2017 External Quality Assurance (EQA) Program for Neonatal G6PD Screening Test

I. Introduction

Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has provided "EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Screening Test" for newborn screening centers since 1999. This EQA program was the first international EQA program for Neonatal G6PD Screening Test. Fifty-one screening laboratories (including 4 reagent manufacturers) from 15 countries and regions (AU, CH, CN, DE, FI, GR, IN, LB, MX, PH, TH, TR, TW, US, VN) have participated in the EQA program in 2016.

II. General information

1. Contact information

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

a) Chinese Foundation of Health, Taipei, Taiwan (R.O.C.) (ISO 15189 certified)

5F., No.55, Dongxing Rd., Songshan District,

Taipei City 105, Taiwan (R.O.C.)

Phone：+886-2-8768-1020

b) Taipei Institute of Pathology (ISO 15189 certified)

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Taipei City 103, Taiwan (R.O.C.)

Phone：+886-2-8596-2065

3. Eligibility criteria for participation

a) Newborn screening centers assigned by Health Promotion Administration, Ministry of Health and Welfare, Taiwan；

b) Overseas newborn screening laboratories.

4. Schedule for 2017

Six EQA surveys for screening test are scheduled in 2017 (10 QC samples per survey)

No.	Survey No	Scheduled Shipping Date *	Scheduled Survey Starting Date *	Scheduled Reporting Deadline* (Domestic)	Scheduled Reporting Deadline* (Foreign)
1	NS2017-01	01/09	01/09	01/12	01/16
2	NS2017-02		03/06	03/09	03/13
3	NS2017-03	05/08	05/08	05/11	05/15
4	NS2017-04		07/03	07/06	07/10
5	NS2017-05	09/04	09/04	09/07	09/11
6	NS2017-06		11/06	11/09	11/13

* Date: MM/DD

5. QC samples

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

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

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

d) All of the QC samples have been tested and were found negative for HBsAg, Anti-HCV, STS (RPR), HIV-1/HIV-2 Ag/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 QC samples conform to the

requirements of ISO17043.

6. Requirements of G6PD screening test used by participants
   a) Using dry 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
   Consensus results of decisions (“Positive” or “Negative”) made by participants will be analyzed.

8. The assigned value will be the consensus decision 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).
   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) Summary Report of EQA Survey on website < http://g6pd.qap.tw > ；
   d) Annual report.

11. The participant (individual laboratory) report is confidential, 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.

12. Reissue of the QC samples
   12.1 When dirt on the dry blood spots of the QC samples is found, please

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.

12.2 The reporting deadline will not be extended, please report the result in time.

13. Proof of participation

13.1 Proof of participation letter：

a) In principle, "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.

13.2 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.

14. To apply "2017 External Quality Assurance (EQA) Program for Neonatal G6PD Screening Test", please download the application form on our website < http://g6pd.qap.tw/app_doc_en.htm >, or contact us to request the application form. Participants who have already enrolled before 2017 do not need to apply again

15. This program is free of charge for all the participating laboratories in 2017. But the commercial laboratories need to pay the sample shipping fee to couriers.

16. Complain and suggestion

16.1 Participants or related parties may make a complaint and/or suggestion to PMF QAP center for the EQA programs or the service provided by PMF QAP center.

16.2 If you would like to make a complaint and/or suggestion, you may call us on: +886-2-2703-6080. Alternatively you may send us your comments and/or complaints to g6pd@g6pd.tw. Anonymous complaints will not be considered.

17. Appeal

17.1 Participants may appeal against the evaluation of EQA survey to PMF QAP center within 30 days after received the EQA survey reports.

17.2 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. You may submit the formal appeal via email < g6pd@g6pd.tw > or Fax (+886-2-27036070) to PMF QAP center.

18. If participants would like to change data or other laboratory information, please download the application form on our website < http://g6pd.qap.tw/app_doc_en.htm >, or contact us to request the application form.