

First Nations Health and Social Secretariat of Manitoba - Diabetes Integration Project

The FNHSSM – Diabetes Integration Project (DIP) operates a mobile diabetes screening program that uses specially trained nurses for the "finger stick" blood testing of hemoglobin A1c, creatinine / eGFR, and for urine testing of microalbumin and creatinine.

CEQAL has assessed the analytical performances of the analyzers that are being used in this program. This assessment utilized human whole blood, serum and urine samples covering the clinical range of interest for the analytes in question. Reference and target values for the measurement of these analytes were assigned using approved reference methods. For HbA1c, the reference values were assigned by the DCCT reference laboratory at the University of Missouri. This laboratory operates the glycated hemoglobin A1c standardization program in the United States. The reference values for the creatinine were assigned using a JCTLM-listed isotope dilution gas chromatograph mass spectrometry methodology as carried out in the reference method laboratory at the University of Gent, Belgium.

Hemoglobin A1c is measured in whole blood using the Siemens DCA analyzer. The total error performance limit for this analyte has been set at target value +/- 9%. The urinary microalbumin / creatinine ratio is also being measured using the Siemens DCA analyzer. The total error performance limit for this test has been set at +/- 15% of target value. The day-to-day performance of these analyzers in the field is being monitored by an internal quality control (IQC) program with an assigned target value and pre-defined performance limits.

David W. Seccombe MD, PhD, FRCPC

wid Descente

Managing Director

dseccombe@ceqal.com

www.ceqal.com

www.cdc.gov/labstandards/crmln.html