

NGSP Level II Laboratory Information Packet

LEVEL II LABORATORY CERTIFICATION

General Instructions: If a laboratory is interested in 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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For Level II Laboratory Certification, laboratories must perform a sample comparison with a Secondary Reference Laboratory (SRL) following the NGSP protocol. The certification process and certification criteria for Level II Laboratory Certification are the same as that for manufacturers.

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 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 6% 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 process and the certification criteria can be found in the NGSP protocol.

LEVEL II LABORATORY CERTIFICATION

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 # |
|---|-------|
| | |
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| Sample collection Device Description (if other than that described by the assay method manufacturer) | Lot # |
|--|-------|
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|--------------------------------------|
| Column (HPLC cartridge) Lot # |
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|--------------------------------------|
| **FOR RE-CERTIFICATION ONLY** |
| Desired date of certification |
| |

LEVEL II LABORATORY CERTIFICATION

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. Samples received on dry ice should be stored at -70°C or colder prior to analysis. 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>5%, 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°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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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 manufacturer or designated 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. Manufacturer provides method comparison data to Network Coordinator.
4. Data analysis by NGSP Administrative Core (NETCORE).

Cost for certification of one method = \$3500.00

B. Additional Data Analysis for Multiple Methods:

1. Data analysis

Cost for data analysis for each additional application / method = \$350.00

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 analyzed by the SRL = \$60.00

D. Special Sample Preparation

1. If dried blood spots are included as part of the certification, then the manufacturer 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.