Annual Summary of External Quality Assurance Survey for Neonatal G6PD Screening Test (2022)

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(2022)

1. Introduction

Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing " EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Screening Test " using dried blood spot samples for newborn screening laboratories since 1999. This EQA program has been officially accredited by Taiwan Accreditation Foundation (TAF , a member of ILAC Mutual Recognition Arrangement Signatories) for conformity to 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

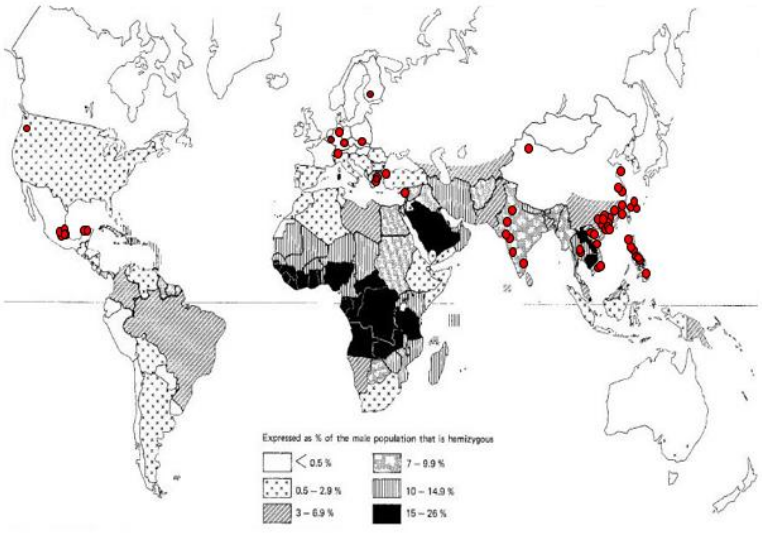
Ching-Chang Lien
Ching-Chang Lien
President, Taiwan Accreditation Foundation
December 30, 2022

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

Fifty- five laboratories (including 3 reagent manufacturers) from 13 countries (AT, BE, CN, DE, FI, GR, IN, MX, PH, TH, TR, TW, and VN) have participated in the EQA program in 2022.



G6PD Deficiency Worldwide Distribution, *WHO working group. Bull WHO 1989;67:601*

Figure 2. Worldwide distribution of participating laboratories.

(● Participate, n = 55)

The number of participants was going down these two years because the laboratories were closed or discontinued neonatal G6PD screening.

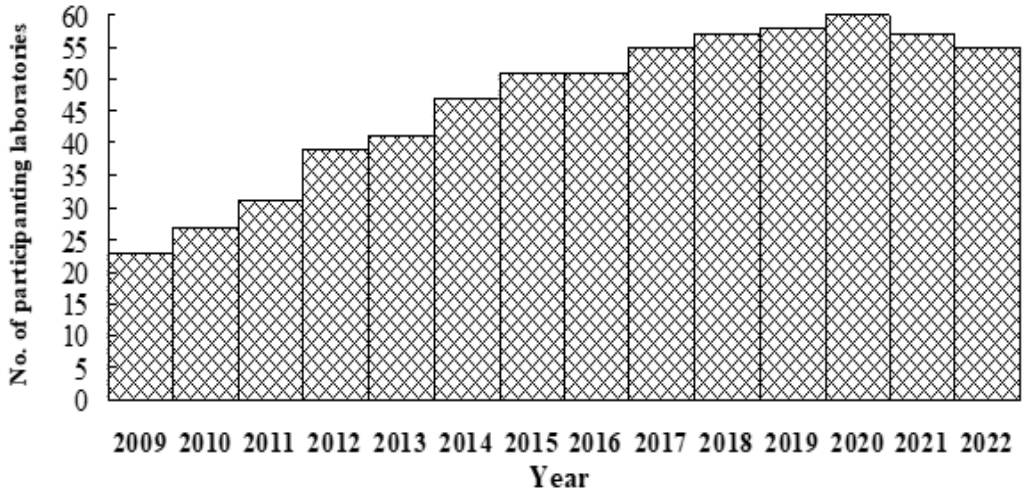


Figure 3. Number of participating laboratories in this program. (2009 ~ 2022).

3. Quality control sample (QC sample)

3.1 Ten QC samples were used in each survey.

3.2 The QC samples were prepared by spotting human blood (no extra G6PD added) on Whatman 903 filter paper. (Taiwan IVD Regist. No.: MOHW-MD-(I)-No.004754)

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

4. Surveys

4.1 There were 3 EQA surveys for screening test performed in 2022. (Table 1)

Table 1. 2022 EQA survey schedule

No.	Survey No	Survey Starting Date *	Reporting Deadline* (Taiwan)	Reporting Deadline* (Others)	Survey Result Released*
1	NS2022-01	02/14	02/17	02/24	03/08
2	NS2022-02	05/30	06/02	06/09**	06/20
3	NS2022-03	09/12	09/15	09/22	09/29

* Date: Month/Day

** Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline was extended to 06/14.

4.2 In 2022, 152 sets of QC samples were sent to participants, 151 (99.3%) reports were returned.

4.3 Most screening laboratories received the QC samples within 4 ~ 9 days (Median：7 days) after the survey started, which is delayed comparing to previous years (2 ~ 4 days, median：2 days).

4.4 Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline of NS2022-02 was extended for 5 days.

4.5 The report returned time were between 1 and 16 days (Median：8 days) after the survey started, which were compatible with previous years. Most reports (89.4%) were returned within target time (10 calendar days after the survey started).

4.6 Only 0.7% (1/151) of the participants had reported the shipping temperature indicator reached 54.4 °C, which were compatible with previous years. No unsatisfactory result was found due to the shipping temperature.

4.7 There are 17.9% (27/151) participants had reported the shipping humidity indicator reached 30%, which were higher than previous years. No unsatisfactory result was found due to this shipping humidity.

4.8 The survey result released between 6 and 12 days (Median：7 days) after reporting deadline, which were compatible to the target time (7 working days).

5. Evaluation Criteria reported results

5.1 The reported results were evaluated with a consensus decision of the same lot QC samples (assigned values) from more than 75% of participants.

5.2 The performance evaluation criteria for participant survey report:

a) Acceptable: all **results** are acceptable；

b) Acceptable with caution: only one **result** is unsatisfactory；

c) Unsatisfactory: more than one **result** are unsatisfactory.

6. Overall result of performance evaluation

6.1 Overall results of the four EQA surveys for screening test：

a) 134 (88.7%) reports were “Acceptable”；

b) 5 (3.3%) reports were “Acceptable with caution”；

c) 12 (7.9%) reports were “Unsatisfactory”.

6.2 The unsatisfactory reports rate (7.9 %) was higher than 2022 (6.5%) (Figure 4).

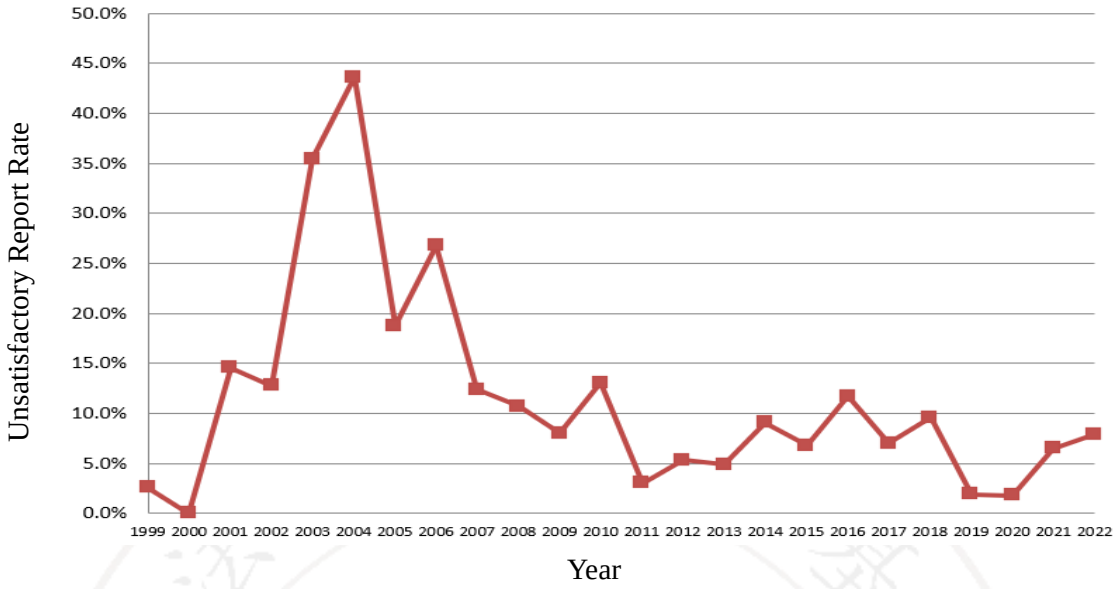


Figure 4. Unsatisfactory rates of the survey reports (1999 ~ 2022).

a) There were 37 false negative results (2.5%) and no false positive results were reported (Table 2)；

Table 2. EQA results of neonatal G6PD screening test at different ranges of G6PD activity in 2022.

G6PD Activity*	Specimens	Positive (P)	Negative (N)	False P	False N
0.1 – 2.0	188	186	2	0	**2 (1.1%)**
2.1 – 3.2	505	470	35	0	**35 (6.9%)**
6.0 – 8.0	468	0	468	0	0
> 8	349	0	349	0	0
Total	1510	656	854	0	**37 (2.5%)**

* EQA reference lab cut off value = 4.4 U/gHb (using Trinity Biotech 345 reagent at 37°C)

b) The major of unsatisfactory results were caused by the G6PD activity of test samples that close to the cut off value or inappropriate cut off value used by the participants (Table 2, Table 3).

Table 3. Reagent kits of G6PD blood spot screening test used by the screening laboratory in 2022 (Survey：NS2022-03).

Reagent kit	No. of laboratory	Cut off value
Quantitative		
Born Safe	1	3.5 (U/g Hb)
Guangzhou Fenghua	4	2.6, 2.7, 2.75, 4.0 (U/g Hb)
Laboratory prepared	3	2.0, 2.2, 6.2 (U/g Hb)
Labsystems Diagnostics	2	3.0, 3.5 (U/g Hb)
PE (ND-1000)	17	2.1, 2.2, 2.5, 2.6 (U/g Hb)
PE GSP Neonatal G6PD (3310-0010)	14	16.0, 17.2, 20.0, 22.0, 23, 23.7, 24.0, 26.0, 29.0 (U/dL)
R&D Diagnostics (OSMMR2000-D)	2	2.5 (U/g Hb)
Zentech	3	2.48, 2.5, 3.0, 3.64 (U/g Hb)
Qualitative		
R&D Diagnostics (SQMMR500)	2	—
Laboratory prepared	1	—

* EQA reference lab cut off value = 4.4 U/gHb (using Trinity Biotech 345 reagent at 37°C)

6.3 To evaluate the within laboratory test repeatability of each participant, we compared the performance within a run for each participant who used quantitative test. CVs of “Repeatability of Neonatal G6PD Quantitative Screening Test” were calculated for sample number ≥ 3 from the same QC sample lot. Repeatability (within run precision) can monitor the participant performance in different activity within a run for each lab. For the annual report, we summarized the “Repeatability of Neonatal G6PD Quantitative Screening Test” for each survey.

a) The median of CVs for within lab repeatability were between 3.9% and 4.3%. (Table 4)；

b) The range of CVs for within lab repeatability was between 0% and 51.1% (Table 4)；

c) Most screening laboratories present a good within lab repeatability (CV < 10%) using neonatal G6PD quantitative screening test.

Table 4. Median and range of CVs for repeatability of Neonatal G6PD Quantitative Screening Test.

Reagent code [1]	NS2022-01		NS2022-02		NS2022-03		Total
	n/s [2]	CVs (%) [3]	n/s [2]	CVs (%) [3]	n/s [2]	CVs (%) [3]	
15	17/2	4.4 (0 – 10.8)	17/3	4.3 (0.0 – 13.1)	17/2	4.0 (0 – 9.4)	4.2 (0 – 13.1)
19	16/2	4.4 (0.8 – 21.3)	12/3	3.5 (0.1 – 8.7)	14/2	3.5 (0.6 – 13.7)	3.6 (0.1 – 21.3)
21	4/2	5.7 (3.3 – 21.4)	4/3	7.6 (1.8 – 13.7)	4/2	7.8 (1.5 – 11.7)	5.8 (1.5 – 21.4)
18	3/2	2.2 (0.9 - 5.1)	3/3	3.1 (1.4 - 5.9)	4/2	4.1 (2.5 – 11.7)	3.0 (0.9 – 11.7)
20	3/2	3.8 (2.2 – 4.6)	3/3	5.0 (0 – 8.8)	4/2	4.5 (0.4 - 48.8)	4.4 (0 - 48.8)
99	3/2	4.9 (0.6 – 51.1)	2/3	8.8 (1.6 – 50.0)	3/2	3.7 (2.8 – 23.7)	6.6 (0.6 – 51.1)
3	2/2	6.2 (4.1 – 13.2)	2/3	0 (0 – 4.0)	2/2	3.8 (0 – 8.8)	2.7 (0 – 13.2)
22	1/2	(2.1, 5.8)	1/3	7.8 (7.3 – 8.6)	1/2	(3.0, 3.1)	5.8 (2.1 – 8.6)
Total		4.3 (0 – 51.1)		3.9 (0 – 50)		3.9 (0 – 48.8)	0 – 51.1

Note：

1. Reagent code：https://g6pd.qap.tw/NSdata.php?BatchNo=NS2022-03
2. n/s：number of participants / number of QC sample lots for repeatability
3. Median (Range of CVs.)　CVs are from each repeatability sample lot in a participant.

6.4 All the results of EQA surveys for screening test in 2022 were posted on website < ***https://g6pd.qap.tw/111nsrep-eng.htm*** >.

7. Conclusion of customer satisfaction survey

In 2022, 55 customer satisfaction surveys were sent to participants, 45 (82%) questionnaires were returned.　Among the returned questionnaires, 80% of the participants rate “Excellent” performance and 17.8% of the participants rate “Great” performance in overall satisfaction.