



# VCT Case Highlight:

## Delivering Efficient and Specialized Diagnostic Testing Services

### Overview

Versiti Clinical Trials (VCT) partnered with a large biopharmaceutical company to provide HLA typing services in support of their clinical trial project. Working within a tight deadline, Versiti was able to quickly deliver on processing and testing a large number of samples to meet the client's needs.

### Challenge

Referred by another partner, the client came to VCT looking for a partner to process and test more than 1,500 samples within a three-month timeline. During initial conversations, the VCT team sought to understand the full scope of the project and how to best meet the client's needs and ensure success utilizing VCT's extensive services.

Transparency was key during these initial talks, especially around capacity to ensure that routine clinical testing within Versiti's Histocompatibility (HLA) Lab would continue to achieve promised turnaround times regardless of the increased volume.

#### Client Needs:

- Process and isolate DNA on more than 1,500 samples
- HLA high-resolution typing by NGS on each sample
- Bulk delivery of final testing data
- Project start date within a month of initial talks
- Process and test all samples within three months

### Solution

Stakeholders across VCT worked together to optimize internal operations and logistics, providing a nimble and effective approach to meet the study's timeline and testing scope. Sample accessioning, processing and testing was divided between Cenetron, VCT's central laboratory in Austin, TX, and Versiti's HLA Laboratory in Milwaukee, WI. Samples were accessioned and DNA isolation was performed at Cenetron. The processed DNA samples were then sent to Versiti's HLA Lab for HLA high-resolution typing.

### Testing Capabilities:

Versiti's HLA Laboratory is a leader in histocompatibility testing and supports a large volume of clinical testing, as well as testing for research purposes. Versiti histocompatibility experts worked with the client to determine the ideal testing needed to get the results and data required for the study. Versiti's HLA High Resolution Typing by NGS panel provides a single test for genotyping the Class I and Class II loci and was used to genotype each sample.

At Cenetron, samples were accessioned, processed and then the DNA was isolated using a high-throughput system. Leveraging the capabilities at Cenetron allowed for quicker sample processing and the ability to handle a large volume of samples with a rapid turnaround.

### Handling Large Volumes:

By taking on this project, the HLA Lab had to balance the increase in testing volume with the daily clinical testing needs without impacting overall turnaround time. Resources and staff throughout the organization

were flexed to meet the increased demand in HLA testing without compromising essential clinical testing. Additional instruments were validated and brought onboard to support this study. Custom protocols were developed during contract negotiations to ensure seamless workflow between Cenetron and the Versiti HLA Lab, resulting in a smooth transfer of results.

### Solving Problems:

The trial was a retrospective study with a pre-defined number of samples. Versiti worked closely with the client and performed a feasibility study to ensure that samples were able to be accepted and tested despite the collected whole blood volume being below Versiti's recommended amount. Throughout the project, VCT had an open line of communication with the client and provided a weekly status call to give insight and transparency on the project progress.

### Key Highlights:

- 1,500 samples tested
- Only 0.3% of samples were QNS
- DNA isolation and HLA high-resolution typing performed
- Testing completed in less than 12 weeks, 2 weeks prior to deadline
  - July: first sample tested
  - Early September: all samples were processed
  - Mid-October: final sample tested

### Conclusion

VCT provided a nimble and personalized approach for this client and the study. Through cohesive planning, optimization of staffing and operating procedures, and transparent communication, VCT was able to complete this project effectively and efficiently. The testing provided by Versiti equipped the client with the conclusive data needed to make future decisions about the trial outcomes.



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