

Premium Grade Biospecimens



Overview

Indivumed's Premium Grade biospecimens capture the molecular reality and allow a holistic view of the tumor landscape of the patient's disease state at the highest level of clinical relevance. Thus, Indivumed's Premium Grade samples enable you to excel in your research and development of personalized medicine along the value chain from target identification to drug discovery, and for biomarker exploration and validation. Indivumed's capability is to accelerate your time to market without having to compromise on quality and clinical data integrity.

Indivumed has established a unique high-quality human cancer tissue and fluids biobank that collects and processes all biospecimen products using a completely standardized ISO-certified protocol. Our unique clinical network spans clinical sites across the globe with an "Indivumed Standard for Biobanking" being firmly established and acknowledged as synonymous with unparalleled quality. We are globally recognized and trusted as setting the highest level for biospecimen and clinical data collection. Quality assessment performed by our certified

in-house pathologists guarantees that the risk factors often associated with tissue samples, such as poor tissue or block quality, insufficient tumor cell content, or high levels of necrosis, are reduced. Simultaneously, our data management team and study nurses ensure completeness and accuracy of the clinical data before final data storage.

For our Premium Grade biospecimens, tissue and blood are collected immediately after surgical resection by Indivumed study nurses who are present in the operating room and who then preserve the tissues in under 10 minutes, thus ensuring the biological sample closely mimics the molecular reality of the patient's cancer status. In addition, this process is fully controlled over the entire workflow, from the time of resection to biospecimen collection, clinical data verification, and storage. Indivumed provides a broad spectrum of systematic sample quality and clinical data with Premium Grade, Advanced Grade, and Basic Grade samples, from the most stringent requirements to routine and standard operations.

Your Benefits

- Complete cancer biospecimen set including matched normal tissue
- Comprehensive clinical data including follow-up (over 300 data points)
- Large biospecimen repository
- Custom prospective collections through our global clinical network
- Lowest usability failure rate (<1%) of quality controlled biospecimens performed by in-house pathologists
- Mean ischemia time of tissue <10 minutes
- Comprehensive patient consent
- Biomarker analyzed tissue for a variety of mutation characterized cancers (MSI, MSS, KRAS, BRAF, BRCA1/2, EGFR, ROS1, HER2, ER, PR, etc.)

Biospecimen Types



Tissue – tumor & matched normal

- Formalin fixed paraffin embedded
- Fresh frozen
- Fresh tissue
- Tissue microarray
- Core needle biopsies
- Fine needle aspirates



Fluids

- Plasma
- Serum
- Snap frozen PBMCs
- Urine – supernatant and sediment

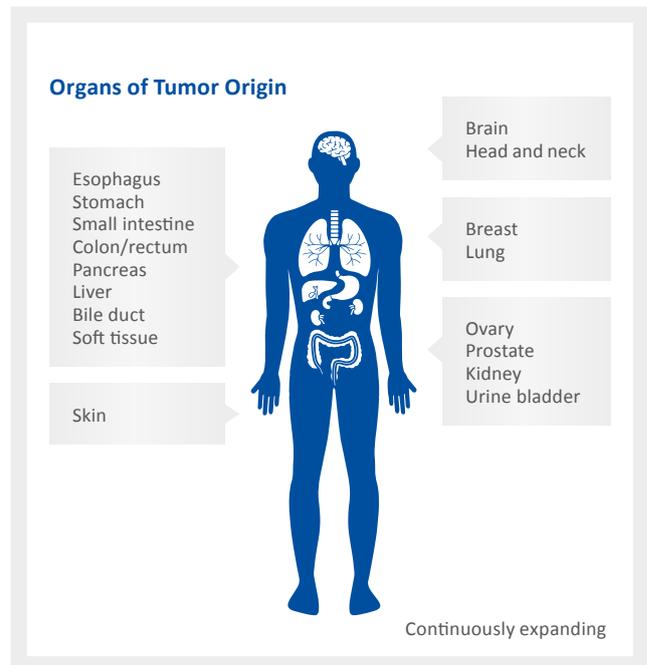
Clinical Data

Indivumed collects extensive clinical data from fully consenting and informed patients including their medical records, notes taken during surgical tumor resection, and comprehensive interviews with the patient's physician. Outcome and follow-up

data is collected beginning six months post-surgery and annually up to 10 years. Clinical data is thoroughly cross-checked for completeness and accuracy prior to final data storage in IndivuNet, the Indivumed biospecimen database.

We offer four data packages:

- Basic: general patient information, current disease, surgical findings, tumor size, ischemia time, histological type, stage, TNM, grade
- Comprehensive: includes basic data and current medications, drugs (intolerances, addictive, anesthesia), previous disease, neoadjuvant therapies, previous surgeries or cancer, family history, presurgical diagnostics, hematology, clinical chemistry, serology, warm and cold ischemia time
- Follow-up: includes basic and comprehensive data including detailed follow-up records on remission, relapse, and outcome including surgery and other therapies
- Additional data (e.g., biomarker status): Biomarkers – MSI, MSS, KRAS, BRAF, BRCA1/2, EGFR, ROS1, HER2, ER, PR, etc. for select cancers. Melanoma, colorectal cancer, ovarian cancer, stomach and lung cancer analyzed using Illumina's TruSeq Amplicon Cancer Panel (48 cancer genes).



Custom Prospective Collections

Indivumed offers customized biospecimen collection services that utilize our standard operating procedures under the guidance of a trained collection specialist. We can collect and process the biospecimens according to custom designed protocols to match

the requirements of your research. Additionally, we ensure short delivery times (24 to 48 hours) for time sensitive collections and worldwide logistics for sample delivery.

About Indivumed

Indivumed GmbH is a physician-led, integrated global oncology company for personalized medicine with the world's premier high-content tumor database and highest quality biobank. Indivumed's standard operating procedures are trusted as the global benchmark for biospecimen and clinical data collection.

Our long-standing biobanking expertise is ISO 9001-certified and includes strict protocols for tissue sampling and processing with regard to crucial parameters such as tumor region, ischemia time, and information management.

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