

Summary Report of IQC program for G6PD Quantitative Test - AMP Group - May 2017 -

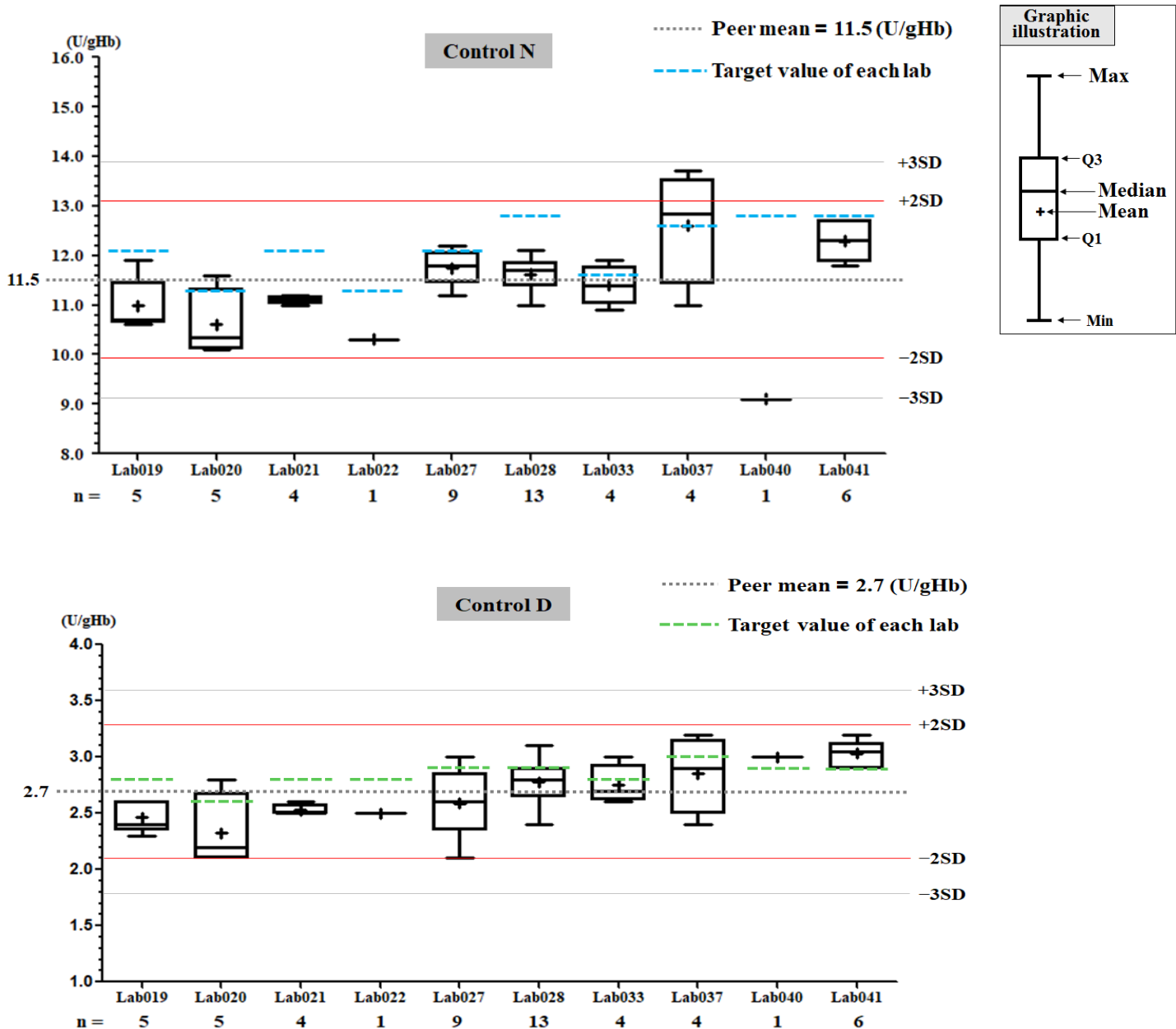
I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AC1203N)	Control D (Lot No.:AC1203D)
Labs	10	10
Received results number (n)	51	51
Median	11.6 (U/gHb)	2.7 (U/gHb)
Mean	11.5 (U/gHb)	2.7 (U/gHb)
SD	0.8	0.3
CV	7.0%	11.1%
Range of G6PD	9.1 ~ 13.7 (U/gHb)	2.1 ~ 3.2 (U/gHb)
Range of Hb	2.0 ~ 2.9 (g/dL)	2.2 ~ 3.4 (g/dL)

*The statistic results are calculated from all labs reported in this month

** G6PD Method = AMP reagent kit, 37°C

II. The distribution of G6PD reported for each lab in this survey



QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

Lab020

QC Control Lot No.	Control N		Control D	
	AC1203N		AC1203D	
Duration of the Analyzing	Month (2017/05)	CUM (2014/02/01~2017/05/31)	Month (2017/05)	CUM (2014/02/01~2017/05/31)
Runs (N)	4	23	4	23
Mean (U/gHb)	10.6	11.6	2.3	2.7
SD	0.7	1.4	0.3	0.5
CV (%)	6.6	12.1	13.0	18.5
Target Value (U/gHb)	11.3	11.3	2.6	2.6
Total Error (%)	19.4	26.8	37.6	40.9
TEa (%)	20	20	20	20
σ	2.1	1.4	0.7	0.9

Bias (%) = [(| Mean - Target |) / Target] x 100%
 TE : Total Error(%) = Bias (%) + 2 x CV (%)
 σ (Sigma) = [TEa% - Bias (%)] / CV (%)

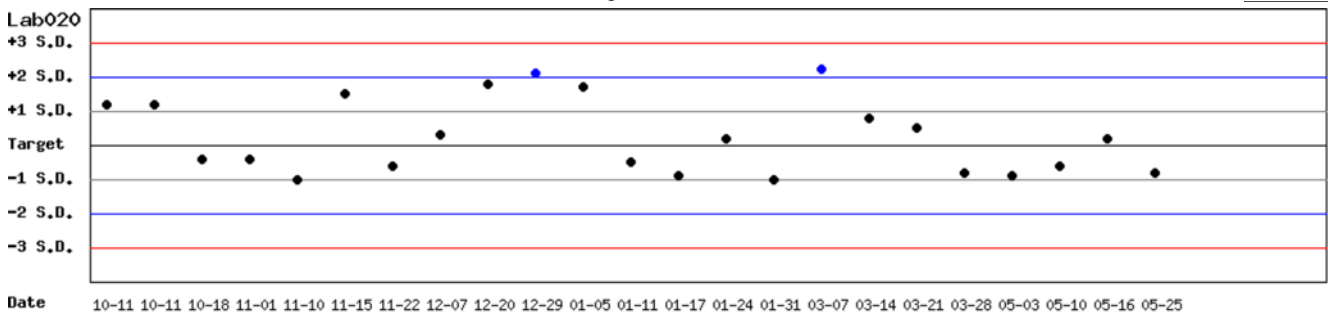
Month : 2017 05 [Change](#) ; Cumulative : from 2014 02 01 to 2017 05 31 [Change](#)

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Control N SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2017-05-31 ; Target : 11.3 ; SD : 1.30

Lab020



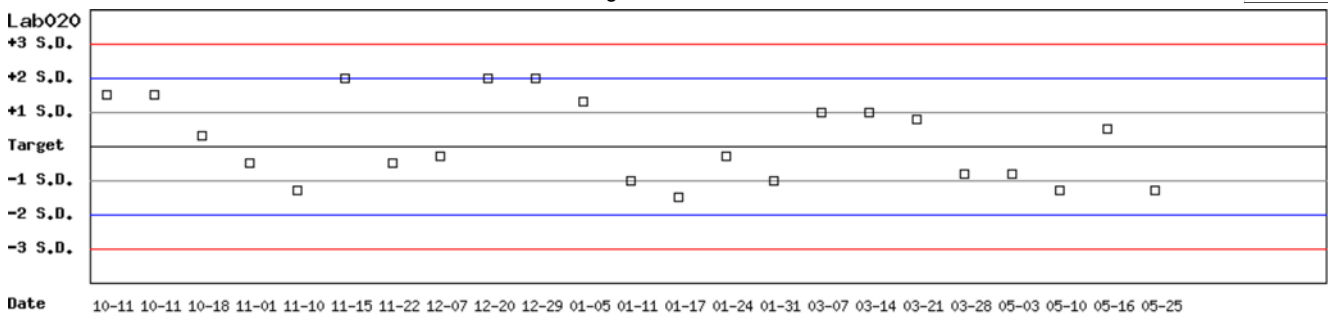
Month : 2017 05 [Change](#) ; Cumulative : from 2014 02 01 to 2017 05 31 [Change](#)

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Control D SDI QC Chart

Lot No.: AC1203D ; Duration : 2014-02-01 to 2017-05-31 ; Target : 2.6 ; SD : 0.40

Lab020



Month : 2017 05 [Change](#) ; Cumulative : from 2014 02 01 to 2017 05 31 [Change](#)

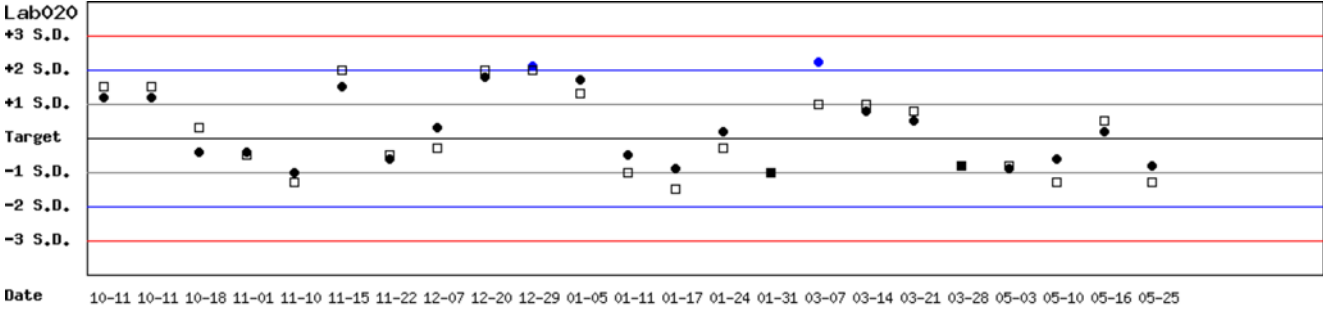
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Control N and Control D SDI QC Chart

Lot No.: AC1203N ; Duration : 2014-02-01 to 2017-05-31 ; Target : 11.3 ; SD : 1.30 (●)

Lot No.: AC1203D ; Duration : 2014-02-01 to 2017-05-31 ; Target : 2.6 ; SD : 0.40 (□)

Lab020



Date 10-11 10-11 10-18 11-01 11-10 11-15 11-22 12-07 12-20 12-29 01-05 01-11 01-17 01-24 01-31 03-07 03-14 03-21 03-28 05-03 05-10 05-16 05-25

Month : 2017 05 ; Cumulative : from 2014 02 01 to 2017 05 31

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Peer Group Statistics (Table 1)

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 2 - AMP Change

Print Table 1

Monthly

Month : 2017 05 Change

UnitID	Reagent Kit (Code)	Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
		Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab019	2	12.1	11.0	5	0.5	4.5	18.2	20	2.4	2.8	2.5	5	0.1	4.0	18.7	20	2.3
Lab020	2	11.3	10.6	4	0.7	6.6	19.4	20	2.1	2.6	2.3	4	0.3	13.0	37.6	20	0.7
Lab021	2	12.3	11.1	4	0.1	0.9	11.6	20	>6	2.8	2.5	4	0.1	4.0	18.7	20	2.3
Lab022	2	11.3	10.3	1	-	-	-	20	-	2.8	2.5	1	-	-	-	20	-
Lab027	2	12.3	11.7	9	0.3	2.6	10.0	20	5.8	2.9	2.6	9	0.3	11.5	33.4	20	0.8
Lab028	2	12.8	11.6	13	0.3	2.6	14.5	20	4.1	2.9	2.8	13	0.2	7.1	17.7	20	2.3
Lab033	2	11.6	11.4	4	0.4	3.5	8.7	20	5.2	2.8	2.8	4	0.2	7.1	14.3	20	2.8
Lab037	2	12.6	12.6	4	1.1	8.7	17.5	20	2.3	3.0	2.9	4	0.3	10.3	24.0	20	1.6
Lab040	2	12.8	9.1	1	-	-	-	20	-	2.9	3.0	1	-	-	-	20	-
Lab041	2	12.8	12.3	6	0.4	3.3	10.4	20	4.9	2.9	3.0	6	0.1	3.3	10.1	20	5.0
Total	-	-	11.5	51	0.8	7.0	-	-	-	-	2.7	51	0.3	11.1	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

[TOP](#)

Cumulative

Cumulative : from 2014 02 01 to 2017 05 31 Change

UnitID	Reagent Kit (Code)	Control N (Lot No.: AC1203N)								Control D (Lot No.: AC1203D)							
		Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	14.2	13.8	36	1.6	11.6	26.0	20	1.5	3.3	3.9	36	1.4	35.9	90.0	20	0.1
Lab018	2	10.6	10.9	113	1.3	11.9	26.7	20	1.4	4.1	2.6	113	0.9	34.6	105.8	20	-0.5
Lab019	2	12.1	12.1	166	1.1	9.1	18.2	20	2.2	2.8	2.8	166	0.4	14.3	28.6	20	1.4
Lab020	2	11.3	11.6	23	1.4	12.1	26.8	20	1.4	2.6	2.7	23	0.5	18.5	40.9	20	0.9
Lab021	2	12.3	13.4	94	1.1	8.2	25.4	20	1.3	2.8	3.2	94	0.4	12.5	39.3	20	0.5
Lab022	2	11.3	11.5	70	1.1	9.6	20.9	20	1.9	2.8	2.9	70	0.3	10.3	24.3	20	1.6
Lab024	2	11.6	11.1	58	1.2	10.8	25.9	20	1.5	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	11.6	11.5	212	1.6	13.9	28.7	36	2.5	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	12.3	11.4	176	1.9	16.7	40.7	20	0.8	2.9	2.7	176	0.5	18.5	43.9	20	0.7
Lab028	2	12.8	13.4	362	1.3	9.7	24.1	20	1.6	2.9	3.3	362	0.5	15.2	44.1	20	0.4
Lab031	2	12.8	10.4	89	1.5	14.4	47.6	20	0.1	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	13.2	11.5	222	1.9	16.5	45.9	20	0.4	5.4	2.7	222	0.5	18.5	87.0	20	-1.6
Lab033	2	11.6	11.9	160	1.0	8.4	19.4	20	2.1	2.8	2.9	160	0.3	10.3	24.3	20	1.6
Lab034	2	12.8	12.3	94	0.7	5.7	15.3	20	2.8	2.9	3.0	94	0.3	10.0	23.4	20	1.7
Lab035	2	12.8	12.4	55	0.7	5.6	14.4	20	3.0	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	12.6	12.2	74	1.2	9.8	22.8	20	1.7	3.0	2.9	74	0.4	13.8	30.9	20	1.2
Lab038	2	12.8	12.7	60	1.0	7.9	16.5	20	2.4	2.9	3.2	60	0.5	15.6	41.6	20	0.6
Lab040	2	12.8	11.9	23	0.9	7.6	22.2	20	1.7	2.9	2.7	23	0.4	14.8	36.5	20	0.9
Lab041	2	12.8	11.1	14	1.4	12.6	38.5	20	0.5	2.9	2.8	14	0.3	10.7	24.9	20	1.5
Total	-	-	12.1	2101	1.6	13.2	-	-	-	-	2.9	2101	0.6	20.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

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Reagent Kit	Reagent Code
AMP	2

Peer Group Statistics (Table 2)

Select LotNo : AC1203N (2014-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 2 - AMP Change

[Print Table 2](#)

Control N Month vs. Cumulative

		Control N (Lot No.: AC1203N)															
		Month (2017/05)									CUM (2014/02/01~2017/05/31)						
UnitID <input type="text"/>	Reagent Kit (Code) <input type="text"/>	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	14.2	-	0	-	-	-	20	-	14.2	13.8	36	1.6	11.6	26.0	20	1.5
Lab018	2	10.6	-	0	-	-	-	20	-	10.6	10.9	113	1.3	11.9	26.7	20	1.4
Lab019	2	12.1	11.0	5	0.5	4.5	18.2	20	2.4	12.1	12.1	166	1.1	9.1	18.2	20	2.2
Lab020	2	11.3	10.6	4	0.7	6.6	19.4	20	2.1	11.3	11.6	23	1.4	12.1	26.8	20	1.4
Lab021	2	12.3	11.1	4	0.1	0.9	11.6	20	>6	12.3	13.4	94	1.1	8.2	25.4	20	1.3
Lab022	2	11.3	10.3	1	-	-	-	20	-	11.3	11.5	70	1.1	9.6	20.9	20	1.9
Lab024	2	11.6	-	0	-	-	-	20	-	11.6	11.1	58	1.2	10.8	25.9	20	1.5
Lab026	2	11.6	-	0	-	-	-	36	-	11.6	11.5	212	1.6	13.9	28.7	36	2.5
Lab027	2	12.3	11.7	9	0.3	2.6	10.0	20	5.8	12.3	11.4	176	1.9	16.7	40.7	20	0.8
Lab028	2	12.8	11.6	13	0.3	2.6	14.5	20	4.1	12.8	13.4	362	1.3	9.7	24.1	20	1.6
Lab031	2	12.8	-	0	-	-	-	20	-	12.8	10.4	89	1.5	14.4	47.6	20	0.1
Lab032	2	13.2	-	0	-	-	-	20	-	13.2	11.5	222	1.9	16.5	45.9	20	0.4
Lab033	2	11.6	11.4	4	0.4	3.5	8.7	20	5.2	11.6	11.9	160	1.0	8.4	19.4	20	2.1
Lab034	2	12.8	-	0	-	-	-	20	-	12.8	12.3	94	0.7	5.7	15.3	20	2.8
Lab035	2	12.8	-	0	-	-	-	20	-	12.8	12.4	55	0.7	5.6	14.4	20	3.0
Lab037	2	12.6	12.6	4	1.1	8.7	17.5	20	2.3	12.6	12.2	74	1.2	9.8	22.8	20	1.7
Lab038	2	12.8	-	0	-	-	-	20	-	12.8	12.7	60	1.0	7.9	16.5	20	2.4
Lab040	2	12.8	9.1	1	-	-	-	20	-	12.8	11.9	23	0.9	7.6	22.2	20	1.7
Lab041	2	12.8	12.3	6	0.4	3.3	10.4	20	4.9	12.8	11.1	14	1.4	12.6	38.5	20	0.5
Total	-	-	11.5	51	0.8	7.0	-	-	-	-	12.1	2101	1.6	13.2	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2017 05 Change

Cumulative : from 2014 02 01 to 2017 05 31 Change

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Control D Month vs. Cumulative

		Control D (Lot No.: AC1203D)															
		Month (2017/05)									CUM (2014/02/01~2017/05/31)						
UnitID <input type="text"/>	Reagent Kit (Code) <input type="text"/>	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab017	2	3.3	-	0	-	-	-	20	-	3.3	3.9	36	1.4	35.9	90.0	20	0.1
Lab018	2	4.1	-	0	-	-	-	20	-	4.1	2.6	113	0.9	34.6	105.8	20	-0.5
Lab019	2	2.8	2.5	5	0.1	4.0	18.7	20	2.3	2.8	2.8	166	0.4	14.3	28.6	20	1.4
Lab020	2	2.6	2.3	4	0.3	13.0	37.6	20	0.7	2.6	2.7	23	0.5	18.5	40.9	20	0.9
Lab021	2	2.8	2.5	4	0.1	4.0	18.7	20	2.3	2.8	3.2	94	0.4	12.5	39.3	20	0.5
Lab022	2	2.8	2.5	1	-	-	-	20	-	2.8	2.9	70	0.3	10.3	24.3	20	1.6
Lab024	2	2.7	-	0	-	-	-	20	-	2.7	2.7	58	0.3	11.1	22.2	20	1.8
Lab026	2	2.7	-	0	-	-	-	36	-	2.7	2.8	212	0.5	17.9	39.4	36	1.8
Lab027	2	2.9	2.6	9	0.3	11.5	33.4	20	0.8	2.9	2.7	176	0.5	18.5	43.9	20	0.7
Lab028	2	2.9	2.8	13	0.2	7.1	17.7	20	2.3	2.9	3.3	362	0.5	15.2	44.1	20	0.4
Lab031	2	2.9	-	0	-	-	-	20	-	2.9	2.5	89	0.5	20.0	53.8	20	0.3
Lab032	2	5.4	-	0	-	-	-	20	-	5.4	2.7	222	0.5	18.5	87.0	20	-1.6
Lab033	2	2.8	2.8	4	0.2	7.1	14.3	20	2.8	2.8	2.9	160	0.3	10.3	24.3	20	1.6
Lab034	2	2.9	-	0	-	-	-	20	-	2.9	3.0	94	0.3	10.0	23.4	20	1.7
Lab035	2	2.9	-	0	-	-	-	20	-	2.9	2.8	55	0.3	10.7	24.9	20	1.5
Lab037	2	3.0	2.9	4	0.3	10.3	24.0	20	1.6	3.0	2.9	74	0.4	13.8	30.9	20	1.2
Lab038	2	2.9	-	0	-	-	-	20	-	2.9	3.2	60	0.5	15.6	41.6	20	0.6
Lab040	2	2.9	3.0	1	-	-	-	20	-	2.9	2.7	23	0.4	14.8	36.5	20	0.9
Lab041	2	2.9	3.0	6	0.1	3.3	10.1	20	5.0	2.9	2.8	14	0.3	10.7	24.9	20	1.5
Total	-	-	2.7	51	0.3	11.1	-	-	-	-	2.9	2101	0.6	20.7	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%

TE : Total Error(%) = Bias (%) + 2 × CV (%)

σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2017 05 Change

Cumulative : from 2014 02 01 to 2017 05 31 Change

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Reagent Kit	Reagent Code
AMP	2