# Tacrolimus Assay Comparison: Analytical and Operational Considerations for Immunoassay vs Mass Spectrometry Testing in a High Volume Clinical Laboratory

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**Guests:** Rebekah Goldblatt is a development and technology scientist for both automated and esoteric analytical chemistry at TriCore in Albuquerque, New Mexico. Dr. Melissa Budelier is Section Chief and Medical Director of Clinical Chemistry and Toxicology at TriCore.

Randye Kaye: Hello and welcome to this edition of *JALM* Talk from *The Journal of Applied Laboratory Medicine*, a publication of the Association for Diagnostics & Laboratory Medicine. I'm your host, Randye Kaye.

After organ transplantation, patients are given immunosuppressant medications to ensure that organs are not rejected by the body. One common immunosuppressant medication used for this purpose is tacrolimus. Tacrolimus has a narrow therapeutic index, meaning that the range of concentrations in the body that are therapeutic is small and anything above that narrow concentration range is toxic for the patient. Additionally, there is a large interpatient variation in how the drug is absorbed and metabolized.

For medications like this, the concentration in the blood needs to be monitored very closely for every patient. This practice is known as therapeutic drug monitoring, TDM. The TDM of tacrolimus is typically performed using liquid chromatography, tandem mass spectrometry, LC-MS/MS, or via immunoassay. LC-MS/MS has the benefit of being able to measure parent drug in the patient's sample, but at the cost of being a time intensive manual process that needs highly trained and knowledgeable staff to run. On the other hand, immunoassays are quick and automated but have traditionally not been as specific for the parent drug, as they may detect metabolites or other medications that cross-react with the assay, which can lead to falsely elevated measurements.

The May 2026 issue of *JALM* am features an article in which the authors evaluate an immunoassay method for tacrolimus that has been reported to have lower interferences than other immunoassays on the market. The authors compare this immunoassay method to their in-house LC-MS/MS method and evaluated impact on clinical workflow and turnaround time.

Today, we are joined by the article's first and corresponding authors, Rebekah Goldblatt and Dr. Melissa Budelier.

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Rebekah Goldblatt is a Development and Technology Scientist at TriCore for both automated and esoteric analytical chemistry. In her role, Rebekah is responsible for researching and developing analytical methods for the routine analysis of different compounds in patient specimens. Rebekah is a certified Medical Laboratory Scientist through the American Society of Clinical Pathologists, ASCP, and holds a Bachelor's of Science in Medical Laboratory Sciences and a Master's of Science in Health Science.

Dr. Melissa Budelier is Section Chief and Medical Director of Clinical Chemistry and Toxicology at TriCore and serves as CLIA Laboratory Director for TriCore's core laboratory in Albuquerque, New Mexico. She is also affiliated with the University of New Mexico as a clinical associate professor of pathology and is board certified in clinical chemistry. Welcome, Rebekah and Dr. Budelier.

Dr. Budelier, why did you decide to evaluate the Roche tacrolimus assay for immunosuppressant testing? Most laboratories transition from immunoassay to mass spectrometry, not the other way around.

Melissa Budelier: Great question. For us, the primary driver was turnaround time. We had an opportunity to move testing into a lab with 24/7 staffing, which meant we could deliver results much faster. In a transplant population, that kind of improvement in turnaround time can have a real clinical impact. Additionally, the Roche tacrolimus package insert had promising performance characteristics that suggested minimal interference with common tacrolimus metabolites. This led us to say, 'why not take a closer look?' Honestly, though, even when we made the decision to evaluate the method, we were very skeptical. Immunosuppressants are one class of drugs we thought we'd always measure by mass spectrometry. However, technology is rapidly improving, so we were open to at least evaluating the method and letting the data speak for itself.

Randye Kaye: Thank you. Rebekah, can you briefly describe how you compared the immunoassay to your mass spectrometry method, and what you found? Were there any findings that surprised you?

Rebekah Goldblatt: Sure. We started with a direct method comparison between the Roche tacrolimus immunoassay and our in-house mass spectrometry method, using patient samples that covered as much of the reportable range as possible on both platforms. Before we started, our biggest concern with the immunoassay method was accuracy. Metabolites and other drugs are known to cross react with immunosuppressant immunoassays, leading to biased results.

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If we had observed bias in our method comparison, we would not have proceeded with the rest of the experiments. Like Dr. Budelier mentioned, the package insert suggested there would be minimal interference and good agreement, but we wanted to see that for ourselves. To our surprise, the comparison looked far better than we imagined. When we saw the data, it was the first time we thought, 'wow, this tacrolimus immunoassay might actually be a viable alternative to mass spectrometry.' After the method comparison, we did precision and linearity studies, which also performed really well. Taken together, the data gave us confidence in the method and led us to do full verification studies on multiple clinical analyzers.

Randye Kaye: All right, thank you. Dr. Budelier, one of the key aspects of your study is workflow. So, what impact did implementation have on turnaround time and laboratory operations?

Melissa Budelier: Switching to an immunoassay for tacrolimus testing cut our turnaround times nearly in half. This was a huge win for both the laboratory and our providers. It did come with a few operational challenges though. Mainly, there is still a manual sample preparation step prior to loading. Pretreatment is something that our mass spectrometry staff are very familiar with but is much less common in our automated chemistry laboratory. We address this through focused training and competency assessments and our chemistry staff have become very proficient with the precise pipetting required for the assay.

Operationally, the pre-treatment step also meant this test could not be performed in a typical random-access workflow used in our automated chemistry laboratory. It required us to run testing in batches multiple times a day. The team spent a lot of time evaluating and re-evaluating when to do these batches. We looked at heat maps of sample receipt times and collection times and compared those to the other duties staff were performing throughout the day. Ultimately, one of the biggest advantages of moving this test to the chemistry lab was having more staff trained to perform the assay along with the 24/7 coverage, which gave us flexibility in scheduling runs.

Randye Kaye: Thank you. Well, back to you Rebekah. Maybe you can talk about the limitations, any limitations you encountered in your study, and what should laboratories consider when implementing this method more broadly?

Rebekah Goldblatt: One limitation labs may face when implementing this assay is the lack of availability of immunoassays for other immunosuppressants such as cyclosporine and sirolimus. While some methods exist, we haven't found any that perform as well as this tacrolimus assay. One advantage of

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mass spectrometry is the ability to multiplex analytes. Multiple immunosuppressants are often measured simultaneously. For many labs, it may not make sense to move just one analyte to immunoassay platform. For us, though, tacrolimus represents the majority of our immunosuppressant testing, so moving it to an immunoassay made sense.

From a clinical perspective, we did encounter some skepticism from providers similar to what we initially felt ourselves. While most clinicians were happy with the change, a few questioned the immunoassay results given the long-standing concern about bias with immunoassay methods. To address this, upon request, we briefly performed parallel testing for selected cases. Once providers saw how closely the immunoassay results aligned with mass spectrometry results for their patients, confidence in the method appeared to increase. Ultimately, the benefits of measuring immunosuppressants by mass spectrometry were so ingrained that it took seeing data firsthand to trust the new approach.

Randye Kaye: Thanks. So, let's just wrap up here. As we wrap up, we'll start with you, Rebekah. What's the one thing you want listeners to remember from your study?

Rebekah Goldblatt: My main takeaway is that while the tacrolimus immunoassay compares very well analytically to mass spectrometry, whether it's the right fit for the lab also depends on operational considerations. Key factors include the volume of tacrolimus testing relative to other immunosuppressants and the need for manual pretreatment, which requires special training and equipment beyond what's typically needed for automated immunoassays.

Melissa Budelier: I agree with what Rebekah said about operational considerations. Additionally, and more generally, my main takeaway is don't let preconceived biases prevent you from considering new technology. If we hadn't kept an open mind, we would have never evaluated this method. Technology is advancing rapidly and some of the limitations we've long assumed may no longer be relevant. It's important to stay curious, be willing to reassess long-standing assumptions, and ultimately make data-guided decisions.

Randye Kaye: Well, that's very good advice all across the board for many things. So, thank you so much Dr. Budelier and Rebekah Goldblatt, thank you for joining us.

Rebekah Goldblatt: Thank you.

Randye Kaye: That was Rebekah Goldblatt and Dr. Melissa Budelier discussing the *JALM* article "Tacrolimus Assay Comparison:

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Analytical and Operational Considerations for Immunoassay vs Mass Spectrometry Testing in a High Volume Clinical Laboratory." Thanks for tuning in to this episode of *JALM* Talk. See you next time, and don't forget to submit something for us to talk about.

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