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No disclosures

DIAGNOSING DIABETES: THE ROLE OF HBA1C ASSAY

- The diagnosis of diabetes is clinical and biochemical
- Random glucose values greater than 200 mg/dl accompanied by symptoms and signs of diabetes
- Several random glucose values greater than 200 mg/dl
- Glucose values greater than certain cutpoints on glucose tolerance tests
- Fasting glucose values greater than certain cutpoints
- AND NOW HBA1C > 6.5%

DIAGNOSING DIABETES: THE ROLE OF HBA1C ASSAY

IT ALL DEPENDS WHAT YOU MEAN BY GLUCOSE

IS IT PLASMA GLUCOSE, WHOLE BLOOD GLUCOSE, FINGERSTICK GLUCOSE?

IS IT 115 MG/DL, 120 MG/DL?

IS IT DIABETES OR PRE-DIABETES OR IMPAIRED GLUCOSE TOLERANCE OR IMPAIRED FASTING GLUCOSE?

DIFFERS FOR PREGNANCY

THE HBA1C DEFINITION WAS A CORRELATION WITH RETINOPATHY, NOT GLUCOSE!

DIAGNOSING DIABETES: THE ROLE OF HBA1C ASSAY

IT ALL DEPENDS WHAT YOU MEAN BY HBA1C

IS IT HPLC?

IS IT AFFINITY?

IS IT IMMUNOASSAY?

IS IT PERCENT OR MG/DL?

THE HBA1C DEFINITION WAS A CORRELATION WITH RETINOPATHY, NOT GLUCOSE!

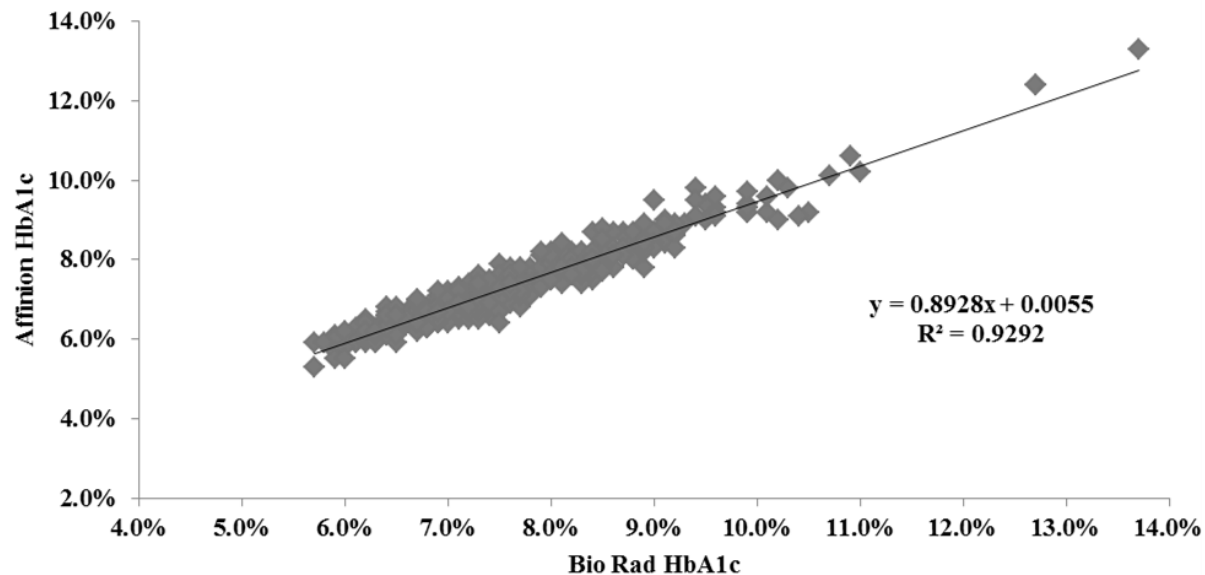
The National Glycohemoglobin Standardization Program (NGSP) Attempts to Standardize All Assays Against an HPLC Standard

COMPARISON OF POC WITH CENTRAL LAB

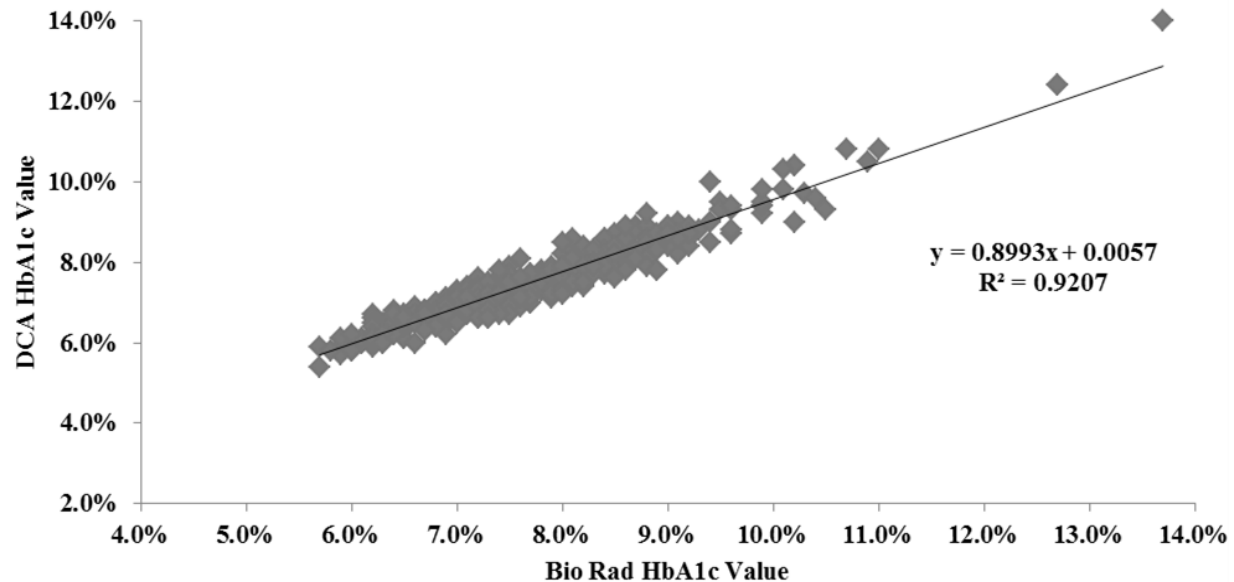
GOOD AT A SINGLE TIME POINT, BUT WE NEED LONG TERM DATA

- We compared two POC techniques, Afinion and DCA with two Central Lab techniques, Biorad and Tosoh over a three year time period in a large patient population
- We followed NGSP bias of the assays over this duration

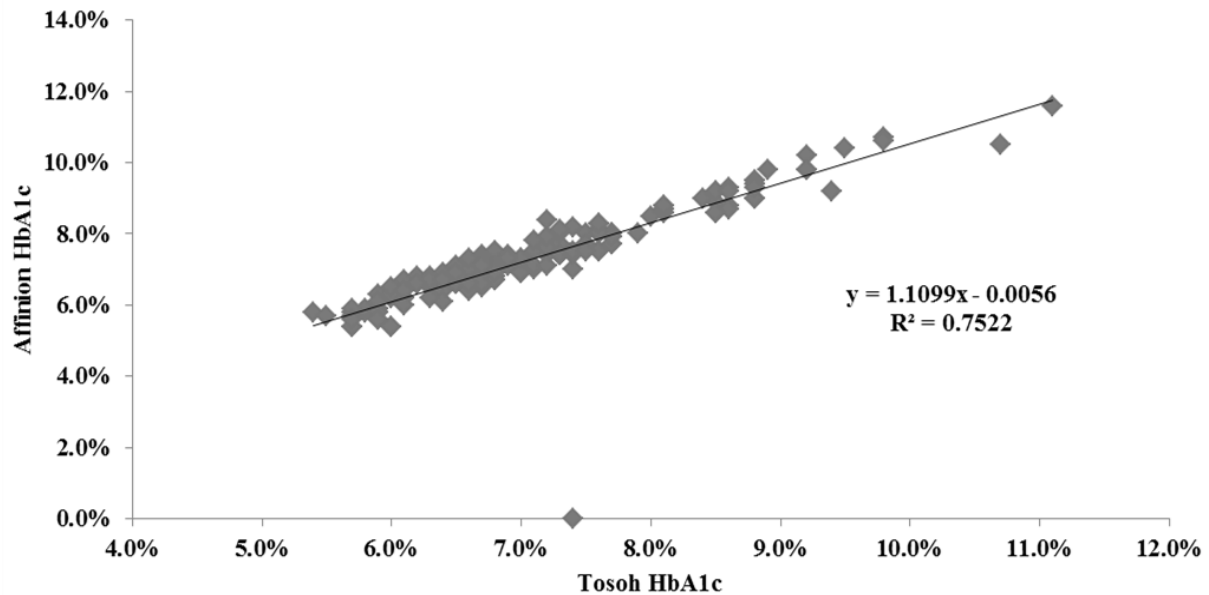
Correlation of Affinon Vs Bio Rad



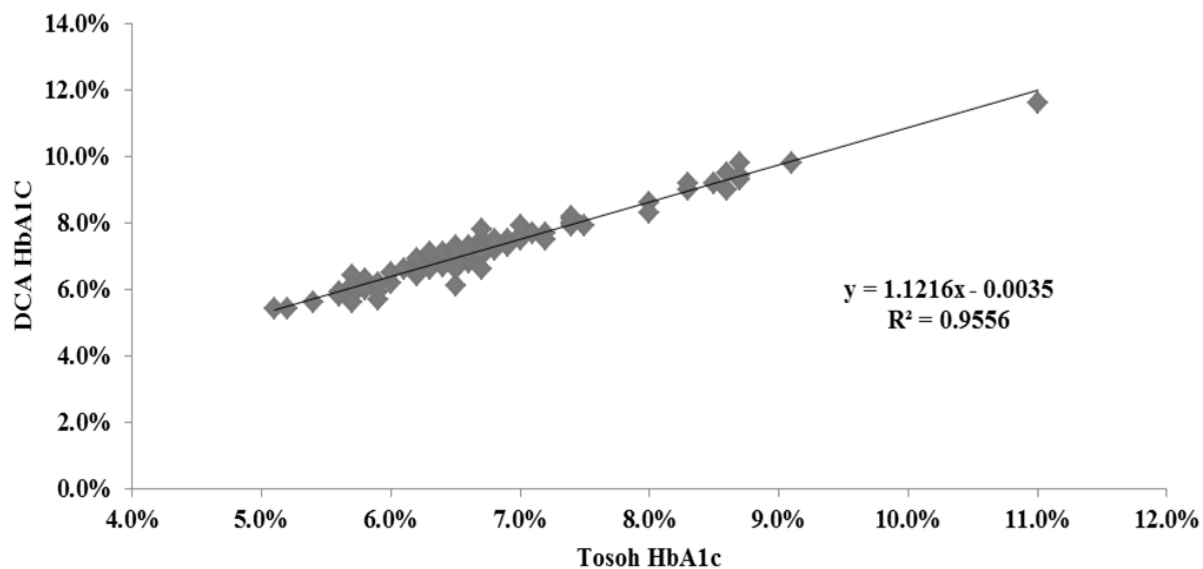
Correlation of DCA Vs Bio Rad



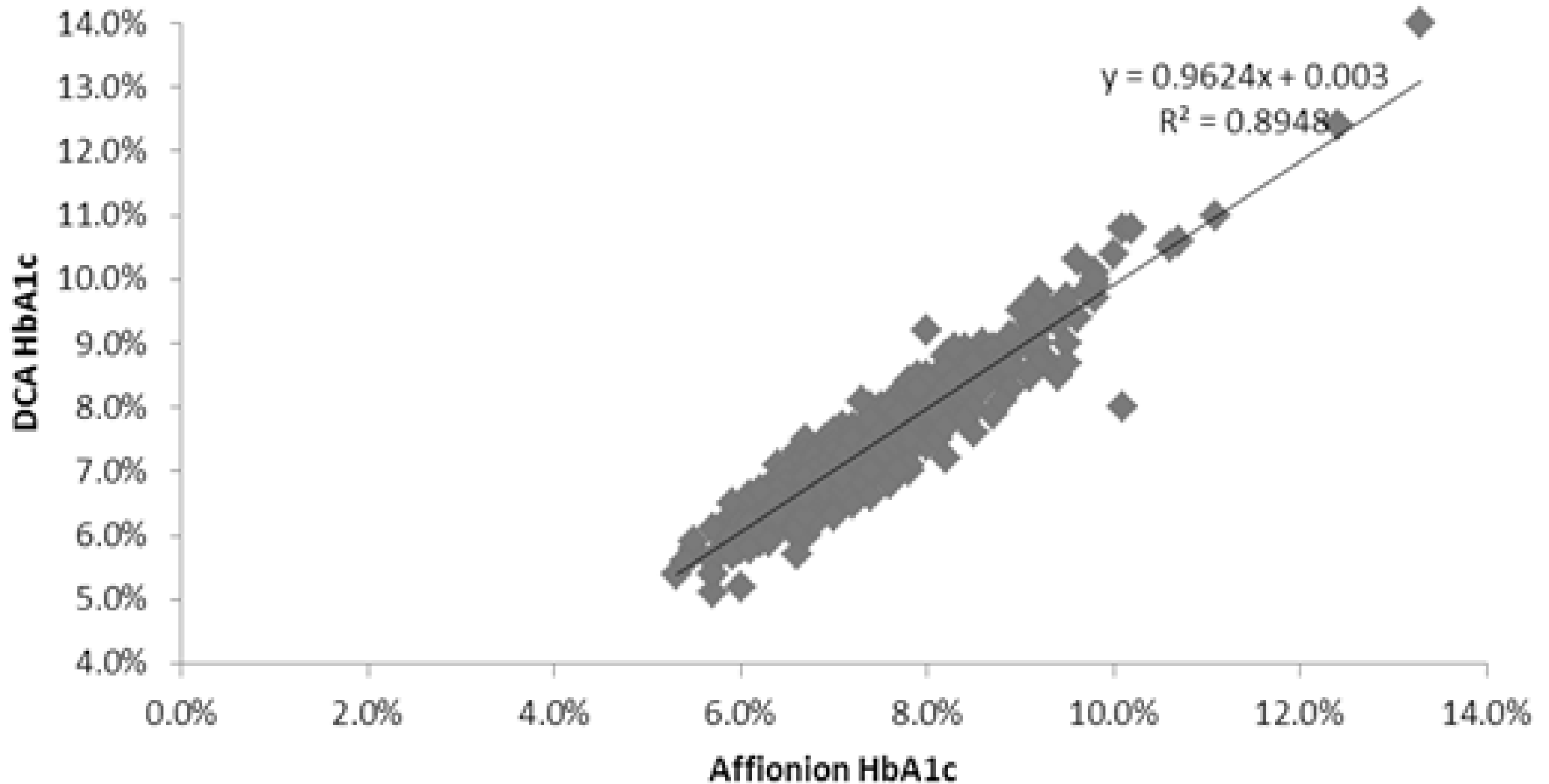
Correlation of Affinon Vs Tosoh



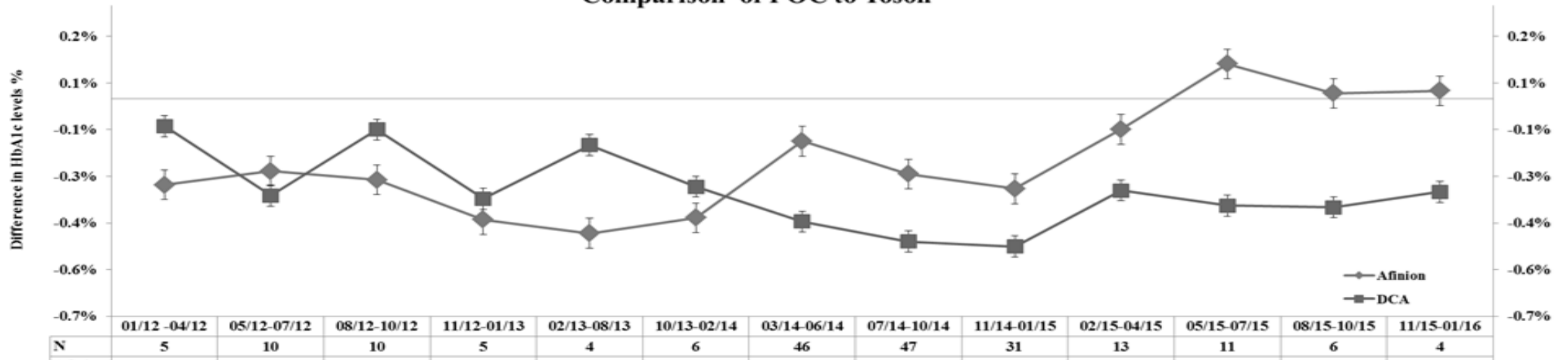
Correlation of DCA vs Tosoh



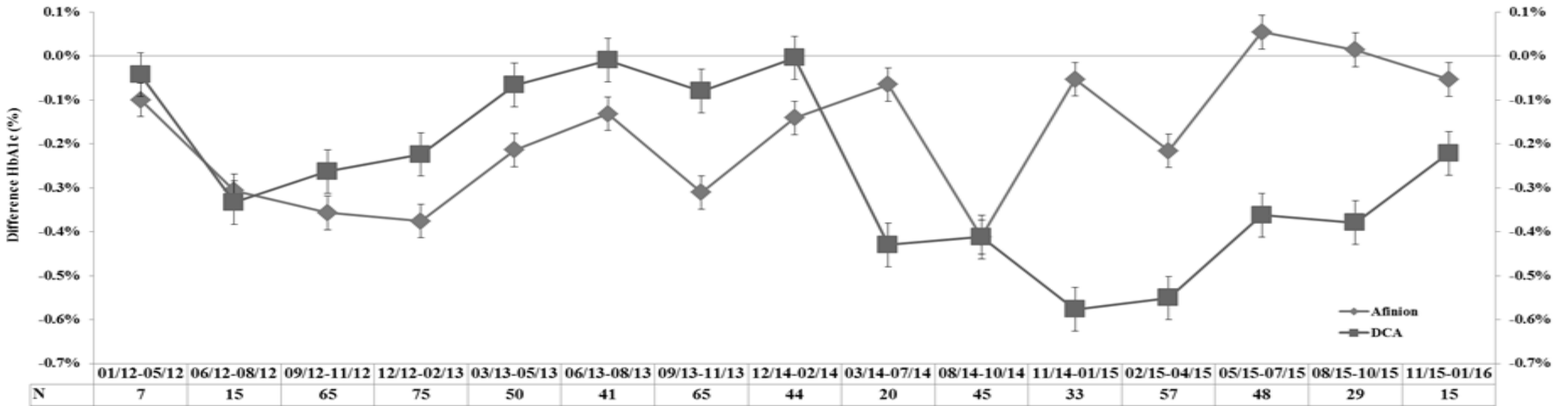
Correlation of DCA vs Affinion



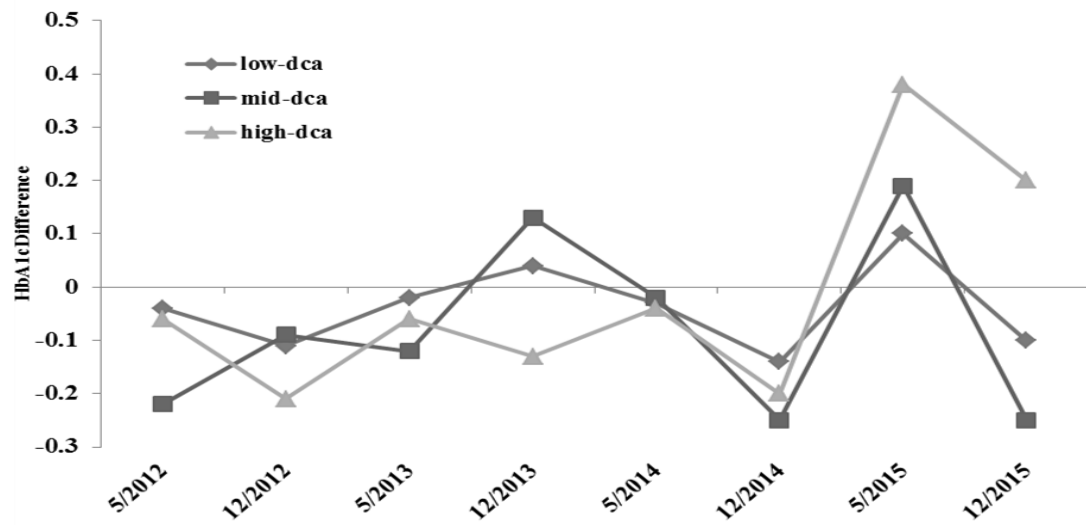
Comparison of POC to Tosoh



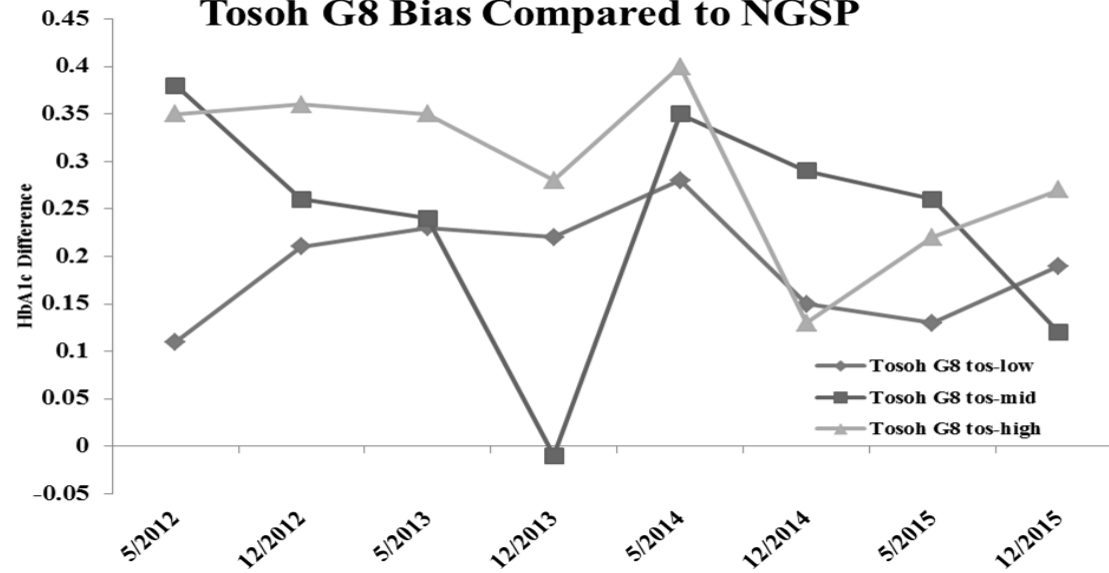
Comparison of POC to BioRad



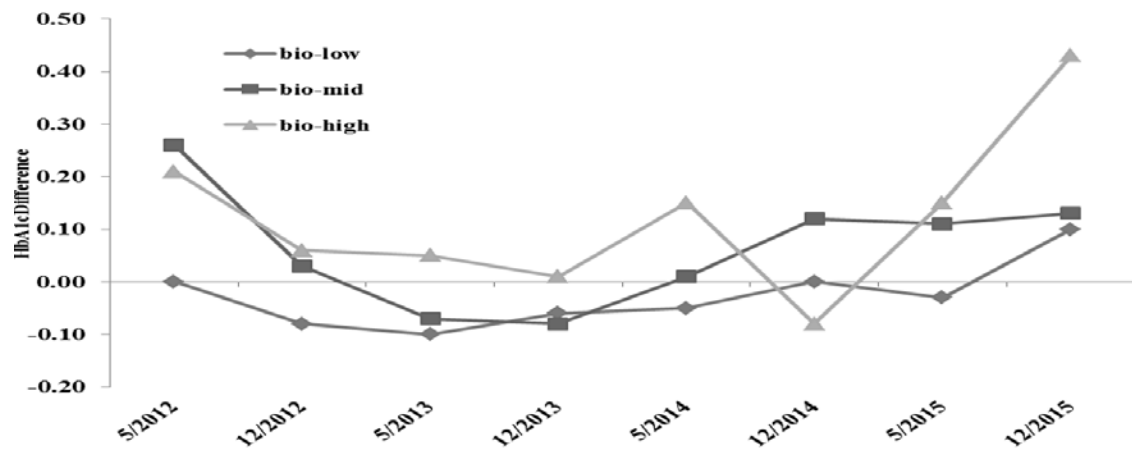
DCA Bias Compared to NGSP



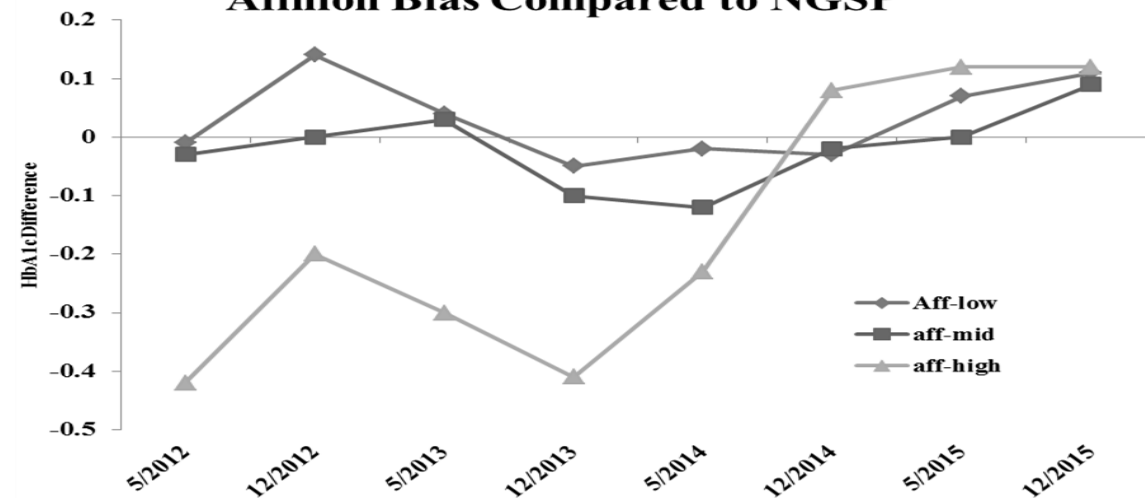
Tosoh G8 Bias Compared to NGSP



Bio-rad Variant II Bias Compared to NGSP



Afinion Bias Compared to NGSP



CONCLUSIONS

- Hemoglobin A1c Bias with POC techniques in the diabetes diagnostic range varied from -0.4% to 0.4%
- Hemoglobin A1c Bias with Central Lab techniques in the mid range varied from -0.1% to 0.5%.
- The Bias values varied widely over the three years

- POINT OF CARE TECHNIQUES ARE NO WORSE THAN CENTRAL LAB ASSAYS FOR MEASUREMENT OF HBA1C
- IT IS QUESTIONABLE WHETHER ANY SINGLE HBA1C MEASUREMENT BY ANY TECHNIQUE SHOULD BE USED TO MAKE A DIAGNOSIS OF DIABETES