

# List of Diagnostic Services

FISHseq (FISH + 16S rRNA gene PCR/sequencing)

Molecular biological infection diagnostics



## General information

Our laboratory Moter Diagnostics is specialized on molecular biological infection diagnostics by FISHseq, which combines Fluorescence in situ Hybridization (FISH) with PCR amplification and Sanger sequencing of the microbial 16S rRNA gene. FISHseq allows in situ visualization and identification of bacteria and fungi in clinical samples. Combination of FISH with microbiome analysis (microbiome-guided FISH, MG-FISH) allows simultaneous detection of all microbial species that are present in a given sample.

All steps of FISHseq are performed on every business day. First results for FISH are usually available one business day after sample entry, first sequencing results after two business days. Total turnaround time is one to five days. In some cases, more time is necessary for additional confirmatory or additional tests.

Real-time PCR for *Tropheryma whippelii* is performed one to three times per week.

MG-FISH is performed on demand.

Diagnostic test results will be provided by letter, fax, encrypted e-mail or according to individual set-ups. For urgent samples and in case of therapy-relevant test results, we will contact the sender directly including Sundays and holidays.

Please contact us, if you have any questions or concerns regarding our laboratory tests.

You can call us +49 (0)151 2204 7978 or write an e-mail to [service@moter-diagnostics.com](mailto:service@moter-diagnostics.com).

## Specimen Requirements

To ensure optimal test results, we recommend sending all FISHseq specimens in FISHopt® fixation solution (available by MoKi Analytics GmbH, [www.moki-analytics.com](http://www.moki-analytics.com)). This way, the sample arrives in our laboratory already fixated and can be directly processed further.

Unfixated specimens should be shipped at 4 – 10 °C after adding some sterile saline solution to prevent drying out.

Each specimen container must be clearly labeled, and the Laboratory Analysis Order Form needs to be filled out with patient data (name and surname of the patient, birthdate and date of birth). In addition, please provide:

- If possible, clinical information and suspected diagnosis
- Indication which diagnostic analyses are ordered
- Time and date of sample collection
- Signature of the responsible physician.

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## FISHseq

- **Specimens**

Specimens from normally sterile sites. Please contact us if you want to submit specimens from normally non-sterile sites.

- **Method**

FISHseq: Fluorescence in situ hybridization (FISH), 16S rRNA gene amplification with polymerase chain reaction (PCR) followed by Sanger sequencing.

- **Turnaround Time**

1 - 5 days

- **Reference range**

Positive / negative / Biofilm-staging / localization / microbial species identification

- **Accreditation**

No

- **General Information**

FISHseq is a diagnostic method in clinical microbiology, with the purpose to diagnose infections caused by bacteria and fungi. FISHseq combines FISH with PCR and sequencing to detect microbial ribosomal RNA and DNA. This is particularly promising in tissues or explants from primarily sterile sites, but is also possible in mixed infections or device infections (e.g. drivelines, urine or dialysis catheters). The specimens are embedded and sectioned. Through hybridization with fluorescence-labeled probes, the microorganisms are identified, localized and quantified. The FISH signal intensity correlates with the activity of the microorganisms via the microbial ribosome content.

In parallel, pan-bacterial 16S rRNA gene PCR and Sanger sequencing are used to identify pathogens. FISH and PCR results are assessed together. In case of mixed infections by multiple microbial species, their identification is possible via FISH in combination with microbiome analysis by Next Generation Sequencing (NGS).

- **Indication**

Suspected infection by bacteria or fungi

- **Sampling and sample shipment**

Ideally, contamination-free sampling of the specimens (intraoperative tissue or device specimen, implants/prostheses)

Direct, intraoperative fixation of the samples in the FISH fixation solution FISHopt® ([www.moki-analytics.com](http://www.moki-analytics.com)). Please package and ship according to the requirements for Biological Substance, Category B (UN 3373). If shipping cannot take place immediately, please store at 4 °C (40 °F).

- **Assessment**

FISH: Bacteria/fungi positive, negative, localization, quantity, formation and activity

PCR: positive, negative, inhibition

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## Quantitative real-time PCR (qPCR) for *Tropheryma whipplei*

- **Synonyms**

qPCR; quantitative real-time polymerase chain reaction

- **Specimens**

Gastrointestinal and other tissue biopsies, cerebrospinal fluid (CSF), urine, synovial fluid, vitreous body specimens. Please contact us, if you intent to submit specimens from other body sites.

- **Method**

PCR/sequencing (real-time PCR with specific probe hybridization or 16S rRNA gene PCR with Sanger sequencing).

FISH in special cases.

- **Turnaround Time**

2 - 5 days

- **Reference range**

Positive / negative

- **Accreditation**

No

- **Indication**

Suspected infection by *Tropheryma whipplei*

- **Sampling and sample shipment**

Ideally, contamination-free sampling of the specimens and shipment in sterile saline solution (tissue biopsies) or sterile containers (liquid samples) according to the requirements for Biological Substance, Category B (UN 3373).

- **Assessment**

PCR: positive, negative, inhibition

- **Limitations**

This test is not suitable for blood samples.

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## MG-FISH (microbiome-guided FISH)

- **Specimens**

Specimens from normally sterile sites. Please contact us if you want to submit specimens from normally non-sterile sites.

- **Method**

MG-FISH: Fluorescence in situ hybridization (FISH), 16S rRNA gene amplification with polymerase chain reaction (PCR) followed by microbiome analysis.

- **Turnaround Time**

1 - 5 days

- **Reference range**

Positive / negative / Biofilm-staging / localization / microbial species identification

- **Accreditation**

No

- **General Information**

MG-FISH, the combination of FISH with PCR amplification and microbiome analysis by Next Generation Sequencing (NGS), is a diagnostic method in clinical microbiology with the purpose to diagnose multi-species infections caused by bacteria and fungi. MG-FISH combines FISH with PCR and microbiome analysis to detect microbial ribosomal RNA and DNA. This is particularly promising in tissues or explants from primarily sterile sites, but is also possible in mixed infections or device infections (e.g. drivelines, urine or dialysis catheters). The specimens are embedded and sectioned. Through hybridization with fluorescence-labeled probes, the microorganisms are identified, localized and quantified. The FISH signal intensity correlates with the activity of the microorganisms via the microbial ribosome content.

In parallel, pan-bacterial 16S rRNA gene PCR and microbiome analysis are used to identify pathogens. FISH and microbiome analysis results are assessed together.

- **Indication**

Suspected infection by bacteria or fungi

- **Sampling and sample shipment**

Ideally, contamination-free sampling of the specimens (intraoperative tissue or device specimen, implants/prostheses)

Direct, intraoperative fixation of the samples in the FISH fixation solution FISHopt® ([www.moki-analytics.com](http://www.moki-analytics.com)). Please package and ship according to the requirements for Biological Substance, Category B (UN 3373). If shipping cannot take place immediately, please store at 4 °C (40 °F).

- **Assessment**

FISH: Bacteria/fungi positive, negative, localization, quantity, formation and activity

PCR: positive, negative, inhibition

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## Quality Management

Our goal is to provide our services correctly and rapidly to our senders and patients. If there are any discrepancies, questions or worries, please do not hesitate to contact us immediately. You are welcome to address your concerns by telephone (+49 (0)151 2204 7978), by email ([service@moter-diagnostics.com](mailto:service@moter-diagnostics.com)) or by mail (Moter Diagnostics, Deutscher Platz 5d, 04103 Leipzig, Germany). We will take care of your concern immediately and will inform you within five working days about the result. We will do everything in our power to find a satisfactory solution.

Please note, that complaints have no influence on the cooperation with the respective sender or patient. We use them as an opportunity to identify possibilities for improvement and to optimize our work.

Services for private patients, self-paying patients or elective laboratory services are billed directly by Moter Diagnostics, unless otherwise agreed. For this purpose, the sender will forward the necessary patient data to Moter Diagnostics and ensure that the patients are informed about and consent to the laboratory analysis and organizational measures by Moter Diagnostics, including billing by us.

Our spectrum of examinations does not claim to be complete. A quality assurance system in accordance with the guidelines of the German Medical Association (RiLiBÄK) is in place.

## Measurement uncertainty and significance

Every measurement result is subject to measurement uncertainty, which is due to errors and uncertainties arising from the various stages of sampling and analysis. Knowledge of measurement uncertainty can be very helpful when assessing the significance of medical laboratory findings, but plays less of a role in this laboratory because currently mainly qualitative results are collected.

## Quality management

The quality management (QM) system set up in MoKi Analytics and Moter Diagnostics ensures transparency and traceability through documentation of all quality-relevant processes.

### *Internal quality assurance*

Our internal quality controls are carried out according to the guidelines of the German Medical Association (RiLiBÄK). We have developed particularly high QM standards, especially for FISH examinations, that enable standardized and high-quality processing of samples. This includes our patented quality controls for FISH, which ensure the sensitivity and specificity of the FISH assay in every analysis.

### *External quality assurance*

Since no ring trials are offered for FISHseq, MG-FISH and *T. whipplei* diagnostics, external quality assurance is carried out through annual participation in laboratory comparisons. We participate in a ring trial for microbiome analysis.