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Annual Report of External Quality Assurance Survey for Neonatal G6PD Screening Test (2019)

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

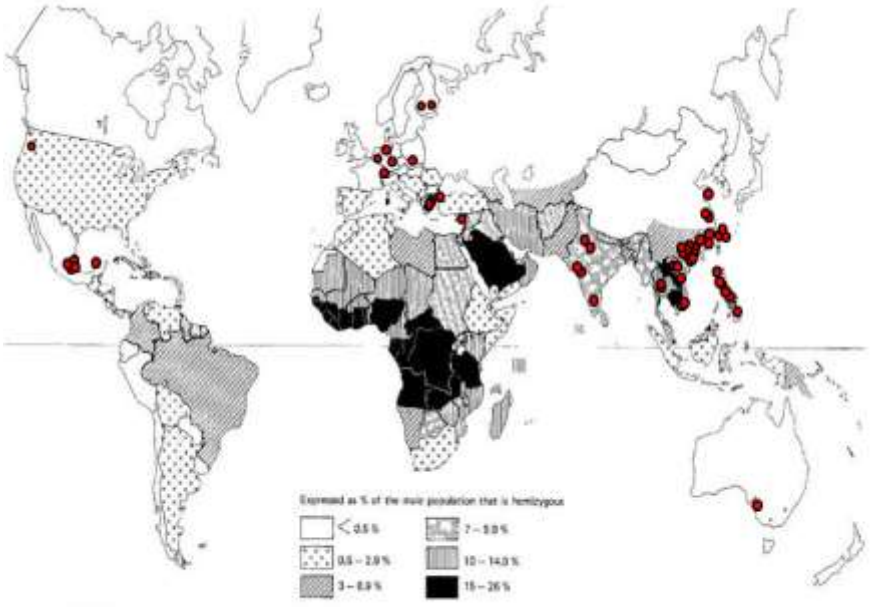
(2019)

1. Introduction

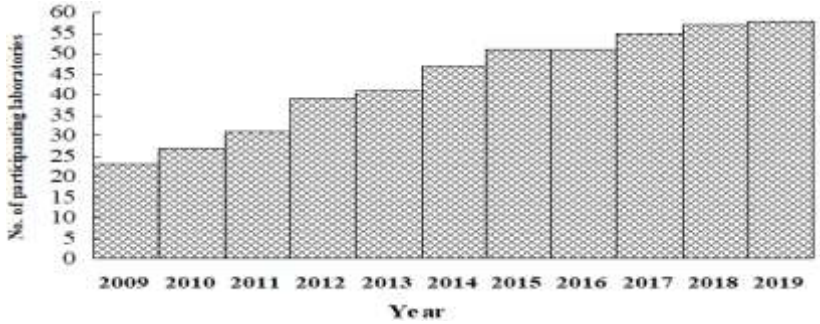
Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing " EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Screening Test " using dried blood spot samples for newborn screening laboratories since 1999. This EQA program has been officially accredited by Taiwan Accreditation Foundation (TAF) for conformity to ISO/IEC 17043:2010 since 2017 (Accreditation No.：P016).

2. Participants

Fifty-eight laboratories (including 5 reagent manufacturers) from 17 countries (AT, AU, BE, CH, CN, DE, FI, GR, IN, LB, MX, PH, TH, TR, TW, US, and VN) have participated in the EQA program in 2019. (• Participants)



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



3. Quality control sample (QC sample)

3.1 10 of 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 ISO17043:2010.

4. Surveys

4.1 There were 4 EQA surveys for screening test performed in 2019：

No.	Survey No	Survey Starting Date *	Reporting Deadline* (Taiwan)	Reporting Deadline* (Others)	Survey Result Released*
1	NS2019-01	01/14	01/17	01/23	01/28
2	NS2019-02	04/15	04/18	04/24	04/26
3	NS2019-03	07/15	07/18	07/24	07/26
4	NS2019-04	10/14	10/17	10/23	10/28

* Date: Month/Day

4.2 In 2019, 226 sets of QC samples were sent to participants, 216 (95.6%) reports were returned.

4.3 Most screening laboratories received the QC samples within 2 ~ 4 days (Median：2 days) after the survey started.

4.4 There is no participants had reported the shipping temperature indicator reached 54.4 ℃, which were compatible with previous years. No unsatisfactory result was due to the shipping temperature.

4.5 Only 5.1% of the participants had reported the shipping humidity indicator reached 30%, which were compatible with previous years. No unsatisfactory result was due to the shipping humidity.

4.6 The report returned time were between 2 and 10 days (Median：7 ~ 8 days) after the survey started, which were compatible with previous years. Most reports (98.1%) were returned within target time (9 calendar days).

4.7 The survey result released time were between 2 and 5 days (Median：4 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) 206 (95.4%) reports were “Acceptable”；

b) 6 (2.8%) reports were “Acceptable with caution”；

c) 4 (1.9%) reports were “Unsatisfactory”.

6.2 The unsatisfactory reports (1.9%) was lower than that reported in 2018 (9.6%) (Figure 1).

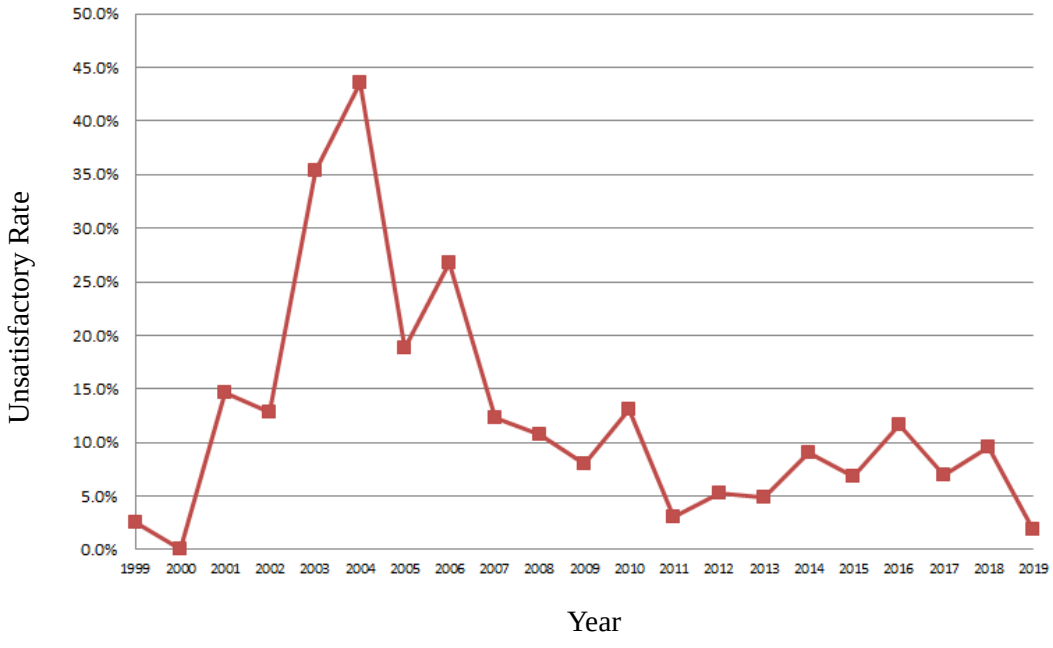


Figure 1. Unsatisfactory rates of the survey reports (1999 ~ 2019).

a) There were 15 false negative results (0.7%) and 3 false positive results (0.1%) were reported (Table 1)；

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 1, Table 2).

6.3 We had provided a new report "Repeatability of Neonatal G6PD Quantitative Screening Test" since NS2019-04. 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 repeatability were between 3.5% and 6.6%. (Table 3)；

b) The range of CVs for repeatability was between 0.0% and 66.3% (Table 3)；.

c) There were 5 results of CVs for repeatability over 20% in low activity (below 3.2 U/gHb) (2.6%) and 10 repeatability results over 20% in high activity (above 9.2 U/gHb) (3.0%) were reported (Table 4).

d) Most screening laboratories present a good repeatability in neonatal G6PD quantitative screening test. Only 6.3% screening laboratories were reported CV >20%. (Table 4)

6.4 All the results of EQA surveys for screening test in 2019 were posted on website

< ***https://g6pd.qap.tw/108nsrep-eng.htm*** >.

7. Conclusion of customer satisfaction survey

In the 2019 customer satisfaction survey, we had collected participants' opinions on the quantity of EQA samples for each survey (10 QC samples/survey or 6 QC samples/survey) and in order to improve the efficiency of delivering report, and to prevent the loss of reports, we also had collected participants' opinion on receiving electronic files only.

7.1 Among the returned questionnaires (return rate: ~75%), more laboratories are preferred to have 10 quality control samples for each survey. Therefore, the quantity of EQA samples for each survey of 2020 EQA program will be keep to10 QC samples / survey.

7.2 Among the returned questionnaires (return rate: ~75%), all laboratories are agreed to receive the electronic report file only. Therefore, in 2020, we will put the reports in the MIS system, participants could login the MIS system and download their reports.

7.3 There were also several suggestions provided by our participants,

a) If possible start lysosomal enzyme on DBS at least common disorders like Gaucher, Pompe, Fabry, MPSI. ;

- If more and more participants would like to have these items, we will try to develop this EQA program in the future.

b) You should have reports on your website to help your participants print out the reports in case of losing their previous ones. ;

- We will provide the electronic reports for download in the MIS system, participants may login the MIS system and download reports by themselves.

c) Is it possible 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, i.e. 3 days for screening centers in Taiwan and 9 days for overseas screening centers (after the samples were sent). We also hope that the short summary report releasing period could help participants to take troubleshooting action as soon as possible in case there is a need.

8. G6PD EQA Program Participants Workshop

The 10th International Society for Neonatal Screening (ISNS) International Symposium was held in Hangzhou (China) in September, 2019. We are glad to have the opportunity to meet and communicate with participants of G6PD EQA program. We held two EQA participants workshops during the conference. Twenty-one participants from 8 newborn screening laboratories (from Philippines, Vietnam, Lebanon, Turkey and R.O.C.), and our partners from the Newborn Screening Reference Center (NSRC) N.I.H., U.P. Manila were attended the workshop in English (2019.09.19).

G6PD EQA Program Participants Workshop 2019.09.19, Hangzhou

Thirty-three participants from 17 newborn screening centers (form Fujian, Guangdong, Guangxi, Hunan, Jiangxi, Shandong, Shanghai and Taipei) joined the workshop in Chinese (2019.09.20).

G6PD EQA Program Participants Workshop 2019.09.20, Hangzhou

In these workshops, Ms. Laura Fan (QA Technical Manager of PMF QAP Center) reported the EQA program results and discussed the performance of the EQA program. In addition to EQA program , she also shared how to set up or adjust the cut-off value for G6PD newborn screening test, and introduced the “Internal Quality Control Program (IQC) for Neonatal G6PD Screening Test” provided by PMF to attendees.

The attendees had a lively discussion on several issues about quality control and EQA programs. They also shared their experience about the challenges G6PD screening laboratories and interchanged their experiences and ideas. In attendees' feedback, we are glad to know that this EQA program is of great benefit to improve the test quality.

Table 1. EQA results of neonatal G6PD screening test at different ranges of G6PD activity in 2019.

G6PD Activity*	Specimens	Positive (P)	Negative (N)	False P	False N
0.1 – 1.0	0	0	0	0	0
1.1 – 3.2	648	633	15	0	**15 (2.3%)**
6.3 – 8.0	54	2	52	**2 (3.7%)**	0
9.2 – 20.5	1458	1	1457	**1 (0.1%)**	0
Total	2160	636	1524	**3 (0.1%)**	**15 (0.7%)**

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

Table 2. Reagent kits of G6PD blood spot screening test used by the screening laboratory in 2019 (Survey：NS2019-04).

Reagent kit	No. of laboratory	Cut off value
Quantitative		
Guangzhou Fenghua	4	2.5, 2.6, 2.7 (U/g Hb)
Laboratory prepared	3	2.2, 2.75, 7.2 (U/g Hb)
Labsystems Diagnostics	4	3.5, 4.0 (U/g Hb)
PE (ND-1000)	23	2.1, 2.2, 2.5, 2.6, 2.9 (U/g Hb)
PE GSP Neonatal G6PD (3310-0010)	7	16.0, 17.2, 20.0, 22.0, 23.7 (U/dL)
R&D Diagnostics (OSMMR2000-D)	2	2.5 (U/g Hb)
Spotcheck G6PD 50 hour reagent	3	6.0 (μmol NADPH/g Hb), 49 (μM)
Zentech	3	2.2, 2.6, 7.4 (U/g Hb)
Qualitative		
R&D Diagnostics (SQMMR500)	2	-
Laboratory prepared	4	-

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

Table 3. Median and range of CVs for repeatability of Neonatal G6PD Quantitative Screening Test.

Reagent code [1]	NS2019-01		NS2019-02		NS2019-03		NS2019-04		Total
	n/s[2]	CVs [3]	n/s[2]	CVs [2]	n/s[2]	CVs [2]	n/s[2]	CVs [2]	
15	25/3	4.2% (0%-31.5%)	24/2	4.7% (0%-37.7%)	24/3	7.2% (0%-38.5%)	23/3	3.9% (0%-27.3%)	4.6% (0%-37.7%)
19	7/3	3.5% (0%-11.0%)	7/2	5.0% (1.2%-11.3%)	6/3	6.9% (3.2%-17.5%)	7/3	4.3% (1.8%-13.3%)	5.0% (0.5%-17.5%)
99	4/3	2.6% (0%-15.1%)	4/2	2.4% (1.4%-14.7%)	4/3	5.7% (1.3%-66.3%)	4/3	2.4% (1.0%-47.2%)	3.6% (1.0%-66.3%)
18	3/3	1.6% (0.4%-3.8%)	4/2	3.0% (1.4%-10.0%)	4/3	3.5% (1.7%-6.0%)	4/3	2.7% (1.2%-5.9%)	2.7% (0.4%-10.0%)
20	3/3	2.0% (0%-3.5%)	4/2	6.4% (4.4%-13.4%)	4/3	10.2% (0%-34.0%)	4/3	5.5% (1.7%-9.8%)	5.5% (1.7%-34.0%)
3	2/3	5.4% (0%-13.7%)	2/2	10.0% (3.9%-11.1%)	2/3	9.0% (3.1%-13.1%)	2/3	8.8% (0%-10.6%)	9.2% (0%-13.7%)
16	2/3	18.3% (3.7%-38.7%)	2/2	7.0% (2.7%-19.8%)	2/3	5.0% (2.4%-23.1%)	2/3	5.7% (1.3%-18.3%)	6.1% (1.3%-44.9%)
21	2/3	2.3% (1.0%-14.2%)	1/2	(6.3, 9.5)	2/3	7.7% (4.5%-12.6%)	3/3	7.3% (2.3%-29.9%)	6.7% (1.0%-14.2%)
Total		3.5% (0.0%-44.9%)		5.0% (0.0%-37.7%)		6.6% (0.0%-66.3%)		4.0% (0.0%-47.2%)	0.0%-66.3%

Note：

1. Reagent code：https://g6pd.qap.tw/NSdata.php?BatchNo=NS2019-04
2. n/s：number of participants / number of QC sample lots for repeatability
3. Median and Range of CVs. CVs are from each repeatability sample lot in a participant.

Table 4. Reported the CV > 20% of Repeatability of Neonatal G6PD Quantitative Screening Test.

Survey No.	Reports returned[1]	1.1 – 3.2 (U/gHb)	9.2 – 20.5 (U/gHb)	Reported CV > 20%
NS2019-01	48	1/48	4/96	3 labs
NS2019-02	48	2/48	0/48	2 labs
NS2019-03	45	1/45	6/90	7 labs
NS2019-04	49	1/49	3/98	3 labs
Total	190	5/190 (2.6%)	10/332 (3.9%)	15/190 (7.9%)

Note：

1. Only compare the performance within a run for each participant who used quantitative test.