

**On What Basis  
can the Scantibodies' PTH  
Assays be Considered the  
"Reference PTH Assays?"**

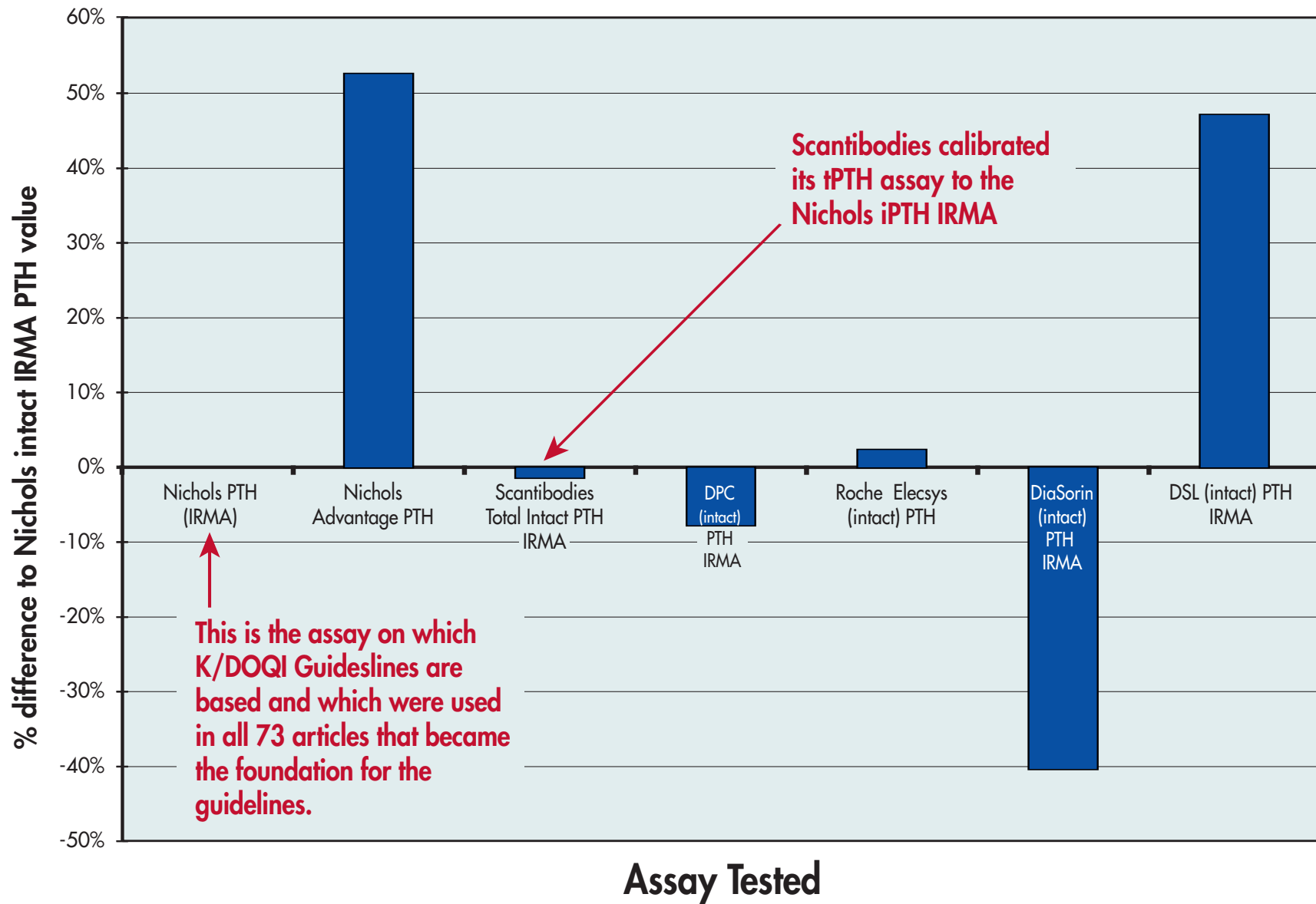
**In 1987, Nichols had the first 2nd Generation  
iPTH IRMA assay;**

**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.**

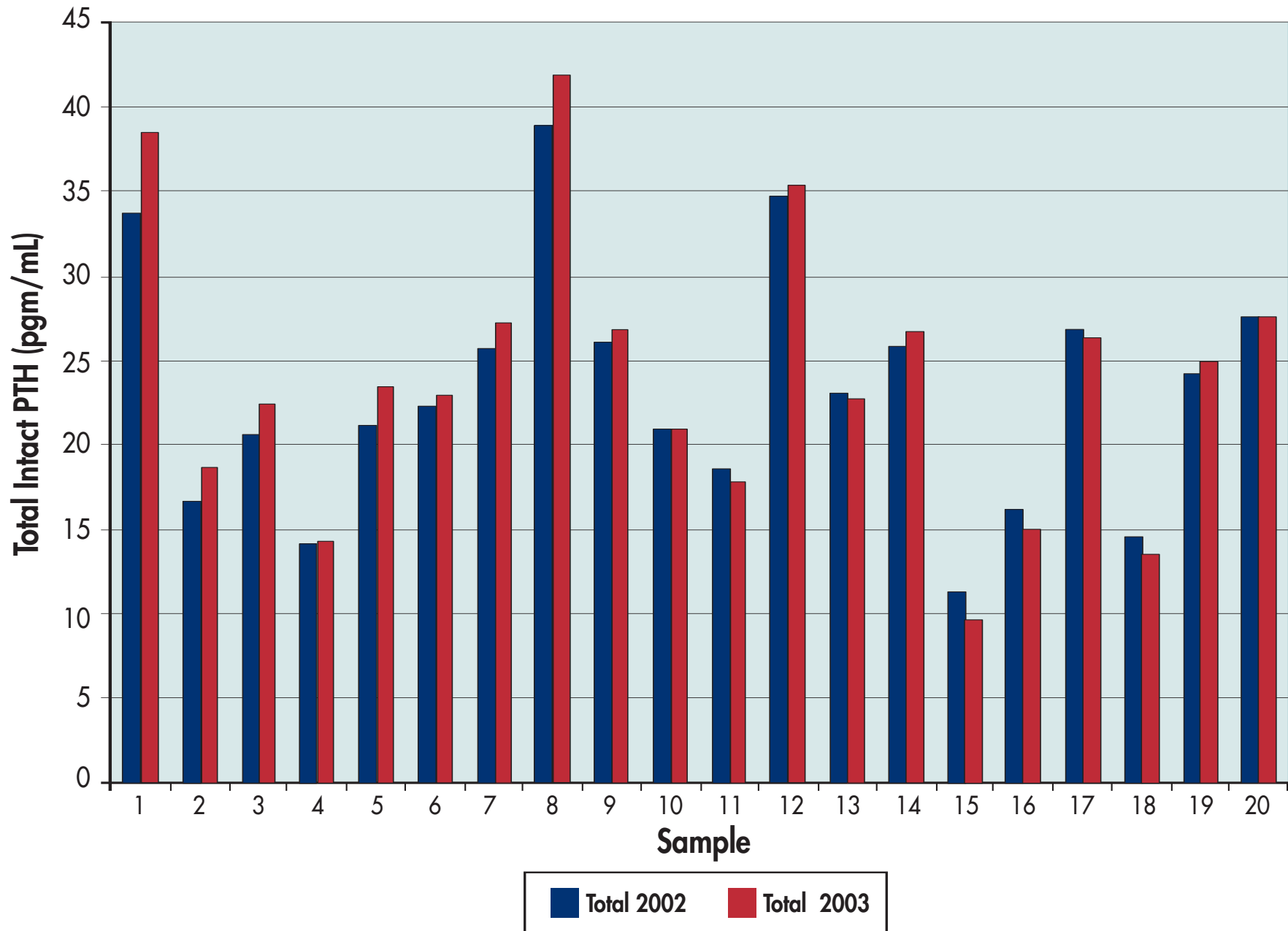
# Intact PTH Assay Comparison - <u>2003



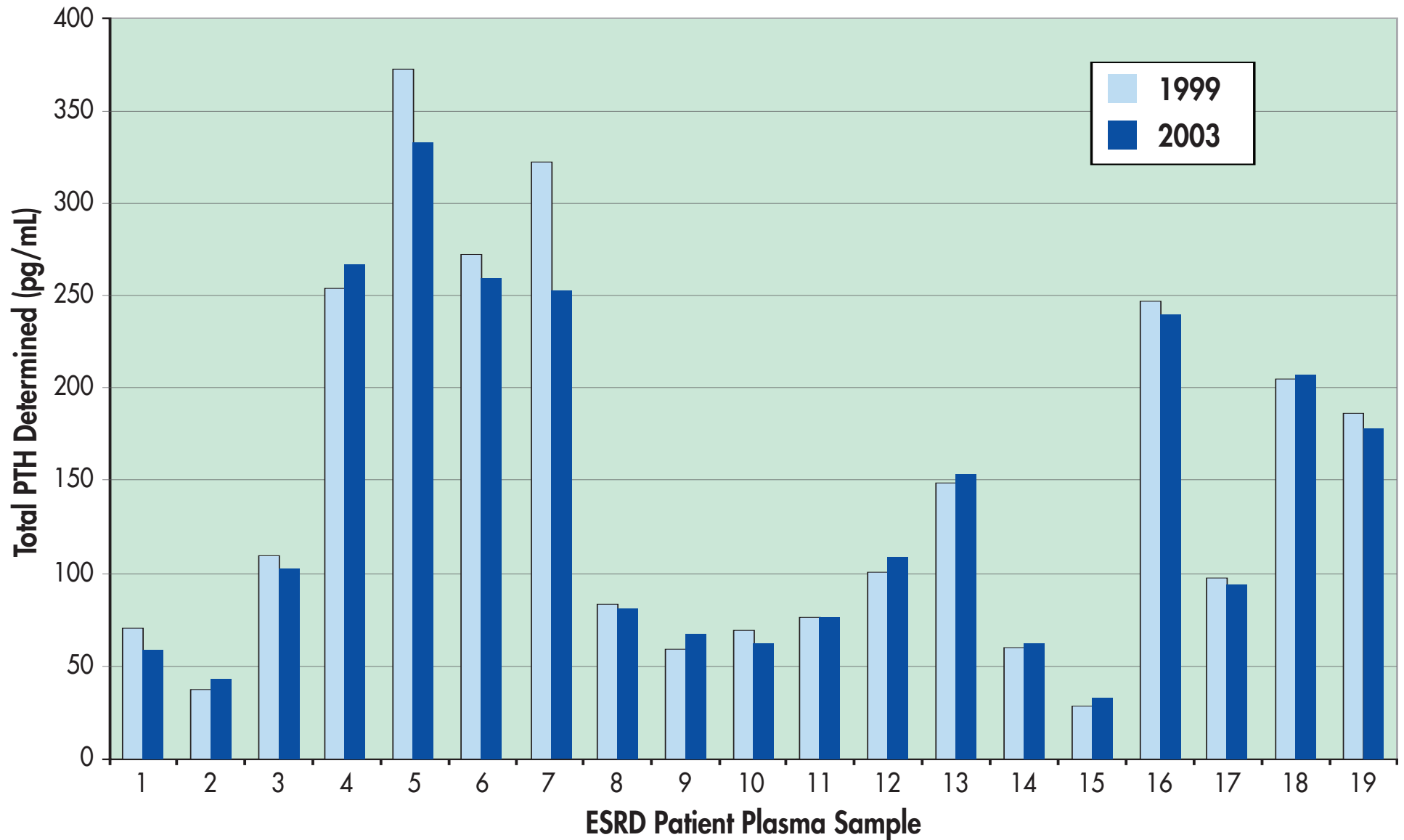
Cantor T, Glowacki P, Scheibel S. Large Differences Between Commercial Intact PTH Assays. *J Am Soc Nephrol* 2003 (Nov); 14:698.

**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

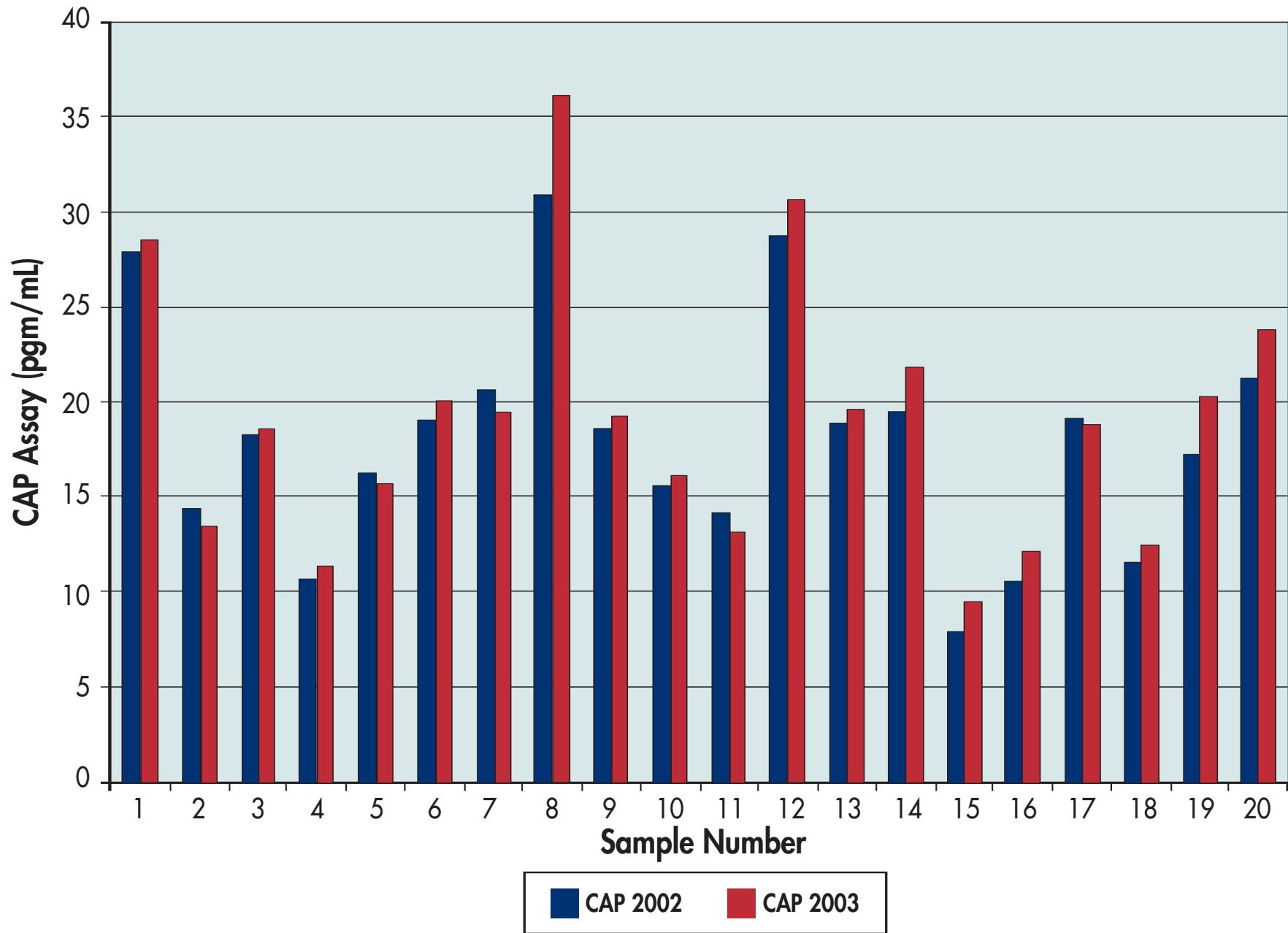


# Comparison of Total PTH Concentrations Determined in ESRD Samples Between 1999 and 2003

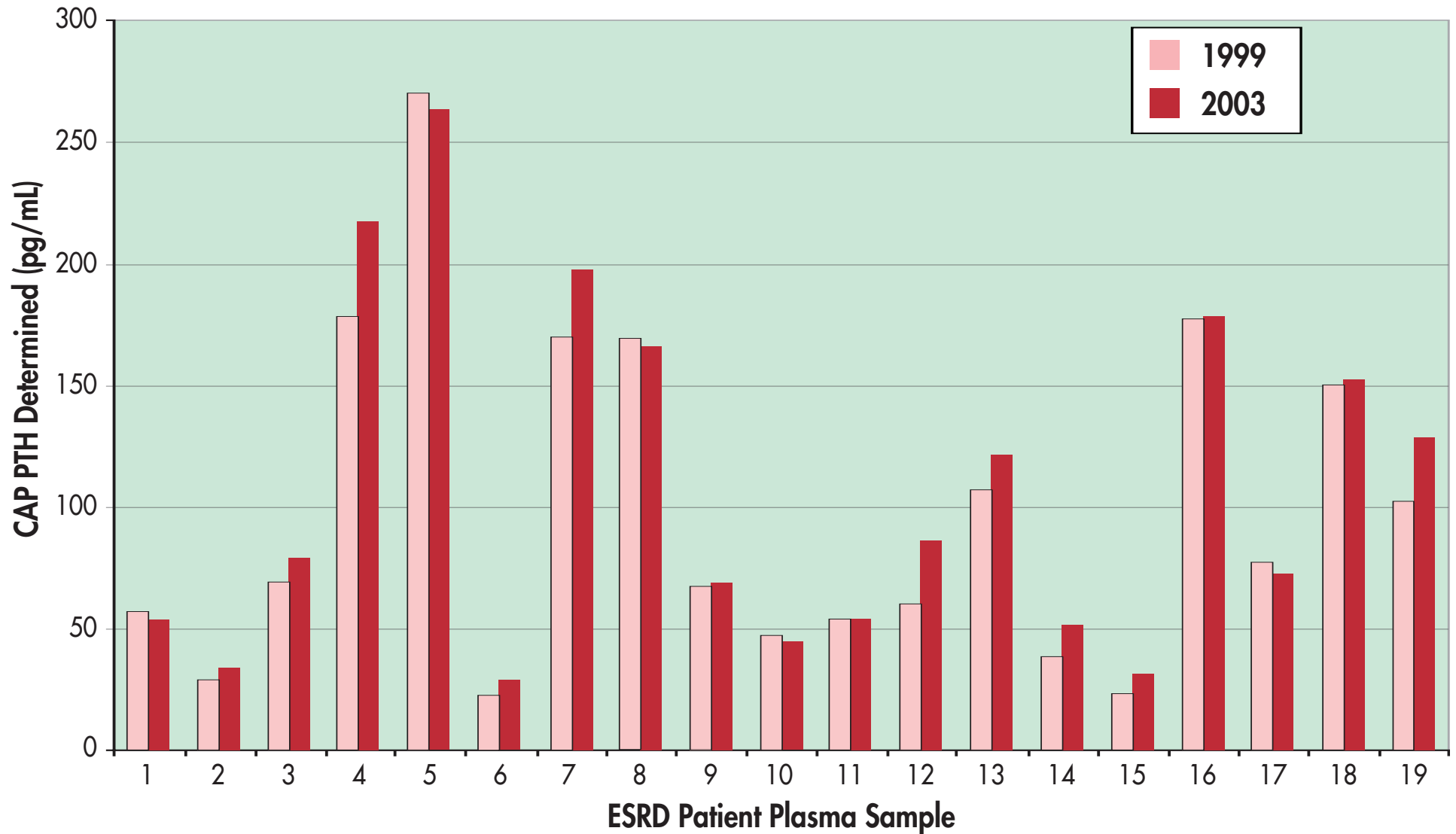


**Every Two Weeks, Scantibodies Verifies that its CAP™ Assay Does Not Shift. Scantibodies developed the first 1-84 PTH Assay (CAP™ or "Whole PTH") in 1998. Therefore, the Scantibodies CAP™ Assay is the "Reference" 1-84 PTH Assay.**

# CAP™ Assay Values 2002 to 2003

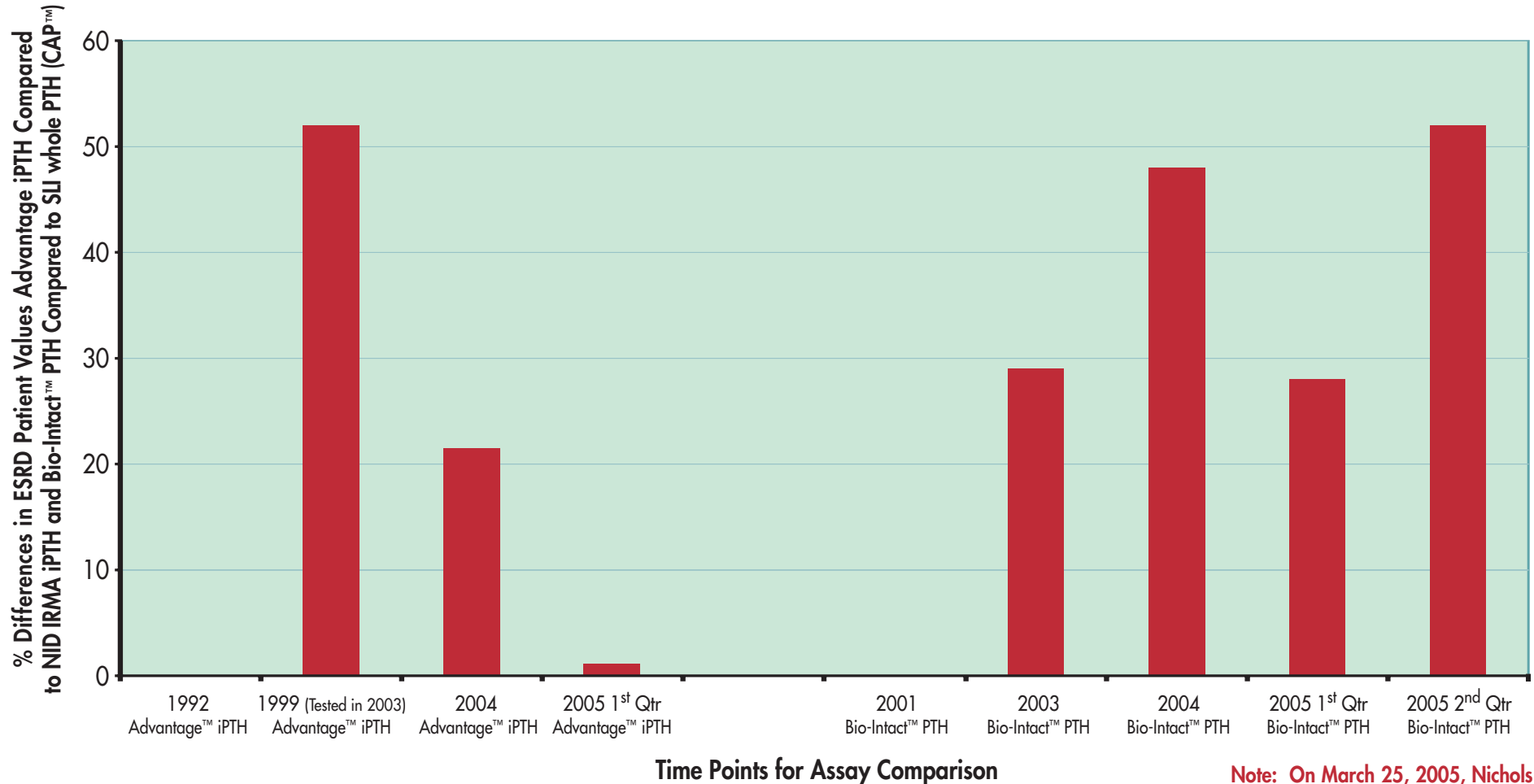


# Comparison of CAP PTH Concentrations Determined in ESRD Samples Between 1999 and 2003



# The Nichols PTH Assays have Shifted

# Changes in the Nichols Advantage iPTH and Bio-Intact™ PTH Assays Over Time



(1) Cantor T, Glowacki P, Scheibel S. Large Differences Between Commercial Intact PTH Assays. *J Am Soc Nephrol* 2003 (Nov); 14:SU-PO698, 688A.  
 (2) Data on file at Scantibodies Laboratory, Inc.

## **“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.

Tom Cantor. Parathyroid Hormone Assay Drift: An Unappreciated Problem in Dialysis Patient Management. *Sem in Dialy* 2005 (Sep-Oct); 18(5):359-364.