2017 External Quality Assurance (EQA) Program for G6PD Quantitative Test in Philippines

I. Introduction

Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has provided "EQA Program for Glucose-6-Phosphate Dehydrogenase (G6PD) Quantitative Test" for G6PD confirmatory laboratories in Taiwan since 1988. This EQA program has been adopted by Newborn Screening Reference Center (NSRC) in the Philippines since 2009. Twenty-four G6PD confirmatory laboratories in the Philippines 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

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3. Collaborative institution

NSRC, Manila, Philippines
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4. Eligibility criteria for participation

G6PD confirmatory centers assigned by NSRC, Manila, Philippines.

5. Schedule for 2017

Four EQA surveys for G6PD quantitative test are scheduled in 2017 (3 QC samples per survey)

No.	Survey No	Scheduled Shipping Date*	Scheduled Reporting Deadline*
1	RH2017-01	02/13	02/20
2	RH 2017-02	04/17	04/24
3	RH 2017-03	07/03	07/10
4	RH2017-04	10/16	10/23

* Date: MM/DD

6. QC samples

a) The QC samples (Medical Device Registration No.: MOHW-MD-(I)-No.004851) were lyophilized hemolysate prepared from human red blood cells with no extra G6PD added；

b) Analyte : G6PD (U/gHb);

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

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.

7. Requirements of G6PD quantitative test used by participants

a) Using "Enzyme Kinetic Method" (kinetic at 37℃) to determine G6PD activity ;

b) All quantitative methodologies for Hb are acceptable.

8. Terms, definitions, and statistic methods

8.1 The assigned value (Xa) = the median of all the results reported for this QC sample.

8.2 Uncertainty of the assigned value (u_{Xa}) = (Factor x SD) / (n)$^{1/2}$ (according to ISO 13528:2015 Section 7.7). The coverage factor = 1.1 will be used in this survey.

8.3 SD for proficiency assessment (σ_p) = 7% x Xa ; but when Xa < 2.9 U/gHb , σ_p = 0.2 U/gHb.

8.4 Adjusted SD for proficiency assessment (σ_p') = ($\sigma_p^2 + u_{Xa}^2$)$^{1/2}$, σ_p' is used for proficiency assessment when $u_{Xa} \geq 0.3\sigma_p$. (ISO 13528:2015 Section 9.5)

8.5 *D*% = [(X – Xa) / Xa] x 100% ; X = Your Results , Xa = Assigned Value.

8.6 *z* score = D / σ_p ; D = X–Xa , σ_p = SD for proficiency assessment.

8.7 Maximum Allowable Deviation (MAD) = 3 x (σ_p / Xa) x 100% or 3 x (σ_p' / Xa) x 100% when $u_{Xa} \geq 0.3\ \sigma_p$.

8.8 Robust results (Mean and SD) were calculated by Algorithm A according to ISO 13528:2015.

8.9 SDI = (X – Mean) / SD ; SD = standard deviation of peer group ; SDI is not calculated when SD equals 0.

9. Evaluation criteria

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

a) Acceptable : $|z| \leq 2$;

b) Caution : $2 < |z| \leq 3$;

c) Unsatisfactory : $|z| > 3$.

9.2 The performance evaluation criteria for participant survey report:

a) Acceptable：all results | z | < 3 and more than two results | z | ≤ 2；
b) Acceptable with caution：only one result | z | > 3 or more than two results 2 < | z | ≤ 3；
c) Unsatisfactory：more than two results | z | > 3.

10. Reports provided by PMF QAP center

a) Summary report of EQA survey for G6PD quantitative test；
b) Participant report of EQA survey for G6PD quantitative test；
c) Summary report of EQA survey on website
< http://g6pd.qap.tw/phi.htm >；
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. Proof of participation

12.1 Proof of participation letter：


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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.

12.2 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.

13. To apply “2017 External Quality Assurance (EQA) Program for G6PD

Quantitative Test in Philippines”, please contact us or NSRC to request the application form. Participants who have already enrolled before 2017 do not need to apply again

14. This program is free of charge for all the participating laboratories in 2017.

15. Complain and suggestion

15.1 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.

15.2 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.

16. Appeal

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

16.2 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.

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