

LAB ALERT

Date: February 22, 2021

Recalibration of Immunosuppressant Drug Assays

Dear Regional Pathology Services Clients,

On February 22, 2021, the Core Laboratory will recalibrate the current immunosuppressant drug assays in whole blood. The calibration kit manufacturer, RECIPE, has implemented a corrective action for their calibrator kits to more closely align immunosuppressant assay results with International Reference Materials.

For the previously assigned target values of tacrolimus and sirolimus of the above-mentioned products, deviations from the respective European Reference Materials ERM-DA110a and ERM-DA111a were determined. For cyclosporine A and everolimus, deviations of the target values to the respective Certified Reference Materials of Cerilliant CRM C-093 and E-068 were determined. The deviations depend on the individual analyte and the corrections of the target values to the certified reference materials are summarized for each analyte and concentration level (see Table 1):

Table 1: Correction of the target values in % to the certified reference materials

Order nos.	9933						9033			9028
Lot	1428						1379			1457
Level	L 1	L 2	L 3	L 4	L 5	L 6	L 1	L 2	L 3	L 7
Cyclosporine A	- 14	-9	-6	- 4	- 3	- 3	- 14	- 6	- 3	- 3
Tacrolimus	+4	- 2	- 4	- 5	-6	-6	+ 4	- 4	- 6	-6
Sirolimus	- 2	- 8	- 11	- 13	- 14	- 14	- 1	- 11	- 13	- 14
Everolimus	- 12	- 15	- 16	- 17	- 18	- 18	- 11	- 16	- 18	- 18

Note that most assays will see a drop in values based on recalibration. The most significantly affected drugs are Sirolimus and Everolimus.

If you have questions or concerns about this change please contact; Samuel J. Pirruccello, M.D., page: 888-1640, phone: 559-7707 or contact client services at 402-559-6420 and ask to speak with one of the client coordinators.