Guideline for Collecting and Packing Samples for Diagnostic Testing

For Immune Cell Monitoring with Epiontis ID Technology

Status 15DEC2025

Precision for Medicine GmbH

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This guideline outlines information for users of the laboratory as follows:

Change History

This is the second version (Rev002) of this document.

1. *General Laboratory Information*

Opening Hours

The laboratory operates from 08:00 to 16:30 Monday – Friday. It is therefore recommended to ship samples on Monday or Tuesday to reduce the likelihood of delays over the weekend.

Note: Precision has processes in place to receive and store samples outside of the laboratory opening hours to protect the integrity of the sample.

Turnaround Times

The laboratory offers standard and expedited turnaround times which can be selected on the Sample Collection Form.

Standard Turnaround	5 business days (Monday-Friday) from sample receipt to report issue.
Expedited Turnaround	48 hours from sample receipt to report issue, measured in business days (Monday -Friday).

Note*:* For the purpose of this guideline, clinical samples are defined as human derived materials (e.g., non-infectious, or potentially infectious) including blood, PBMC, tissue and genomic DNA. Informed Consent must always be obtained by the party responsible for taking any sample from the patient for laboratory analysis. This must be documented and maintained by the requesting party. Precision for Medicine GmbH does not routinely collect or store this information.

Quality Management

Precision for Medicine GmbH is accredited by the German Accreditation Body ("Deutsche Akkreditierungsstelle", DAkkS) for epigenetic qPCR testing in accordance with DIN EN ISO/IEC 17025:2018 according to the scope. This accreditation does not apply to diagnostic testing services; however, it is the objective of Precision for Medicine GmbH to perform diagnostic testing in accordance with the requirements of ISO 15189:2022 and gain accreditation to this standard.

Important Notice for Patients and Clients:

In order to ensure the highest level of transparency and traceability, Precision for Medicine GmbH is pleased to provide patients and clients, upon request, with comprehensive information regarding the examinations offered, associated costs, processing times, and any other relevant details.

Prior to the dispatch of samples, we kindly request that you contact us directly. This enables us to clarify all outstanding matters—particularly those concerning costs, scope of examination, and processing times—on an individual basis, and to ensure that all requirements of both parties are met in accordance with ISO 15189.

2. Diagnostics Tests and Sample Input Requirements

The epigenetic testing procedures conducted by Precision for Medicine GmbH may be utilized in the diagnosis and therapeutic monitoring of immune disorders, such as regulatory T-cell deficiencies. These procedures can support clinical decision-making and are implemented in collaboration with medical institutions.

Table 1 lists the standard inputs for the parallel measurement of three epigenetic assays (FoxP3, CTLA-4 and CD3). Certain combinations of epigenetic assays might result in slightly increased sample requirements. For materials not listed, a pilot study is recommended with around 5 separate donors as e.g., tissue type, disease stage, age, fixation, or storage can influence the DNA yield.

Sample Material [1]	Sample amount for epigenetic analysis of 1-4 cell types	Recommended total amount for potential repeat analysis	Absolute Quantification applicable
Whole blood (frozen):			
✓ **any commercially available anticoagulant**	75 µl	250 µl	+
DNA (frozen):			
✓ **Genomic DNA**	2.5 µg	7.5 µg	-

Table 1: Recommended sample amounts for the measurement of three epigenetic assays.

3. Sample Collection

All sample containers must be labelled with a unique sample ID or the patient's name, or both. At least one clear, unique identifier must be provided.

The identity of the patient must be verified prior to sample collection, for instance, by inspection of personal identification document or card.

Complete a Sample Collection Form (PfM document number: QMF 508-29e) with all the requested sample collection information [1, 2]. A Sample Collection Form must be completed for each sample. Signature of the Sample Collection Form affirms the sample has been collected in accordance with these instructions, all information is correct, and the sample is correctly labelled.

Whole Blood (EDTA,)

- Collect samples in standard blood collection tubes; gently invert the tube a few times to mix the blood with the anticoagulant.
- Recommendation for whole blood:
  - BD Vacutainer Plus 4 ml lavender/EDTA with Hemogard, part number 368861 (Europe) or 367844 (US, other countries),
- After collection, blood samples can be kept at 4°C for up to 24 hours before freezing at or below -20°C.
- Samples should be shipped on dry ice.

[1] ***Note***: If the patient has received bone marrow transplants, or if the biological sex is for any other reason unclear, please indicate this on the form.
[2] ***Note***: Sample collection time is not strictly required; however, this may be used to help determine the integrity of samples should any issues occur during transport or otherwise.

4. Shipment of Samples

Sample Name Clarification

Sample ID or patient name and additional sample information are required to be submitted along with samples using the Sample Collection Form. The completed form should be shipped with the samples. Otherwise, a copy may be emailed to *EPI_med_shipment@precisionformedicine.com*.

Please ensure that the sample IDs or names on the tubes and on the Sample Collection Form are consistent with each other, and the Sample Acceptance Criteria listed in section 6.

General Packaging Requirements

All shipments must comply with all applicable laws governing packing, marking, and labeling.

Please ensure that the dry ice load/cool pads will be sufficient to keep samples frozen/cooled during the entire shipment and that the samples are surrounded by cooling material on all sides. Use proper protection for your shipment to prevent sample tubes from breaking.

Address and Package Labelling Information

To avoid any customs delays over the weekend, please ship samples on a Monday or Tuesday where possible. For frozen samples, World Courier or MARKEN are recommended shipping agencies.

If applicable, specify samples in the cover/consignment letter as follows:

- biological samples of human origin,
- non-toxic, non-hazardous, non-infectious,commercial value: 1 US $ / 1 Euro

Collected and packaged specimens should be sent to:

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12489 Berlin, Germany

Phone: +49 30 6392 3493
Fax: +49 30 6392 3476

EPI_med_shipment@precisionformedicine.com
www.precisionformedicine.com

Please contact us prior to shipment to ensure that all details can be clarified and also provide the tracking number of your shipment after package pick up.

The progress of the shipment will be continuously monitored by customer service representatives. The integrity of sample containers and material will be checked upon receipt and sample arrival at Precision for Medicine GmbH and will be confirmed by E-mail.

5. Sample Acceptance Criteria

Please note: Precision for Medicine GmbH applies criteria for the acceptance of received samples for diagnostic testing. These criteria have been determined based on the risk to patients and laboratory personnel from compromised traceability or quality of the testing process, or exposure to biological hazards, respectively.

- A minimum of one (1) unique identifier must be provided: **Full name** or **Patient ID**
  - The unique identifier on the tube must match the Sample Collection Form.
- At least the minimum volume of sample material specified in **section 3.** must be provided.
- The date of sample draw must be included on the Sample Collection Form.
- Samples must be collected in one of the above specified collection tube types.
- Leaking sample tubes may be rejected, due to the health and safety risk of handling.
- Where there is evidence samples have been subject to excessive heat during transport, the sample may be rejected due to compromised integrity.

If any of the above criteria are not met, Precision for Medicine GmbH laboratory management will determine the most appropriate action to protect the safety of the patient and laboratory personnel, and any results reported will include appropriate contextual comments regarding any acceptance criteria not wholly met. The sample acceptance criteria will be reviewed on a regular basis.