



UW Medicine
Department of Laboratory Medicine

Tacrolimus - Laboratory Measurements

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This note is to clarify the recently observed variability in tacrolimus measurements. We currently do tacrolimus measurements using a commercial immunoassay. When we put a new lot of reagents into service on July 14, we noticed that our control values had shifted down. We then tested a series of specimens from patients that had previously been measured with the old reagent lot, and confirmed a similar drop in patient results, averaging about 25% (range 0 - 50%). We attempted to obtain another lot of reagents immediately, but none was available. Not wanting to have doses changed due to a change in measured concentration that was due solely to the change in reagents, we began appending comments to each result, noting the expected 25% drop relative to previous results. We expected this condition to be short-lived, with a return to the previous performance when the next lot of reagent became available.

We have now evaluated two additional new lots of reagents and find that both give results comparable to those produced by the lot initiated on July 14. This suggests that there may have been changes in bulk materials used to prepare individual reagent lots, and that future assay results will continue at the current status indefinitely.

This raises the issue of which results are right, the ones obtained with the "old" (pre July 14) reagents or the ones with the "new" (July 14 and thereafter) reagents. Because there is no reference standard for tacrolimus, the question cannot be answered definitively. Comparing the results of proficiency testing done by labs across the country when the "old" reagents were in use with results from labs using liquid chromatography-tandem mass spectroscopy (LC-MS/MS) suggests that the results with the "old" reagents may have in fact been too high, with the results using the "new" reagents being more correct. Thus, we will no longer add any comments to the results, and suggest that the results with the "new" reagents be interpreted with regard to reference ranges without any adjustment, either to the value or to the reference range.

Because of continued performance problems with the tacrolimus immunoassay, we are working to change our method for tacrolimus to LC-MS/MS. We expect to make this change in mid to late Fall. We regret any inconvenience that may have resulted from the changes in immunoassay reagent performance.

Please address any questions to Petrie Rainey, MD, PhD, Director of Clinical Chemistry (206-598-6140).