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No disclosures
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 PREGANCY

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
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