2023 External Quality Assurance (EQA) Program for Neonatal G6PD Dried Blood Spot Screening Test

I. Introduction

Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing "EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Dried Blood Spot Screening Test" using dried blood spot samples collected on filter paper for newborn screening centers since 1999. This EQA program has been officially accredited by Taiwan Accreditation Foundation (TAF, a member of ILAC Mutual Recognition Arrangement Signatories) for conformity to ISO/IEC 17043:2010 since 2017. More than 50 laboratories (including reagent manufacturer QA laboratories) worldwide (AT, BE, CN, DE, FI, GR, IN, MX, PH, TH, TR, TW, and VN etc.) have participated in the EQA program at present time.

II. General information

1. Contact information

Ms. Laura Fan, Program Manager

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Phone：+886-2-27036080

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2. Subcontract laboratory for determination of G6PD activities for evaluation of the homogeneity and stability of the quality control (QC) samples

a) Chinese Foundation of Health, Taipei

Address：5F., No.55, Dongxing Rd., Taipei City 105, Taiwan (R.O.C.)

Phone：+886-2-87681020

b) Taipei Institute of Pathology

Address：No.146, Sec.3, Chongqing N. Rd., Taipei City 103, Taiwan (R.O.C.)

Phone：+886-2-85962065

3. Eligibility criteria for participation

a) Newborn screening laboratories；

b) Manufacturer QA laboratories.

4. Schedule for 2023

Three EQA surveys for G6PD screening test are scheduled in 2023 (10 QC samples per survey).

No.	Survey No	Scheduled Survey Starting Date *	Scheduled Reporting Deadline* (Domestic)	Scheduled Reporting Deadline* (Overseas)
1	NS2023-01	02/13	02/16	02/23
2	NS2023-02	05/29	06/01	06/08
3	NS2023-03	09/11	09/14	09/21

* Date: Month/Day

a) As the ongoing COVID 19 pandemic has caused worldwide delays in shipping. If overseas participants cannot receive the QC samples before the reporting deadline, the reporting deadline will be postponed for another 5 days.

b) If an overseas participant cannot receive the QC samples within 15 days after the Survey Starting Date, the result of the participant will not be included in the statistics of that survey. But the annual participation record of the participant will not be affected.

5. QC samples

a) The QC samples were prepared by spotting human whole blood (no extra G6PD added) on Whatman 903 filter paper ("UNION" Newborn Screening Quality Control Material, Medical Device Registration No.: MOHW-MD-(I)-No.004754)；

b) Analyte : G6PD (report the screening final decision : “Positive” or “Negative”)

c) The G6PD activity of the QC samples conforms to the activity range required for neonatal screening;

d) All of the blood materials used to produce QC samples have been tested and were found negative for HBsAg, Anti-HCV, STS (RPR or TPPA), HIV-1/HIV-2 /HIV-O Ab, HIV p24 antigen, and Anti-HTLV. However, presence of these or other infectious agents cannot be excluded absolutely and therefore the QC samples should be treated as potential biohazards in use and for disposal ;

e) The homogeneity and stability of the QC samples met the acceptance criteria set by QAP center, which conformed to the ISO requirements for proficiency testing (ISO/IEC 17043:2010) .

6. Requirements of G6PD screening test used by participants

a) Using dried blood spots collected on filter paper as test samples ;

b) Using cut-off values for newborns ;

c) Both qualitative and quantitative methodologies are acceptable.

7. Result analysis

7.1 Consensus Results of screening final decisions (“Positive” or “Negative”) made by participants will be analyzed.

7.2 The repeatability of each participant who used quantitative test will be analyzed when there are more than 2 QC samples from the same lot in one survey. Repeatability is expressed as the analytical Coefficient of Variation (CV) of QC samples from the same lot.

8. Assigned Value

The Assigned Value will be the consensus decision of the same lot QC samples from more than 75% participants.

9. Evaluation criteria

9.1 The evaluation criteria for measurement result of "each QC sample "

a) Acceptable：Neither False Positive (FP) nor False Negative (FN) ;

b) Unsatisfactory：False Positive (FP) or False Negative (FN).

c) Not evaluated：For example, when no assigned value could be set.

9.2 The performance evaluation criteria for participant survey report

a) Acceptable : all results are acceptable ;
b) Acceptable with caution : only one result is unsatisfactory ;
c) Unsatisfactory : more than one result are unsatisfactory.

10. Reports provided by PMF QAP center

a) Summary Report of EQA Survey for Neonatal G6PD Screening Test；
b) Participant Report of EQA Survey for Neonatal G6PD Screening Test；
c) The a) and b) reports will be provided to participants in electronic file format. If you would like to request hard copy of the reports, please contact us.

11. Annual Summary

The Annual Summary of EQA Program will be published online.

12. Confidentiality

The participant (individual laboratory) report is confidential, and will only be released to individual laboratory and the authority concerned. Every participant is shown by its unit code on the disclosed summary reports of EQA Surveys.

13. Delivery and reissue of the QC samples

13.1 QC samples will be sent by express delivery (e.g. FedEx, UPS, DHL etc.).

13.2 When dirt on the dried blood spots of the QC samples is found, take a photo of the QC samples and email to QAP center immediately. The QAP center will re-send the QC samples as soon as possible.

13.3 The reporting deadline will not be extended for those QC samples re-sent, the result need to be reported in time.

14. Proof of participation

14.1 Proof of participation letter

a) “Proof of Participation Letter” is issued annually；

b) All participants will receive this letter to prove that they have participated in which survey(s) of the year and reported results in time.

14.2 Certificate of participation

a) "Certificate of Participation" is issued annually；

b) The certificate is issued to whom has participated in all the surveys of the year and reported results in time；

c) If the participates already have a certificate from previous year, an annual certification label will be issued only.

15. Application for participation

To apply for participating in "2023 External Quality Assurance (EQA) Program for Neonatal G6PD Screening Test", please download the application form from the website < *https://g6pd.qap.tw/pdf/R409010101G6Nen.pdf* >, or contact us to request the application form. Participants who have already enrolled before 2023 do not need to apply again.

16. Charge

This program is free of charge for all the participating laboratories in 2023. But the commercial laboratories need to pay the sample shipping fee to couriers.

17. Complain and suggestion

17.1 Participants or related parties may make a complaint or suggestion to PMF QAP center regarding the EQA programs or the services provided by PMF QAP center.

17.2 If you are dissatisfied with our service and would like to make a complaint or suggestion, you may call us on: +886-2-27036080. Alternatively you may send us your comments and complaints via email < g6pd@g6pd.tw / g6pdqa@gmail.com > or Fax (+886-2-27036070). Anonymous complaints will not be considered.

18. Appeal

18.1 Participants may appeal against the evaluations of EQA surveys to PMF QAP center within 30 days after received the EQA survey reports.

18.2 A formal appeal must be submitted in written form (with contact information) within 30 days after received the EQA survey reports. Anonymous appeals will not be considered. The formal written appeal may be submitted via email < g6pd@g6pd.tw / g6pdqa@gmail.com >or Fax (+886-2-27036070) to PMF QAP center.

19. Changes of data or information

If participants would like to change data or institution information, please download the application form from the website < *https://g6pd.qap.tw/pdf/R406010103G6Nen.pdf* > , or contact us to request the application form.