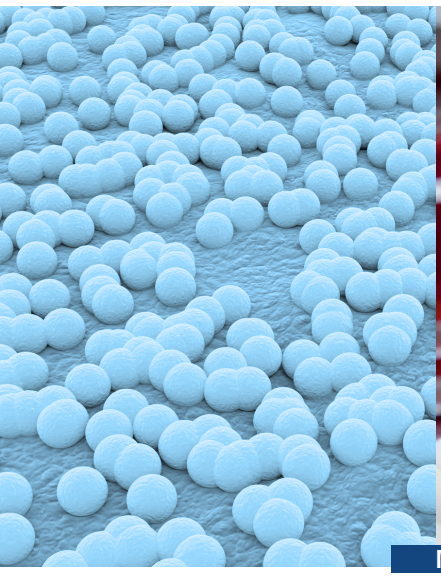
charles river



MICROBIAL SOLUTIONS

AccuGENX-ID® FunITS

Advantages:

- Over ½ million identifications made over the last 10 years
- AccuGENX-ID® identification process is cGMP-compliant
- Industry's highest reportable rate of 98%
- Rapid results, including same-day, with a 99% on-time delivery rate
- Validated fungal libraries with over 3400 entries
- More reliable, more reproducible and less subjective than traditional methodologies

Charles River provides identification for unknown fungal and yeast isolates through our AccuGENX-ID® FunITS service. FunITS utilizes comparative DNA sequencing of the ITS2 rRNA region, recognized across the industry as the most accurate and reproducible method for identifying unknown organisms, and can produce reliable results in as little as four hours.

The Advantages of ITS2 Sequencing

The identification of fungi, especially filamentous fungi, has historically been a very difficult task. Due to the amount of experience and time required to accurately identify filamentous fungi to the species level, it has been common practice to either identify these organisms to the genus level, or, in some cases, simply identify them as "molds."

Accugenix uses the ITS2 sequence, which has proven to be the most widely accepted DNA sequence for fungal identification. ITS2 has more variability than the D2 expansion segment DNA sequence, thus providing greater specificity. This yields a much higher resolution in species identification than D2.[1,2] ITS2 is recognized for the identification of fungal species via DNA sequence signatures by the European Consortium for the Barcode of Life.[3]

The AccuGENX-ID® Database

Charles River is committed to providing the most accurate identifications to the industries we serve. This commitment requires that we continuously update our Accugenix® validated libraries to stay current with an evolving microbial world. The direct benefit of sending your mold and yeast samples to us is our ability to identify more samples to the species level than our competitors. Outsourcing your samples to Charles River allows you to gain access to the most relevant, up-to-date and validated fungal libraries in the industry. Since our objective is to achieve the highest percentage of species-level identifications, we compare sample sequence data that do not result in a species-level match against a variety of publicly available sequence databases. If a newly described organism is a good match for those sample sequences and is validly named and published, the sequence proceeds to our validated library entry process.[4]

EVERY STEP OF THE WAY

Case Studies: The Greater Resolution of AccuGENX-ID® over D2 Sequencing

The ability of the ITS2 region to clearly distinguish two *Aspergillus* spp.

Aspergillus brasiliensis was described as a newly discovered species in 2007,[5] which was in part created by the transfer of several existing *Aspergillus niger* strains to *A.brasiliensis*. The significance of being able to differentiate these two species from each other is that *A. niger* ATCC 16404 is cited as a QC organism in many USP chapters, such as USP <61> and USP<71>. Unfortunately, due to the lack of diverse morphological features, unstable phenotypic characteristics and culture conditions make it difficult to differentiate these two species. D2 DNA sequencing provides no additional information, as the DNA sequences for all strains of these two species are identical.

ITS2 sequencing, however, clearly distinguishes the two *Aspergillus spp*, despite there being only one nucleotide difference in the ITS2 sequence between the two species. This difference has been shown to be extremely reproducible and is considered to be a diagnostic indicator of the species.

The ability of the ITS2 region to clearly distinguish *Komagatella pastoris/phaffii/pseudopastoris*

K. pastoris is a common organism used in the production of biologicals. It is important to be able to confidently ensure a correct species-level identification throughout your fermentation-production process to confirm that it is, in fact, *K. pastoris* being used, rather than having the organism only identified to the genus-level as *Komagatella spp.* or indistinguishable from *K. phaffii* and *K. pseudopastoris*. ITS2 sequencing offers a significant advantage in this identification. It demonstrates increased resolution over D2 DNA sequencing, identifying 16 nucleotide differences between *K. pastoris* and *K. phaffii* and 18 nucleotide differences between *K. pastoris* and *K. pseudopastoris*, as opposed to the 1-2 nucleotide differences that can be found through D2 DNA sequencing.

References

1. The Utility of ITS2 Sequencing for Identifying Fungal Contaminants

2. ITS2 Sequencing as a Method for the Identification of Fungal Environmental Isolates

3. Chase et al. *Science*. **325**, 682-83 (Aug. 7, 2009).

4. Creating and Maintaining Validated Microbial Identification Libraries within a cGMP Quality Environment

5. Varga et al. *International Journal of Systematic and Evolutionary Microbiology (IJSEM)*. **57**, 1925-1932 (2007).

Service	Turnaround Time	Code
AccuGENX-ID® fungi (ITS2)	Same day	FunITS-0
	1 day	FunITS-1
	2 day	FunITS-2
	5 day	FunITS-5

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