

Division of Laboratory Medicine

Mycology

Aspergillus quantitative PCR on respiratory samples

ELITech *Aspergillus* PCR: this test is indicated to support a diagnosis of *Aspergillus*-related lung disease.

General information

Turnaround time: This assay is performed twice weekly, on Tuesday and Friday morning. Turnaround time: 95% within 7 days of sample receipt.

Sample type/container:

Bronchoalveolar lavage fluid (BALF) samples:

- Send minimum of 1-2 mL collected into appropriate UKCA/CE-marked sterile leakproof container.
- **Do not** send containers with trap tubing still attached. These samples are prone to leaking and contamination. The trap tubing **must** be replaced with a secure screw cap lid prior to placing in the specimen bag.



Other sample types:

- The test is only validated for BALF.
- The test can be performed on other body fluids such as sputum, pleural fluid, and cerebrospinal fluid (CSF) but clear evidence-based guidance for interpretation of the results cannot be provided.

Transportation

- Samples should be placed into a plastic Ziploc bag, sealed, and then placed into another sealed plastic Ziploc bag (preferably with a biohazard label on the outside), as shown below.

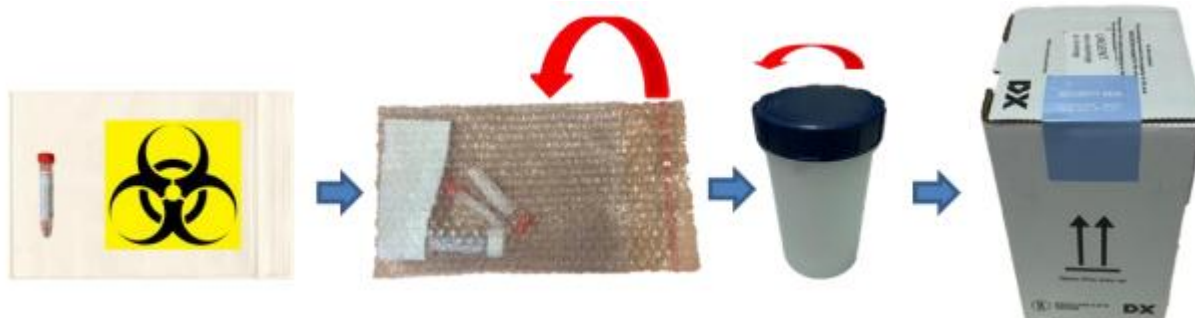


Category B transport boxes or an appropriate transport bag (i.e., one which adheres to regulations governing the transportation of diagnostic specimens) must be used for transport by road or between Manchester University Foundation Trust sites (but are not necessary within Wythenshawe hospital grounds). Please see

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below for packaging requirements.



For more information - <https://mrcm.org.uk/sample-collection/>

Laboratory Information

Biological interval/clinical decision values:

The ELITech *Aspergillus* PCR results are expressed as copies/mL of *Aspergillus* spp. 18S rDNA; Cq values are also provided.

Values of <120 copies/mL are interpreted as negative results.

Values >210 copies/mL are interpreted as positive results.

Values from 120 to 210 copies/mL are interpreted as indeterminate results and may reflect colonisation but do not exclude infection with *Aspergillus*. Testing of additional samples and/or use of additional diagnostic tests (*Aspergillus* galactomannan and high-volume fungal culture) is recommended to clarify the diagnosis.

A single negative result does not rule out the diagnosis of invasive aspergillosis (IA). Repeat testing and additional alternative modalities of testing are recommended if the result is negative, but disease is suspected.

Conversely, a single positive *Aspergillus* PCR does not solely constitute the diagnosis of IA and testing of additional samples and/or use of additional diagnostic tests is needed. Recent data requires the need for 2 consecutive positive results in BAL as positive mycological criterion for IA. According to EORTC/MSGERC criteria, the combination of a positive *Aspergillus* PCR with two weak positive or a single positive GM test result (e.g., one in serum/plasma (≥ 0.7) or one in BALF (≥ 0.8)), may suggest the presence of IA.

Clinical Information

No specific time of optimal collection. First clinical indication of pulmonary or invasive aspergillosis.

This assay detects the 18S rDNA of *Aspergillus fumigatus*, *Aspergillus terreus*, *Aspergillus niger* and possibly other species of *Aspergillus*.

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Assay for the quantitative detection of *Aspergillus* species genomic DNA extracted from respiratory specimens from the lower respiratory tract, as an aid to the diagnosis of invasive and non-invasive pulmonary aspergillosis. The results need to be interpreted in the context of the clinical condition of the patient and other diagnostic test results.

This test should be used in conjunction with other diagnostic procedures and biomarkers to increase the likelihood of diagnosing aspergillosis.

Limitations:

Possible causes of false negatives:

False negative results may occur for a variety of reasons, for example inappropriate quality or volume of sample and antifungal prophylaxis interference with assay.

Possible causes of false positives:

False positive results may occur if genera closely related to *Aspergillus* spp., e.g. *Penicillium* spp., are also present in the sample and detected due to the sequence similarity in the 18S rDNA.

References:

ELITech *Aspergillus* spp. ELITe MGB Kit product insert, SCH mRTS110PLD, 28/07/2023, Review 10

Donnelly JP, Chen SC, Kauffman CA, et al., Revision and Update of the Consensus Definitions of Invasive Fungal Disease From the European Organization for Research and Treatment of Cancer and the Mycoses Study Group Education and Research Consortium, Clinical Infectious Diseases, Volume 71, Issue 6, 15 September 2020, Pages 1367–1376, <https://doi.org/10.1093/cid/ciz1008>.

White PL, Bretagne S, Caliendo AM, et al., Aspergillus Polymerase Chain Reaction—An Update on Technical Recommendations, Clinical Applications, and Justification for Inclusion in the Second Revision of the EORTC/MSGERC Definitions of Invasive Fungal Disease, Clinical Infectious Diseases, Volume 72, Issue Supplement 2, 15 March 2021, Pages S95–S101, <https://doi.org/10.1093/cid/ciaa1865>.

Ullmann AJ, Aguado JM, Arian-Akdagli S, et al., Diagnosis and management of Aspergillus diseases: executive summary of the 2017 ESCMID-ECMM-ERS guideline. Clin Microbiol Infect. 2018 May;24 Suppl 1:e1-e38. doi: 10.1016/j.cmi.2018.01.002.

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