

Summary of NGSP Manufacturer Certification _ ASRL#1 (ReCCS), Japan

Purpose: For a Certification of a method as traceable to the Diabetes Control and Complications Trial (DCCT) Reference Method, manufacturers must perform a sample comparison with a Second Reference Laboratory (in the case ASRL#1) following the NGSP Protocol.

The specimens are shipped frozen on dry ice. Keep them in a freezer at a temperature below -70°C.

Specimens (n = 40) Characteristics:

Origin:	Human
Contents:	Type A: Hemolysed erythrocytes in a physiological solution (not including plasma). Volume of each Type A specimen is 0.1mL. Type B: Separated and concentrated red cells (not including plasma). Volume of each Type B specimen is 0.05mL. Type C: Hemolysed whole blood. Volume of each Type C specimen is 0.1mL.
Total Hb concentration:	Type A: approximately 10~15 g/dL Type B: approximately 30 g/dL Type C: approximately 10~15 g/dL

Precautions:

1. For *in vitro* diagnostic use only.
2. Specimens should be handled with care as handling any biological material of human origin.
3. Take the vials from the freezer and thaw the samples at room temperature. After the sample has been thawed, mix it carefully. Centrifuge the vial (together with other vials) at 600xg for about 1 min to collect the sample at the bottom of the vial. Use the samples for measurement within 2 hours after thawing.
4. Then you should dilute the samples manually or automatically so that the total Hb concentration of the diluted sample satisfies that required by your analytical system/method.

Procedure:

1. At NGSP Home Page <https://ngsp.org/protcert.asp> is written:
“Before pursuing certification through the SRL, manufacturers should establish that their analytical instrument systems / methods:

have had all required preventive maintenance procedures performed
be in peak operating condition
be operated with the same parameters in all runs of the comparison and precision studies (e.g. instrument, reagent lot, calibrator lot, calibrator assigned values)
be operated in the same manner as they would by a customer.”
2. **Single measurement of each specimen** is run for 40 specimens where the 40 assays should be distributed in at least 5 runs on 5 separate days.
3. Be sure to collect raw data including either raw data printout copies (including date/time/results) or photos (e.g. in the case of some POC methods) showing screen results that include date, time and results.
4. Follow the laboratory’s routine quality control procedures during these analyses.
5. Record data on Data Sheet 2 at the Manufacturer Data Sheets. Please, follow the instructions written there. For obtaining the sheets, please visit <https://ngsp.org/packets.asp>
<https://ngsp.org/cert/Manuf0814.xls>
<https://ngsp.org/cert/Manufinfo1221.pdf>
6. Please send the filled Manufacturer Data Sheets to both e-mails:
LittleR@health.missouri.edu (Dr. Randie R. Little, NGSP Network Coordinator)
ngspd@reccs.net (Office of NGSP ASRL#1)

The POCT manufacturers must send the raw data along with their data sheets.

The raw data must include “date, time, and results for each of the 40 samples. Therefore, these data should be collected when the samples are analyzed.” <https://ngsp.org/protcert.asp>

Important notes:

- ① The pre-calibration test using Pre-Calibration Test material for NGSP certification JCTCM 430 is at your choice.

In order to check the bias of your system, prior to the certification test, we recommend **manufacturers** to calibrate or check their calibrators' values using Pre-Calibration Test material for NGSP certification.

Regarding **Level I, II Laboratories**, the calibration test is not prerequisite, but we recommend them to undergo the pre-calibration test.

The Pre-Calibration Test material for NGSP Certification JCTCM 430 consists of 10 vials, HbA1c levels ranging from 5 to 11%.

For manufacturers:

If your bias is over 0.2% HbA1c, your calibrator values should be corrected to produce non-bias values. If you correct your calibrator to pass the certification test, the corrected values should be assigned to your calibrator and the correction should be notified to end-users.

If the amount of correction is less than <0.2% HbA1c, the correction is at your choice.

Unless you take the pre-calibration, go forward to (6).

- ② We will usually prepare hemolyzed 40 samples which we will send you on dry ice.

※ **If your system has a problem with hemolyzed material, let us know immediately.**

- ③ We will send you an Proforma Invoice (see below point (3) after receiving your "Data Sheet A" of the file Manuf0814.xls (1).

- ④ The certification testing fee and samples cost should be billed when the samples have been shipped whether your method is certified or not.

[NGSP Certification Procedure_ASRL#1]

- (1) Fill in the "Data Sheet A" of the file Manuf0814.xls (1) and send it to us, ASRL#1(ngspdata@reccs.net).

- (2) Shipping schedule of samples is informed. (←After receiving your reply, we will inform you of shipping schedule.)

- (3) Along with (2) Proforma Invoice is sent. The price of NGSP Manufacturer Certification is \$3500, each additional application/method price is \$350. One set of certification samples price is \$600. The price of one set of Pre-Calibration Test material for NGSP Certification JCTCM 430 is \$600. Shipping fee and handling fee for bank transfer are also included.

- (4) After shipping the samples, Invoice is sent. Please, pay for the Invoice as soon as possible.

- (5) If you decide to undergo the pre-calibration test, the Pre-Calibration Test material for NGSP certification JCTCM 430 **will be shipped prior** to the 40 specimens for NGSP certification.

※ The pre-calibration test prior to NGSP certification is at your choice.

If you would like to take the pre-calibration test, please let us know your reply by return.

For manufacturers: "If your bias is over 0.2% HbA1c your calibrator values should be corrected to produce non bias values and the correction should be notified to end-users."

If you would **not** like to take the pre-calibration test, you can proceed to the step (8).

- (6) Assay the Pre-Calibration Test Material (JCTCM 430). These results shall be reported **only** to ASRL#1 (v-raneva@reccs.net) using (2) Data Sheet for Pre-Calibration Test.xls

- (7) The results of the pre-calibration test are informed. If the bias is over 0.2 HbA1c %, we recommend that you should correct your system or the assigned values of your calibrator and to communicate the changes to the end-users.

- (8) Assay 40 specimens, and report your values to both Dr. R. Little LittleR@health.missouri.edu and ASRL#1 ngspdata@reccs.net simultaneously, using the file (1) Manuf0814.xls

(9) NGSP Certificate is issued by the NGSP NETCORE.

(1)~(9) takes about one and half months if the samples are shipped soon after application.

Attached:

- (1) Manuf0814.xls: including “Data Sheet A” as the application form
- (2) Data Sheet for Pre-Calibration Test.xls

Inquires at:

ASRL#1

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