

# Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - May 2019 -

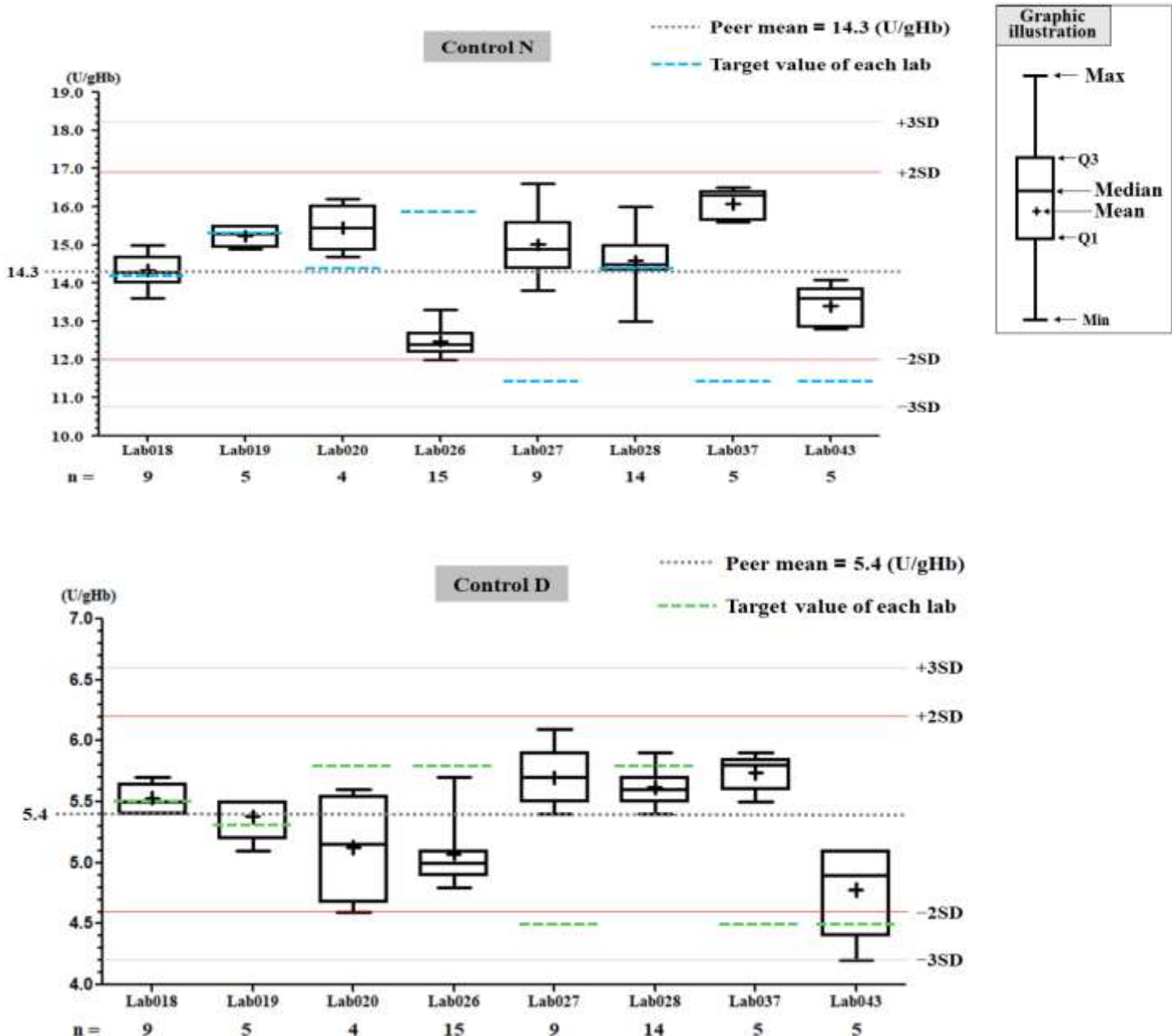
## I. The statistic results of all laboratories in this month

G6PD	Control N (Lot No.:AE0909N)	Control D (Lot No.:AE0909D)
Labs	8	8
Received results number (n)	66	66
Median	14.5 (U/gHb)	5.5 (U/gHb)
Mean	14.3 (U/gHb)	5.4 (U/gHb)
SD	1.3	0.4
CV	9.1%	7.4%
Range of G6PD	12.0 ~ 16.6 (U/gHb)	4.2 ~ 6.1 (U/gHb)
Range of Hb	1.6 ~ 3.3 (g/dL)	1.9 ~ 2.5 (g/dL)

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

\*\* G6PD Method = Medicon 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 : AE0909N (2016-01-01 ~ 2100-12-31) [Change](#)

[Print Table](#)

## Lab020

QC Control Lot No.	Control N		Control D	
	AE0909N		AE0909D	
Duration of the Analyzing	Month (2019/05)	CUM (2016/02/01~2019/05/31)	Month (2019/05)	CUM (2016/02/01~2019/05/31)
Runs (N)	2	24	2	24
Mean (U/gHb)	15.1	15.2	5.5	5.4
SD	-	0.4	-	0.1
CV (%)	-	2.6	-	1.9
Target Value (U/gHb)	14.4	14.4	5.8	5.8
Total Error (%)	-	10.8	-	10.6
TEa (%)	20	20	20	20
$\sigma$	-	5.6	-	>6

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

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

$\sigma$  (Sigma) = [TEa% - Bias (%) ] / CV (%)

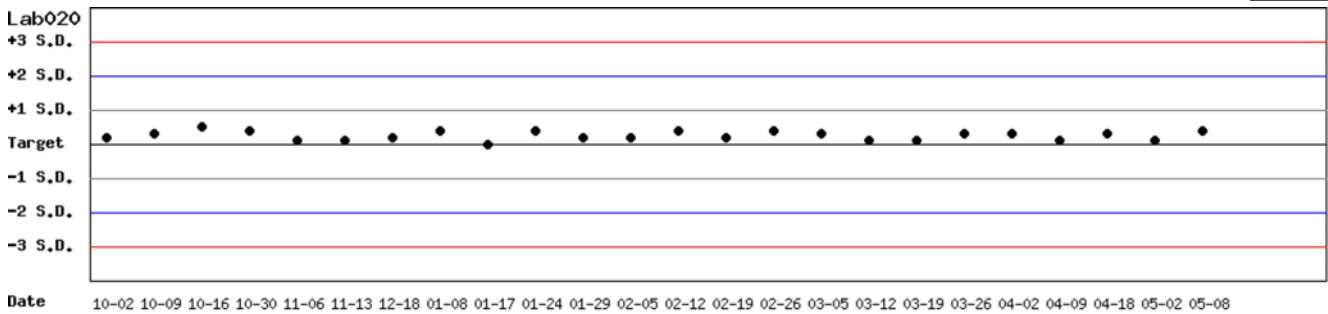
Month : 2019 05 [Change](#) ; Cumulative : from 2016 02 01 to 2019 05 31 [Change](#)

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## Control N SDI QC Chart

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-05-31 ; Target : 14.4 ; SD : 2.90

Lab020



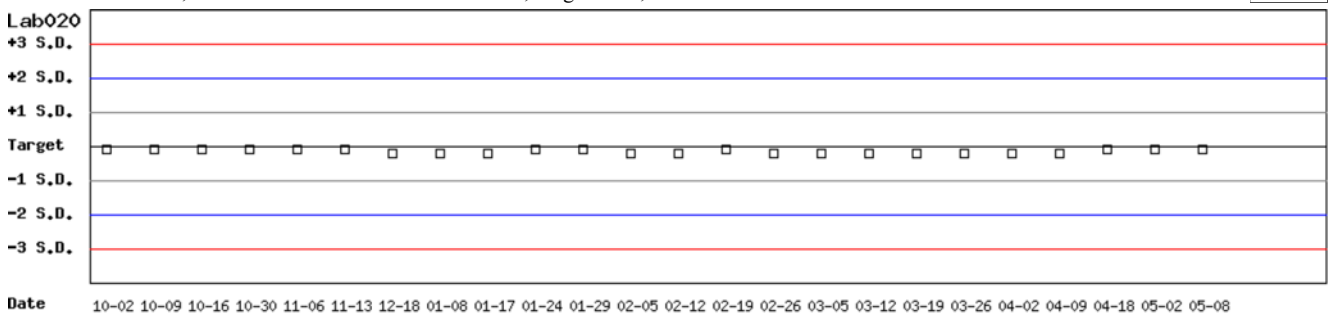
Month : 2019 05 [Change](#) ; Cumulative : from 2016 02 01 to 2019 05 31 [Change](#)

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## Control D SDI QC Chart

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-05-31 ; Target : 5.8 ; SD : 2.90

Lab020



Month : 2019 05 [Change](#) ; Cumulative : from 2016 02 01 to 2019 05 31 [Change](#)

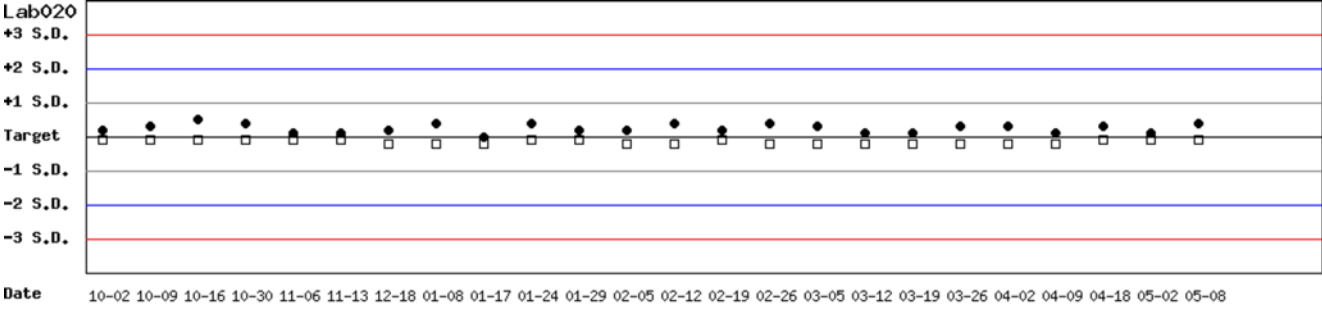
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**Control N and Control D SDI  
QC Chart**

Lot No.: AE0909N ; Duration : 2016-02-01 to 2019-05-31 ; Target : 14.4 ; SD : 2.90 (●)

Lot No.: AE0909D ; Duration : 2016-02-01 to 2019-05-31 ; Target : 5.8 ; SD : 2.90 (□)

Lab020



Month : 2019 | 05 |  ; Cumulative : from 2016 | 02 | 01 to 2019 | 05 | 31 |

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## Peer Group Statistics (Table 1)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31) ▼ Change

Select Reagent Kit : 5 - Medicon ▼ Change

Print Table 1

### Monthly

Month : 2019 ▼ 05 ▼ Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
		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	
<a href="#">Lab018</a>	5	14.2	14.3	9	0.4	2.8	6.3	20	>6	5.5	5.5	9	0.1	1.8	3.6	20	>6	
<a href="#">Lab019</a>	5	15.3	15.2	5	0.3	2.0	4.6	20	>6	5.3	5.4	5	0.2	3.7	9.3	20	4.9	
<a href="#">Lab020</a>	5	14.4	15.5	4	0.6	3.9	15.4	20	3.2	5.8	5.1	4	0.5	9.8	31.7	20	0.8	
<a href="#">Lab026</a>	5	15.9	12.5	15	0.4	3.2	27.8	20	-0.4	5.8	5.1	15	0.2	3.9	19.9	20	2.0	
<a href="#">Lab027</a>	5	11.5	15.0	9	0.9	6.0	42.4	20	-1.7	4.5	5.7	9	0.2	3.5	33.7	20	-1.9	
<a href="#">Lab028</a>	5	14.4	14.6	14	0.7	4.8	11.0	20	3.9	5.8	5.6	14	0.1	1.8	7.0	20	>6	
<a href="#">Lab037</a>	5	11.5	16.1	5	0.4	2.5	45.0	20	-8.0	4.5	5.7	5	0.2	3.5	33.7	20	-1.9	
<a href="#">Lab043</a>	5	11.5	13.4	5	0.5	3.7	24.0	20	0.9	4.5	4.8	5	0.4	8.3	23.3	20	1.6	
<b>Total</b>	-	-	14.3	66	1.3	9.1	-	-	-	-	5.4	66	0.4	7.4	-	-	-	

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

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

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

[\[TOP\]](#)

### Cumulative

Cumulative : from 2016 ▼ 02 ▼ 01 ▼ to 2019 ▼ 05 ▼ 31 ▼ Change

UnitID <sup>↑</sup>	Reagent Kit (Code) <sup>↑</sup>	Control N (Lot No.: AE0909N)									Control D (Lot No.: AE0909D)							
		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	
<a href="#">Lab018</a>	5	14.2	15.6	84	1.0	6.4	22.7	20	1.6	5.5	5.7	84	0.2	3.5	10.7	20	4.7	
<a href="#">Lab019</a>	5	15.3	15.2	70	0.3	2.0	4.6	20	>6	5.3	5.3	70	0.1	1.9	3.8	20	>6	
<a href="#">Lab020</a>	5	14.4	15.2	26	0.4	2.6	10.8	20	5.6	5.8	5.3	26	0.2	3.8	16.2	20	3.0	
<a href="#">Lab026</a>	5	15.9	14.6	159	1.3	8.9	26.0	20	1.3	5.8	5.2	159	0.4	7.7	25.7	20	1.3	
<a href="#">Lab027</a>	5	11.5	15.6	87	1.4	9.0	53.6	20	-1.7	4.5	5.6	87	0.4	7.1	38.7	20	-0.6	
<a href="#">Lab028</a>	5	14.4	14.6	62	0.8	5.5	12.3	20	3.4	5.8	5.7	62	0.4	7.0	15.8	20	2.6	
<a href="#">Lab032</a>	5	15.3	15.9	38	0.9	5.7	15.2	20	2.8	5.2	5.7	38	0.3	5.3	20.1	20	2.0	
<a href="#">Lab033</a>	5	14.4	14.9	51	0.7	4.7	12.9	20	3.5	5.8	5.2	51	0.3	5.8	21.9	20	1.7	
<a href="#">Lab034</a>	5	14.4	14.2	50	0.6	4.2	9.8	20	4.4	5.8	5.1	50	0.2	3.9	19.9	20	2.0	
<a href="#">Lab037</a>	5	11.5	15.2	29	0.8	5.3	42.7	20	-2.3	4.5	5.5	29	0.3	5.5	33.1	20	-0.4	
<a href="#">Lab040</a>	5	14.4	13.3	39	0.7	5.3	18.2	20	2.3	5.8	4.7	39	0.3	6.4	31.7	20	0.2	
<a href="#">Lab043</a>	5	11.5	13.1	68	0.9	6.9	27.7	20	0.9	4.5	4.9	68	0.3	6.1	21.1	20	1.8	
<b>Total</b>	-	-	14.8	763	1.3	8.8	-	-	-	-	5.3	763	0.4	7.5	-	-	-	

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
Medicon	5

## Peer Group Statistics (Table 2)

Select LotNo : AE0909N (2016-01-01 ~ 2100-12-31) Change

Select Reagent Kit : 5 - Medicon Change

Print Table 2

### Control N Month vs. Cumulative

		Control N (Lot No.: AE0909N)															
		Month (2019/05)								CUM (2016/02/01~2019/05/31)							
UnitID ↑	Reagent Kit (Code) ↑	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
<a href="#">Lab018</a>	5	14.2	14.3	9	0.4	2.8	6.3	20	>6	14.2	15.6	84	1.0	6.4	22.7	20	1.6
<a href="#">Lab019</a>	5	15.3	15.2	5	0.3	2.0	4.6	20	>6	15.3	15.2	70	0.3	2.0	4.6	20	>6
<a href="#">Lab020</a>	5	14.4	15.5	4	0.6	3.9	15.4	20	3.2	14.4	15.2	26	0.4	2.6	10.8	20	5.6
<a href="#">Lab026</a>	5	15.9	12.5	15	0.4	3.2	27.8	20	-0.4	15.9	14.6	159	1.3	8.9	26.0	20	1.3
<a href="#">Lab027</a>	5	11.5	15.0	9	0.9	6.0	42.4	20	-1.7	11.5	15.6	87	1.4	9.0	53.6	20	-1.7
<a href="#">Lab028</a>	5	14.4	14.6	14	0.7	4.8	11.0	20	3.9	14.4	14.6	62	0.8	5.5	12.3	20	3.4
<a href="#">Lab032</a>	5	15.3	-	0	-	-	-	20	-	15.3	15.9	38	0.9	5.7	15.2	20	2.8
<a href="#">Lab033</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.9	51	0.7	4.7	12.9	20	3.5
<a href="#">Lab034</a>	5	14.4	-	0	-	-	-	20	-	14.4	14.2	50	0.6	4.2	9.8	20	4.4
<a href="#">Lab037</a>	5	11.5	16.1	5	0.4	2.5	45.0	20	-8.0	11.5	15.2	29	0.8	5.3	42.7	20	-2.3
<a href="#">Lab040</a>	5	14.4	-	0	-	-	-	20	-	14.4	13.3	39	0.7	5.3	18.2	20	2.3
<a href="#">Lab043</a>	5	11.5	13.4	5	0.5	3.7	24.0	20	0.9	11.5	13.1	68	0.9	6.9	27.7	20	0.9
Total	-	-	14.3	66	1.3	9.1	-	-	-	-	14.8	763	1.3	8.8	-	-	-

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

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

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

Month : 2019 05 Change

Cumulative : from 2016 02 01 to 2019 05 31 Change

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### Control D Month vs. Cumulative

		Control D (Lot No.: AE0909D)															
		Month (2019/05)								CUM (2016/02/01~2019/05/31)							
UnitID ↑	Reagent Kit (Code) ↑	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
<a href="#">Lab018</a>	5	5.5	5.5	9	0.1	1.8	3.6	20	>6	5.5	5.7	84	0.2	3.5	10.7	20	4.7
<a href="#">Lab019</a>	5	5.3	5.4	5	0.2	3.7	9.3	20	4.9	5.3	5.3	70	0.1	1.9	3.8	20	>6
<a href="#">Lab020</a>	5	5.8	5.1	4	0.5	9.8	31.7	20	0.8	5.8	5.3	26	0.2	3.8	16.2	20	3.0
<a href="#">Lab026</a>	5	5.8	5.1	15	0.2	3.9	19.9	20	2.0	5.8	5.2	159	0.4	7.7	25.7	20	1.3
<a href="#">Lab027</a>	5	4.5	5.7	9	0.2	3.5	33.7	20	-1.9	4.5	5.6	87	0.4	7.1	38.7	20	-0.6
<a href="#">Lab028</a>	5	5.8	5.6	14	0.1	1.8	7.0	20	>6	5.8	5.7	62	0.4	7.0	15.8	20	2.6
<a href="#">Lab032</a>	5	5.2	-	0	-	-	-	20	-	5.2	5.7	38	0.3	5.3	20.1	20	2.0
<a href="#">Lab033</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.2	51	0.3	5.8	21.9	20	1.7
<a href="#">Lab034</a>	5	5.8	-	0	-	-	-	20	-	5.8	5.1	50	0.2	3.9	19.9	20	2.0
<a href="#">Lab037</a>	5	4.5	5.7	5	0.2	3.5	33.7	20	-1.9	4.5	5.5	29	0.3	5.5	33.1	20	-0.4
<a href="#">Lab040</a>	5	5.8	-	0	-	-	-	20	-	5.8	4.7	39	0.3	6.4	31.7	20	0.2
<a href="#">Lab043</a>	5	4.5	4.8	5	0.4	8.3	23.3	20	1.6	4.5	4.9	68	0.3	6.1	21.1	20	1.8
Total	-	-	5.4	66	0.4	7.4	-	-	-	-	5.3	763	0.4	7.5	-	-	-

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

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

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

Month : 2019 05 Change

Cumulative : from 2016 02 01 to 2019 05 31 Change

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Reagent Kit	Reagent Code
Medicon	5