MAYO CLINIC
LABORATORIES

CONNECTING

Pharma and biotech

to Mayo Clinic diagnostics

FOUR REAL-WORLD
COLLABORATIVE EXAMPLES

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When developing new assays and devices, the step of analytical validation is crucial to the success of a project. Medical device, biopharma, and diagnostic companies are looking for testing partners who fulfill a wide range of requirements, which may vary widely from project to project. A good partner will have the flexibility and range to meet the needs of each new project while bringing specific expertise in the latest scientific and regulatory requirements.

1. Comprehensive menu

Ideally, a testing partner will offer a test menu that covers a diverse range of subspecialties, addressing even the rarest disease state. This will allow you to stick with one reference laboratory for multiple projects, avoiding the pain of transitioning between labs that have more limited menus.

2. Insider access and expertise

An ideal testing partner will offer extensive expertise in assay development and analytical validation services, along with access to biospecimens.

3. End-to-end support

While access to the right testing is critical, a true testing partner will offer strategic insight and support at every phase of the research and development journey. They should be able to organize a team of laboratory, medical, and business professionals to collaborate, develop, and launch tests specific to every partner's therapeutic strategy.

A GOOD TESTING PARTNER

CASE STUDIES

The following cases are examples of how companies can work with Mayo Clinic Laboratories' BioPharma Diagnostics team on their clinical and research testing needs.

These case studies illustrate different capabilities and collaborations and do not contain identifying information.

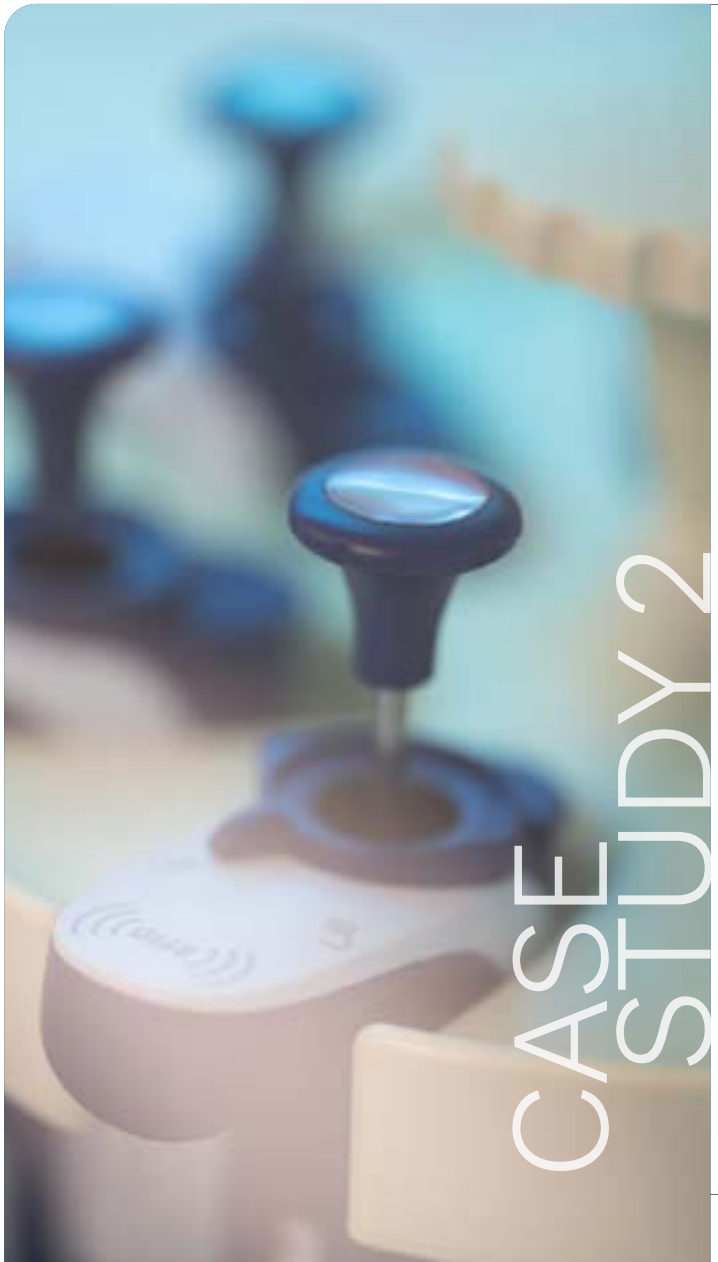
Gastrointestinal study collects and tests patient specimens at multiple time points

Opportunity

An international diagnostics company is completing an observational study of patients with liver cirrhosis with the goal of validating a specific serum metabolite constellation to detect early hepatocellular carcinoma (HCC) lesions in liver cirrhosis. The study population includes patients with liver cirrhosis scheduled for surveillance for HCC using abdominal ultrasound and blood-based liver function tests, which may include testing for biomarkers. Enrolled patients will have specimens and data collected at multiple touchpoints, including a baseline and up to four follow-up visits.

Collaboration

BioPharma Diagnostics screened for patients with liver cirrhosis and approached eligible individuals for enrollment in the study. Serial blood draws from consented patients were collected in Mayo Clinic's Clinical Research and Trials Unit and samples were stored in Biospecimens Accessioning and Processing, after which they were sent to the company for biomarker testing. BioPharma Diagnostics also completed data abstraction from the medical records.



Infectious disease test gains FDA approval

Opportunity

A musculoskeletal diagnostics company is completing a prospective study to demonstrate its test's performance in detecting periprosthetic joint infection (PJI) in synovial fluid. The company is looking to clinically validate its assay for detecting PJI by comparing its performance to the detection of PJI using the Musculoskeletal Infection Society (MSIS) criteria-based definition.

Collaboration

BioPharma Diagnostics screened for patients with suspected PJI and/or who were being considered for a knee or hip revision and approached eligible individuals for enrollment in the study. Synovial fluid from consented patients was collected preoperatively or intra-operatively from the affected prosthetic joint. The Clinical Microbiology Laboratory tested synovial fluid using the company's assays and compared the results to the MSIS criteria for PJI. BioPharma Diagnostics also completed data abstraction from the medical record. The company included these results and data in its successful submission for approval to the U.S. Food and Drug Administration (FDA).

Oncology surveillance biomarker study enrolls patients and evaluates assay

Opportunity

A biotechnology company is completing a surveillance biomarker study to establish a cutoff for its assay developed to monitor progression or regression of disease in patients with well-defined gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The study looks at the biomarker chromogranin A (CGA). The assay is to be used as an aid in monitoring disease progression during the course of disease and treatment in patients with GEP-NETs, in conjunction with other clinical monitoring methods.

Collaboration

BioPharma Diagnostics screened for patients with GEP-NETs for enrollment in the study. Serial blood draws were performed on consented patients and serum was tested on the company's assay in the Clinical Immunoassay Laboratory. BioPharma Diagnostics also completed data abstraction from the medical record.

Neurology study validates Alzheimer's assays

Opportunity

A research healthcare company is evaluating the clinical performance of three assays designed to aid in the diagnosis of Alzheimer's disease and other causes of cognitive impairment. The study aims to validate the new assays in two well-characterized cohorts with the goal of showing concordance to PET, under consideration of additional clinical information.

Collaboration

BioPharma Diagnostics provided annotated and banked cerebral spinal fluid samples from an Alzheimer's archive at Mayo Clinic. Those samples were tested on the company's assay in the Clinical Immunoassay Laboratory, providing clinical validation of the assay.

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NEXT STEPS

Mayo Clinic Laboratories collaborates with biopharma, diagnostic, and other biotech companies to offer a wide range of laboratory testing and biopharma support for all phases of clinical trials.

Consulting and partnering from discovery to post-market, our team can facilitate consulting engagements with Mayo Clinic physicians and scientists to help you ensure your pipeline aligns with the latest science and clinical needs.

Learn more about how we support assay development and validation, or reach out directly to start a discussion about your project.

Learn more

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