



Empowering laboratories with superior, diagnostic accuracy for fungal infections, anti-fungal resistance and more.

# **PathoNostics**

## Leading with Care

With 20 years of combined expertise, PathoNostics, alongside its sister company PathoFinder, have been empowering laboratories worldwide with superior diagnostic accuracy. Specializing in diagnostic multiplex real-time PCR kits, we provide rapid and precise identification of infectious diseases and fungal infections.



### ① Comprehensive Solutions

Our kits cover a wide spectrum of pathogens including viral, bacterial, parasitic and fungal.

### ② Advanced Technology

CE-IVD Certified and utilizing proprietary real-time PCR and melting curve analysis, our kits offer exceptional specificity and sensitivity.

### ③ Diverse Applications

From respiratory and gastroenteritis to meningitis/encephalitis, STDs, and invasive fungal pathogens, our products cater to various medical needs.

### ④ Fungal Infection Expertise

Since 2011, we've been at the forefront, recognizing the global health threat of invasive fungal infections. Through PathoNostics, we offer advanced solutions targeting a range of pathogens with our multiplex PCR kits.

### ⑤ Empowering Clinicians

Our aim is to enable clinicians to promptly initiate effective therapeutic interventions, minimizing side effects and optimizing healthcare costs.



**Trust PathoFinder and PathoNostics** for accurate diagnostics, backed by two decades of excellence in the field.



**Ensuring quality isn't just a mandate; it's a testament to how much we care!**

With unwavering commitment, we transition from CE Certification to meet IVDR standards for our products while maintaining ISO 13485:2016 compliance. We prioritize regular post-market surveillance, monitoring our product performance through External Quality Assessment panels including QCMD. We continually invest in clinical studies in support of our IVDR transition, we prioritize safety and efficacy, ensuring you have ultimate peace of mind when trusting our results.

## Big Enough to Lead, Small Enough to Care

### Driving Healthcare Forward Together

At PathoFinder and PathoNostics, we strike the perfect balance. With a presence in over 70 countries worldwide, we've established ourselves as a serious supplier and global player in the diagnostics industry.

We pride ourselves on being small enough to care deeply about each partnership. Caring is at the heart of everything we do. We prioritize not only identifying pathogens that cause large-scale pandemics but also addressing the often overlooked and neglected diagnostic needs of the market.

We care deeply about the most vulnerable in our population, particularly those who are immunocompromised and at the highest risk.

Our commitment to caring extends to our clients as well. We listen attentively and work tirelessly to build genuine, trusted relationships because we understand that their success is intertwined with ours.



## Challenges in the Diagnostic Landscape:

- Rising global health threats heighten the vulnerability of immunocompromised individuals.
- Syndromic testing emerges as a pivotal tool, enabling swift identification of microbial targets.
- Comprehensive identification of pathogens and resistance patterns enhances treatment outcomes.
- According to the World Health Organization (WHO), bacterial antimicrobial resistance results in approximately 1.14M deaths globally annually.
- Increasing rates of antimicrobial resistance and infectious disease incidence underscore the urgency for advanced diagnostic solutions.
- Traditional methods, known for their low sensitivity, struggle to meet the diagnostic demands of the current landscape.



Our dedication is underscored by our remarkable **Net Promoter Score**, a testament to the satisfaction and trust our partners have in us. Here's a glimpse of what some of them have to say:

“ The Pathonostics crew is helpful, interested in your lab and lab setting, and thinks together with you what could be innovative steps.

**Medical Microbiology,  
Hospital Lab, NL**

“ The communication is fast, and there is also reliable technical support for more detailed questions.

**EXOMedica, Baltic States**

“ I wouldn't hesitate for a moment to recommend this company to others. The culture is incredible – a perfect blend of professionalism, support, and innovation.

**Panagiotis Travlos, Greece**

“ Clonit is very grateful for the partnership with PathoFinder/PathoNostics. We greatly appreciate the relationships with your entire team, who are always attentive and proactive. The quality of PathoFinder/PathoNostics products is highly appreciated by our customers in Italy.

**Clonit, Italy**

## PCR: The Gold Standard in Molecular Diagnostics for Precision and Speed



### Accuracy and Specificity

Offers unparalleled precision, ensuring accurate identification of target pathogens with high specificity.



### Sensitivity

PCR assays are highly sensitive, capable of detecting even low levels of target pathogens enhancing diagnostic accuracy.



### Rapid Diagnosis

PCR provides rapid results compared to traditional methods, enabling timely interventions and improved patient outcomes.



### Syndromic/ Multiplex Testing

With PCR you can obtain comprehensive results for multiple pathogens in a single assay.



### Trustworthy Results

With robust controls and stringent quality assurance measures, PCR delivers reliable and trustworthy diagnostic outcomes, instilling confidence.

## AsperGenius® 2.0 Species Multiplex real-time PCR kit

Detection of *Aspergillus fumigatus/ flavus/terreus* and species. To aid in the diagnosis of aspergillosis.

### Targets

- *Aspergillus fumigatus*
- *Aspergillus flavus*
- *Aspergillus terreus*\*\*
- *Aspergillus* species

\*\*Only in PCR instruments with a crimson detection channel.

### Specimen

- Bronchoalveolar lavage (BAL) Samples
- Serum and plasma samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyclers (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive control included
- Validated on clinical samples
- Validated on proficiency (QCMD) panels

**Technology:** real-time PCR  
**PCR Run-time:** 1h (dependent on PCR instrument)  
**Product code:** PN-101  
**Kit size:** 50 reactions/kit

## AsperGenius® 2.0 Resistance TR Multiplex real-time PCR kit

Detection of TR34/TR46 azole resistance markers in *Aspergillus fumigatus*. To aid in a tailored treatment of aspergillosis.

### Targets

- *Aspergillus fumigatus* WT
- *Aspergillus fumigatus* TR34
- *Aspergillus fumigatus* TR46

### Specimen

- Bronchoalveolar lavage (BAL) samples
- Serum and plasma samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyclers (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive control included
- Validated on clinical samples
- Validated on proficiency (QCMD) panels

**Technology:** real-time PCR  
**PCR Run-time:** 1h (dependent on PCR instrument)  
**Product code:** PN-201  
**Kit size:** 50 reactions/kit



## PneumoGenius® Multiplex real-time PCR kit

For detection and quantification of *Pneumocystis jirovecii* and DHPS mutations linked to sulfa drug resistance. To aid in the diagnosis of pneumocystosis.

### Targets

- *Pneumocystis jirovecii* mtLSU (multicopy gene)
- *Pneumocystis jirovecii* DHPS *fas* (single-copy gene)
- DHPS mutations:
  - THR55Ala
  - Pro57Ser

### Specimen

- Bronchoalveolar lavage (BAL) samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyclers (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive control included
- Validated on clinical samples
- Validated on proficiency (QCMD) panels

**Technology:** real-time PCR with additional melting curve analysis  
**PCR Run-time:** max 2 hrs (dependent on PCR instrument)  
**Product code:** PN-600  
**Kit size:** 25 reactions/kit

## MucorGenius® Multiplex real-time PCR kit

For detection of clinically relevant Mucorales species. To aid in the diagnosis of mucormycosis.

### Targets

- Pan-Mucorales\*:
  - *Rhizopus* spp.
  - *Mucor* spp.
  - *Rhizomucor* spp.
  - *Lichtheimia* spp.
  - *Cunninghamella* spp.

### Specimen

- Bronchoalveolar lavage (BAL) samples
- Serum samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyclers (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive control included
- Validated on clinical samples

**Technology:** real-time PCR  
**PCR Run-time:** max 2 hrs (dependent on PCR instrument)  
**Product code:** PN-700  
**Kit size:** 25 reactions/kit

## CandidaGenius® *C. auris* screening assay

A qualitative real-time PCR for the rapid screening of *Candida auris* in 75 minutes.

### Target

- *Candidozyma (Candida) auris*

### Specimen

- ESswabs from nares, mouth/throat, perineum, bilateral axillae and groin

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyclers (Bio Molecular Systems)

### Quality

- For Research Use Only (RUO)
- Not for use in clinical diagnostic procedures
- Internal control included
- Positive control included

**Technology:** real-time PCR  
**PCR Run-time:** 75 mins  
**Product code:** PN-900  
**Kit size:** 50 reactions/kit



As antimicrobial and antifungal resistance continues to rise globally, accurate identification of resistance markers through PCR testing becomes paramount. With statistics showing increasing mortality rates due to resistant infections, swift and accurate diagnoses hold the key to improving patient outcomes and combating this growing threat. It's in this context that we offer a range of products that detect resistance markers:

## AsperGenius® 2.0 Resistance TR Multiplex real-time PCR Kit

To detect the most prevalent environmental azole-resistance mechanisms in *Aspergillus fumigatus*.

## DermaGenius® Resistance Multiplex real-time PCR Kit

Detects the most prevalent mutations causing terbinafine resistance in dermatophytes.

## PneumoGenius® Multiplex real-time PCR kit

Detects DHPS mutations linked to sulfa drug resistance in *Pneumocystis jirovecii*.

\*Detected but not discriminated.

## DermaGenius® 3.0 Nail Multiplex real-time PCR kit

For detection and identification of dermatophyte infections in nail samples. To aid in the diagnosis of dermatophytosis.

### Targets

- *Trichophyton rubrum*
- *Trichophyton interdigitale*
- *Candida albicans*
- *Candida parapsilosis*
- *Scopulariopsis brevicaulis*

### Specimen

- Nail samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyler (Bio Molecular Systems)

### Quality

- Research Use Only (RUO)
- Not for use in clinical diagnostic procedures
- Internal control included
- Positive control included

**Technology:** real-time PCR with additional melting curve analysis

**PCR Run-time:** max 2 hrs (dependent on PCR instrument)

**Product code:** PN-302

**Kit size:** 50 reactions/kit

## DermaGenius® 3.0 Complete Multiplex real-time PCR kit

For detection and identification of dermatophyte infections in nail, hair and skin samples including a pan-derma detection. To aid in the diagnosis of dermatophytosis.

### Targets

- *Trichophyton rubrum/Trichophyton soudanense\**
- *Trichophyton interdigitale/Trichophyton mentagrophytes\**
- *Trichophyton tonsurans*
- *Trichophyton schoenleinii/Trichophyton quinckeanum\**
- *Trichophyton violaceum*
- *Trichophyton benhamiae*
- *Trichophyton verrucosum*
- *Microsporum canis*
- *Microsporum audouinii*
- *Nannizzia gypsea*
- *Epidermophyton floccosum*
- *Candida albicans*
- *Candida parapsilosis*
- *Scopulariopsis brevicaulis*
- Pan-dermatophyte

### Specimen

- Nail, hair and skin samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyler (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive controls included
- Validated on clinical samples
- Validated on proficiency (QCMD/ INSTAND) panels

**Technology:** real-time PCR with additional melting curve analysis

**PCR Run-time:** max 2 hrs (dependent on PCR instrument)

**Product code:** PN-402

**Kit size:** 50 reactions/kit

## DermaGenius® 2.0 Complete Multiplex real-time PCR kit

For detection and identification of dermatophyte infections in nail, hair and skin samples. To aid in the diagnosis of dermatophytosis.

### Targets

- *Trichophyton rubrum/Trichophyton soudanense\**
- *Trichophyton interdigitale/Trichophyton mentagrophytes\**
- *Trichophyton tonsurans*
- *Trichophyton violaceum*
- *Trichophyton benhamiae*
- *Microsporum canis*
- *Microsporum audouinii*
- *Epidermophyton floccosum*
- *Candida albicans*

### Specimen

- Nail, hair and skin samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyler (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE** 2797IVD
- Internal control included
- Positive controls included
- Validated on clinical samples
- Validated on proficiency (QCMD/ INSTAND) panels

**Technology:** real-time PCR with additional melting curve analysis

**PCR Run-time:** max 2 hrs (dependent on PCR instrument)

**Product code:** PN-401

**Kit size:** 50 reactions/kit

## DermaGenius® Resistance Multiplex real-time PCR kit

For detection of the most clinically relevant point mutations in the SQLE gene, causing terbinafine resistance. To aid in a tailored treatment of dermatophytosis.

### Targets

- *Trichophyton rubrum/Trichophyton soudanense\**
- *Trichophyton interdigitale/Trichophyton mentagrophytes\**
- *Trichophyton mentagrophytes* (ITS type IV)
- *Trichophyton tonsurans*
- *Trichophyton schoenleinii/Trichophyton quinckeanum\**
- *Trichophyton violaceum*
- SQLE Wildtype
- SQLE mutant:
  - Leu393Phe
  - Phe397Ile
  - Phe397Leu
  - Phe397Val
  - Leu393Ser

### Specimen

- Nail, hair and skin samples

### Instruments

- LightCycler 480 II (Roche)
- Rotor-Gene Q (QIAGEN)
- CFX96 (Bio-Rad)
- QuantStudio 5 (Thermo Fisher Scientific)
- Mic qPCR cyler (Bio Molecular Systems)

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD
- Internal control included
- Positive control included
- Validated on clinical samples
- Validated on proficiency (QCMD/ INSTAND) panels

**Technology:** real-time PCR with additional melting curve analysis

**PCR Run-time:** max 2 hrs (dependent on PCR instrument)

**Product code:** PN-303

**Kit size:** 25 reactions/kit

## PathoNostics® Extraction kit

For extraction of dermatophytes from nail, hair and skin samples. A fast and simple extraction method to be used in combination with DermaGenius® assays.

### Quality

- Designed and manufactured under EN ISO 13485:2016
- **CE**-IVD

**Product code:** PN-502

**Processing time:** 20 min

**Kit size:** 50 reactions/kit



\*Detected but not discriminated.

**Originating in Europe**, our company proudly exhibits a global footprint, spanning over 70 countries and reaching every continent (except Antarctica).

With customers both direct and indirect, we pride ourselves on our diverse reach and commitment to serving clients worldwide.



**Europe**

- Austria
- Belgium
- Bulgaria
- Croatia
- Czech Republic
- Denmark
- England
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Northern Ireland
- Norway
- Poland
- Portugal
- Romania
- Scotland
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- The Netherlands
- Turkey
- Wales

**Middle East**

- Bahrain
- Israel
- Kuwait
- Lebanon
- Oman
- Saudi Arabia
- United Arab Emirates

**Africa**

- Kenya
- South-Africa
- Tunisia
- Uganda

**North and South America**

- USA
- Argentina
- Brazil
- Chile
- Costa Rica
- Curaçao
- Ecuador
- Mexico
- Panama
- Peru
- Suriname
- Trinidad and Tobago
- Uruguay

**Asia Pacific**

- Australia
- Bangladesh
- China
- Hong Kong
- India
- Indonesia
- Malaysia
- Mongolia
- Nepal
- Pakistan
- Philippines
- Singapore
- South Korea
- Sri Lanka
- Taiwan
- Thailand
- Vietnam

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