2022 External Quality Assurance (EQA) Program for G6PD Blood Quantitative Test in Philippines

I. Introduction

Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing " EQA Program for Glucose-6-Phosphate Dehydrogenase (G6PD) Blood 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. More than 28 G6PD confirmatory laboratories in the Philippines have participated in the EQA program at the present time. 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.

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) Union Clinical Laboratory (ISO 15189 and CAP certified)
1F., No.33, Ln. 151, Sec. 2, Fuxing S. Rd., Taipei City 106, Taiwan (R.O.C.)

Phone：+886-2-27049980

b) Taipei Institute of Pathology （ISO 15189 certified）

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3. Collaborative institution

NSRC, Manila, Philippines

Contact information

Ms. Maria Truda Dizon- Escoreal

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4. Eligibility criteria for participation

G6PD confirmatory laboratories designated by NSRC, Manila, Philippines.

5. Schedule for 2022

Three EQA surveys for G6PD quantitative test are scheduled in 2022（3 QC samples per survey）.

No.	Survey No	Scheduled Shipping Date*	Scheduled Reporting Deadline*
1	RH2022-01	02/21	02/28
2	RH2022-02	05/23	05/30
3	RH2022-03	09/12	09/19

* Date: Month/Day

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/g Hb) ;

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

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 QC samples conform to the requirements of ISO/IEC 17043:2010.

7. Requirements of G6PD quantitative test used by participants

a) To determine G6PD activity by " Enzyme Kinetic Method " (at 37℃) with the reagents using the maleimide inhibition method (Deutsch J. Clin Chem 1978; 24: 885-9) or a similar reaction principle ;

b) All routine quantitative methodologies for Hb used in the participating laboratories 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/g Hb , σ_p = 0.2 U/g Hb.

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

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

8.9 Repeatability of each laboratory will be analyzed when there are more than 1 QC samples from the same lot in one survey, and it is calculated as the ratio of " difference of the measurement results of QC samples from the same lot " to the " average of the measurement results of QC samples from the same lot ", expressed as a percentage (Δ%). $\Delta\% = \{ |(X_1-X_2)| / [(X_1+X_2) / 2] \} \times 100\%$.

8.10 Coefficient of Variation Ratio (CVR) = Individual CV / Mean of All Individual CVs.

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 one result $|z| \leq 2$;
b) Acceptable with caution : only one result $|z| > 3$ (other results $|z| < 3$) or more than one result $2 < |z| \leq 3$;
c) Unsatisfactory : more than one result $|z| > 3$.

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 ;
d) Annual report (announced on website).

11. 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.

12. Delivery of the QC samples

QC samples will be sent to participating laboratories via express delivery (e.g. FedEx, UPS, DHL etc.) by NSRC, Manila.

13. Proof of participation

13.1 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.

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 participants already have a certificate from previous year, an annual certification label will be issued only.

14. Application for participation

To apply for participating in " 2022 External Quality Assurance (EQA) Program for G6PD Quantitative Test in Philippines " , please download the application form from the website < *https://g6pd.qap.tw/pdf/R409010101G6Ren.pdf* >, or contact us or NSRC to request the application form. Participants who have already enrolled before 2022 do not need to apply again.

15. Charge

This program is free of charge for all the participating laboratories in 2022.

16. Complain and suggestion

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

16.2 If you would like to make a complaint and/or suggestion, you may call us on: +886-2-27036080. Alternatively you may send us your comments and/or complaints via email < g6pd@g6pd.tw / g6pdqa@gmail.com > or Fax (+886-2-27036070). 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. The formal written appeal may be submitted via email < g6pd@g6pd.tw / g6pdqa@gmail.com >or Fax (+886-2-27036070) to PMF QAP center.

18. Changes of data or information

If participants would like to change data or laboratory information, please download the application form from the website < *https://g6pd.qap.tw/pdf/R406010103G6Ren.pdf* >, or contact us to request the application form.