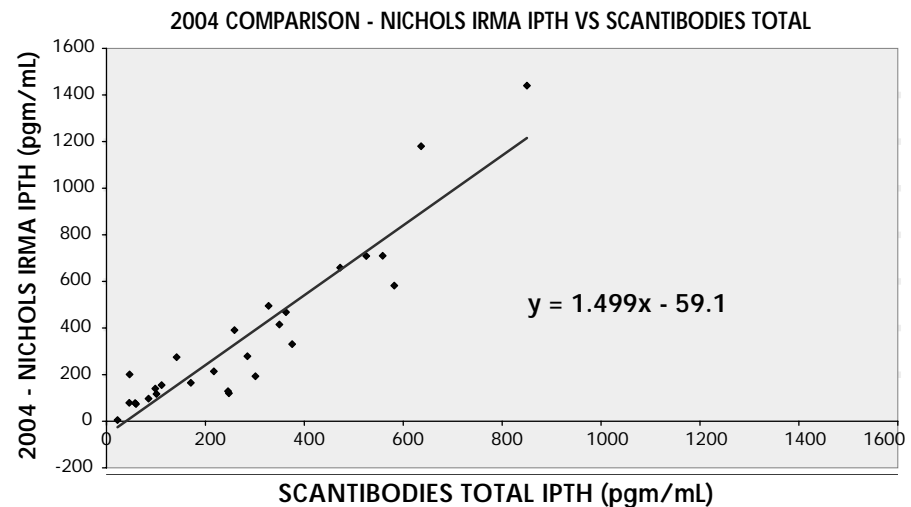
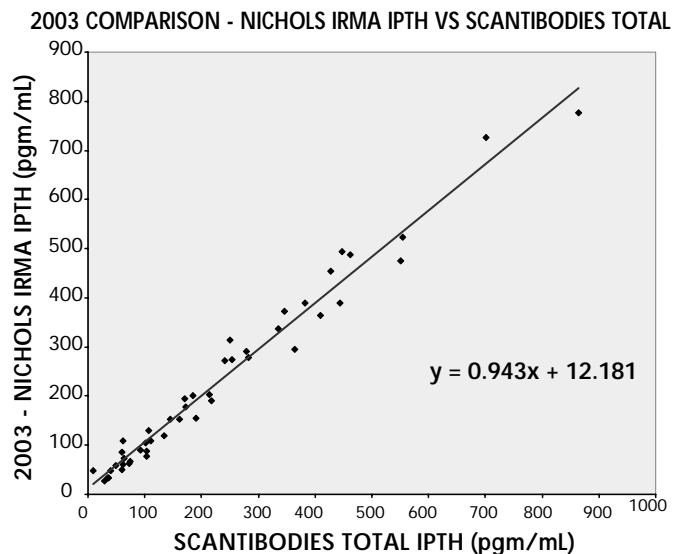


Change in the Comparability of the Nichols iPTH IRMA with the Scantibodies iPTH

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K/DOQI is based on the Nichols iPTH IRMA. There is no assurance that changes in productions might not result in a change in assay values from an assay. When an assay is used in a clinical trial or to diagnose a renal bone disease condition or to monitor therapy it is important to know that the assay has not shifted. Assay stability must be monitored to avoid inappropriate treatments of patients. Monitoring assay stability is not an easy task. Government regulations require laboratories to use control sera to check for assay drift with regular performance of assay stability monitors (i.e., Levey Jennings Analysis). Oftentimes due to large volume requirements, control serum used for this purpose is made up of synthetic 1-84 PTH and does not reflect the fragment composition typically found in patient specimens. One preferable method to check for assay stability with patient plasma is to use a previously assayed ESRD specimen in the PTH assay being monitored. The method is reliable to alert and instigate further investigation to protect patients. Alternatively a PTH assay can be routinely checked for consistency of bias against another assay. The Nichols iPTH assay was checked for comparability with the Scantibodies iPTH assay and the results are shown below.



Cantor T. Change in the Comparability of the Nichols iPTH IRMA with the Scantibodies iPTH. *J Am Soc Nephrol* 2004; 15(10):PUB042, p. 770A-771A.