

Controls: BioRad Lyphochek Immunoassay Plus Ref. 370

Sample Name B1 40301: BioRad Lyphochek Immunoassay Level 1 Lot 40301

Sample Name B2 40302: BioRad Lyphochek Immunoassay Level 2 Lot 40302

Sample Name B3 40303: BioRad Lyphochek Immunoassay Level 3 Lot 40303

## EP5 Precision

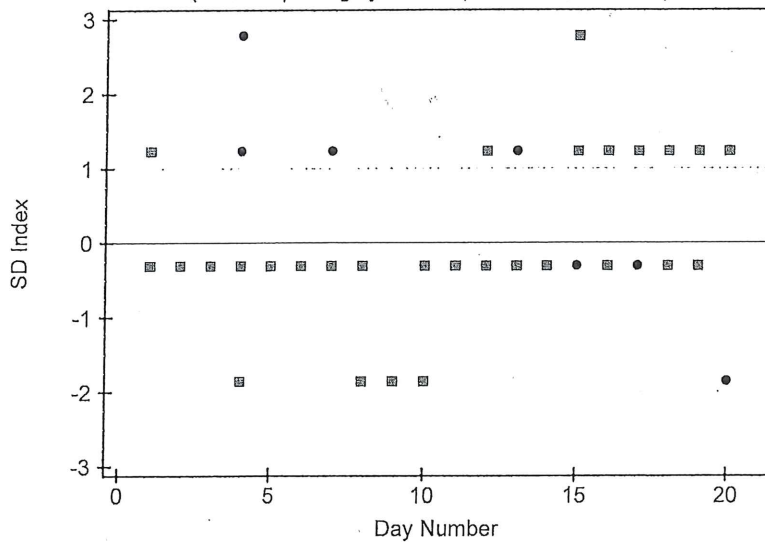
### Precision Estimate

User's Concentration: 61.2

	Within Run	Between Run	Between Day	Total	Medically Required	Verification Value (95%)	Pass/Fail
Std. Dev	0.5	0.3	0.2	0.6	5.0	5.7	Pass
% CV	0.8	0.5	0.4	1.1	8.2		
df	40	--	--	65			

### Precision Plot

(Different plotting symbols represent different runs)



### Outlier Rejection Criteria

SD	0.5 (calculated)
Multiplier	5.5
Max difference between duplicates	2.75

### Preliminary estimate of precision

Mean	62.2	CV	0.8%
SD	0.5	N	20

### Results:

63	63	62	62	63
62	62	62	62	62
62	62	63	62	62
63	62	62	62	61

### Supporting Data

Analyst	Lo'ha
Analysis Date	22 Jun 2015 to 20 Jul 2015
Days (total/excl)	20 / 0
Runs per Day	2
Reps per Run	2
Critical Value	95%
Reagent	506-30, Lot 47569/70
Calibrator	Aceta STD, Lot 47695
Units	umol/L
Verify Mode	Establish Claim
Allowable Total Error	15.0 umol/L
Random Error Budget	33.33%
Allowable Rand Error	5.0 umol/L
Comment	Total Precision

### Upper 95% tolerance limit for 95% of user estimates

df for user's experiment	within run SD	total SD
10	0.7	0.9
20	0.6	0.8
30	0.6	0.8
40	0.6	0.8
50	0.6	0.8
60	0.6	0.7
70	0.6	0.7
80	0.6	0.7
90	0.6	0.7
100	0.6	0.7

This table provides data for a manufacturer to include in published materials for users.

Accepted by:

*Lorna White*  
Signature

*21-Jul-2015*  
Date

**EP5 Precision**

**Experimental Results**

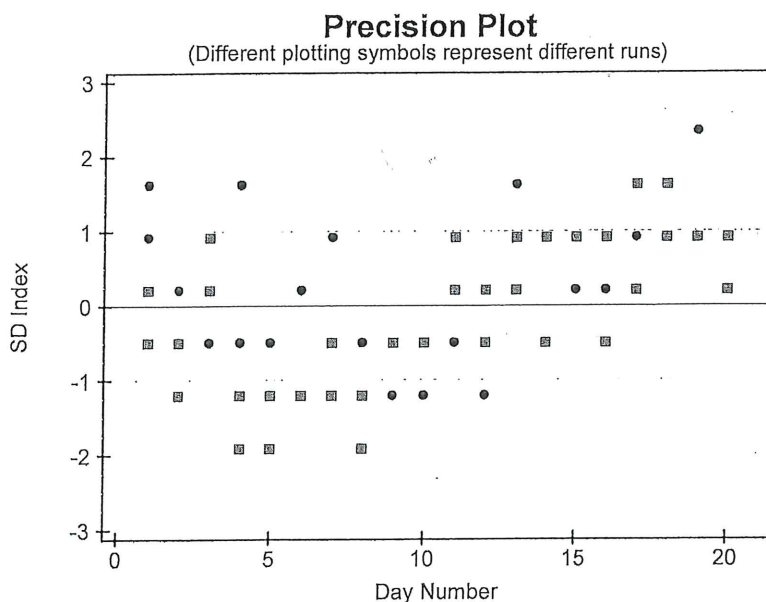
Date	Results		Date	Results		Date	Results	
22 Jun 2015	62	62	02 Jul 2015	61	61	13 Jul 2015	61	61
	62	61		60	61		63	62
23 Jun 2015	61	61	03 Jul 2015	60	60	14 Jul 2015	61	62
	61	61		60	60		62	61
24 Jun 2015	61	61	06 Jul 2015	61	61	15 Jul 2015	61	61
	61	61		60	61		62	62
25 Jun 2015	63	62	07 Jul 2015	61	61	16 Jul 2015	62	61
	60	61		61	61		62	61
26 Jun 2015	61	61	08 Jul 2015	61	62	17 Jul 2015	62	61
	61	61		62	61		61	62
29 Jun 2015	61	61	09 Jul 2015	61	62	20 Jul 2015	60	62
	61	61		61	61		62	62
30 Jun 2015	61	62	10 Jul 2015	61	61			
	61	61		61	61			

'X' indicates an excluded run, 'O' indicates an outlier run, and 'S' indicates a day that does not have a full complement of results. In all of these cases, the entire day is excluded from the calculations.

## EP5 Precision

### Precision Estimate User's Concentration: 257.7

	Within Run	Between Run	Between Day	Total	Medically Required	Verification Value (95%)	Pass/Fail
Std. Dev	0.9	0.7	0.9	1.4	5.0	5.9	Pass
% CV	0.3	0.3	0.4	0.5	1.9		
df	40	--	--	44			



### Outlier Rejection Criteria

SD	1.1 (calculated)
Multiplier	5.5
Max difference between duplicates	6.05

### Preliminary estimate of precision

Mean	257.9	CV	0.4%
SD	1.1	N	20

### Results:

259	259	258	261	257
257	258	257	260	257
258	258	257	257	257
257	258	257	258	257

### Supporting Data

Analyst	Lo/ha
Analysis Date	22 Jun 2015 to 20 Jul 2015
Days (total/excl)	20 / 0
Runs per Day	2
Reps per Run	2
Critical Value	95%
Reagent	506-30, Lot 47569/70
Calibrator	Aceta STD, Lot 47695
Units	umol/L
Verify Mode	Establish Claim
Allowable Total Error	15.0 umol/L
Random Error Budget	33.33%
Allowable Rand Error	5.0 umol/L
Comment	Total Precision

### Upper 95% tolerance limit for 95% of user estimates

df for user's experiment	within run SD	total SD
10	1.1	1.9
20	1.1	1.8
30	1.0	1.7
40	1.0	1.7
50	1.0	1.6
60	1.0	1.6
70	1.0	1.6
80	1.0	1.6
90	1.0	1.6
100	0.9	1.6

This table provides data for a manufacturer to include in published materials for users.

Accepted by:

*Sanna White*  
Signature

21-Jul-2015  
Date

## EP5 Precision

### Experimental Results

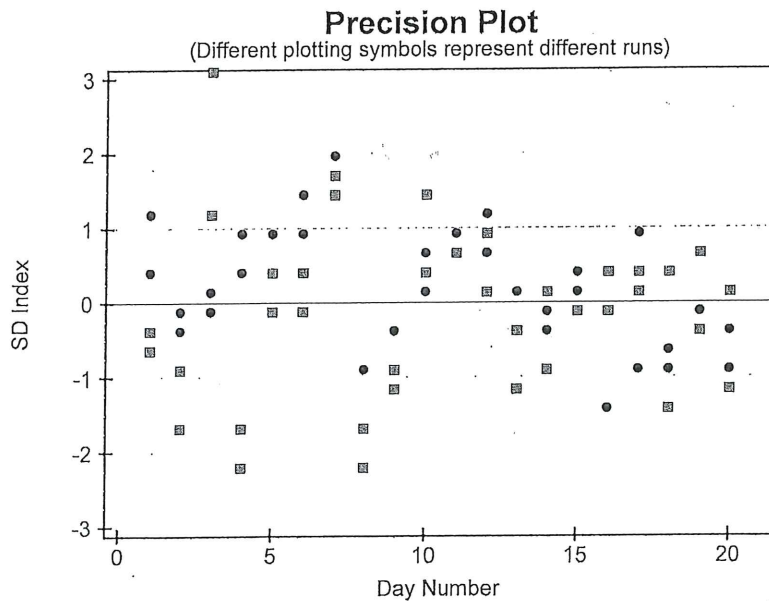
Date	Results		Date	Results		Date	Results	
22 Jun 2015	260	259	02 Jul 2015	257	255	13 Jul 2015	258	259
	258	257		256	255		259	259
23 Jun 2015	258	257	03 Jul 2015	256	256	14 Jul 2015	258	257
	257	256		257	257		259	257
24 Jun 2015	257	257	06 Jul 2015	257	256	15 Jul 2015	258	259
	259	258		257	257		258	260
25 Jun 2015	260	257	07 Jul 2015	257	258	16 Jul 2015	259	259
	256	255		258	259		260	259
26 Jun 2015	257	256	08 Jul 2015	256	256	17 Jul 2015	261	259
	255	256		258	257		259	259
29 Jun 2015	258	258	09 Jul 2015	260	260	20 Jul 2015	258	259
	256	256		258	259		259	258
30 Jun 2015	259	257	10 Jul 2015	259	257			
	256	257		259	257			

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**EP5 Precision**

Precision Estimate  
User's Concentration: 735.5

	Within Run	Between Run	Between Day	Total	Medically Required	Verification Value (95%)	Pass/Fail
Std. Dev	2.0	2.3	2.3	3.8	5.0	5.9	Pass
% CV	0.3	0.3	0.3	0.5	0.7		
df	40	--	--	43			



**Outlier Rejection Criteria**

SD 2.3 (calculated)  
Multiplier 5.5  
Max difference between duplicates 12.65

**Preliminary estimate of precision**

Mean 734.5 CV 0.3%  
SD 2.3 N 20

**Results:**

735	741	735	735	735
734	736	736	734	737
732	737	733	733	732
733	730	733	734	735

Upper 95% tolerance limit for 95% of user estimates		
df for user's experiment	within run SD	total SD
10	2.7	5.2
20	2.5	4.8
30	2.4	4.6
40	2.4	4.5
50	2.3	4.4
60	2.3	4.4
70	2.3	4.4
80	2.3	4.3
90	2.3	4.3
100	2.2	4.3

This table provides data for a manufacturer to include in published materials for users.

**Supporting Data**

Analyst Lorha  
Analysis Date 22 Jun 2015 to 20 Jul 2015  
Days (total/excl) 20 / 0  
Runs per Day 2  
Reps per Run 2  
Critical Value 95%  
Reagent 506-30, Lot 47569/70  
Calibrator Aceta STD, Lot 47695  
Units umol/L  
Verify Mode Establish Claim  
Allowable Total Error 15.0 umol/L  
Random Error Budget 33.33%  
Allowable Rand Error 5.0 umol/L  
Comment Total Precision

Accepted by: Lorha White  
Signature

21-Jul-2015  
Date

## EP5 Precision

### Experimental Results

Date	Results		Date	Results		Date	Results	
22 Jun 2015	740	737	02 Jul 2015	732	729	13 Jul 2015	736	737
	734	733		729	727		735	735
23 Jun 2015	734	735	03 Jul 2015	734	734	14 Jul 2015	730	730
	732	729		731	732		737	735
24 Jun 2015	735	736	06 Jul 2015	738	736	15 Jul 2015	739	732
	747	740		741	737		736	737
25 Jun 2015	739	737	07 Jul 2015	739	739	16 Jul 2015	732	733
	729	727		738	738		737	730
26 Jun 2015	739	737	08 Jul 2015	738	740	17 Jul 2015	735	735
	737	735		739	736		734	738
29 Jun 2015	741	739	09 Jul 2015	736	734	20 Jul 2015	734	732
	737	735		734	731		731	736
30 Jun 2015	741	743	10 Jul 2015	734	735			
	742	741		736	732			

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