NGSP Level I Laboratory Information Packet

LEVEL I LABORATORY CERTIFICATION

General Instructions: If a laboratory is interested in directly certifying their method as traceable to the Diabetes Control and Complications Trial Reference Method, the laboratory should contact the NGSP Network Coordinator:

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NGSP Network Coordinator
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1 Hospital Dr.
Columbia, MO 65212
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For Level I Certification, laboratories must perform a sample comparison with a Secondary Reference Laboratory (SRL) following the NGSP protocol. The certification process for Level I Laboratory Certification is the same as that for manufacturers but the certification criteria are more stringent. Level I laboratories are also monitored on a quarterly basis via the exchange of 10 fresh/frozen samples.

Before pursuing certification, laboratories should establish that their analytical instrument systems / methods:

- have had all required preventive maintenance procedures performed
- be operated with the same parameters in all runs of the comparison studies (e.g. instrument, reagent lot, calibrator lot, calibrator assigned values)
- **be operated in the same manner as it is routinely used in the laboratory**

All data should be sent by from the laboratory and from the SRL by e-mail directly to the NGSP Network Coordinator (above address).

Laboratories are awarded Certificates of Traceability for specific methods, reagent lots, calibrator lots, instrumentation, etc, if 37/40 of the individual results are within 5% of the SRL mean. Each certificate is effective for one year from the date of certification. In order to maintain continuous certification, the certification process has to be repeated each year. A detailed description of the certification and monitoring process and the certification and monitoring criteria can be found in the NGSP protocol.

Monitoring criteria are identical to those used for network laboratory monitoring (mean difference between laboratories $\leq$ 0.35% HbA1c, SD of the difference in sample replicates $\leq$ 0.229). Level I Laboratories must submit quarterly monitoring data within 2 weeks of receipt of monitoring samples and pass the criteria in order to maintain their certification status.

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DATA SHEET #A:

Laboratory Name: _____

Method / Manufacturer Name: _____

Contact person:
Address:
Phone:
FAX:
e-mail:

fill in all that apply to your method as used during the certification process:

Instrument

Program, Application, or Conversion Equation (if applicable)

Calibrator Lot #	**Assigned Value**

Reagent ID (e.g. buffers, hemolyzing reagents, reagent cartridges, etc)	**Lot #**

Sample collection Device Description (if other than that described by the assay method manufacturer)	**Lot #**

Column (HPLC cartridge) Lot #

****FOR RE-CERTIFICATION ONLY**** Desired date of certification

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METHOD COMPARISON AND BIAS ESTIMATION

For the method comparison, 40 samples are analyzed by both the laboratory and by the SRL; one set of fresh samples may be split and used to evaluate several applications or methods, thus necessitating only one evaluation of 40 samples by the SRL. Patient samples may be collected by either the laboratory or by the SRL as long as the protocol requirements and the sample stability requirements for both the SRL and the laboratory's method can be met.

Procedure:

1. Specimens (n=40) should be collected with values distributed over a clinically meaningful range, as close as possible to the following:
   20% from 5.0-6.0%
   30% from 6.0-7.0%
   30% from 7.0-8.5%
   20% from 8.5-10.0%
   The specimens do not necessarily have to be collected in a single day since they will be analyzed over a period of at least 5 days.
2. Keep whole blood samples frozen at –70°C or colder prior to analysis within 2 weeks of receipt of samples. Do **NOT** store samples at –20°C
3. Each specimen should be analyzed singly.
4. The analyses should be distributed in at least 5 runs on 5 separate days.
5. Follow the laboratory's routine quality control procedures during these analyses; repeat any run that is rejected.
6. Record data on Data Sheet #2

Special Instructions for Shipping WB Samples to an SRL for Certification

1. Be sure to collect samples in the HbA1c ranges outlined in the NGSP method comparison procedures:
   20% from 5.0-6.0%
   30% from 6.0-7.0%
   30% from 7.0-8.5%
   20% from 8.5-10.0%

   Samples must not have hemoglobin variants or HbF>2%, and a minimum of two extra samples should be included for each specified HbA1c range (total of 48 samples).

2. Label specimens clearly with waterproof pen. If possible, use consecutive numbers (1-40).

3. Pour well-mixed whole blood specimens into screw-cap vials (minimum volume 0.5 mL).

4. Place specimens in a divided specimen box in order according to specimen ID and freeze at –70^{o}C or colder.

5. Place box inside a zip-lock bag with absorbent material.

6. Place frozen specimen box/bag with dry ice in an insulated shipping carton.

7. Include a listing of specimens with your shipment; listing should follow the same order as the samples appear in the box. Specify "NGSP certification samples" and the SRL or method by which the samples should be analyzed. DO NOT include HbA1c results with your specimens.

8. For shipment within the US or Canada, ship priority overnight early in the week. For shipments outside the US, make arrangements with an appropriate courier. Notify the SRL of the date of shipment and anticipated date of specimen receipt.

Universal Precautions should be followed when collecting and handling any biological material of human origin. Federal and State regulations should be followed for handling, packaging, and shipping potentially biohazardous materials with regard to containment, labeling, and other procedures.

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DATA SHEET #2: METHOD COMPARISON & BIAS ESTIMATION

Method: _____ **Sheet #___ of ___**

Contact person:
Address:
Phone:
FAX:
e-mail:

Sample ID	Assay Date	Result

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QUARTERLY MONITORING

Procedure:

1. Specimens (n=10) over the desired clinical range (4-10%) are shipped to the laboratory.
2. Keep samples frozen at –70°C or colder prior to analysis within 2 weeks of receipt of samples. Do **NOT** freeze at –20°C.
3. Each specimen should be analyzed in two separate runs on two separate days.
4. Follow the laboratory's routine quality control procedures during these analyses; repeat any run that is rejected.
5. Enter data on-line at http://www.ngsp.org/mmon. Data must be received within 2 weeks of receipt of monitoring samples.

NOTE: Level I Laboratories must send in data and pass the quarterly monitoring criteria in order to maintain their certification status.

Universal Precautions should be followed when collecting and handling any biological material of human origin. Federal and State regulations will be followed for handling, packaging, and shipping potentially biohazardous materials with regard to containment, labeling, and other procedures.

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DATA SHEET #3: QUARTERLY MONITORING

Laboratory: _____

Method: _____

Contact person:
Address:
Phone:
FAX:
e-mail:

Sample ID	Assay Date	Day 1 Result	Assay Date	Day 2 Result	Comments

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Certification Schedule: Data can be sent anytime. For methods that pass the certification criteria, certificates will be issued within 2 months of receipt of data.

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Fee Schedule:

A. Basic Certification Protocol:

1. Exchange of 40 fresh blood specimens. These may be collected by the laboratory and shipped to the SRL or vice versa. There are additional charges if the specimens are collected by the SRL (see below).
2. Analyses by laboratory (single results) and duplicate analyses by the SRL
3. Laboratory provides method comparison data to Network Coordinator.
4. Data analysis by NGSP Administrative Core (NETCORE).
5. Analysis of 10 specimens shipped quarterly to the SRL.
6. Monitoring data analysis by the NETCORE.

Cost for certification and monitoring of one method = $5000.00

B. Additional Data Analysis (certification and monitoring) for Multiple Applications or Methods:

1. Data analysis
2. Quarterly monitoring

Cost for data analysis and quarterly monitoring for each additional application / method = $1000.00

C. Collection of Specimens or Additional Specimen Analysis:

1. Upon request, the SRL can provide patient specimens
2. Additional specimen analyses may be performed by the SRL

Cost of each specimen shipped by the SRL = $15.00 plus shipping charges
Cost for each additional duplicate specimen analysis by the SRL = $60.00

D. Special Sample Preparation

1. If dried blood spots are included as part of the certification, then the laboratory can either collect blood directly from patients via fingerstick or the SRL must spot blood and check the glucose level of spotted specimens.

Cost for each special sample preparation = $10.00. This is in addition to the cost of sample collection.

E. Payment: all fees for the above services should be paid to the SRL upon receipt of an invoice from the SRL.