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Annual Report of External Quality Assurance Survey for Neonatal G6PD Screening Test

(2021)

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

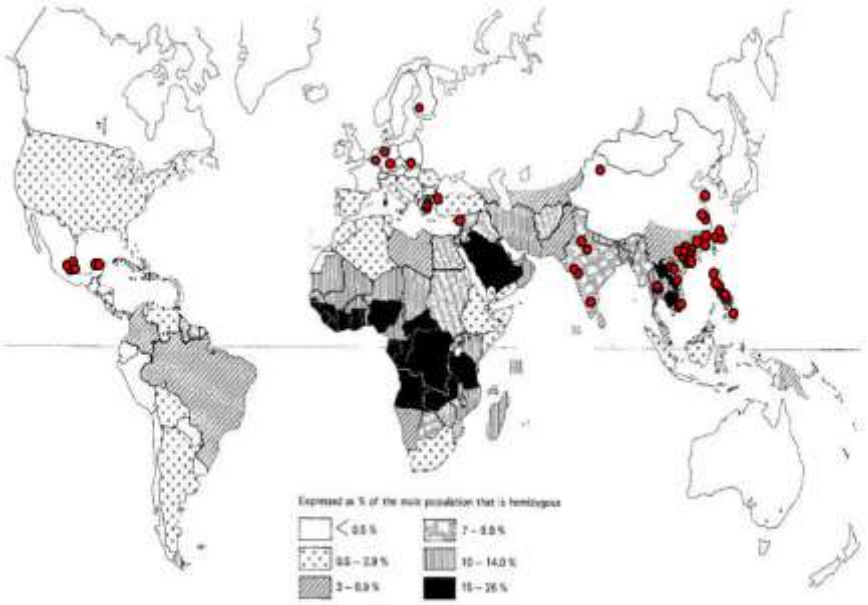
(2021)

1. Introduction

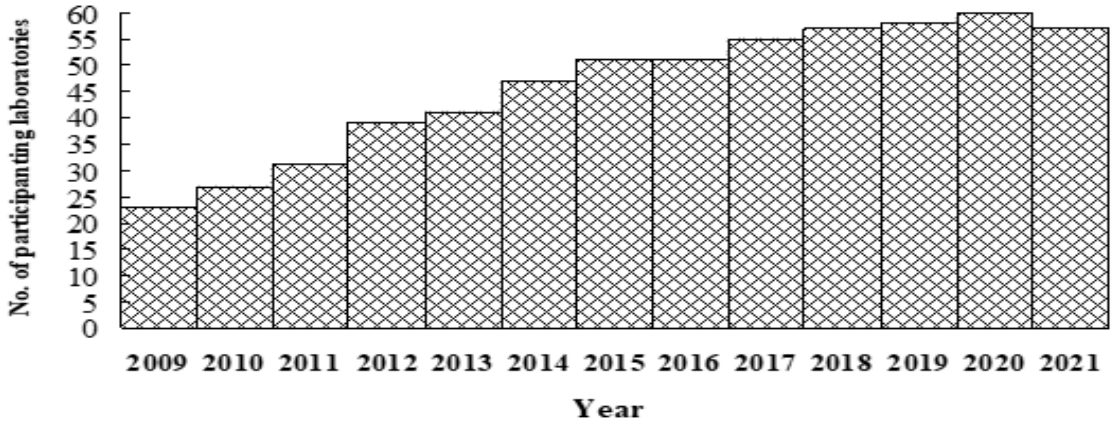
Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing " EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Screening Test " using dried blood spot samples for newborn screening laboratories since 1999. This EQA program has been officially accredited 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).

2. Participants

Fifty-seven laboratories (including 3 reagent manufacturers) from 15 countries (AT, BE, CH, CN, DE, FI, GR, IN, LB, MX, PH, TH, TR, TW, and VN) have participated in the EQA program in 2021. (• Participants)



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



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 ISO/IEC 17043:2010.

4. Surveys

4.1 There were 4 EQA surveys for screening test performed in 2021. (Table 1)

Table 1. 2021 EQA survey schedule

No.	Survey No	Survey Starting Date *	Reporting Deadline* (Taiwan)	Reporting Deadline* (Others)	Survey Result Released*
1	NS2021-01	02/22	02/25	03/03	03/11
2	NS2021-02	05/17	05/20	05/26	06/02
3	NS2021-03	08/09	08/12	08/18	08/26
4	NS2021-04	11/01	11/04	11/10**	11/23

* Date: Month/Day

** Due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, the reporting deadline was adjusted to 11/15.

4.2 In 2021, 225 sets of QC samples were sent to participants, 219 (97.3%) reports were returned.

4.3 Most screening laboratories received the QC samples within 4 ~ 8 days (Median：5 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 NS2021-04 was adjusted for additional 5 days later than the originally scheduled.

4.5 The report returned time was between 1 and 14 days (Median：8 days) after the survey started, which were compatible with previous years. Most reports (89.8%) were returned within target time (10 calendar days after the survey started).

4.6 There are 4 laboratories reports (C06 and D06 in NS2021-02 survey; C05 and C22 in NS2021-03 survey) not included in the total reported counts and excluded from survey evaluation due to delays in survey sample delivery, which may have been caused by the COVID-19 pandemic, or

exposure to extremely high-temperature (over 65.5 degree C) conditions during transportation. Apart from the reports of these 4 laboratories, no unsatisfactory report was found due to the shipping temperature.

4.7 There are 4.7% (10/215) participants, which were higher than previous years, reported the shipping humidity indicator reached 30%. However, no unsatisfactory result was found due to this shipping humidity.

4.8 The survey result released between 7 and 8 days (Median：8 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 consensus of the decision (assigned values) from more than 75% 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) 197 (91.6%) reports were “Acceptable”；

b) 4 (1.8%) reports were “Acceptable with caution”；

c) 14 (6.4%) reports were “Unsatisfactory”.

6.2 The unsatisfactory reports rate (6.4%) was higher than 2020 (1.8%) (Figure 1).

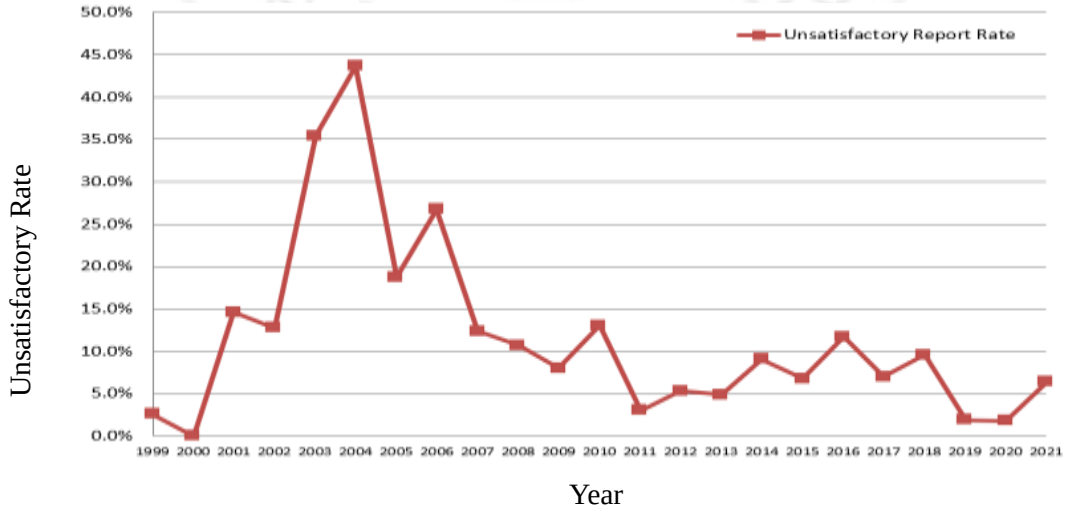


Figure 1. Unsatisfactory rates of the survey reports (1999 ~ 2021).

a) There were 11 false negative results (0.5%) and 49 false positive results (2.2%) were reported (Table 2)；

Table 2. EQA results of neonatal G6PD screening test at different ranges of G6PD activity in 2021.

G6PD Activity*	Specimens	Positive (P)	Negative (N)	False P	False N
0.1 – 2.0	277	269	8	0	**8 (2.9%)**
2.1 – 3.2	381	378	3	0	**3 (0.8%)**
6.0 – 6.8	946	45	901	**45 (4.8%)**	0
15.7 – 20.5	546	4	542	**4 (0.7%)**	0
Total	2150	696	1454	**49 (2.3%)**	**11 (0.5%)**

* 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 2021 (Survey：NS2021-04).

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, 3.0 (U/g Hb)
Laboratory prepared	3	2.2, 6.2, 14.9 (U/g Hb)
Labsystems Diagnostics	2	3.5 (U/g Hb)
PE (ND-1000)	23	2.0, 2.1, 2.2, 2.5, 2.6 (U/g Hb)
PE GSP Neonatal G6PD (3310-0010)	7	16.0, 17.2, 20.0, 20.5, 22.0, 23.7, 24.0, 25.5, 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, 3.67 (U/g Hb)
Qualitative		
R&D Diagnostics (SQMMR500)	2	—
Laboratory prepared	2	—

* 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 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 4.9%. (Table 4)；

b) The range of CVs for within lab repeatability was between 0% and 25.6% (Table 4)；.

c) Most screening laboratories present a good within lab repeatability (<10%) in neonatal G6PD quantitative screening test. Only two screening laboratories had CVs for within lab repeatability >20%.

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

Reagent code [1]	NS2021-01		NS2021-02		NS2021-03		NS2021-04		Total
	n/s [2]	CVs (%) [3]	n/s [2]	CVs (%) [3]	n/s [2]	CVs (%) [3]	n/s [2]	CVs (%) [3]	
15	25/2	3.7 (0 - 19.6)	21/1	4.3 (2.4 - 9.6)	22/2	4.7 (0 - 13.9)	21/2	4.7 (0 - 14.8)	4.3 (0 - 19.6)
19	11/2	2.7 (1.4. - 6.3)	12/1	3.4 (1.5 - 5.1)	14/2	4.2 (0.5 - 10.1)	15/2	4.4 (1.7 - 15.0)	3.5 (0.5 - 15.0)
18	5/2	2.3 (0 - 4.1)	5/1	2.5 (1.8 - 2.9)	4/2	5.6 (1.2 - 7.1)	4/2	1.8 (0.8 - 3.8)	2.6 (0 - 7.1)
21	3/2	5.1 (3.8 - 7.1)	3/1	4.4 (3.7 - 25.6)	1/2	3.3 (2.9, 3.7)	4/2	5.7 (1.9 - 10.3)	4.6 (1.9 - 25.6)
20	3/2	5.2 (0.9 - 7.2)	2/1	4.0 (3.5 - 4.5)	2/2	4.3 (2.1 - 8.7)	2/2	6.5 (2.4 - 24.4)	5.1 (0.9 - 24.4)
99	3/2	3.2 (0.5 - 10.9)	3/1	4.8 (1.5 - 6.8)	2/2	6.9 (1.5 – 12.5)	3/2	3.3 (1.2 – 7.7)	4.2 (0.5 - 12.5)
3	2/2	4.4 (0 - 12.4)	1/1	(2.2)	1/2	(2.5, 9.3)	2/2	3.6 (1.0 - 7.9)	4.1 (0 - 12.4)
22	1/2	(5.2, 7.5)	1/1	(8.4)	1/2	(1.5, 10.2)	1/2	(6.5, 12.9)	7.5 (1.5 - 12.9)
16	—	—	—	—	1/2	(6.3, 7.4)	—	—	(6.3, 7.4)
Total		4.0 (0 - 12.4)		3.9 (1.5 - 25.6)		4.9 (1.8 - 13.9)		4.7 (0.8 - 24.4)	0 - 25.6

Note：

1. Reagent code：https://g6pd.qap.tw/NSdata.php?BatchNo=NS2021-03
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 2021 were posted on website

< ***https://g6pd.qap.tw/110nsrep-eng.htm*** >.

7. Conclusion of customer satisfaction survey

In 2021, 56 customer satisfaction surveys were sent to participants (as one participant's laboratory was closed in August of 2021, only 56 customer surveys were sent) , 49 (88%) questionnaires were returned.

- It was suggested to extend the reporting deadline.

In order to prevent G6PD deficient newborns from severe neonatal jaundice attack, most of neonatal G6PD screening centers try to report the positive G6PD result as soon as possible. Most of neonatal G6PD screening centers try to report the positive G6PD result within 48 hours after they received the screening samples. Our EQA program reporting deadline is designed accordingly.

However, as the ongoing COVID 19 pandemic has caused worldwide delays in shipping. We will extend the reporting deadline for overseas screening centers to 10 days (after the samples were sent) for 2022 surveys. If overseas participants cannot receive the QC samples before the reporting deadline, the reporting deadline will be postponed for another 5 days. If an overseas participant cannot receive the QC samples within 15 days after the Survey Starting Date, the result of the participant will not be included in the statistics of that survey. But the annual participation record of the participant will not be affected.