

External Quality Assurance (EQA) of G6PD Quantitative Test

Survey No. : RH2019-02
 Sample sent : 28 set

Sample sent on : 2019/04/15
 Results reported (%) : 28 (100%)

Reporting deadline : 2019/04/22

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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	7	5	12.7	7.6%	1.1	1.6	3.4	0.0%	0.0	0.0	12.5	5.0%	0.7	1.3	1.8	1.9	1.9
F03	F03	4	5	11.5	-2.5%	-0.4	-0.5	3.5	2.9%	0.4	0.5	11.9	0.0%	0.0	0.0	1.9	2.2	1.9
F04	F04	6	5	11.6	-1.7%	-0.2	-0.4	3.4	0.0%	0.0	0.0	12.1	1.7%	0.2	0.4	1.8	2.1	1.9
F05	F05	5	5	12.0	1.7%	0.2	0.4	3.2	-5.9%	-0.8	-1.1	11.8	-0.8%	-0.1	-0.2	1.9	2.1	1.9
F07	F07	7	5	11.7	-0.8%	-0.1	-0.2	3.8	11.8%	1.7	2.1	11.6	-2.5%	-0.4	-0.7	2.2	2.3	2.2
F08	F08	5	5	12.0	1.7%	0.2	0.4	3.6	5.9%	0.8	1.1	11.6	-2.5%	-0.4	-0.7	2.2	2.4	2.0
F09	F09	7	5	11.8	0.0%	0.0	0.0	3.6	5.9%	0.8	1.1	12.3	3.4%	0.5	0.9	2.0	2.2	1.9
F10	F10	2	5	11.4	-3.4%	-0.5	-0.7	3.2	-5.9%	-0.8	-1.1	11.3	-5.0%	-0.7	-1.3	1.9	2.1	1.9
F11	F11	7	5	11.1	-5.9%	-0.8	-1.3	3.2	-5.9%	-0.8	-1.1	11.5	-3.4%	-0.5	-0.9	2.1	2.2	2.2
F12	F12	7	5	10.7	-9.3%	-1.3	-2.0	3.4	0.0%	0.0	0.0	11.1	-6.7%	-1.0	-1.8	2.3	2.4	2.3
F13	F13	7	5	11.9	0.8%	0.1	0.2	3.3	-2.9%	-0.4	-0.5	11.9	0.0%	0.0	0.0	2.2	2.4	2.3
F14	F14	7	5	9.2	-22.0%	-3.1	-4.7	2.6	-23.5%	-3.4	-4.2	8.9	-25.2%	-3.6	-6.7	2.6	2.8	2.7
F15	F15	4	5	12.2	3.4%	0.5	0.7	3.4	0.0%	0.0	0.0	12.1	1.7%	0.2	0.4	2.1	2.3	2.0
F17	F17	4	5	12.7	7.6%	1.1	1.6	3.7	8.8%	1.3	1.6	13.7	15.1%	2.2	4.0	1.9	2.2	2.0
F18	F18	3	5	11.8	0.0%	0.0	0.0	3.3	-2.9%	-0.4	-0.5	11.3	-5.0%	-0.7	-1.3	1.9	2.2	2.0
F19	F19	2	5	12.6	6.8%	1.0	1.5	3.3	-2.9%	-0.4	-0.5	12.1	1.7%	0.2	0.4	1.8	2.1	1.9
F20	F20	8	5	11.5	-2.5%	-0.4	-0.5	3.1	-8.8%	-1.3	-1.6	11.4	-4.2%	-0.6	-1.1	1.9	2.5	1.9
F21	F21	7	5	11.8	0.0%	0.0	0.0	3.3	-2.9%	-0.4	-0.5	11.9	0.0%	0.0	0.0	1.9	2.2	1.9
F22	F22	6	5	11.8	0.0%	0.0	0.0	3.3	-2.9%	-0.4	-0.5	12.3	3.4%	0.5	0.9	1.8	2.1	1.9
F24	F24	4	5	12.2	3.4%	0.5	0.7	3.5	2.9%	0.4	0.5	12.0	0.8%	0.1	0.2	2.1	2.2	2.0
F25	F25	2	5	12.0	1.7%	0.2	0.4	3.5	2.9%	0.4	0.5	12.3	3.4%	0.5	0.9	2.0	2.1	1.9
F26	F26	8	5	11.0	-6.8%	-1.0	-1.5	3.1	-8.8%	-1.3	-1.6	11.5	-3.4%	-0.5	-0.9	2.0	2.1	2.0
F27	F27	2	5	11.5	-2.5%	-0.4	-0.5	3.6	5.9%	0.8	1.1	11.9	0.0%	0.0	0.0	2.2	2.5	2.2
F28	F28	7	5	11.7	-0.8%	-0.1	-0.2	3.2	-5.9%	-0.8	-1.1	11.6	-2.5%	-0.4	-0.7	2.0	2.2	1.9
F29	F29	7	5	11.3	-4.2%	-0.6	-0.9	3.2	-5.9%	-0.8	-1.1	11.8	-0.8%	-0.1	-0.2	1.9	2.0	1.9
F30	F30	3	5	12.2	3.4%	0.5	0.7	3.3	-2.9%	-0.4	-0.5	12.2	2.5%	0.4	0.7	1.9	2.1	1.9
F31	F31	7	5	12.5	5.9%	0.8	1.3	3.4	0.0%	0.0	0.0	12.4	4.2%	0.6	1.1	2.0	2.2	2.0
F32	F32	7	5	12.0	1.7%	0.2	0.4	3.4	0.0%	0.0	0.0	11.8	-0.8%	-0.1	-0.2	2.0	2.2	2.0

Total participating laboratories = 28																		
Xa (Median)	-	6.5	-	11.8				3.4				11.9				2.0	2.2	2.0
u _{Xa}	-	-	-	0.114				0.039				0.094				-	-	-
σ _p	-	-	-	0.826				0.238				0.833				-	-	-
σ _{p'}	-	-	-	-				-				-				-	-	-
Range	-	2-8	-	9.2-12.7				2.6-3.8				8.9-13.7				1.8-2.6	1.9-2.8	1.9-2.7
n	-	-	-	28				28				28				28	28	28
Mean	-	-	-	11.8				3.4				11.9				2.0	2.2	2.0
S.D.	-	-	-	0.55				0.19				0.45				0.16	0.15	0.12
C.V.	-	-	-	4.7%				5.6%				3.8%				8.0%	6.8%	6.0%

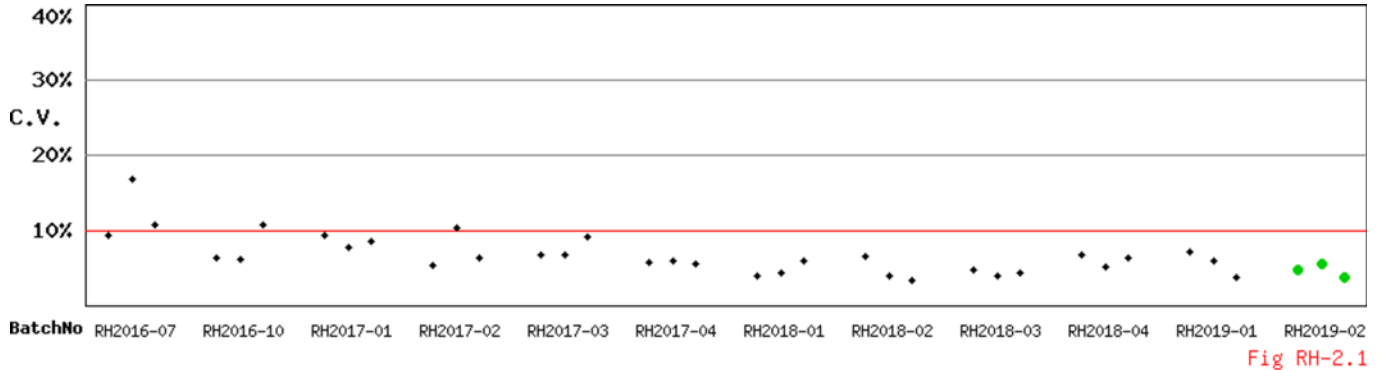
- Note:
- $D\% = [(X - X_a) / X_a] \times 100\%$; X = Your Results, X_a = Assigned value
 - u_{X_a} = uncertainty of the assigned value. $u_{X_a} = 1.1 \times SD / n^{1/2}$
 - SD for proficiency assessment (σ_p) = 7% x X_a; but while X_a < 2.9 U/gHb, $\sigma_p = 0.2$ U/gHb
 - Adjusted SD for proficiency 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 - 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: $|z| > 3$
 - Maximum Allowable Deviation (MAD) = $3 \times (\sigma_p / X_a) \times 100\%$ or $3 \times (\sigma_p' / X_a) \times 100\%$ when $u_{X_a} \geq 0.3\sigma_p$

Reagent Kit	G6PD Reagent Code	Lab
Medicon	5	F02, F03, F04, F05, F07, F08, F09, F10, F11, F12, F13, F14, F15, F17, F18, F19, F20, F21, F22, F24, F25, F26, F27, F28, F29, F30, F31, F32

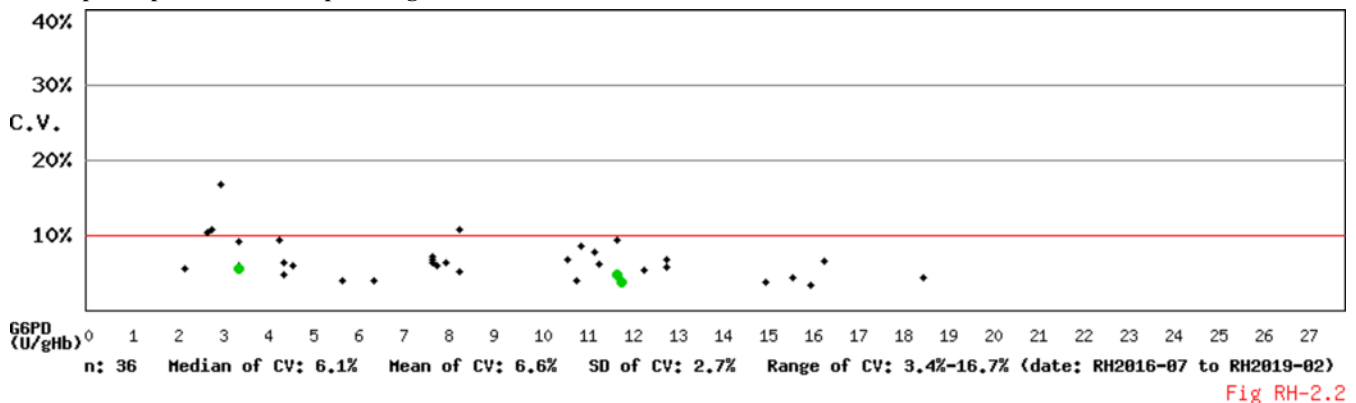
Long Term Observation of Blood G6PD Quantitative Test EQA Survey Results

Survey No : RH2019-02 (in green ●)

- Total participants' CV result plotted against surveys



- Total participants' CV result plotted against G6PD activities



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

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(Report generated at 2019-04-24 14:33:07)

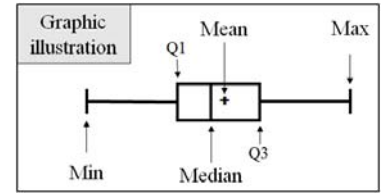
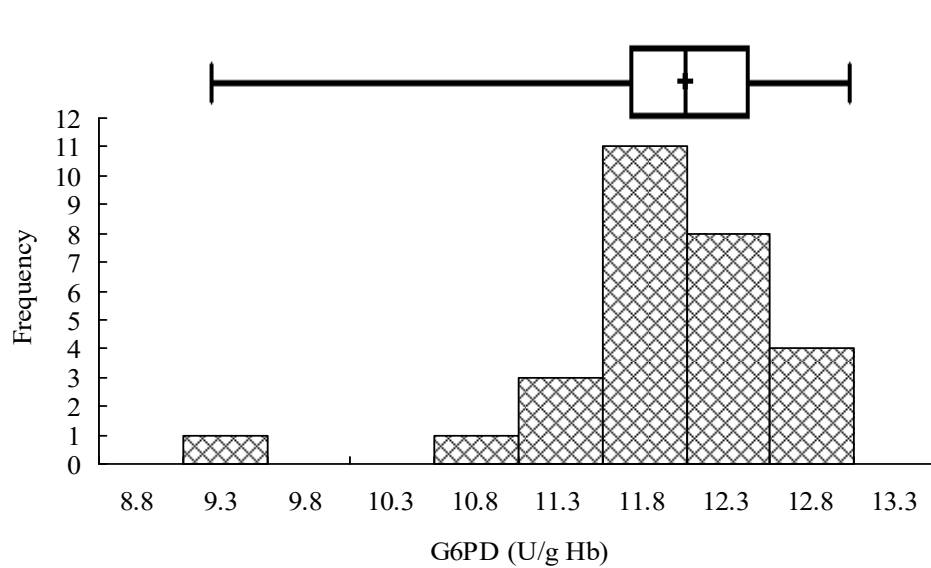
RH2019-02 Distribution of G6PD Test Results

Survey No. : RH2019-02

Sample sent on : 2019/04/15

Reporting deadline : 2019/04/22

Results reported (%) : 100%



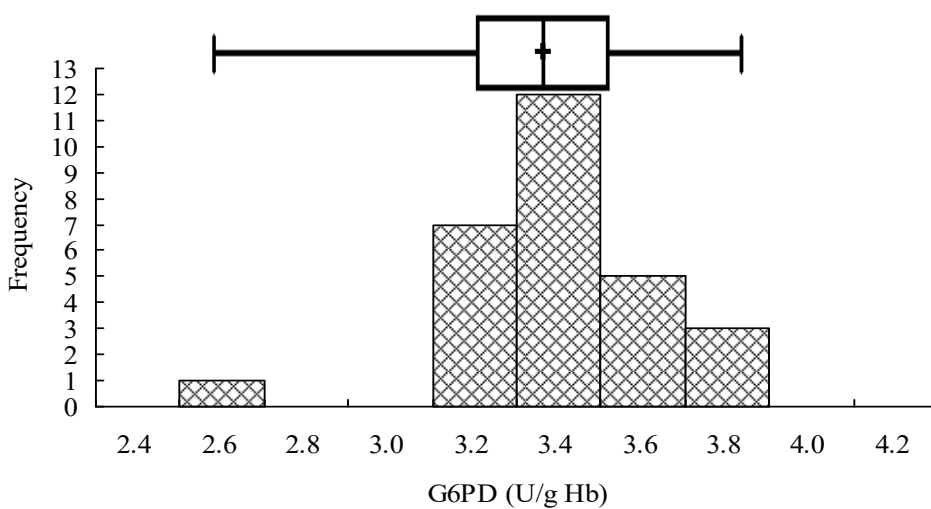
Sample 1

Median = 11.8 (n = 28)

Mean* = 11.8 (n = 28)

SD* = 0.55

CV = 4.7%



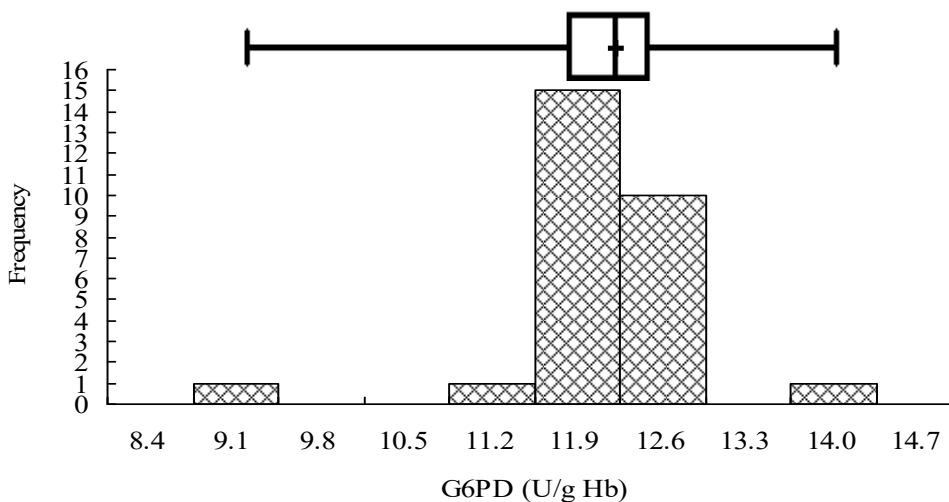
Sample 2

Median = 3.4 (n = 28)

Mean* = 3.4 (n = 28)

SD* = 0.19

CV = 5.6%



Sample 3

Median = 11.9 (n = 28)

Mean* = 11.9 (n = 28)

SD* = 0.45

CV = 3.8%

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

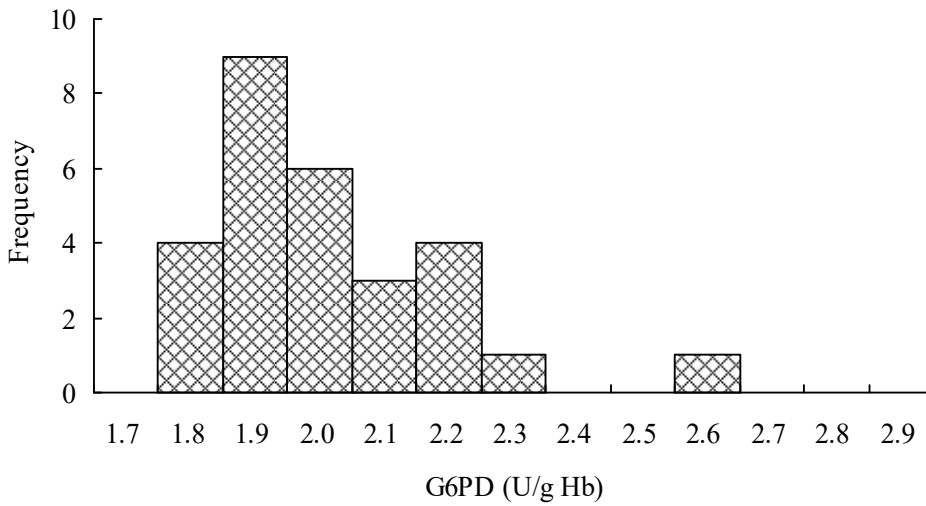
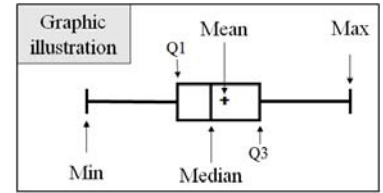
RH2019-02 Distribution of Hb Test Results

Survey No. : RH2019-02

Sample sent on : 2019/04/15

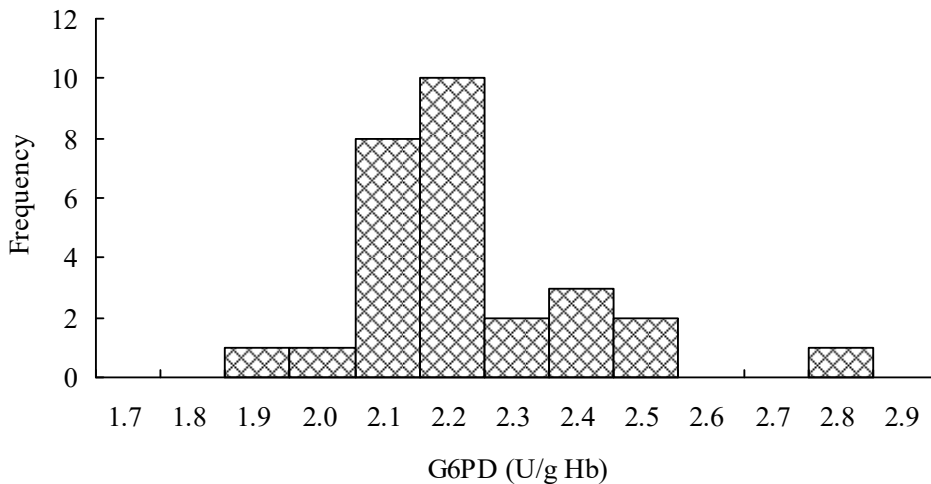
Reporting deadline : 2019/04/22

Results reported (%) : 100%



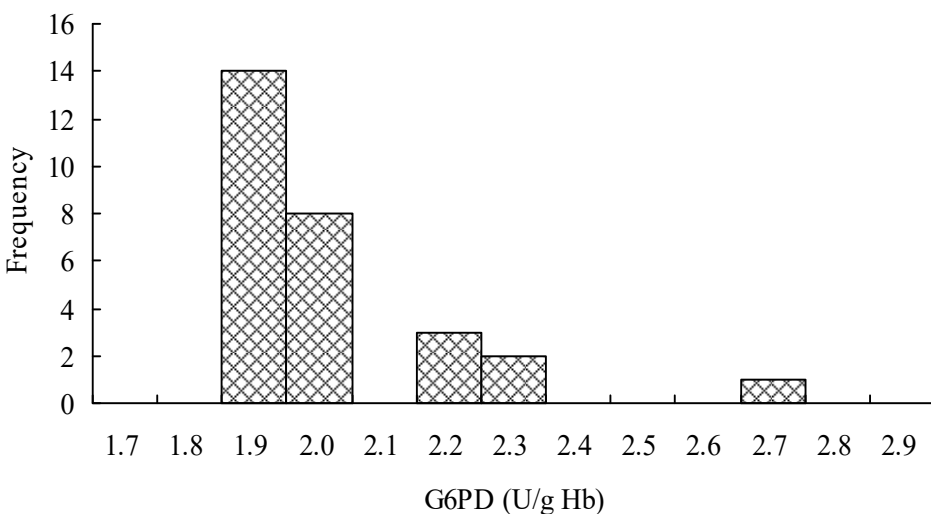
Sample 1

Median = 2.0 (n = 28)
Mean* = 2.0 (n = 28)
SD* = 0.16
CV = 8.0%



Sample 2

Median = 2.2 (n = 28)
Mean* = 2.2 (n = 28)
SD* = 0.15
CV = 6.8%



Sample 3

Median = 2.0 (n = 28)
Mean* = 2.0 (n = 28)
SD* = 0.12
CV = 6.0%

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

Reference Document : Repeatability of G6PD Quantitative Test

Survey No.: RH2019-02 Sample sent on: 2019/04/15 Reporting deadline: 2019/04/22

In this survey (RH2019-02), 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/gHb)	S3 (U/gHb)	Mean ^a (U/gHb)	Δ ^b (U/gHb)	Δ% ^c
F02	12.7	12.5	12.60	0.2	1.6%
F03	11.5	11.9	11.70	0.4	3.4%
F04	11.6	12.1	11.85	0.5	4.2%
F05	12.0	11.8	11.90	0.2	1.7%
F07	11.7	11.6	11.65	0.1	0.9%
F08	12.0	11.6	11.80	0.4	3.4%
F09	11.8	12.3	12.05	0.5	4.1%
F10	11.4	11.3	11.35	0.1	0.9%
F11	11.1	11.5	11.30	0.4	3.5%
F12	10.7	11.1	10.90	0.4	3.7%
F13	11.9	11.9	11.90	0.0	0.0%
F14	9.2	8.9	9.05	0.3	3.3%
F15	12.2	12.1	12.15	0.1	0.8%
F17	12.7	13.7	13.20	1.0	7.6%
F18	11.8	11.3	11.55	0.5	4.3%
F19	12.6	12.1	12.35	0.5	4.0%
F20	11.5	11.4	11.45	0.1	0.9%
F21	11.8	11.9	11.85	0.1	0.8%
F22	11.8	12.3	12.05	0.5	4.1%
F24	12.2	12.0	12.10	0.2	1.7%
F25	12.0	12.3	12.15	0.3	2.5%
F26	11.0	11.5	11.25	0.5	4.4%
F27	11.5	11.9	11.70	0.4	3.4%
F28	11.7	11.6	11.65	0.1	0.9%
F29	11.3	11.8	11.55	0.5	4.3%
F30	12.2	12.2	12.20	0.0	0.0%
F31	12.5	12.4	12.45	0.1	0.8%
F32	12.0	11.8	11.90	0.2	1.7%
Xa (Median)	11.8		11.85	0.3	2.9%
Range	8.9 ~ 13.7		9.05 ~ 13.20	0.0 ~ 1.0	0% ~ 7.6%
Mean	11.8		11.77	0.31	2.6%
Reference	12.9				

Note :

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