

## Diesse CUBE 30 Touch Precision

All the values obtained during the precision evaluation experiment fall within the expected range and confirm the precision and repeatability of the CUBE 30 Touch instrument.

### Overview

This document provides the results of the evaluation of precision of the Diesse CUBE 30 Touch instrument performed by Streck, Inc., April 2018.

### Quality Control Material

ESR-Chex Plus Level 1      Lot 403      Exp. Date 2019-01  
 ESR-Chex Plus Level 2      Lot 403      Exp. Date 2019-01

### Instruments

CUBE 30 Touch    Serial 1039500112    Software Version 1.0

### Statistical Calculation of Precision

#### Intra-assay precision:

For each sample, the Mean (M) and Standard Deviation (SD) of the replicates are calculated. The Intra-assay Variation Coefficient (CV%) is calculated using the following formula:  
 $CV\% = (SD/M) \times 100$ .

#### Acceptance criteria:

$CV\% \leq 15\%$

### Data

#### ESR-Chex Plus Data

ESR-Chex Plus data was collected in each sample position on a single instrument by a single operator during 3 working days spanning the open-vial stability period of the control.

Position	ESR Value (mm/h) Level 1, Lot 403			ESR Value (mm/h) Level 2, Lot 403		
	Day 1	Day 5	Day 7	Day 1	Day 5	Day 7
1	1	1	1	47	47	51
2	1	1	6	47	47	49
3	2	1	2	47	47	49
4	1	2	4	49	47	47
5	1	1	1	49	47	49
6	1	1	1	47	47	47
7	2	1	4	47	49	49
8	3	5	1	47	47	49
9	1	2	4	47	49	47
10	4	5	1	49	47	47
11	2	2	2	49	47	47
12	1	1	1	49	47	47
13	2	1	1	49	47	49
14	2	4	3	49	47	47
15	1	2	3	49	47	49
16	3	1	2	49	47	47
17	2	2	1	47	47	49
18	2	1	2	47	45	45
19	2	2	1	49	49	47
20	3	1	4	47	47	49
21	1	1	3	49	49	47
22	1	2	1	47	47	47
23	2	2	3	47	47	49
24	2	1	1	47	47	49
25	1	2	1	49	49	51
26	2	2	2	49	49	51
27	1	1	1	49	49	49
28	1	1	1	47	47	49
29	3	2	2	49	49	51
30	4	4	2	47	47	49

Table 1: ESR-Chex Plus Data Table, lot 403

## Results

### Intra-assay precision (Repeatability):

Means of 30 replicates of each QC blood sample tested on one instrument by a single operator during 1 working day.

	ESR Value (mm/h) Level 1, Lot 403	ESR Value (mm/h) Level 2, Lot 403
Mean	2	48
SD	1.3	1.3
CV%	—*	2.6%

Table 2: Intra-assay precision, Repeatability

### Intra-assay precision (Within-lab):

Means of 90 replicates of each QC blood sample tested on one instrument by a single operator during 3 working days spanning the open-vial stability of the control.

	ESR Value (mm/h) Level 1, Lot 403	ESR Value (mm/h) Level 2, Lot 403
Mean	2	48
SD	1.8	1.4
CV%	—*	2.9%

Table 3: Intra-assay precision, Within-lab

*\*When the mean value is close to zero, the coefficient of variation will approach infinity and is sensitive to small changes in the mean. Therefore, CV% is not reported for this value.*

## Conclusion

All the values obtained during the precision evaluation experiment fall within the expected range and confirm the precision and repeatability of the CUBE 30 Touch instrument.