

External Quality Assurance (EQA) of G6PD Quantitative Test

Survey No. : RH2021-02
 Sample sent : 28 set

Sample sent on : 2021/06/14
 Results reported (%) : 28 (100%)

Reporting deadline : 2021/06/21

1. [Long term observation of inter laboratory CV vs. surveys](#)

4. [The distribution of G6PD reported in this survey](#)

2. [Long term observation of inter laboratory CV vs. G6PD activities](#)

5. [The distribution of Hb reported in this survey](#)

3. [Deviation graph for individual laboratory](#)

6. [Others](#)

Summary Report of G6PD and Hemoglobin (Hb) Quantitative Test Results

| Lab | Referral Hosp. | Report (day) | G6PD Reagent Code | Sample 1 | | | | Sample 2 | | | | Sample 3 | | | | Hb 1 (g/dL) | Hb 2 (g/dL) | Hb 3 (g/dL) |
|---------------------------------------|----------------|--------------|-------------------|----------|-------|---------|------|-----------|-------|---------|------|----------|--------|---------|------|-------------|-------------|-------------|
| | | | | (U/gHb) | D% | z score | SDI | (U/gHb) | D% | z score | SDI | (U/gHb) | D% | z score | SDI | | | |
| F02 | F02 | 4 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.6 | 1.8% | 0.3 | 0.5 | 4.6 | 2.2% | 0.3 | 1.1 | 2.0 | 2.2 | 2.1 |
| F03 | F03 | 6 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.1 | -1.2% | -0.2 | -0.3 | 4.5 | 0.0% | 0.0 | 0.5 | 2.0 | 2.2 | 2.0 |
| F04 | F04 | 4 | 5 | 4.3 | -4.4% | -0.6 | -0.9 | 16.0 | -1.8% | -0.3 | -0.5 | 4.4 | -2.2% | -0.3 | 0.0 | 2.1 | 2.4 | 2.3 |
| F05 | F05 | 2 | 5 | 4.1 | -8.9% | -1.3 | -1.8 | 15.6 | -4.3% | -0.6 | -1.2 | 4.2 | -6.7% | -1.0 | -1.1 | 2.1 | 2.2 | 2.1 |
| F07 | F07 | 5 | 5 | 4.3 | -4.4% | -0.6 | -0.9 | 15.1 | -7.4% | -1.1 | -2.0 | 4.2 | -6.7% | -1.0 | -1.1 | 2.2 | 2.4 | 2.2 |
| F09 | F09 | 7 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 17.1 | 4.9% | 0.7 | 1.4 | 4.7 | 4.4% | 0.6 | 1.6 | 2.0 | 1.9 | 2.0 |
| F10 | F10 | 7 | 5 | 4.1 | -8.9% | -1.3 | -1.8 | 14.8 | -9.2% | -1.3 | -2.5 | 4.0 | -11.1% | -1.6 | -2.1 | 2.0 | 2.2 | 2.0 |
| F11 | F11 | 7 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.6 | 1.8% | 0.3 | 0.5 | 4.4 | -2.2% | -0.3 | 0.0 | 2.0 | 2.2 | 2.2 |
| F12 | F12 | 7 | 5 | 4.8 | 6.7% | 1.0 | 1.4 | 16.1 | -1.2% | -0.2 | -0.3 | 4.7 | 4.4% | 0.6 | 1.6 | 2.0 | 2.7 | 2.1 |
| F13 | F13 | 7 | 5 | 4.1 | -8.9% | -1.3 | -1.8 | 15.4 | -5.5% | -0.8 | -1.5 | 4.1 | -8.9% | -1.3 | -1.6 | 2.0 | 2.2 | 2.1 |
| F14 | F14 | 7 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.6 | 1.8% | 0.3 | 0.5 | 4.5 | 0.0% | 0.0 | 0.5 | 2.1 | 2.1 | 2.0 |
| F15 | F15 | 3 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.1 | -1.2% | -0.2 | -0.3 | 4.4 | -2.2% | -0.3 | 0.0 | 2.2 | 2.2 | 2.2 |
| F17 | F17 | 4 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.4 | 0.6% | 0.1 | 0.2 | 4.6 | 2.2% | 0.3 | 1.1 | 2.1 | 2.2 | 2.1 |
| F18 | F18 | 5 | 5 | 4.4 | -2.2% | -0.3 | -0.5 | 16.3 | 0.0% | 0.0 | 0.0 | 4.5 | 0.0% | 0.0 | 0.5 | 2.0 | 2.0 | 2.0 |
| F19 | F19 | 7 | 5 | 4.3 | -4.4% | -0.6 | -0.9 | 16.1 | -1.2% | -0.2 | -0.3 | 4.4 | -2.2% | -0.3 | 0.0 | 2.1 | 2.2 | 2.1 |
| F20 | F20 | 5 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.2 | -0.6% | -0.1 | -0.2 | 4.6 | 2.2% | 0.3 | 1.1 | 2.1 | 2.3 | 2.1 |
| F21 | F21 | 4 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.4 | 0.6% | 0.1 | 0.2 | 4.3 | -4.4% | -0.6 | -0.5 | 2.0 | 2.1 | 2.0 |
| F22 | F22 | 2 | 5 | 4.1 | -8.9% | -1.3 | -1.8 | 15.5 | -4.9% | -0.7 | -1.4 | 4.3 | -4.4% | -0.6 | -0.5 | 2.2 | 2.2 | 2.1 |
| F24 | F24 | 3 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 17.0 | 4.3% | 0.6 | 1.2 | 4.7 | 4.4% | 0.6 | 1.6 | 2.2 | 2.4 | 2.2 |
| F25 | F25 | 4 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.6 | 1.8% | 0.3 | 0.5 | 4.5 | 0.0% | 0.0 | 0.5 | 2.1 | 2.3 | 2.2 |
| F26 | F26 | 4 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.3 | 0.0% | 0.0 | 0.0 | 4.1 | -8.9% | -1.3 | -1.6 | 2.2 | 2.3 | 2.3 |
| F27 | F27 | 4 | 5 | 4.5 | 0.0% | 0.0 | 0.0 | 16.5 | 1.2% | 0.2 | 0.3 | 4.5 | 0.0% | 0.0 | 0.5 | 2.1 | 2.3 | 2.1 |
| F28 | F28 | 7 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 17.1 | 4.9% | 0.7 | 1.4 | 4.6 | 2.2% | 0.3 | 1.1 | 2.1 | 2.2 | 2.1 |
| F29 | F29 | 7 | 5 | 4.3 | -4.4% | -0.6 | -0.9 | 16.0 | -1.8% | -0.3 | -0.5 | 4.4 | -2.2% | -0.3 | 0.0 | 2.4 | 2.5 | 2.3 |
| F30 | F30 | 6 | 5 | 4.3 | -4.4% | -0.6 | -0.9 | 16.1 | -1.2% | -0.2 | -0.3 | 4.3 | -4.4% | -0.6 | -0.5 | 2.0 | 2.1 | 2.0 |
| F31 | F31 | 4 | 5 | 4.7 | 4.4% | 0.6 | 0.9 | 16.9 | 3.7% | 0.5 | 1.0 | 4.5 | 0.0% | 0.0 | 0.5 | 2.1 | 2.3 | 2.2 |
| F32 | F32 | 3 | 5 | 4.6 | 2.2% | 0.3 | 0.5 | 16.6 | 1.8% | 0.3 | 0.5 | 4.4 | -2.2% | -0.3 | 0.0 | 2.1 | 2.2 | 2.1 |
| F33 | F33 | 4 | 5 | 4.8 | 6.7% | 1.0 | 1.4 | 17.2 | 5.5% | 0.8 | 1.5 | 4.6 | 2.2% | 0.3 | 1.1 | 2.0 | 2.2 | 2.1 |
| Total participating laboratories = 28 | | | | | | | | | | | | | | | | | | |
| Xa (Median) | - | 4.5 | - | 4.5 | | | | 16.3 | | | | 4.5 | | | | 2.1 | 2.2 | 2.1 |
| uXa | - | - | - | 0.046 | | | | 0.123 | | | | 0.039 | | | | - | - | - |
| σp | - | - | - | 0.315 | | | | 1.141 | | | | 0.315 | | | | - | - | - |
| σp' | - | - | - | - | | | | - | | | | - | | | | - | - | - |
| Range | - | 2-7 | - | 4.1-4.8 | | | | 14.8-17.2 | | | | 4.0-4.7 | | | | 2.0-2.4 | 1.9-2.7 | 2.0-2.3 |
| n | - | - | - | 28 | | | | 28 | | | | 28 | | | | 28 | 28 | 28 |
| Mean | - | - | - | 4.5 | | | | 16.3 | | | | 4.4 | | | | 2.1 | 2.2 | 2.1 |
| S.D. | - | - | - | 0.22 | | | | 0.59 | | | | 0.19 | | | | 0.09 | 0.12 | 0.10 |
| C.V. | - | - | - | 4.9% | | | | 3.6% | | | | 4.3% | | | | 4.3% | 5.5% | 4.8% |

Note:

- $D\% = [(X - X_a) / X_a] \times 100\%$; X = Your Results, X_a = Assigned value
- u_{X_a} = uncertainty of the assigned value. $u_{X_a} = 1.1 \times SD / n^{1/2}$
- SD for proficiency assessment (σ_p) = 7% x X_a; but while X_a < 2.9 U/gHb, $\sigma_p = 0.2$ U/gHb
- Adjusted SD for proficiency assessment (σ_p') = $(\sigma_p^2 + u_{X_a}^2)^{1/2}$. σ_p' is used for proficiency assessment when $u_{X_a} \geq 0.3\sigma_p$
- z score = D / σ_p ; D = X - X_a, σ_p = SD for proficiency assessment
- SDI = $(X - \text{Mean}) / SD$; SD = standard deviation of peer group; SDI is not calculated when SD equals 0
- The assigned value (X_a) is the **median** of all the results reported of this EQA sample
- Robust results (Mean and SD) were calculated by Algorithm A according to ISO 13528
- The evaluation criteria for measurement result of each specimen : Acceptable : $|z| \leq 2$; Caution : $2 < |z| \leq 3$; Unsatisfactory : $|z| > 3$

| Reagent Kit | G6PD Reagent Code | Lab |
|-------------|-------------------|--|
| Medicon | 5 | F02, F03, F04, F05, F07, F09, F10, F11, F12, F13, F14, F15, F17, F18, F19, F20, F21, F22, F24, F25, F26, F27, F28, F29, F30, F31, F32, F33 |

Long Term Observation of Blood G6PD Quantitative Test EQA Survey Results

Survey No : RH2021-02 (in green ●)

- Total participants' CV result plotted against surveys

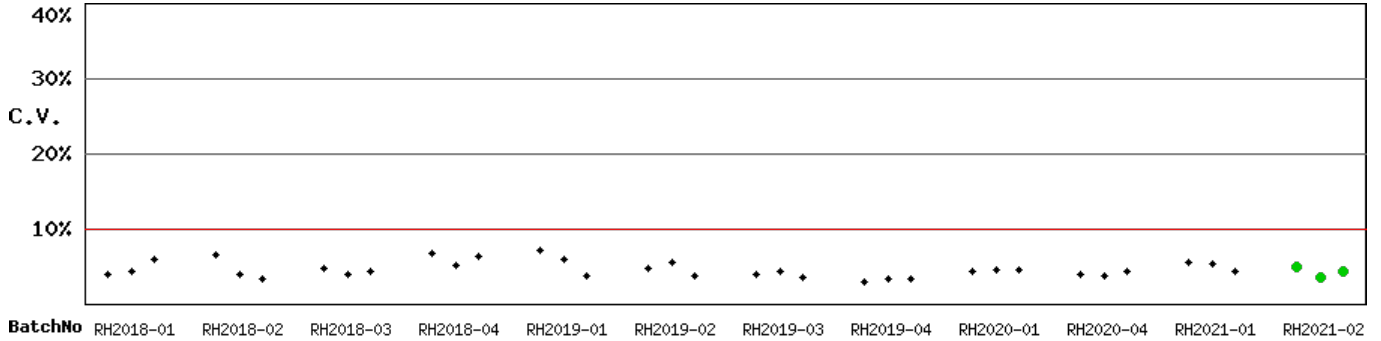


Fig RH-2.1

- Total participants' CV result plotted against G6PD activities

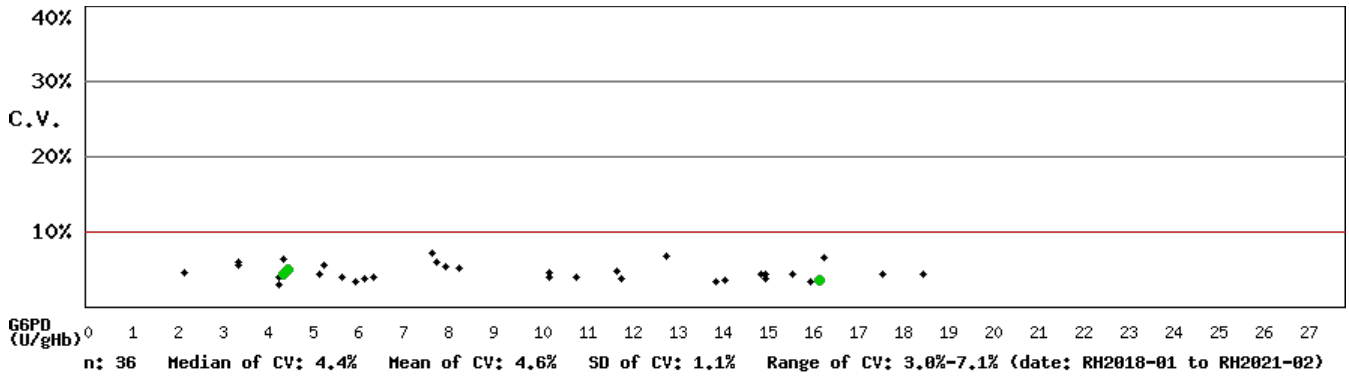


Fig RH-2.2

* Mean and SD are calculated by Robust method according to ISO 13528 since 2014

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(Report generated at 2021-06-21 17:02:58)

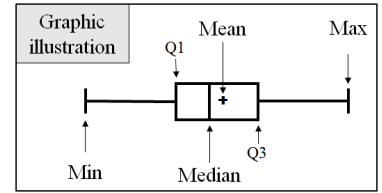
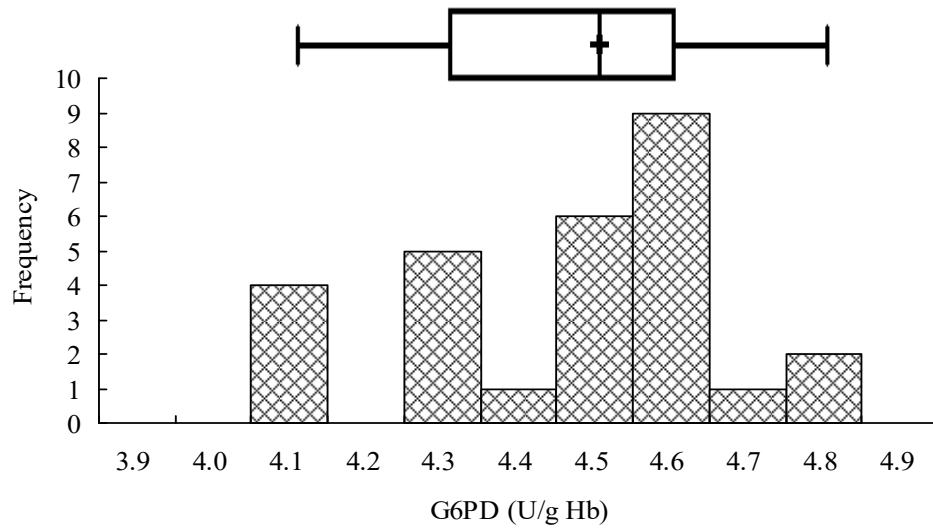
RH2021-02 Distribution of G6PD Test Results

Survey No. : RH2021-02

Sample sent on : 2021/06/14

Reporting deadline : 2021/06/21

Results reported (%) : 100%



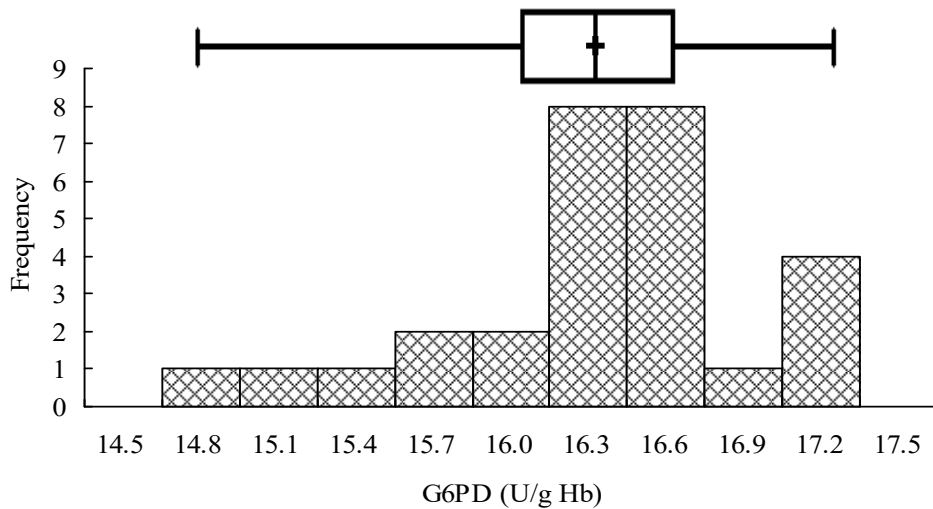
Sample 1

Median = 4.5 (n = 28)

Mean* = 4.5 (n = 28)

SD* = 0.22

CV = 4.9%



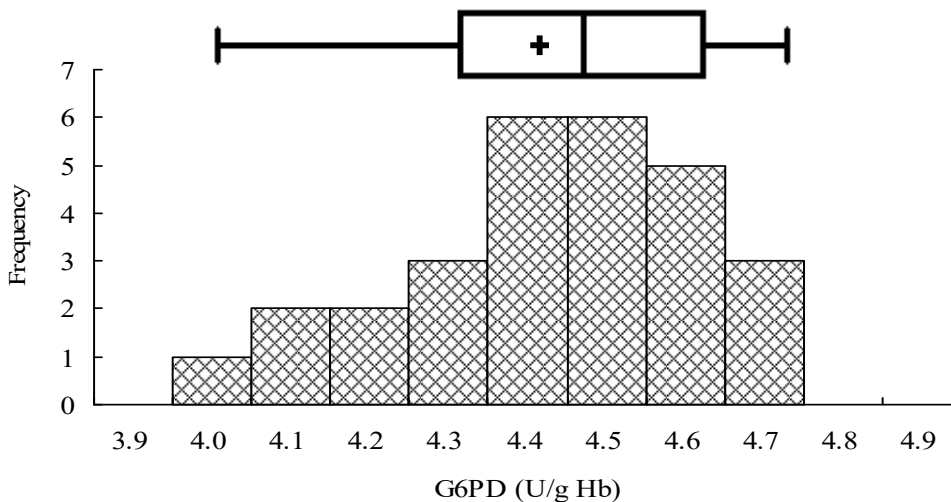
Sample 2

Median = 16.3 (n = 28)

Mean* = 16.3 (n = 28)

SD* = 0.59

CV = 3.6%



Sample 3

Median = 4.5 (n = 28)

Mean* = 4.4 (n = 28)

SD* = 0.19

CV = 4.3%

*Robust results (Mean and SD) were calculated by Algorithm A according to ISO 13528

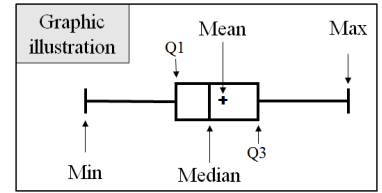
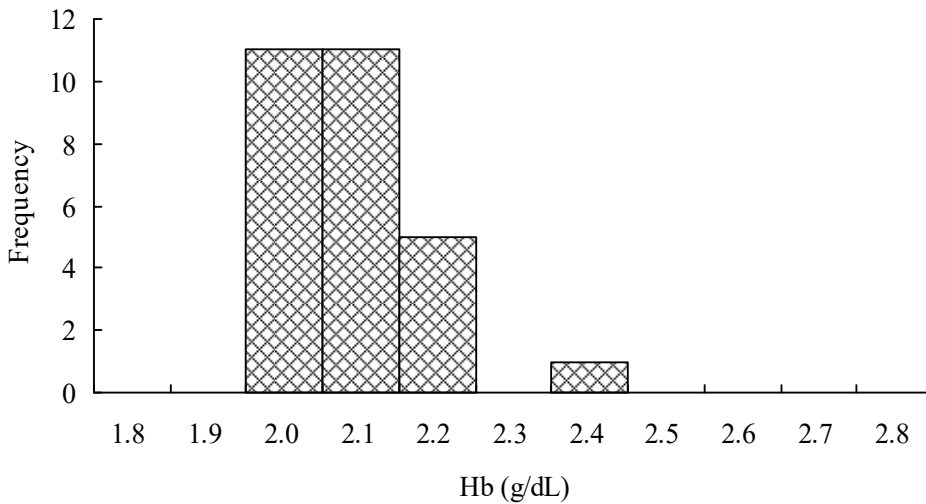
RH2021-02 Distribution of Hb Test Results

Survey No. : RH2021-02

Sample sent on : 2021/06/14

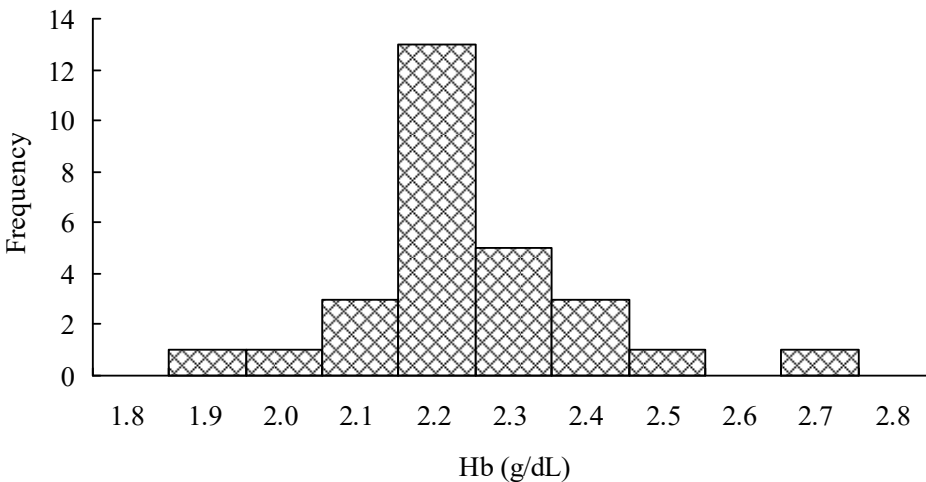
Reporting deadline : 2021/06/21

Results reported (%) : 100%



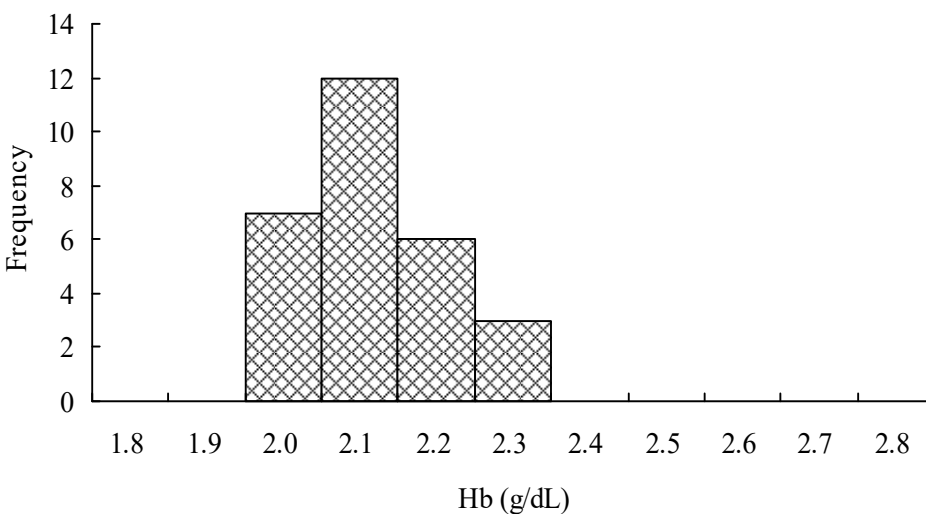
Sample 1

Median = 2.1 (n = 28)
Mean* = 2.1 (n = 28)
SD* = 0.09
CV = 4.3%



Sample 2

Median = 2.2 (n = 28)
Mean* = 2.2 (n = 28)
SD* = 0.12
CV = 5.5%



Sample 3

Median = 2.1 (n = 28)
Mean* = 2.1 (n = 28)
SD* = 0.10
CV = 4.8%

*Robust results (Mean and SD) were calculated by Algorithm A according to ISO 13528

Repeatability of G6PD Quantitative Test (I)

Survey No.: RH2021-02 Sample sent on: 2021/06/14

Reporting deadline: 2021/06/21

In this survey, Sample 1 and Sample 3 used the same lot of quality control sample. To evaluate the repeatability of each participant, we compared the difference between the test results of the two samples and its percentage of the mean.

| LabID | S1 (U/g Hb) | S3 (U/g Hb) | Mean ^a (U/g Hb) | Δ ^b (U/g Hb) | Δ% ^c |
|-------------|----------------|----------------|-------------------------------|----------------------------|-----------------|
| F02 | 4.5 | 4.6 | 4.55 | 0.10 | 2.2% |
| F03 | 4.6 | 4.5 | 4.55 | 0.10 | 2.2% |
| F04 | 4.3 | 4.4 | 4.35 | 0.10 | 2.3% |
| F05 | 4.1 | 4.2 | 4.15 | 0.10 | 2.4% |
| F07 | 4.3 | 4.2 | 4.25 | 0.10 | 2.4% |
| F09 | 4.6 | 4.7 | 4.65 | 0.10 | 2.2% |
| F10 | 4.1 | 4.0 | 4.05 | 0.10 | 2.5% |
| F11 | 4.6 | 4.4 | 4.50 | 0.20 | 4.4% |
| F12 | 4.8 | 4.7 | 4.75 | 0.10 | 2.1% |
| F13 | 4.1 | 4.1 | 4.10 | 0.00 | 0.0% |
| F14 | 4.5 | 4.5 | 4.50 | 0.00 | 0.0% |
| F15 | 4.6 | 4.4 | 4.50 | 0.20 | 4.4% |
| F17 | 4.5 | 4.6 | 4.55 | 0.10 | 2.2% |
| F18 | 4.4 | 4.5 | 4.45 | 0.10 | 2.2% |
| F19 | 4.3 | 4.4 | 4.35 | 0.10 | 2.3% |
| F20 | 4.5 | 4.6 | 4.55 | 0.10 | 2.2% |
| F21 | 4.5 | 4.3 | 4.40 | 0.20 | 4.5% |
| F22 | 4.1 | 4.3 | 4.20 | 0.20 | 4.8% |
| F24 | 4.6 | 4.7 | 4.65 | 0.10 | 2.2% |
| F25 | 4.6 | 4.5 | 4.55 | 0.10 | 2.2% |
| F26 | 4.6 | 4.1 | 4.35 | 0.50 | 11.5% |
| F27 | 4.5 | 4.5 | 4.50 | 0.00 | 0.0% |
| F28 | 4.6 | 4.6 | 4.60 | 0.00 | 0.0% |
| F29 | 4.3 | 4.4 | 4.35 | 0.10 | 2.3% |
| F30 | 4.3 | 4.3 | 4.30 | 0.00 | 0.0% |
| F31 | 4.7 | 4.5 | 4.60 | 0.20 | 4.3% |
| F32 | 4.6 | 4.4 | 4.50 | 0.20 | 4.4% |
| F33 | 4.8 | 4.6 | 4.70 | 0.20 | 4.3% |
| Xa (Median) | — | | 4.50 | 0.10 | 2.3% |
| Range | — | | 4.05 ~ 4.75 | 0.00 ~ 0.50 | 0.0% ~ 11.5% |
| Mean | — | | 4.45 | 0.12 | 2.7% |

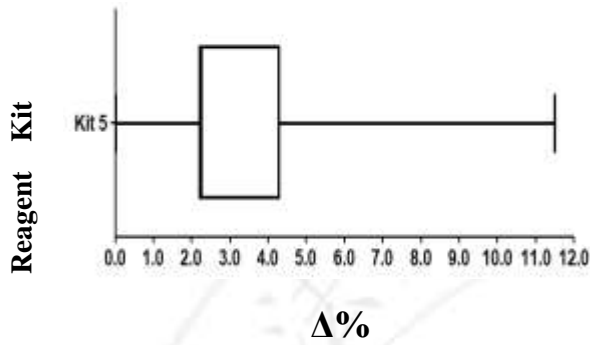
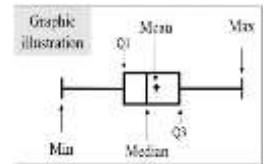
Note :

- a) Mean = (S1 + S3) / 2
- b) Δ = | S1 - S3 |
- c) Δ% = Δ / (Mean)

Repeatability of G6PD Quantitative Test (II)

Survey No.: RH2021-02 Sample sent on: 2021/06/14

Reporting deadline: 2021/06/21



| Reagent Kit | Labs (n) | $\Delta\%$ median | $\Delta\%$ mean | $\Delta\%$ range |
|-------------|----------|-------------------|-----------------|------------------|
| 5 | 28 | 2.3% | 2.7% | 0.0% ~ 11.5% |

Reagent kit 5 : Medicon
 n < 5, NOT calculated

