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

(2020)

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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 2020. (Fig. 1 and 2)

Fig. 1. Distribution of participating laboratories in Philippines.

● Participating laboratory (n=29)

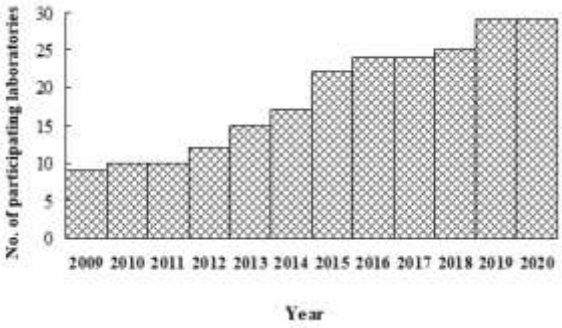

Fig. 2. Number of participating laboratories in Philippines

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 ISO17043:2010.

4. Surveys

4.1 There were 2 EQA surveys performed in 2020. Due to the COVID-19 pandemic, survey RH2020-02 and RH2020-03 were cancelled (Table 1).

Table 1. 2020 EQA survey schedule

No.	Survey No	Shipping Date*	Reporting Deadline*	Survey Result Released*
1	RH2020-01	02/24	03/02	03/11
2	RH2020-02	Due to the COVID-19 pandemic, this survey was canceled.		
3	RH2020-03	Due to the COVID-19 pandemic, this survey was canceled.		
4	RH2020-04	11/10	11/17	11/25

* Date: MM/DD

4.2 There were 29 laboratories that participated in the EQA survey. In survey RH2020-04, the EQA samples cannot be sent to 4 of the participants in time due to the COVID-19 pandemic.

4.3 In 2020, 54 sets of QC samples were sent to participants, all (100%) reports were returned.

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

4.5 More than 35% 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.

4.6 The reports returned time was between 2 and 7 days (median = 5 days) after the survey started, which were compatible with previous years. All 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 8 and 9 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/gHb , σ_p = 0.2 U/gHb.

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 Two EQA surveys for G6PD Quantitative test were performed in 2020.

a) All (n = 54) reports were “Acceptable” ;

b) No report was rated as “Acceptable with Caution” or “Unsatisfactory” ;

c) Both acceptable with caution rate and unsatisfactory rate of the reports were better than 2019 (Fig. 3).

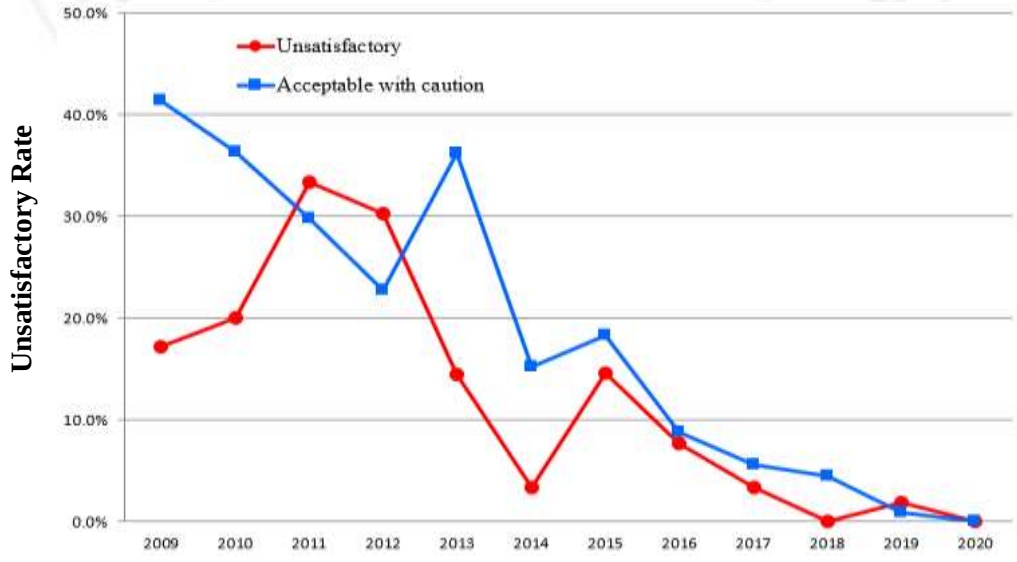

Fig. 3. Acceptable with caution and unsatisfactory rates of the survey reports (2009 ~ 2020)

6.2 The G6PD activity (assigned value；Xa) of 6 QC samples used in 2surveys (RH2020-01 and RH2020-04) were between 2.2 and 17.7 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 2020

Survey	Sample	N	Median* (Xa)	Mean*	SD*	CV%	Min*	Max*
RH2020-01	S1	29	17.7	17.7	0.76	4.3	16.1	18.9
	S2	29	2.2	2.2	0.10	4.5	2.0	2.5
	S3	29	10.3	10.3	0.47	4.6	9.4	11.4
RH2020-04	S1	25	4.3	4.3	0.17	4.0	3.9	4.6
	S2	25	6.2	6.2	0.23	3.7	5.6	6.6
	S3	25	14.9	15.0	0.64	4.3	13.8	16.0

*U/gHb

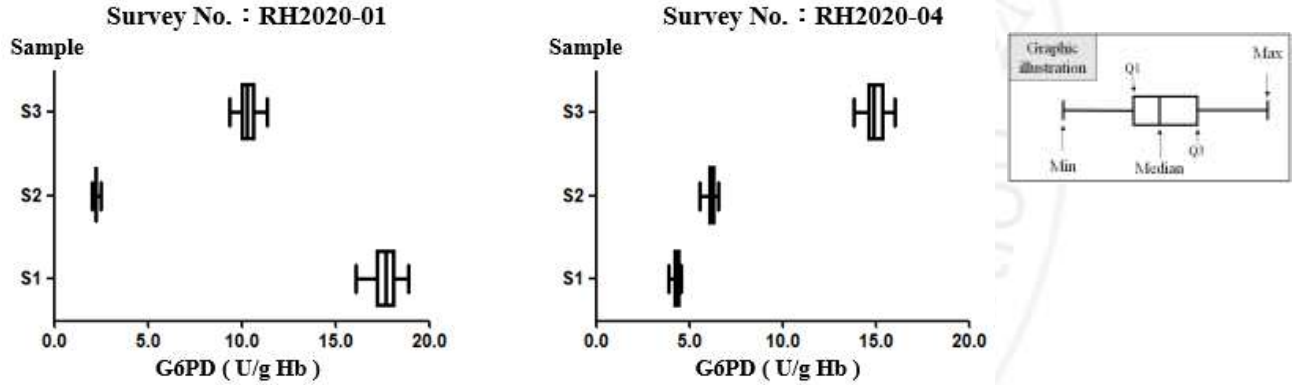

Fig. 4. Distribution of G6PD test results of each survey

6.3 Between Laboratory Variations

Compare to the results between 2018 and 2020, all the interlaboratory C.V. of QC samples in 2020 were all lower than 5% (3.7 ~ 4.6% ; Table 2), which has shown improvement (Fig. 5 and 6).

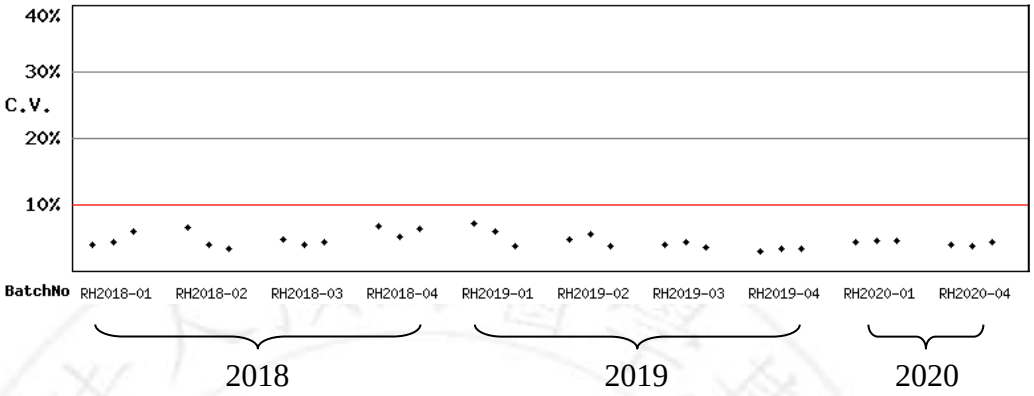

Fig. 5. Inter laboratory C.V. vs. surveys (2018 ~ 2020)

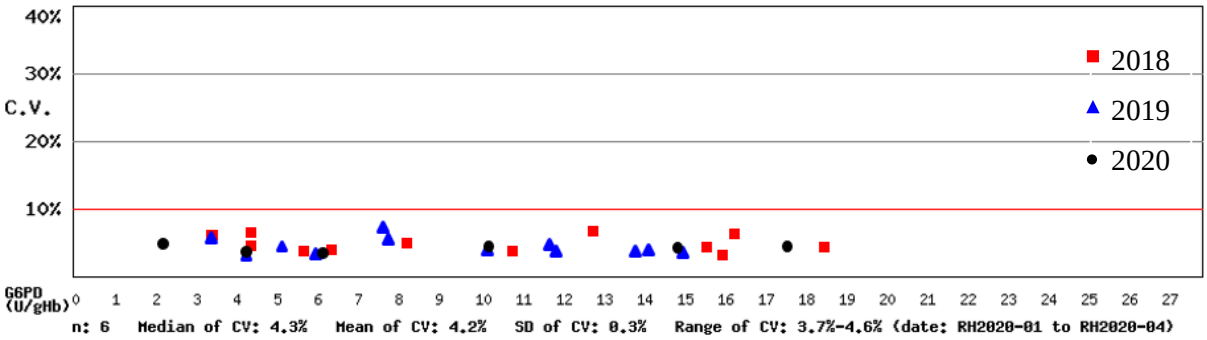

Fig. 6. Inter laboratory C.V. vs. G6PD activities (2018 ~ 2020)

6.4 There is no assessment of repeatability of G6PD quantitative test in the RH2020-01 and RH2020-04 surveys.

6.5 As all participants changed their reagent kits since the end of 2017, the test results were significantly different from the previous reagent test results, which hindered cumulating the survey results between 2018 and 2020 with the previous results. There were no same lot of EQA samples used more than four times between 2018 and 2020. Therefore, no report of the within-laboratory intermediate measurement precision of G6PD quantitative test can be provided this year.

6.6 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：

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 2020 customer satisfaction survey, the return rate was only 34% (10/29). Among the returned questionnaires, 80% of the participants give “Excellent” performance and 20% of the participants give “Great” performance in overall satisfaction.