Annual Summary of External Quality Assurance Survey for G6PD Blood Quantitative Test in Philippines (2023)

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(2023)

1. 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. In cooperation with PMF QAP Center, the Newborn Screening Reference Center (NSRC) Manila, has adopted this EQA program for the newborn screening referral hospitals in the Philippines since 2009. This EQA program has been officially accredited by Taiwan Accreditation Foundation (TAF, a member of ILAC Mutual Recognition Arrangement Signatories) for conformity to international standard ISO/IEC 17043:2010 since 2017 (Accreditation No.：P016) and was extended the certification on December 30, 2022.

財團法人全國認證基金會
Taiwan Accreditation Foundation

Certification Accreditation

(Certificate No：P016-221230)

This is to certify that

Preventive Medicine Foundation
Preventive Medicine Foundation QAP Center
6F., No.182, Sec. 1, Da'an Rd., Da'an Dist., Taipei City 10684, Taiwan (R.O.C.)

is accredited in respect of Proficiency Testing Provider

Accreditation Criteria ： ISO/IEC 17043:2010
Accreditation Number ： P016
Originally Accredited ： December 13, 2017
Effective Period ： December 30, 2022 to December 29, 2027
Accredited Scope ： Proficiency testing provider, see described in the Appendix

Ching-Chang Lien
Ching-Chang Lien
President, Taiwan Accreditation Foundation
December 30, 2022

P1, total 2 pages.
The Appendix forms an integral part of this Certificate, which shall be invalid when use without the Appendix

Figure 1. Certification Accreditation (Certificate No：P016-221230)

2. Participants

Thirty-one G6PD confirmatory laboratories have participated in the EQA program in 2023. (Fig. 2 and 3)

Fig. 2. Distribution of participating laboratories in Philippines. (● Participating laboratory, n=31)

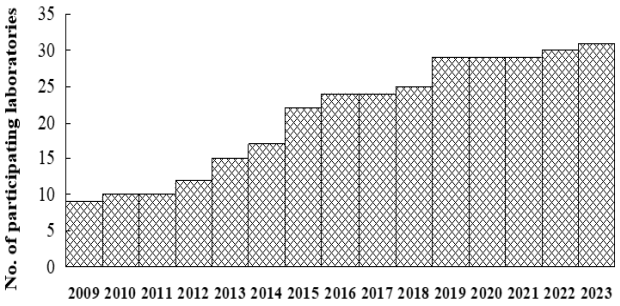


Fig. 3. Number of participating laboratories in Philippines (2009 ~ 2023)

3. Quality Control Sample (QC Sample)

3.1 Three QC samples were used in each survey.

3.2 The QC samples were lyophilized hemolysate prepared from human red blood cells with no extra G6PD added. (Taiwan IVD Register. No.: MOHW-MD-(I)-No.004851)

3.3 The homogeneity and stability of QC samples conform to the requirements of the international standard ISO/IEC 17043:2010.

4. Surveys

4.1 There were three EQA surveys performed in 2023. (Table 1).

Table 1. 2022 EQA survey schedule

No.	Survey No	Shipping Date*	Reporting Deadline*	Survey Result Released*
1	RH2023-01	02/13	02/20	03/02
2	RH2023-02	05/29	06/05	06/13
3	RH2023-03	09/18	09/25	09/28

* Date: MM/DD

4.2 In 2023, 91 sets of QC samples were sent to participants, 91 (100%) reports were returned.

4.3 Most laboratories received the QC samples within 1 ~ 3 days (median = 2 days) after samples were sent out when the survey started.

4.4 More than 42.9% of the participants, which were less than previous years, reported that dry ice was sublime completely when they received the QC samples. However, there is no unsatisfactory report this year.

4.5 The reports returned time was between 1 and 8 days (median = 7 days) after the survey started. Eighty-eight (96.7%) reports were returned within the target time (7 calendar days after the survey started).

4.6 The survey summary reports were released on the website between 3 and 6 working days after reporting deadline, which conformed to the target time (7 working days after reporting deadline).

5. Evaluation Criteria

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

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

5.3 Adjusted SD for proficiency assessment (σ_p') = ($\sigma_p^2 + u_{Xa}^2$)$^{1/2}$. σ_p' is used for proficiency assessment when $u_{Xa} \geq 0.3\sigma_p$

5.4 z score = D / σ_p ; D = X – Xa , σ_p = SD for proficiency assessment. When adjusted SD (σ_p') is used for proficiency assessment, z score = D /σ_p'.

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

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

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

c) Unsatisfactory : $|z| \geq 3$.

5.6 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 $|z| \geq 3$ (other results $|z| < 3$) or more than one result $2 < |z| < 3$;

c) Unsatisfactory : more than one result $|z| \geq 3$.

6. Result of EQA surveys

6.1 Three EQA surveys for G6PD quantitative test were performed in 2023.

a) Eighty-eight (96.7%) reports were “Acceptable” ;

b) Three (3.3%) reports were “Acceptable with Caution” ;

c) No report was “Unsatisfactory” ;

d) The “Acceptable with caution” rate and “Unsatisfactory” rate of the report were similar to recent years (Fig. 4).

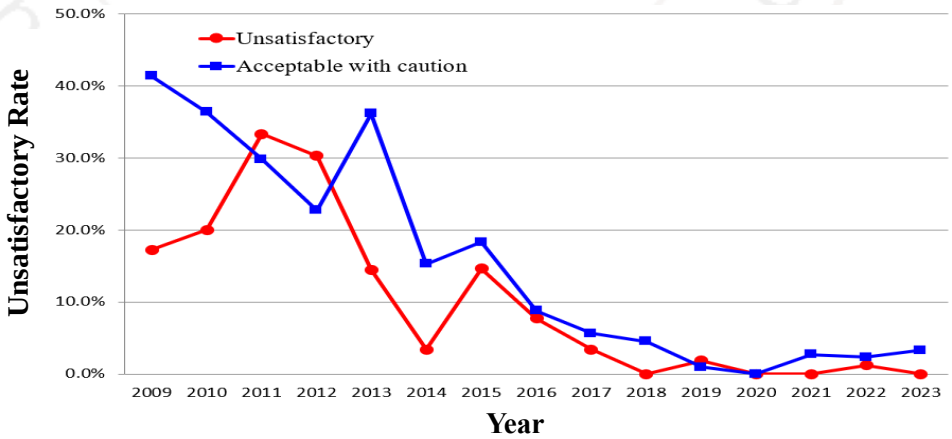


Fig. 4. “Unsatisfactory” and “acceptable with caution” rates of the survey reports (2009 ~ 2023).

6.2 The G6PD activity (assigned value；Xa) of 9 QC samples used in 3 surveys (RH2023-01, RH2023-02 and RH2023-03) were between 3.8 and 16.4 U/g Hb (Table 2). The distributions of G6PD test results reported in each survey were shown in Fig. 5.

Table 2. Summary of the survey results of each QC samples in 2023

Survey	Sample	N	Median* (Xa)	Mean*	SD*	CV%	Min*	Max*
RH2023-01	S1	30	3.8	3.8	0.22	5.8%	3.1	4.3
	S2	30	6.1	6.0	0.35	5.8%	5.5	6.8
	S3	30	6.1	6.1	0.39	6.4%	5.3	9.0
RH2023-02	S1	30	14.7	14.6	0.79	5.4%	12.7	16.9
	S2	30	4.5	4.4	0.31	7.0%	3.8	5.0
	S3	30	10.9	10.8	0.65	6.0%	9.7	11.9
RH2023-03	S1	31	4.6	4.7	0.16	3.4%	3.7	5.0
	S2	31	16.4	16.4	0.88	5.4%	13.6	17.7
	S3	31	11.3	11.3	0.59	5.2%	9.0	12.3

*U/g Hb

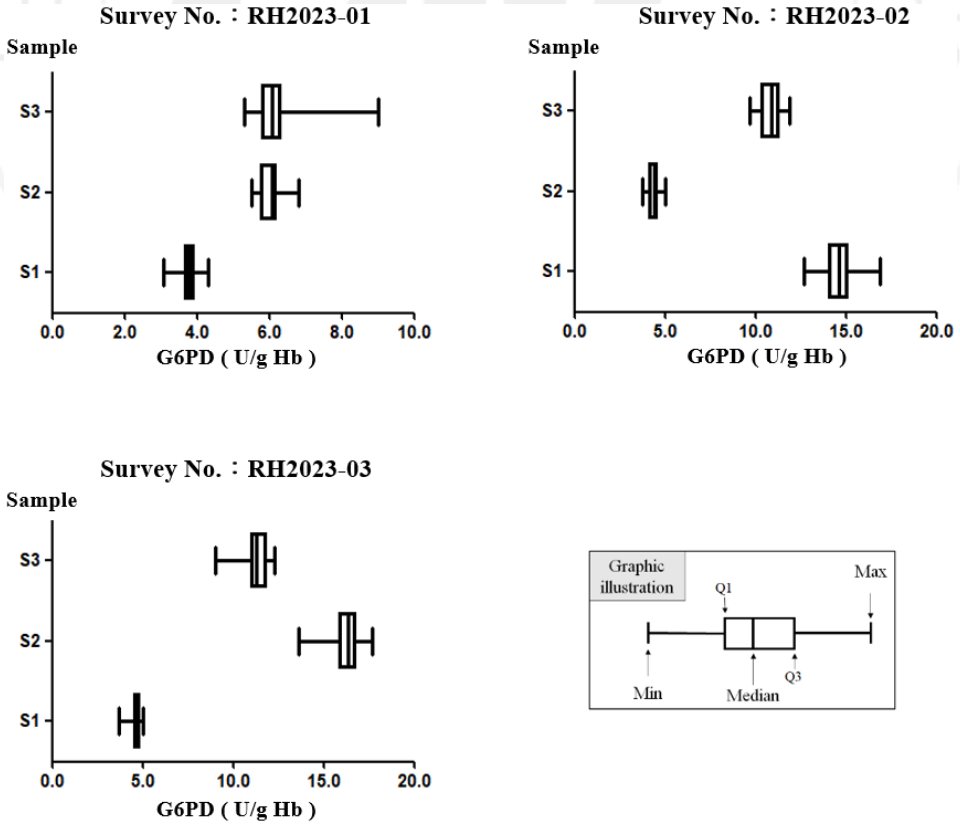


Fig. 5. Distribution of G6PD test results of each survey in 2023

6.3 Between Laboratory Variations

Compare to the results between 2021 and 2023, all the interlaboratory C.V. of QC samples in 2023 were all lower than 10% (3.4 ~ 7.0% ; Table 2), which has shown improvement (Fig. 5 and 6).

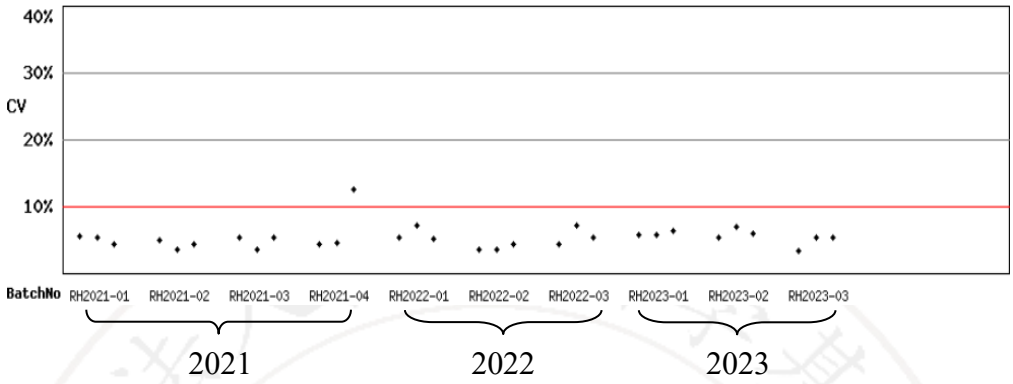


Fig. 5. Inter laboratory C.V. vs. surveys (2021 ~ 2023)

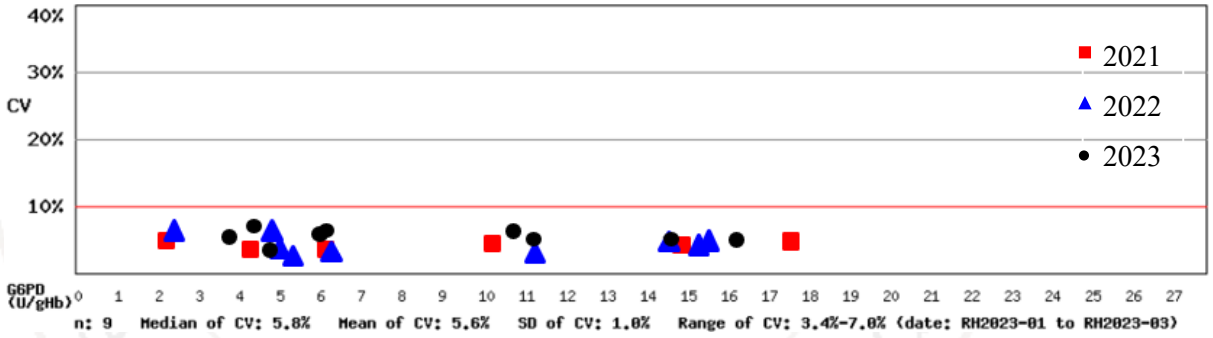
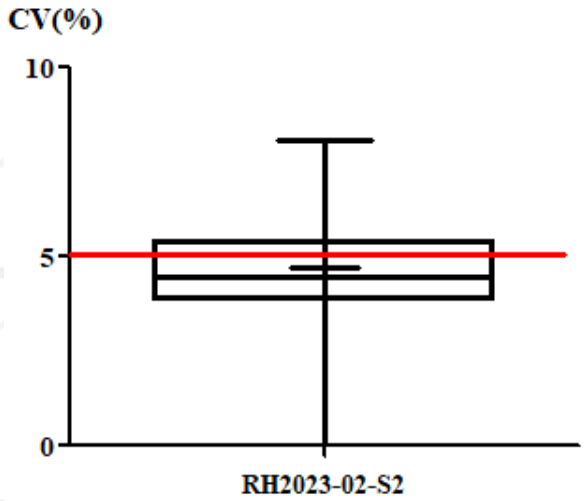


Fig. 6. Inter laboratory C.V. vs. G6PD activities (2021 ~ 2023)

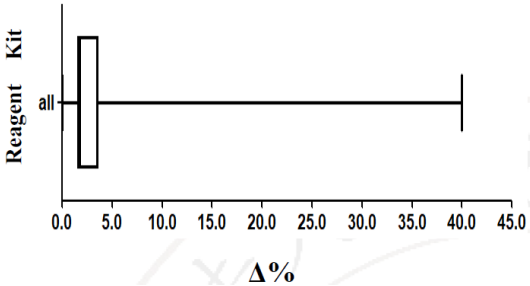
6.4 In these surveys, one lot of QC sample has been used many times (n = 5) in different EQA surveys between 2018 and 2023. The long term (over 5 years) within-laboratory between run CV (intermediate measurement precision) of the G6PD blood confirmatory quantitative test in most participating laboratories were good (Range 0 ~ 8.1%, median 4.5%). Currently, this is the only program that can provide this long-term surveillance capability.

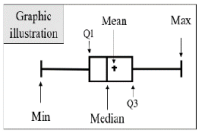


G6PD (U/g Hb)*	4.5
No. of Run	5
No. of Lab	18
Period	2018-2023

Fig. 6. Intermediate Measurement Precision

6.5 In the survey RH2023-01, Sample 2 and Sample 3 were the same lot of QC sample. To evaluate each participant's repeatability, we compared the difference between the test results of the two samples and its percentage of the mean (Δ%). The range of repeatability (Δ%) was 0.0% ~ 40.0% and the median value was 1.8%. The repeatability of most participants (24/30) were good (Δ% ≤ 3.6%, two times the median).





Reagent Kit	Labs (n)	Δ% median	Δ% mean	Δ% range
5	30	1.8	4.1	0.0 ~ 40.0

Reagent kit 5 : Medicon

n < 5, NOT calculated.

Fig. 7. Repeatability of G6PD Quantitative Test

6.6 All the results of EQA surveys for G6PD blood quantitative test in 2023 were posted on website：

< ***https://g6pd.qap.tw/112rep-phi.htm*** >

The content of the website including following parts：

a) Summary report of G6PD and Hemoglobin (Hb) quantitative test results of each survey；
b) Long-term observation of EQA survey results for G6PD quantitative test；
c) Distribution of G6PD test results of each survey；
d) Distribution of Hb test results of each survey；
e) Deviation graphs (*z* score, *D*%, SDI) for individual laboratory；
f) Intermediate measurement precision of G6PD quantitative test；
g) Repeatability of G6PD Quantitative Test.

7. Conclusion of the customer satisfaction survey

In the 2023 customer satisfaction survey, the return rate was 39% (12/31). Among the returned questionnaires, all the participants rate "Excellent" performance in overall satisfaction.