STRECK

Diesse MINI-CUBE Precision

Overview

This document provides the results of the evaluation of precision of the Diesse MINI-CUBE instrument performed by Streck, November 2022.

Quality Control Material

ESR-Chex Plus Level 1 (Normal) Lot 818 Exp. Date 05-31-2023
ESR-Chex Plus Level 2 (Abnormal) Lot 818 Exp. Date 05-31-2023

MINI-CUBE Instruments

Instrument A	Serial 0983	Software Version 1.26
Instrument B	Serial 1440	Software Version 1.26
Instrument C	Serial 0576	Software Version 1.26

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)*100.

Inter-assay precision:

For each sample, the total Mean and SD from all the results obtained over the 5 days of the experiment are computed and Inter-assay CV% is calculated.

Inter-instrument precision:

For each sample, the total Mean and SD from all the results obtained over the 5 days of the experiment performed on 3 different instruments are computed and Inter-instrument CV% is calculated.

Acceptance criteria:

For Level 1 (Normal), SD ≤ 1.8
For Level 2 (Abnormal), CV% ≤ 15%

Results

Intra-assay precision:

Means of 4 replicates of each QC blood sample tested on one instrument by a single operator during 1 working day.

	ESR Value (mm/h)	
	Streck ESR-Chex Plus	
Replicate	Normal	Abnormal
1	2	53
2	1	55
3	3	60
4	1	56
Mean	1.75	56
SD	0.96	2.94
CV%	54.71	5.26

Table 1: Intra-assay precision

Inter-assay precision:

Means of 20 replicates of each QC blood sample tested on one instrument by a single operator during 5 working days.

	ESR Value (mm/h)				
	Streck ESR-Chex Plus				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	2	1	1	2	1
2	1	1	2	1	3
3	3	1	2	1	4
4	1	1	1	1	3

Mean	1.65
SD	0.93
CV%	56.55

Table 2a. Inter-assay precision, Normal Level

	ESR Value (mm/h)				
	Streck ESR-Chex Plus				
Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
1	53	55	55	55	56
2	55	57	56	57	60
3	60	57	56	63	63
4	56	56	56	55	57

Mean	56.9
SD	2.63
CV%	4.63

Table 2b. Inter-assay precision, Abnormal Level

Inter-instrument precision:

Means of 60 replicates of each QC blood sample tested on 3 instruments by a single operator during 5 working days.

		ESR Value (mm/h)				
		Streck ESR-Chex Plus				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	2	1	1	2	1
	2	1	1	2	1	3
	3	3	1	2	1	4
	4	1	1	1	1	5
Instrument B	1	1	1	1	1	1
	2	1	1	1	1	1
	3	1	1	1	3	4
	4	1	1	1	4	2
Instrument C	1	1	1	1	1	1
	2	1	1	1	1	4
	3	1	1	1	1	1
	4	1	1	1	2	2

Mean	1.45
SD	0.89
CV%	61.46

Table 3a. Inter-instrument precision, Normal Level

		ESR Value (mm/h)				
		Streck ESR-Chex Plus				
Instrument	Replicate	Day 1	Day 2	Day 3	Day 4	Day 5
Instrument A	1	53	55	55	55	56
	2	55	57	56	57	60
	3	60	57	56	63	63
	4	56	56	56	55	57
Instrument B	1	50	50	54	48	53
	2	55	53	52	55	55
	3	54	56	52	56	56
	4	54	52	51	52	54
Instrument C	1	56	56	59	54	55
	2	59	57	55	57	57
	3	55	59	59	59	56
	4	57	58	60	57	59

Mean	55.73
SD	2.89
CV%	5.18

Table 3b. Inter-instrument precision, Abnormal Level

Conclusion

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