

# 【Summary of NGSP Certification and Procedure\_ASRL#1】

Reference Material Institute for Clinical Chemistry  
Standards

Reference Laboratory, ReCCS (ISO 15195, ISO 17025)

## 【NGSP Certification Procedure\_ASRL#1】

- (1) Fill the “Data Sheet #A” and send it to us, ASRL#1([ngspdata@reccs.net](mailto:ngspdata@reccs.net)).
  - (2) Shipping schedule of samples is informed. (← After receiving your reply, we will inform you of the shipping schedule.)
  - (3) The pre-calibration test material and the 40 specimens for NGSP certification are shipped **separately**.  
Keep those at a temperature lower than  $-70^{\circ}\text{C}$ .  
※The pre-calibration test is at your choice.  
If you would like to take the pre-calibration test, please let us know your reply by return.  
If you would **not** like to take the pre-calibration test, you can proceed to the step (6).
  - (4) Assay the pre-calibration test material for NGSP certification and report your values to [ngspdata@reccs.net](mailto:ngspdata@reccs.net).
  - (5) The results of the pre-calibration test are informed. If the bias is over 0.2% HbA1c, you should correct your system or the assigned values of your calibrators, and communicate the changes to the end-users.
  - (6) Send the application e-mail for NGSP Certification to Dr. Randie R. Little [LittleR@health.missouri.edu](mailto:LittleR@health.missouri.edu) and ASRL #1 [ngspdata@reccs.net](mailto:ngspdata@reccs.net)
  - (7) Assay 40 specimens, and report your values to both Dr. R. Little [LittleR@health.missouri.edu](mailto:LittleR@health.missouri.edu) and ASRL#1 [ngspdata@reccs.net](mailto:ngspdata@reccs.net) simultaneously using the respective data sheets.  
You can download the data sheets from “Type of NGSP Certification” at [NGSP Certification | Reference Material Institute for Clinical Chemistry Standards \(ReCCS\)](#)
- Or you can download the data sheets from [NGSP Cert Packets](#)
- (8) NGSP Certificate is issued by NGSP NETCORE.

### The points are :

- (1) Pre-calibration test material for NGSP certification

We offer pre-calibration test material for NGSP certification which consists of 10 vials with HbA1c levels ranging from 5% to 11%.

We recommend **manufacturers** to check their calibrators' values using the pre-calibration test material **prior** to NGSP certification. If their bias is over 0.2% HbA1c, the manufacturers should calibrate their values in a way to produce non-bias values.

If the manufacturers correct their calibrator values to pass the certification test, the corrected values should be assigned to their calibrators and the manufacturers should communicate the changes to the end-users. If the amount of correction is less than  $<0.2\%$  HbA1c, the correction is at manufacturer's choice.

**Level I and Level II Laboratories** can use the pre-calibration test material for NGSP certification in order to check if their analytical instrument systems / methods are operated correctly **prior** to NGSP certification.

- (2) We usually prepare 40 hemolyzed samples shipped on dry ice.

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

- (3) We will send you an invoice after receiving your “Data Sheet #A” .

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