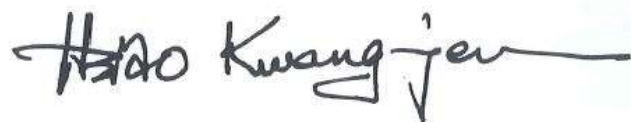


Annual Report of External Quality Assurance Survey for G6PD Blood Quantitative Test in Philippines (2019)



QAP Center
Preventive Medicine Foundation
P.O. Box 624 Taipei Xinwei,
Taipei City 10699, Taiwan, R.O.C.
Tel: +886-2-2703-6080
Fax: +886-2-2703-6070
e-mail: g6pd@g6pd.tw
<http://g6pd.qap.tw/phi.htm>



Kwang-Jen Hsiao Ph.D.
Director, QAP Center

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Annual Report of External Quality Assurance (EQA) Survey for G6PD Blood Quantitative Test in Philippines (2019)

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) for conformity to international standard ISO/IEC 17043:2010 since 2017 (Accreditation No. : P016).

2. Participants

There were twenty-nine G6PD confirmatory laboratories have participated in the EQA program in 2019. (Fig. 1 and 2)



Fig. 1. Distribution of participating laboratories in Philippines.
 ● Participating laboratory (n=29)

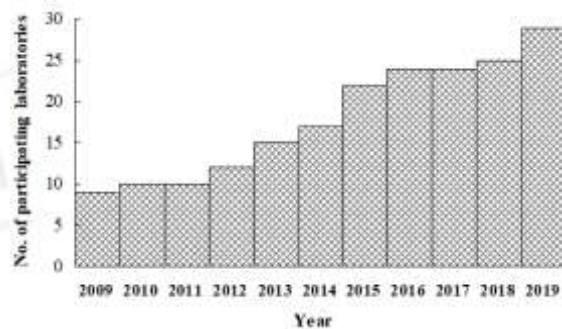


Fig. 2. Number of participating laboratories in Philippines

3. Quality Control Sample (QC Sample)

3.1 Three of 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 Regist. No.: MOHW-MD-(I)-No.004851)

3.3 The homogeneity and stability of QC samples conform to the requirements of the international standard ISO17043:2010.

4. Surveys

4.1 Four EQA surveys for G6PD blood quantitative test were performed in 2019. (Table 1)

Table 1. 2019 EQA survey schedule

No.	Survey No	Shipping Date*	Reporting Deadline*	Survey Result Released*
1	RH2019-01	01/14	01/21	01/25
2	RH2019-02	04/15	04/22	04/26
3	RH2019-03	07/15	07/22	07/24
4	RH2019-04	10/14	10/21	10/28

* Date: MM/DD

4.2 In 2019, 110 sets of QC samples were sent to participants, 110 (100%) reports were returned.

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

4.4 More than 83% of the participants had reported that dry ice was not melted completely when they received the QC samples, which were better than previous years.

4.5 The report returned time were between 1 and 9 days (median = 5 days) after the survey started, which were compatible with previous years. Most reports (97%) were returned within target time (7 calendar days).

4.6 The survey results were released on website between 2 and 7 days (median = 4 days) after reporting deadline, which were compatible to the target time (7 working days).

5. Evaluation Criteria

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

5.2 SD for proficiency assessment (σ_p) = 7% x X_a ; but when $X_a < 2.9$ U/gHb , $\sigma_p = 0.2$ U/gHb.

5.3 z score = D / σ_p ; $D = X - X_a$, $\sigma_p = SD$ 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 2019.

- a) 107 (97.3%) reports were “Acceptable” ;
- b) 1 (0.9%) reports were “Acceptable with Caution” ;
- c) There were two laboratories have “Unsatisfactory” report ;
- d) Acceptable with caution rate of the reports was better than 2018 (Fig. 3).
- e) Unsatisfactory rate of the reports was worse than 2018 but similar to recent years (Fig. 3).

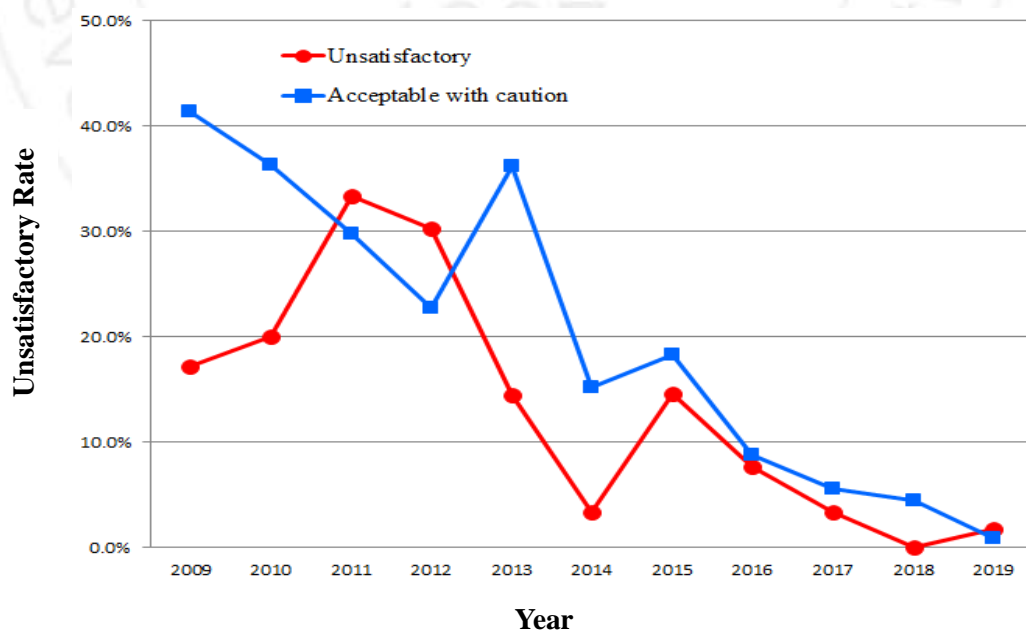


Fig. 3. Acceptable with caution and unsatisfactory rates of the survey reports (2009 ~ 2019)

6.2 The G6PD activity (assigned value ; X_a) of 10 QC samples used in 4 surveys (RH2019-01, RH2019-02, RH2019-03 and RH2019-04) were between 3.4 and 15.1 U/gHb (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 2019

Survey	Sample	N	Median (Xa)	Mean	SD	CV%	Min	Max
RH2019-01	S1	26	7.8	7.7	0.55	7.1	6.4	8.6
	S2	26	7.8	7.8	0.47	6.0	6.1	9.1
	S3	26	15.1	15.1	0.56	3.7	13.6	16.8
RH2019-02	S1	28	11.8	11.8	0.55	4.7	9.2	12.7
	S2	28	3.4	3.4	0.19	5.6	2.6	3.8
	S3	28	11.9	11.9	0.45	3.8	8.9	13.7
RH2019-03	S1	29	10.4	10.3	0.40	3.9	9.7	11.9
	S2	29	5.3	5.2	0.23	4.4	4.8	6.1
	S3	29	14.2	14.2	0.49	3.5	12.9	15.3
RH2019-04	S1	27	4.2	4.3	0.13	3.0	3.1	4.6
	S2	27	6.1	6.0	0.19	3.2	5.0	6.4
	S3	27	13.9	14.0	0.45	3.2	10.4	15.6

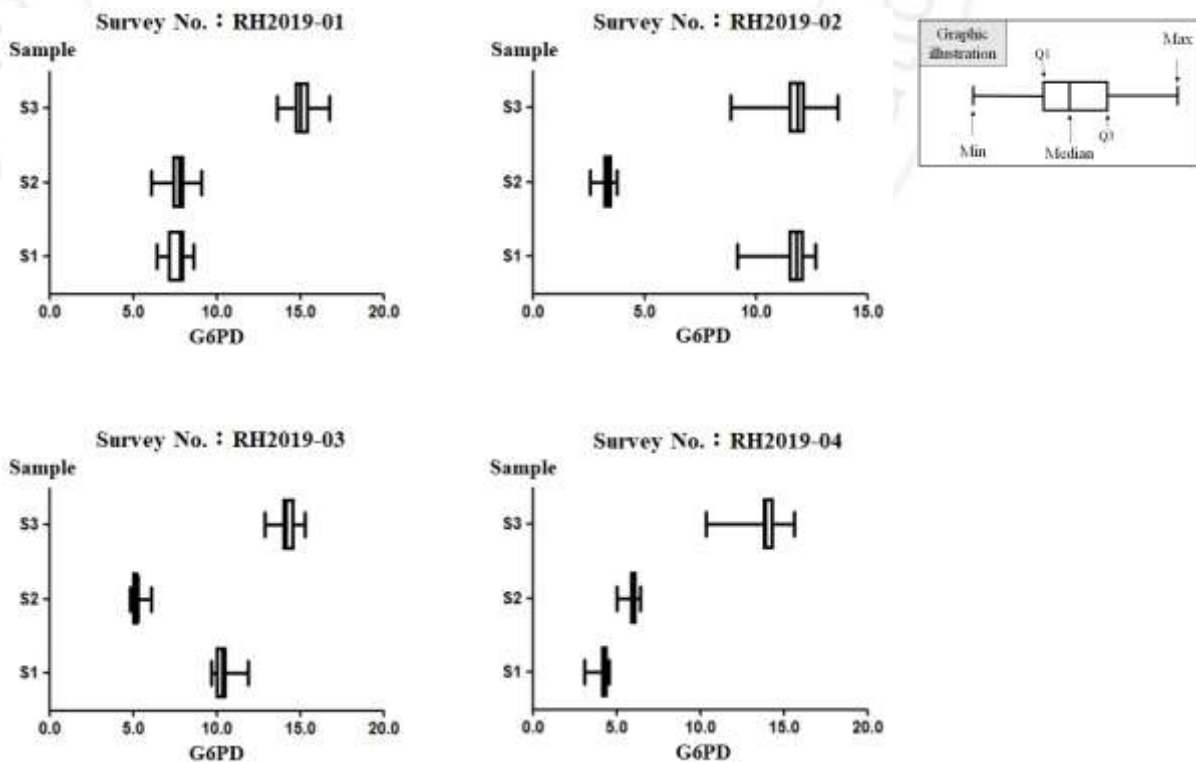


Fig. 4. Distribution of G6PD test results of each survey

6.3 Between Laboratory Variations

- a) The interlaboratory C.V. for all of the QC samples were lower than 10% (3.0 ~ 7.1% ; Table 2) ;
- b) Compare to the results between 2017 and 2019, all the interlaboratory C.V. of QC samples in 2019 were all lower than 10% (9 were lower than 5%), which has shown improvement (Fig. 5 and 6).

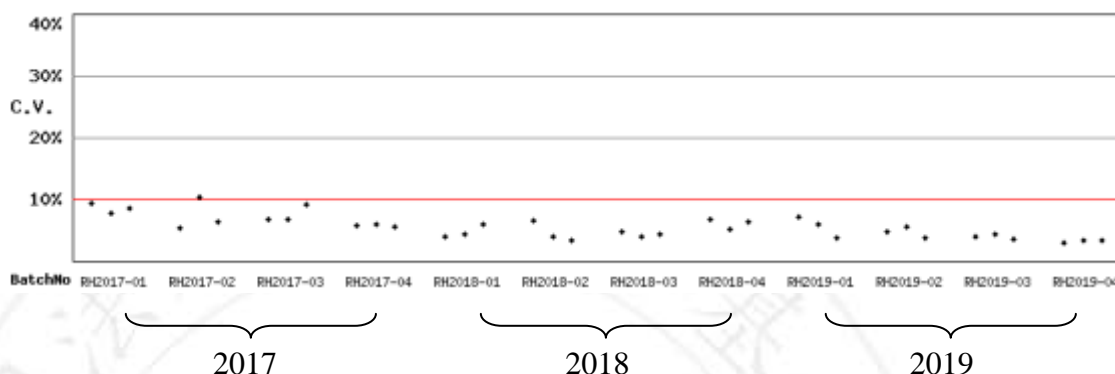


Fig. 5. Inter laboratory C.V. vs. surveys (2017 ~ 2019)

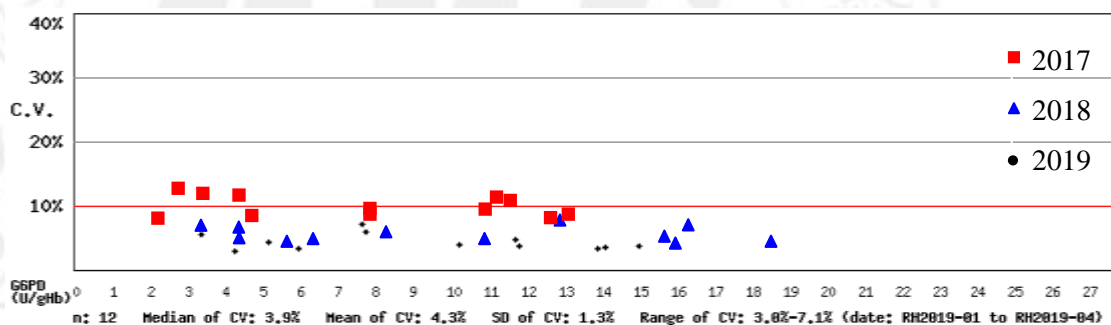
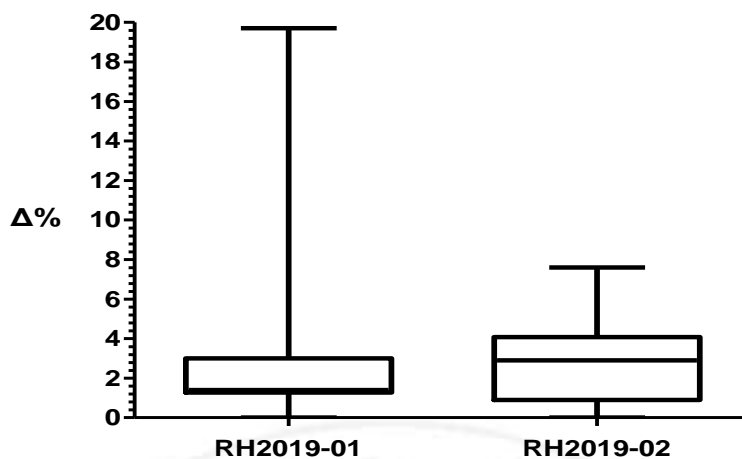


Fig. 6. Inter laboratory C.V. vs. G6PD activities (2017 ~ 2019)

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 RH2019-01 survey, Sample 1 and Sample 2 used the same QC samples lot, the reference G6PD enzyme activity of these samples was 7.8 U/gHb. The repeatability of most participants (80.8%, 21/26) was lower than 5% (Fig. 7) ;
- b) In the RH2019-03 survey, Sample 1 and Sample 3 used the same QC samples, the reference G6PD enzyme activity of these samples was 11.8 U/gHb. The repeatability of most participants (96.4%, 27/28) was lower than 5% (Fig. 7).



G6PD (U/gHb)*	7.8	11.8
No. of Lab	26	28

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

* Xa (Median)

$$\Delta\% = |S_i - S_j| / [(S_i + S_j) / 2]$$

6.5 All the results of EQA surveys for G6PD blood quantitative test in 2019 were posted on website :

< <https://g6pd.qap.tw/108rep-phi.htm> >

The content of the website including following parts :

- Summary report of G6PD and Hemoglobin (Hb) quantitative test results of each survey ;
- Long-term observation of EQA survey results for G6PD quantitative test ;
- Distribution of G6PD test results of each survey ;
- Distribution of Hb test results of each survey ;
- Within-laboratory intermediate measurement precision of G6PD quantitative test ;
- Deviation graphs (z score, D%, SDI) for individual laboratory ;
- Repeatability of G6PD Quantitative Test.

7. Conclusion of customer satisfaction survey

In the 2019 customer satisfaction survey, the return rate was only 48% (14/29). Among the returned questionnaires, 57% of the participants give “Excellent” performance and 43% of the participants give “Great” performance in overall satisfaction.