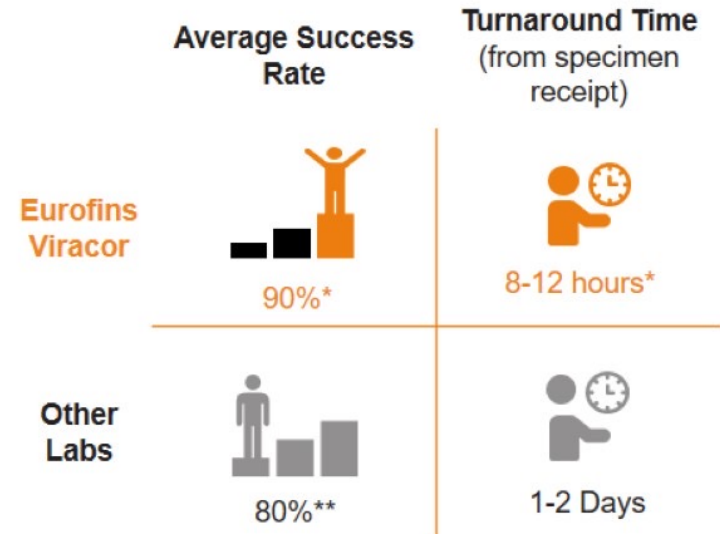
ASSAY NAME	SPECIMEN TYPE	TEST CODE	CPT CODE	TURNAROUND TIME
Fungitell® β-D Glucan	BAL, bronch wash, CSF, serum	1700	87449	Same day (within 8-12 hours from receipt of specimen), Monday through Saturday. Additional 8-24 hours when reflex testing is required
Fungitell® β-D Glucan with Reflex to Titer	BAL, bronch wash, CSF, serum	351700	87449 x 2	

- Ease of ordering, no need to add on testing
- Reflex test automatically reflexes to titer with a >500 result
- Better visibility to clinical deterioration or improvement over time¹

¹Chen TK, Grancy PK, et. al. Successful treatment of *Aspergillus* ventriculitis through voriconazole adaptive pharmacotherapy, immunomodulation, and therapeutic monitoring of cerebrospinal fluid (1→3)-β-D-glucan. Medical Mycology. 2017 Jan 1; 55(1): 109-117.

*Based on Viracor 2018-2020 Data

** Communications from other commercial labs who run Fungitell



BAL BUNDLED: ONE ORDER, MULTIPLE RESULTS

Fungal Plus PCR Profiles

ASSAY NAME	SPECIMEN TYPE	TEST CODE	CPT CODE	Aspergillus PCR	Nocardia PCR	Mucorales PCR	Pneumocystis jiroveci qPCR	TURNAROUND TIME
Fungal Plus PCR Profile I	BAL	PFL8005	87798 x5	●	●	●		Same day (within 12 - 24 hours from receipt of specimen), Monday through Friday
Fungal Plus PCR Profile II	BAL	PFL8006	87798 x5, 87799	●	●	●	●	

- Created to identify fungal or fungal-like infections with similar presentations
- One order, multiple pathogen results

ASPERGILLUS: ONE OF THE MOST COMMON INFECTIONS POST TRANSPLANT

PCR and EIA

ASSAY NAME	SPECIMEN TYPE	TEST CODE	CPT CODE	TURNAROUND TIME
Aspergillus Real-time PCR Panel (Pan-Aspergillus, <i>A. terreus</i> , <i>A. fumigatus</i>)	BAL*	8909	87798 x3	Same day (within 12 - 24 hours from receipt of specimen), Monday through Friday.
	bronch wash*	8926		
Aspergillus Galactomannan EIA	BAL	1600	87305	Same day (within 8 - 12 hours from receipt of specimen), Monday through Saturday.
	Serum	1610		
	CSF	1603		
	bronch wash	1626		

Aspergillosis is the second-most common opportunistic fungal infection in immuno-compromised patients and the third-most common systemic fungal infection requiring hospitalization.*

*Davies, S, et. Al. Aspergillus Infections in Transplant and Non-Transplant Surgical Patients. Surgical Infections. 2014 Jun 1; 15(3): 207-212.

*Tissue, Formalin Fixed – **Coming Soon**



Transplant Diagnostics

Thanks!

