On What Basis can the Scantibodies' PTH Assays be Considered the "Reference PTH Assays?"
In 1987, Nichols had the first 2nd Generation iPTH IRMA assay; therefore, the Nichols iPTH IRMA was the "reference iPTH assay". K/DOQI only used PTH literature that used the Nichols iPTH IRMA for study and research. Scantibodies calibrated its Total PTH™ (tPTH) Assay to the Nichols iPTH IRMA assay.
Intact PTH Assay Comparison - <2003

This is the assay on which K/DOQI Guidelines are based and which were used in all 73 articles that became the foundation for the guidelines.

Scantibodies calibrated its tPTH assay to the Nichols iPTH IRMA

By Testing the Same ESRD and Normal Specimens (Pools) Every Two Weeks, Scantibodies Verifies that its tPTH and CAP™ Assays have not Shifted
Total Intact PTH Assay Values - 2002 to 2003

Sample
Total Intact PTH (pgm/mL)
Total 2002 Total 2003

![Graph showing Total Intact PTH values from 2002 to 2003 for each sample. The graph compares the values between the two years.](image-url)
Comparison of Total PTH Concentrations Determined in ESRD Samples Between 1999 and 2003
Every Two Weeks, Scantibodies Verifies that its CAP™ Assay Does Not Shift. Scantibodies developed the first 1-84 PTH Assay (CAP™ or "Whole PTH") in 1998. Therefore, the Scantibodies CAP™ Assay is the "Reference" 1-84 PTH Assay.
CAP™ Assay Values 2002 to 2003
Comparison of CAP PTH Concentrations Determined in ESRD Samples Between 1999 and 2003
The Nichols PTH Assays have Shifted
Changes in the Nichols Advantage iPTH and Bio-Intact™ PTH Assays Over Time

% Differences in ESRD Patient Values Advantage iPTH Compared to NID IRMA iPTH and Bio-Intact™ PTH Compared to SLI whole PTH (CAP™)

(2) Data on file at Scantibodies Laboratory, Inc.

Note: On March 25, 2005, Nichols recalled the Bio-Intact™ PTH assay in the USA (but, not in Japan. In Europe, it was recalled two weeks later due to a 234% upward shift).
“Parathyroid Hormone Assay Drift: An Unappreciated Problem in Dialysis Patient Management”

Abstract:

The Kidney Disease Outcomes Quality Initiative (K/DOQI) Bone Metabolism Guidelines assume that clinicians use the Nichols intact parathyroid hormone immunoradiometric assay (iPTH IRMA) upon which K/DOQI was based. But for more than a decade, virtually all PTH assay results used for routine end-stage renal disease (ESRD) clinical management have not been generated with this test. Results from the most widely used PTH assays for ESRD patient testing in the United States have varied from 1999 to 2005. The Nichols chemiluminescent Advantage™ iPTH assay results shifted upwards significantly in 1999 and remained elevated until 2005. From 2003 to 2005, results from the Nichols Advantage Bio-Intact PTH assay shifted upward on average by 29% to 52%. These changes in the most widely used PTH assay have made use of the K/DOQI guidelines with these assays both inappropriate and potentially harmful to patients.