Accredited to ISO/IEC 17043

Annual Report of External Quality Assurance Survey for Neonatal G6PD Screening Test (2020)

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

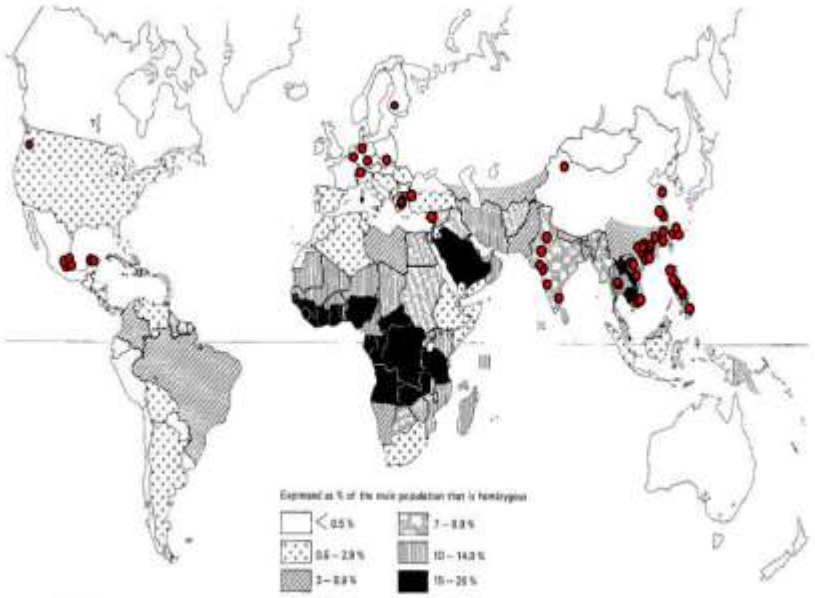
(2020)

1. Introduction

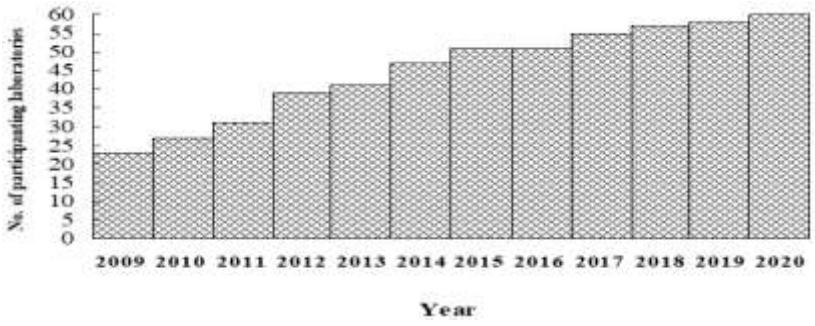
Preventive Medicine Foundation Quality Assurance Program Center (PMF QAP Center) has been providing " EQA Program for Neonatal Glucose-6-Phosphate Dehydrogenase (G6PD) Screening Test " using dried blood spot samples for newborn screening laboratories since 1999. This EQA program has been officially accredited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

Sixty laboratories (including 4 reagent manufacturers) from 16 countries (AT, BE, CH, CN, DE, FI, GR, IN, LB, MX, PH, TH, TR, TW, US, and VN) have participated in the EQA program in 2020. (• Participants)



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



3. Quality control sample (QC sample)

3.1 Ten 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 Due to the COVID-19 pandemic, we had cancelled a schedule survey NS2020-02 and had extended reporting deadline. There were 3 EQA surveys for screening test performed in 2020. (Table 1)

Table 1. 2020 EQA survey schedule

No.	Survey No	Survey Starting Date *	Reporting Deadline* (Taiwan)	Reporting Deadline* (Others)	Survey Result Released*
1	NS2020-01	02/24	02/27	03/04 (extend to 03/05)	03/12
2	NS2020-02	Due to the COVID-19 pandemic, this survey has been canceled.			
3	NS2020-03	08/24	08/27	09/02 (extend to 09/04)	09/10
4	NS2020-04	11/09	11/12	11/18 (extend to 11/19)	11/24

* Date: Month/Day

4.2 In 2020, 170 sets of QC samples were sent to participants, 168 (98.8%) reports were returned.

4.3 Most screening laboratories received the QC samples within 3 ~ 8 days (Median：4 ~ 5 days) after the survey started, which is delayed comparing to previous years (2 ~ 4 days, median：2 days).

4.4 Only 0.6% (1/168) 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.

4.5 11.3% (19/168) of the participants had reported the shipping humidity indicator reached 30%, which were higher than previous years. No unsatisfactory result was found due to the shipping humidity.

4.6 The report returned time were between 2 and 11 days (Median：7 ~ 8 days) after the survey started, which were compatible with previous years. Most reports (92.3%) were returned within target time (9 calendar days).

4.7 The survey result released between 5 and 7 days (Median：6 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) 156 (92.9%) reports were “Acceptable”；

b) 9 (5.4%) reports were “Acceptable with caution”；

c) 3 (1.8%) reports were “Unsatisfactory”.

6.2 The unsatisfactory reports rate (1.8%) was compatible with that reported in 2019 (1.9%) (Figure 1).

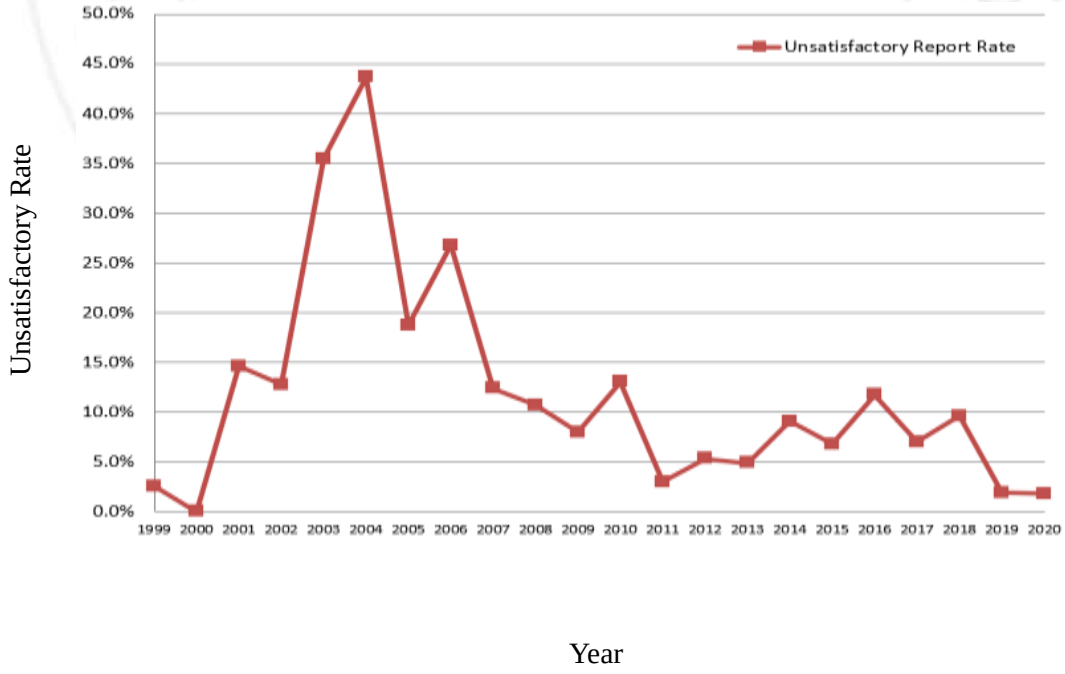


Figure 1. Unsatisfactory rates of the survey reports (1999 ~ 2020).

a) There were 10 false negative results (0.6%) and 8 false positive results (0.5%) were reported (Table 2)；

Table 2. EQA results of neonatal G6PD screening test at different ranges of G6PD activity in 2020.

G6PD Activity*	Specimens	Positive (P)	Negative (N)	False P	False N
0.1 – 2.0	165	163	2	0	**2 (1.2%)**
2.1 – 3.2	223	215	8	0	**8 (3.6%)**
15.7 – 20.5	1292	8	1284	**8 (0.6%)**	0
Total	1680	386	1294	**8 (0.5%)**	**10 (0.6%)**

* 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 2020 (Survey：NS2020-04).

Reagent kit	No. of laboratory	Cut off value
Quantitative		
Born Safe	1	4.0 (U/g Hb)
Guangzhou Fenghua	5	2.6, 2.7, 2.75, 3.0, 4.0 (U/g Hb)
Laboratory prepared	3	2.0, 2.2, 6.2 (U/g Hb)
Labsystems Diagnostics	4	3.5 (U/g Hb)
PE (ND-1000)	23	2.0, 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, 24.0, 25.5, 26.0 (U/dL)
R&D Diagnostics (OSMMR2000-D)	2	2.5 (U/g Hb)
Spotcheck G6PD 50 hour reagent	3	40.0 (μM)
Zentech	3	2.2, 2.48, 8.5 (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. A new report on "Repeatability of Neonatal G6PD Quantitative Screening Test" has been provided since NS2019-04. CVs 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 3.5% and 6.6%. (Table 4)；

b) The range of CVs for within lab repeatability was between 0.0% and 43.7% (Table 4)；.

c) Most screening laboratories present a good within lab repeatability in neonatal G6PD quantitative screening test. But there were still 6.3% screening laboratories CVs for within lab repeatability >20%.

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

Reagent code [1]	NS2020-01		NS2020-03		NS2020-04		Total
	n/s [2]	CVs [3]	n/s [2]	CVs [2]	n/s[2]	CVs [2]	
15	23/2	4.4% (1.3%-16.4%)	23/2	4.3% (0%-43.7%)	25/2	3.8% (0.9%-25.6%)	4.2% (0%-43.7%)
19	7/2	3.6% (1.7%-7.8%)	10/2	3.9% (1.1%-6.7%)	11/2	3.1% (0.7%-4.8%)	3.3% (0.7%-7.8%)
20	5/2	5.7% (1.3%-18.7%)	4/2	6.3% (2.4%-8.7%)	3/2	4.6% (1.3%-16.2%)	5.7% (1.3%-18.7%)
99	5/2	3.8% (1.0%-27.8%)	3/2	5.9% (1.8%-32.3%)	3/2	4.1% (0.7%-7.9%)	3.8% (0.7%-32.2%)
18	4/2	2.2% (0.2%-4.2%)	4/2	2.6% (1.0%-6.7%)	5/2	2.1% (0.8%-3.1%)	2.2% (0.2%-4.2%)
21	3/2	4.4% (2.5%-10.5%)	3/2	3.5% (1.6%-20.5%)	3/2	3.8% (1.7%-13.8%)	3.6% (1.6%-13.8%)
3	2/2	7.4% (5.8%-11.9%)	2/2	4.5% (2.7%-8.3%)	2/2	3.2% (2.2%-9.4%)	5.9% (2.2%-11.9%)
16	2/2	7.4% (3.5%-15.2%)	1/2	(8.6%, 12.8%)	1/2	(8.2%, 10.0%)	8.4% (3.5%-15.2%)
Total		4.2% (0.2%-27.8%)		6.6% (0%-43.7%)		4.0% (0.7%-25.6%)	0%-43.7%

Note：

1. Reagent code：https://g6pd.qap.tw/NSdata.php?BatchNo=NS2020-04
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.

6.4 All the results of EQA surveys for screening test in 2020 were posted on website

< ***https://g6pd.qap.tw/109nsrep-eng.htm*** >.

7. Conclusion of customer satisfaction survey

In 2020, 58 customer satisfaction surveys were sent to participants, 51 (88%) questionnaires were returned.

7.1 Some participants suggest providing *z* score and statistics bias results in the report. However, as there are many different kits used by our participants and some kit groups are too small to evaluate. Even using the same kit, the test result may be different due to the different reaction temperature. Therefore, the assigned values required for calculating *z* score and statistics bias are still under evaluation.

7.2 It was suggested to group the data by reaction methods or brand of reagent kits by our participants. Therefore, we have provided the "Between Lab Variation of DBS G6PD Quantitative Screening Test Using Same Reagent Kit" summary, which is the statistic result of analyzing the data from different reagent kits (reagent kits with labs < 5 are not included.), in each survey report since 2020.