



Certificate of Traceability

Level I Laboratory Certification

This certifies that Covance CLS Indianapolis, using Bio-Rad Variant II Turbo has participated in and successfully completed NGSP Level I Laboratory certification and is traceable to the **Diabetes Control and Complications Trial Reference** method. The comparison was performed with: University of Missouri SRL#9

The system evaluated was:

Instrument: Variant II Turbo	Calibrator Lot: BA10088, BA10089	Column Lot: 2100
Reagent Lot: AA10601, AA10602, AA02557	Calibrator Assigned Values: 5.4%, 10.4%	

Date of Certification: September 1, 2011

Certification Expires: September 1, 2012

David South

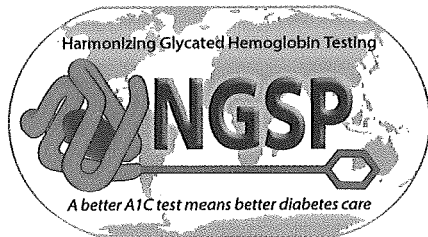
NGSP Steering Committee Chair

Randa R Little PhD.

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July 18, 2011

Michele Durham
Covance CLS Indianapolis
8211 Scicor Dr
Indianapolis IN 46219

Dear Dr. Durham,

Congratulations! We are pleased to inform you that Covance CLS Indianapolis has successfully completed the NGSP **Level I Laboratory** certification for the following method:

Instrument: Variant II Turbo	Calibrator Lot: BA10088, BA10089	Column Lot: 2100
Reagent Lot: AA10601, AA10602, AA02557	Calibrator Assigned Values: 5.4%, 10.4%	

The above method is now considered traceable to the Diabetes Control and Complications Trial (DCCT) Reference Method. Enclosed is a certificate of traceability for this method.

Following is a summary of the method comparison results. Detailed method comparison evaluation reports are also enclosed for your information.

Method	Assessment of Agreement CI; lower 95%, upper 95% (limit $\pm 0.70\%$)
Covance CLS Indianapolis, IN, VII Turbo	-0.30, 0.31

Column 2, Assessment of Agreement CI of diff, lower and upper 95%; (limit $\pm 0.70\%$):
95% Confidence Interval of the differences between methods (test method vs. SRL) must fall within the clinically significant limits of $\pm 0.75\%$ HbA1c for manufacturer methods and Level II Laboratory methods, $\pm 0.70\%$ for Level I Laboratory methods. **Your method's results were within the NGSP assessment of agreement criteria for Level I Laboratory Certification.**

This certification is effective for one year and will expire on September 1, 2012. All data for next year's certification should be received by July, 2012. Your next set of quarterly monitoring samples is tentatively scheduled for October.

If you have any questions about any of the data, please feel free to call. If you or your customers would like updated information about the NGSP (including a list of certified methods and laboratories) they can visit our web site at www.ngsp.org

Sincerely,

Randie R Little Ph.D.

Randie R. Little, Ph.D.,
NGSP Network Coordinator