

NGSP Manufacturer Information Packet

MANUFACTURER CERTIFICATION

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

Randie R. Little, Ph.D.
NGSP Network Coordinator
Department of Pathology & Anatomical Sciences, Rm. M767
University of Missouri School of Medicine
1 Hospital Dr.
Columbia, MO 65212
phone: 573-882-1257
FAX: 573-884-4748
e-mail: LittleR@health.missouri.edu

For certification, manufacturers must perform a sample comparison with a Secondary Reference Laboratory (SRL) following the NGSP protocol.

When testing specimens for certification, manufacturers need to insure that their analytical instrument systems / methods:

- have had all required preventive maintenance procedures performed
- are operated with the same parameters (e.g. instrument, reagent lot, calibrator lot, calibrator assigned values) in all runs of the comparison studies
- **are operated in the same manner as they would by a customer. This includes the use of calibrator and reagent lots that are available to end-users, as well as the use of software parameters and calibrator value assignments that are provided to end-users.**

Manufacturers may perform the comparison analyses at the manufacturing site or they may choose to have a laboratory that is not an NGSP network laboratory using their system perform the testing. All data should be sent from the manufacturer and the SRL directly to the NGSP Network Coordinator by e-mail (above address). **Along with these results, the manufacturer may be asked to submit raw data that includes date, time, and results for each of the 40 samples. Therefore, these data should be collected when the samples are analyzed.**

Manufacturers are awarded Certificates of Traceability for specific reagent lots, calibrator lots, instrumentation, etc, if 36/40 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 process and certification criteria can be found in the NGSP protocol.

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DATA SHEET #A:

Method Name (exact name that will be used for the certificate): _____

Manufacturer Name: _____

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

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

Instrument

Method availability (check one)
<input type="checkbox"/> Method IS currently on the market
<input type="checkbox"/> Method IS NOT currently on the market

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 the usual method described in the package insert)	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 manufacturer (or designated 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 manufacturer or by the SRL as long as the protocol requirements and the sample stability requirements for both the SRL and the manufacturer'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>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°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 manufacturer (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 Applications or 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 manufacturer fees for the above services should be paid to the SRL upon receipt of an invoice from the SRL.