

Annual Summary of External Quality Assurance  
Survey for G6PD Blood Quantitative Test in Philippines  
( 2022 )



QAP Center  
Preventive Medicine Foundation  
P.O. Box 624 Taipei Xinwei  
Taipei, Taiwan 10699, R.O.C.

Tel: +886-2-2703-6080  
Fax: +886-2-2703-6070  
Email: [g6pd@g6pd.tw](mailto:g6pd@g6pd.tw)  
<http://g6pd.qap.tw/en/>

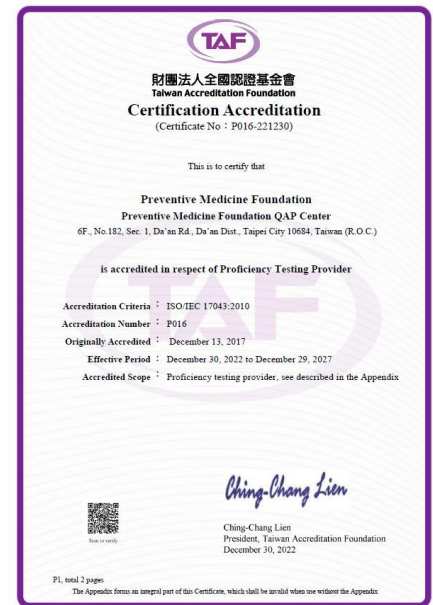
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# Annual Summary of External Quality Assurance (EQA) Survey for G6PD Blood Quantitative Test in Philippines ( 2022 )

## 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.



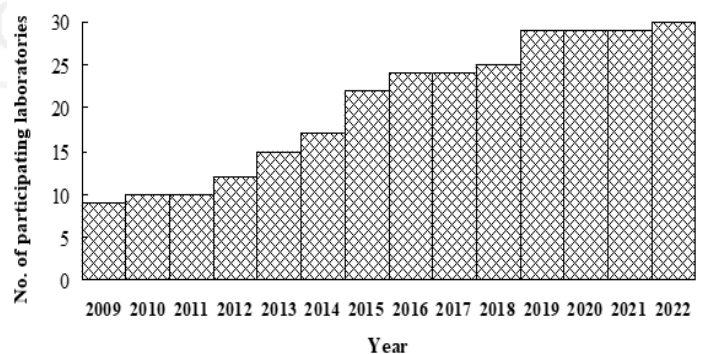
**Figure 1. Certification Accreditation ( Certificate No : P016-221230 )**

## 2. Participants

Twenty-nine G6PD confirmatory laboratories have participated in the EQA program in 2022. (Fig. 2 and 3)



**Fig. 2. Distribution of participating laboratories in Philippines. (● Participating laboratory, n=30)**



**Fig. 3. Number of participating laboratories in Philippines ( 2009 ~ 2022 )**

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 2022. (Table 1).

**Table 1. 2022 EQA survey schedule**

| No. | Survey No | Shipping Date* | Reporting Deadline* | Survey Result Released* |
|-----|-----------|----------------|---------------------|-------------------------|
| 1   | RH2022-01 | 02/21          | 02/28**             | 03/11                   |
| 2   | RH2022-02 | 05/30          | 06/06               | 06/07                   |
| 3   | RH2022-03 | 09/12          | 09/19               | 09/23                   |

\* Date: MM/DD

\*\* Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline of RH2022-01 were extended to 03/07.

4.2 In 2022, 88 sets of QC samples were sent to participants, 86 ( 97.7% ) 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 44% 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 a delay in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline of RH2022-01 was extended to a week later than originally scheduled.

4.6 The reports returned time was between 2 and 12 days ( median = 6 days ) after the survey started. Eighty and six ( 97.7% ) 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 1 and 4 days after reporting deadline, which conformed to the target time ( 7 working days after reporting deadline ).

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 (  $\sigma_p$  ) = 7% x  $X_a$  ; but when  $X_a < 2.9$  U/g Hb ,  $\sigma_p = 0.2$  U/g Hb.

5.3  $z$  score =  $D / \sigma_p$  ;  $D = X - X_a$  ,  $\sigma_p =$  SD for proficiency assessment. When adjusted SD (  $\sigma_p'$  ) is used for proficiency assessment,  $z$  score =  $D / \sigma_p'$ .

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

6. Result of EQA surveys

6.1 Three EQA surveys for G6PD quantitative test were performed in 2022.

- a) Eighty-five ( 96.6% ) reports were “Acceptable” ;
- b) Two ( 2.3% ) reports were “Acceptable with Caution” ;
- c) One ( 1.1% ) report was “Unsatisfactory” ;
- d) The “Acceptable with caution” rate and “Unsatisfactory” rate of the report were similar to recent years ( Fig. 4 ).

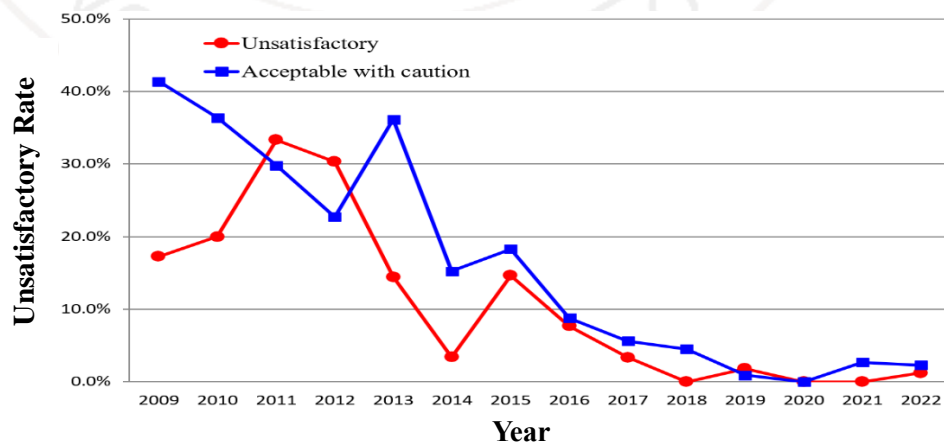


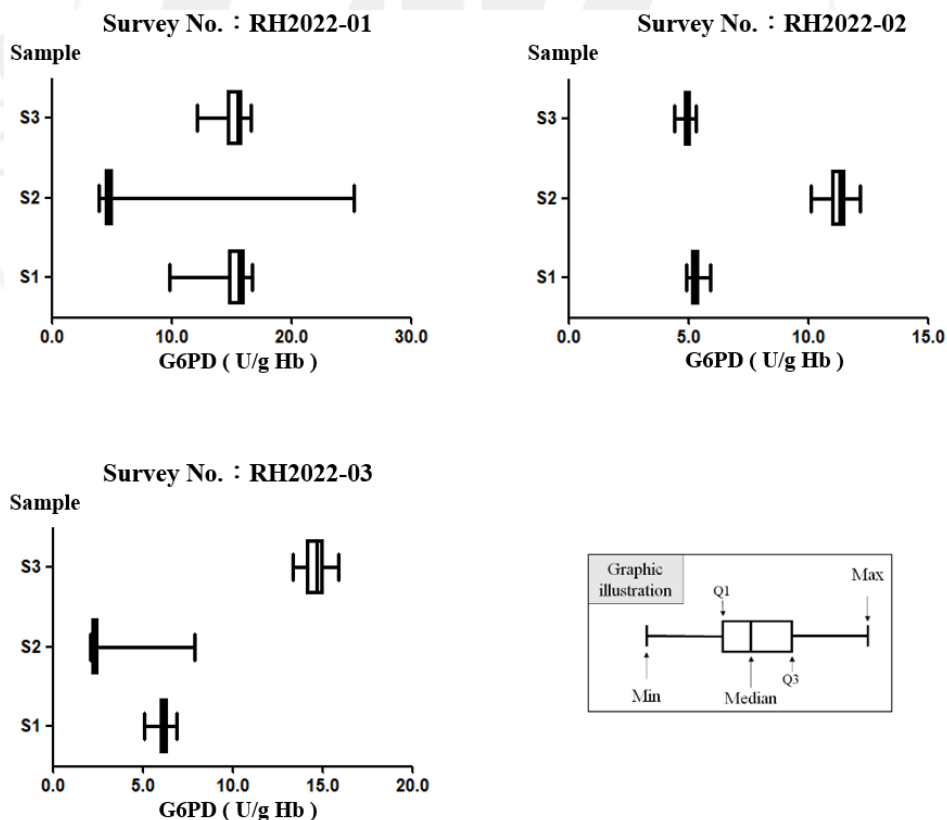
Fig. 4. “Unsatisfactory” and “acceptable with caution” rates of the survey reports ( 2009 ~ 2022 ).

6.2 The G6PD activity (assigned value ;  $X_a$ ) of 9 QC samples used in 3 surveys ( RH2022-01, RH2022-02 and RH2022-03 ) were between 2.4 and 15.7 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 2022**

| Survey    | Sample | N  | Median*<br>( $X_a$ ) | Mean* | SD*  | CV%  | Min* | Max* |
|-----------|--------|----|----------------------|-------|------|------|------|------|
| RH2022-01 | S1     | 28 | 15.7                 | 15.6  | 0.83 | 5.3% | 9.9  | 16.7 |
|           | S2     | 28 | 4.8                  | 4.8   | 0.34 | 7.1% | 3.9  | 25.3 |
|           | S3     | 28 | 15.5                 | 15.4  | 0.78 | 5.1% | 12.2 | 16.6 |
| RH2022-02 | S1     | 29 | 5.3                  | 5.3   | 0.19 | 3.6% | 4.9  | 5.9  |
|           | S2     | 29 | 11.3                 | 11.3  | 0.4  | 3.5% | 10.1 | 12.2 |
|           | S3     | 29 | 4.9                  | 5.0   | 0.21 | 4.2% | 4.4  | 5.3  |
| RH2022-03 | S1     | 29 | 6.2                  | 6.2   | 0.26 | 4.2% | 5.1  | 6.9  |
|           | S2     | 29 | 2.4                  | 2.4   | 0.17 | 7.1% | 2.1  | 7.9  |
|           | S3     | 29 | 14.7                 | 14.6  | 0.76 | 5.2% | 13.4 | 15.9 |

\*U/g Hb



**Fig. 5. Distribution of G6PD test results of each survey in 2022**

### 6.3 Between Laboratory Variations

Compare to the results between 2020 and 2022, all the interlaboratory C.V. of QC samples in 2022 were all lower than 10% ( 3.5 ~ 7.1% ; Table 2 ), which has shown improvement ( Fig. 5 and 6 ).

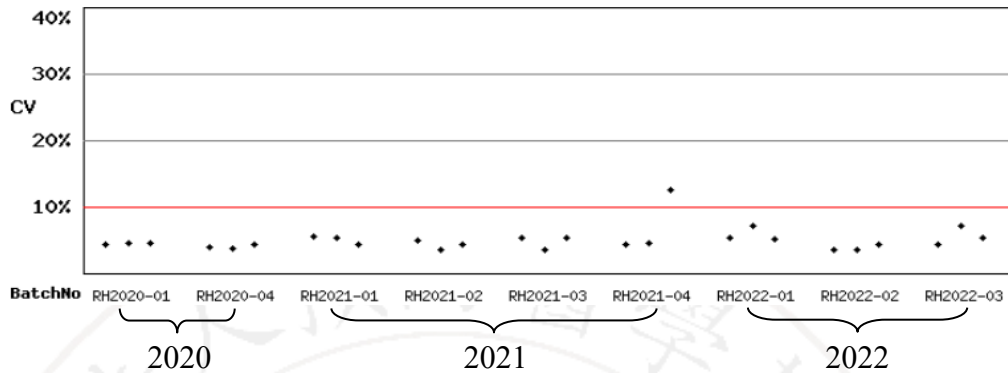


Fig. 5. Inter laboratory C.V. vs. surveys ( 2020 ~ 2022 )

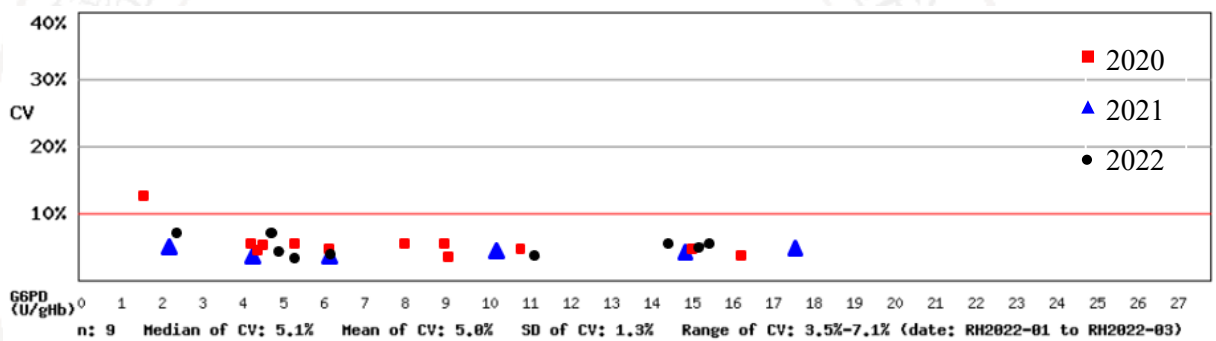


Fig. 6. Inter laboratory C.V. vs. G6PD activities ( 2020 ~ 2022 )

6.4 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 :

- 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 ;
- Deviation graphs ( z score, D%, SDI ) for individual laboratory.

### 7. Conclusion of the customer satisfaction survey

In the 2022 customer satisfaction survey, the return rate was 57% (17/30). Among the returned questionnaires, 82.4% of the participants rate “Excellent” performance and 17.6% of the participants rate “Great” performance in overall satisfaction.

