

Dr Randi Little: Hello, I'm Dr. Randi Little, and I'm happy to join you today to discuss various topics of hemoglobin A1c measurement, standardization, and hemoglobin variants.

The purpose of the NGSP is to standardize and improve hemoglobin A1c results. This is the schematic view of the NGSP. We have a large network that includes 10 network laboratories in the US, the Netherlands, Japan, and China. The network is monitored monthly and is also monitored against the IFCC network twice yearly.

There are three basic processes, calibration, certification and proficiency testing. Calibration is a very informal process by which the NGSP can assist manufacturers and laboratories. Certification is a formal process whereby a manufacturer, or a laboratory completes a 40 sample comparison. The criteria for passing depends on the type of certification. 36 out of 40 results must be within plus/minus 5% for both manufacturer and level two laboratories. For level one lab certification, 37 out of 40 results must be within 5%. There's also a quarterly monitoring of level one laboratories.

The third and very important process is an accuracy based proficiency testing from the College of American Pathologist. This process is used to document the effectiveness of the NGSP. Almost 30 years after the DCCT, hemoglobin A1c measurement has improved from chaos in 1993 to the present order. Each panel shows a different proficiency testing sample for a particular survey. Each point and two SD error bar represents a different method. The dashed yellow line is the NGSP target value for each sample. You can clearly see improvement in both bias and variability since 1993. And as the NGSP tightened its certification criteria, the CAP has tightened their pass/fail limits. The table at the bottom, shows the carbs bonding cap limits at the time of each survey. Currently the cap limits are plus/minus 6%.