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Annual Report of External Quality Assurance Survey for G6PD Blood Quantitative Test in Philippines

(2021)

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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).

2. Participants

Twenty-nine G6PD confirmatory laboratories have participated in the EQA program in 2021. (Fig. 1 and 2)

Fig. 1. Distribution of participating laboratories in Philippines.

● Participating laboratory (n=29)

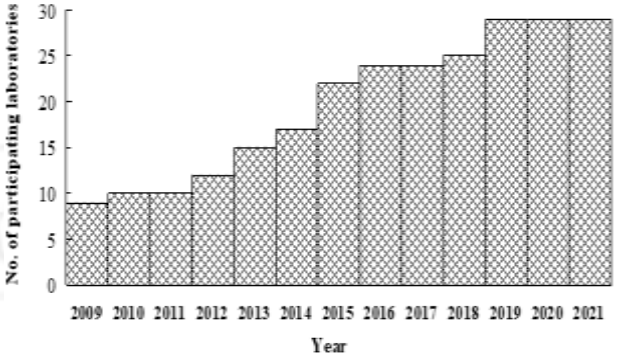


Fig. 2. Number of participating laboratories in Philippines

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 four EQA surveys performed in 2021. (Table 1).

Table 1. 2021 EQA survey schedule

No.	Survey No	Shipping Date*	Reporting Deadline*	Survey Result Released*
1	RH2021-01	02/22	03/01	03/09
2	RH2021-02	06/14	06/21	06/23
3	RH2021-03	09/20	09/27**	10/07
4	RH2021-04*	11/08	11/15**	12/01

* Date: MM/DD

** Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline of RH2021-03 and RH2021-04 were adjusted to 10/04 and 11/22, respectively.

4.2 In 2021, 112 sets of QC samples were sent to participants, 111 (99.1%) 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% of the participants, which were more 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 Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline of RH2021-03 and RH2021-04 were adjusted to a week later than the originally scheduled.

4.6 The reports returned time was between 2 and 15 days (median = 6 days) after the survey started. One hundred and one (91.0%) reports were returned within the target time (7 calendar days after the survey started).

4.7 The survey summary reports were released on the website between 2 and 10 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 z score = D / σ_p ; D = X – Xa , σ_p = SD for proficiency assessment.

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

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

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

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

5.5 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 $|z| > 3$ or more than one result $2 < |z| \leq 3$;

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

6. Result of EQA surveys

6.1 Four EQA surveys for G6PD quantitative test were performed in 2021.

a) 108 (97.3%) reports were “Acceptable” ;

b) 3 (2.7%) reports were “Acceptable with Caution” or “Unsatisfactory” ;

c) There is no laboratory has “Unsatisfactory” report ;

d) “Acceptable with caution” rate of the reports was worse than in 2020 but similar to recent years (Fig. 3).

e) “Unsatisfactory” rate of the reports was the same as 2020 (Fig. 3).

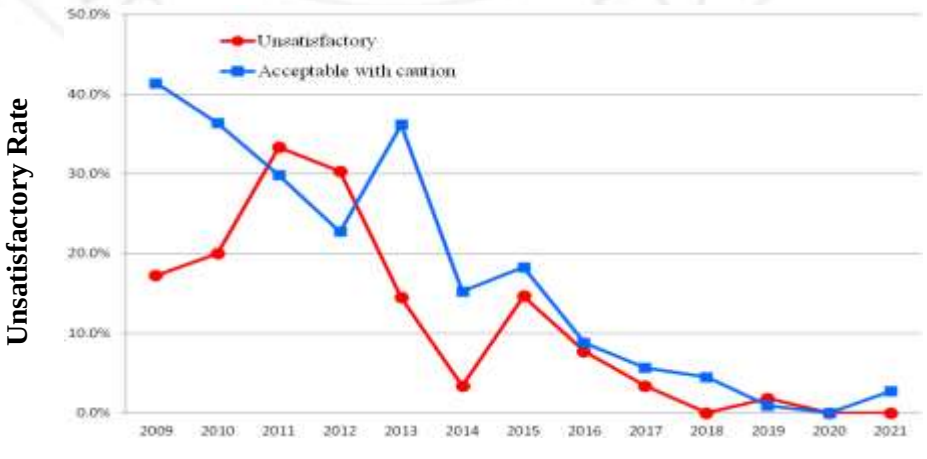


Fig. 3. Acceptable with caution and unsatisfactory rates of the survey reports (2009 ~ 2021)

6.2 The G6PD activity (assigned value；Xa) of 12 QC samples used in 4 surveys (RH2021-01, RH2021-02, RH2021-03 and RH2021-04) were between 1.6 and 16.3 U/g Hb (Table 2). The distributions of G6PD test results reported in each survey were shown in Fig. 4.

Table 2. Summary of the survey results of each QC samples in 2021

Survey	Sample	N	Median* (Xa)	Mean*	SD*	CV%	Min*	Max*
RH2021-01	S1	29	5.4	5.3	0.29	5.5	4.4	5.8
	S2	29	8.0	8.0	0.42	5.3	6.8	9.1
	S3	29	15.1	15.1	0.67	4.4	10.9	17.6
RH2021-02	S1	28	4.5	4.5	0.22	4.9	4.1	4.8
	S2	28	16.3	16.3	0.59	3.6	14.8	17.2
	S3	28	4.5	4.4	0.19	4.3	4.0	4.7
RH2021-03	S1	28	4.3	4.3	0.23	5.3	3.7	4.7
	S2	28	9.0	9.1	0.33	3.6	7.7	9.8
	S3	28	9.1	9.0	0.47	5.2	6.3	9.6
RH2021-04	S1	26	11.0	10.9	0.48	4.4	9.9	11.9
	S2	26	6.1	6.1	0.28	4.6	5.6	6.5
	S3	26	1.6	1.6	0.20	12.5	1.3	2.2

*U/g Hb

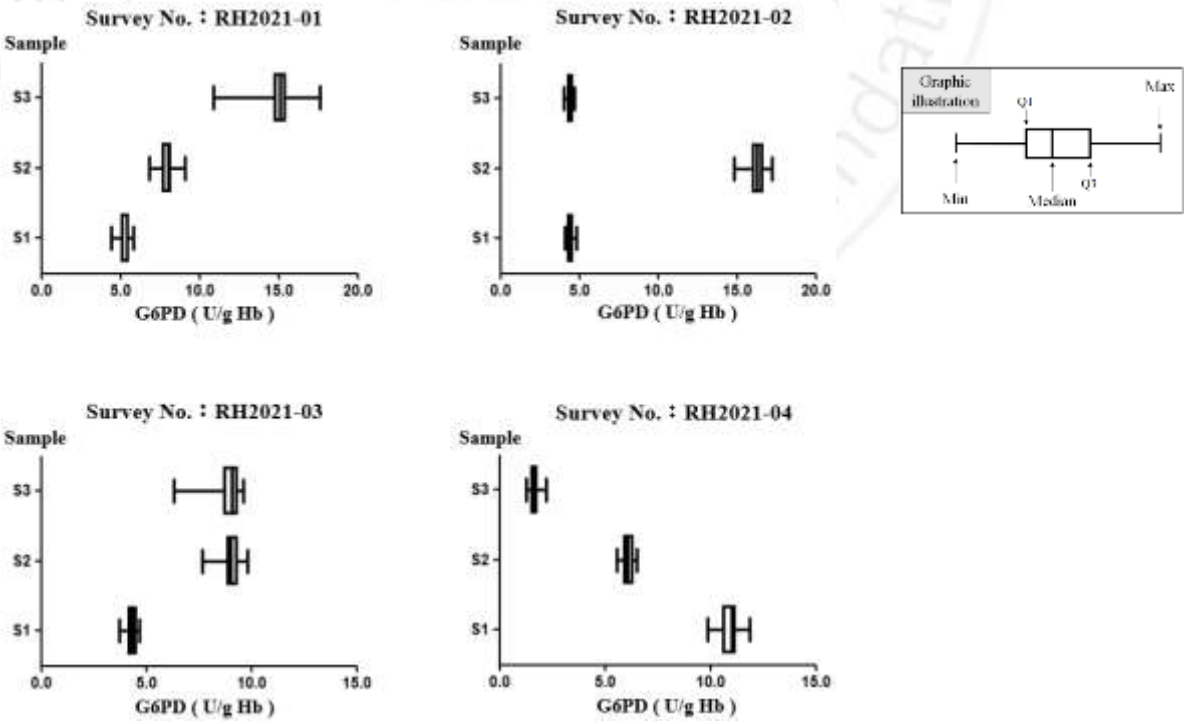


Fig. 4. Distribution of G6PD test results of each survey

6.3 Between Laboratory Variations

a) The interlaboratory C.V.s for the quantitative test were 3.6% ~ 12.5%. (Table 2)

b) Only one interlaboratory C.V. (12.5%) of low G6PD activity (1.6 U/g Hb) was higher than 10% (Figure 6).

c) Five interlaboratory C.V.s were higher than 5% (one of which was higher than 10%). The performance of interlaboratory C.V. in 2021 was a little worse than in 2020 but similar to recent years (Figure 5 and 6).

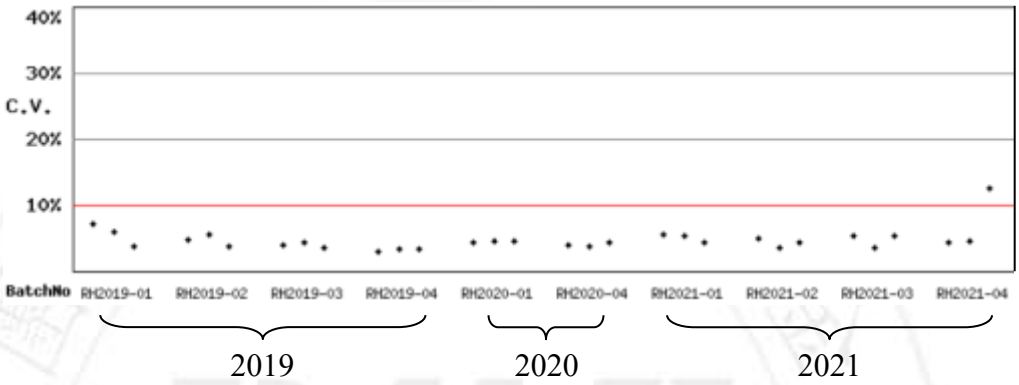


Fig. 5. Inter laboratory C.V. vs. surveys (2019 ~ 2021)

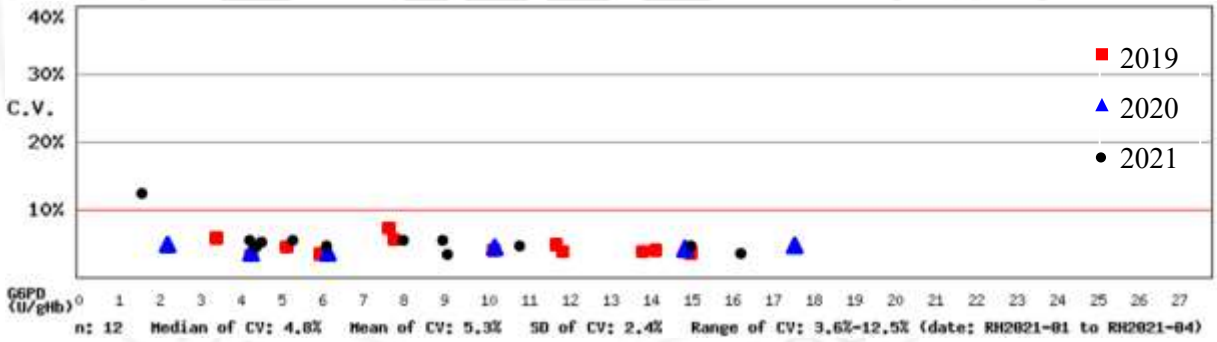


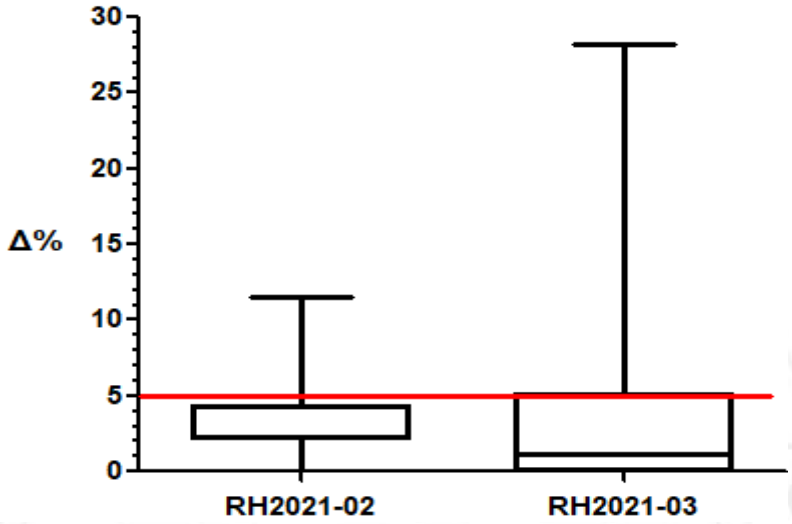
Fig. 6. Inter laboratory C.V. vs. G6PD activities (2019 ~ 2021)

6.4 Repeatability of G6PD Quantitative Test

To evaluate the repeatability of each participant, we compare the difference between the test results of the two QC samples from the same lot and its percentage of the mean.

a) In the RH2021-02 survey, Sample 1 and Sample 3 used the same lot of QC sample, the G6PD enzyme activity of these samples was 4.5 U/g Hb. The repeatability of most participants (96.4%, 27/28) was better than 5% (Fig. 7) ;

b) In the RH2021-03 survey, Sample 2 and Sample 3 used the same lot of QC sample, the G6PD enzyme activity of these samples was 9.0 U/g Hb. The repeatability of most participants (75%, 21/28) was better than 5% (Fig. 7).



G6PD (U/g Hb)*	**4.5**	**9.0**
No. of Lab	**28**	**28**

Fig. 7. Distribution of Within Laboratory Repeatability for G6PD Blood Quantitative Screening Test

*** Xa (Median)**

Δ% = | Si - Sj | / [(Si + Sj) / 2]

6.5 All the results of EQA surveys for G6PD blood quantitative test in 2021 were posted on website：

< ***https://g6pd.qap.tw/110rep-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) Repeatability of G6PD Quantitative Test.

7. Conclusion of the customer satisfaction survey

In the 2021 customer satisfaction survey, the return rate was 55% (16/29). Among the returned questionnaires, 81.3% of the participants give “Excellent” performance and 18.8% of the participants give “Great” performance in overall satisfaction.