

CD-Chex Plus®

Instrument/Serial Number: BD FACSCanto™ II

Lab Acct Number: 000000

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FGH I J K L M N O P Q R

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 4/20/2019

Lot Number: 9021

Due: 3/15/2019

Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

INTERPRETIVE COMMENTS

THIS PAGE IS AN OVERVIEW OF THE SECTIONS CONTAINED IN YOUR REPORT

REVIEWED BY: _____

DATE: _____

DUE DATE FOR NEXT SUBMISSION: 04/15/2019

GENERAL REPORT:

This report separates data in left and right columns to provide calculations for the current cycle submission, and cumulative calculations over the dating of the lot. This report reflects the same units of measure for each parameter as listed on the product assay. On the first submission for each lot, the Current and Cumulative data will be the same. The CV may be large on some parameters due to the small numeric value, and/or the small number of significant digits reported. Levey-Jennings graphs are also provided for selected parameters.

S.D.I. REPORT:

This report is a graphical presentation of your laboratory's data on the current lot. The S.D.I. allows you to inspect results from many different tests at the same time, without having to consider different units and the actual magnitude of the change in the units of the test. In general, any S.D.I. of 2.0 or greater deserves some attention because your method shows a systematic difference from the group. The S.D.I. report is provided for selected parameters.

HISTORICAL DATA COMPARISON REPORT:

This report is a chronological presentation of your laboratory's data over the last six months. These calculations assist you in complying with CLIA regulations for establishing laboratory specific means and ranges on controls. The 2 SD is provided for all levels and parameters reported over the last six months. The historical CV is provided to monitor your method and instrument's performance over multiple lots. The historical SD and CV are comprised of all data points that meet acceptance criteria.

OUTLIERS:

Daily Data Submission: Streck utilizes the Grubbs test for the determination of outliers. Any data point that fails the Grubbs test or is greater than twice the published assay range will be excluded from the data set. Excluded values are marked on the final section of the report.

Summary Data Submission: Streck utilizes the following criterion for the determination of outliers: Any mean that is greater than twice the published assay range or any SD that is greater than the published assay range will be excluded.

Standard Calculations Provided

$$\bar{x} = \frac{\sum x}{n}$$

$$CV = \frac{s}{\bar{x}} \times 100$$

$$SDI = \frac{\bar{x} - \mu}{\sigma}$$

$$s = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

$$\sigma^2 = \frac{\sum [s_i^2 (n_i - 1) + n_i (\bar{x}_i - \mu)^2]}{N - 1}$$

\bar{x} = Lab Mean
n = Lab Count

s = Lab Standard Deviation
CV = Coefficient of Variance

μ = Group Mean
 σ = Group Standard Deviation

N = Group Count

For a detailed explanation of the STATS® report format or more information regarding QC concepts, please visit Streck online at: <http://www.streck.com>

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Instrument/Serial Number: BD FACSCanto™ II

Lab Acct Number: 00100

SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 4/20/2019

Lot Number: 9021

Due: 3/15/2019

Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

CD4 Low 90210072

Current Submission - Number of Instruments: 68

Cumulative Submissions

Total Number of Instruments: 70

Parameter	Assay Mean	Your Mean	Your N	Your SD	Your CV	Group Mean	Group N	Group SD	Group CV	S.D.I.	Your Mean	Your N	Your SD	Your CV	Group Mean	Group N	Group SD	Group CV	S.D.I.
CD3%	62.8	62.9	9	1.02	1.61	62.1	870	1.78	2.87	0.43	62.9	9	1.02	1.61	62.2	1009	1.75	2.81	0.40
CD3#	691	707	9	15.8	2.2	728	636	55.4	7.6	-0.4	707	9	15.8	2.2	725	737	53.0	7.3	-0.3
CD4%	14.8	14.9	8	0.78	5.27	14.5	929	0.88	6.11	0.46	14.9	8	0.78	5.27	14.5	1061	0.87	6.01	0.45
CD4#	168	169	8	11.2	6.6	168	695	12.9	7.6	0.0	169	8	11.2	6.6	168	789	12.6	7.5	0.1
CD8%	41.8	42.6	8	0.78	1.84	43.1	850	2.14	4.96	-0.25	42.6	8	0.78	1.84	43.1	982	2.06	4.77	-0.23
CD8#	460	483	8	12.8	2.7	507	622	40.9	8.1	-0.6	483	8	12.8	2.7	504	716	39.8	7.9	-0.5
16+56%	16.4	15.9	8	0.58	3.68	16.3	660	1.03	6.29	-0.42	15.9	8	0.58	3.68	16.3	757	1.03	6.36	-0.37
16+56#	205	178	8	10.3	5.8	192	467	21.0	10.9	-0.7	178	8	10.3	5.8	191	547	20.5	10.7	-0.6
CD19%	19.1	20.2	8	0.75	3.69	19.8	661	1.02	5.15	0.41	20.2	8	0.75	3.69	19.8	758	1.00	5.04	0.40
CD19#	219	229	8	13.5	5.9	233	467	17.6	7.6	-0.2	229	8	13.5	5.9	232	547	17.2	7.4	-0.2
45#LY	1,148	1,124	9	33.5	3.0	1,201	213	115.9	9.7	-0.7	1,124	9	33.5	3.0	1,187	259	110.5	9.3	-0.6

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1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

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Lot Number: 9021

Due: 3/15/2019

Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

Normal 90210071

Current Submission - Number of Instruments: 75

Cumulative Submissions

Total Number of Instruments: 77

Parameter	Assay Mean	Your Mean	Your N	Your SD	Your CV	Group Mean	Group N	Group SD	Group CV	S.D.I.	Your Mean	Your N	Your SD	Your CV	Group Mean	Group N	Group SD	Group CV	S.D.I.
CD3%	77.4	77.2	11	0.47	0.60	76.5	1037	1.31	1.72	0.56	77.2	11	0.47	0.60	76.5	1176	1.29	1.69	0.55
CD3#	1,673	1,754	11	36.4	2.1	1,767	630	76.8	4.3	-0.2	1,754	11	36.4	2.1	1,765	724	76.5	4.3	-0.1
CD4%	50.2	49.6	8	0.42	0.84	49.6	1013	1.20	2.41	-0.02	49.6	8	0.42	0.84	49.6	1152	1.19	2.40	-0.04
CD4#	1,097	1,103	8	37.3	3.4	1,148	627	52.7	4.6	-0.9	1,103	8	37.3	3.4	1,146	721	52.5	4.6	-0.8
CD8%	24.2	23.9	8	0.49	2.06	24.9	965	1.54	6.19	-0.64	23.9	8	0.49	2.06	24.8	1104	1.50	6.04	-0.62
CD8#	516	533	8	20.5	3.8	586	600	44.1	7.5	-1.2	533	8	20.5	3.8	582	694	44.6	7.7	-1.1
16+56%	9.9	9.6	8	0.31	3.21	9.9	680	0.68	6.87	-0.52	9.6	8	0.31	3.21	9.9	765	0.68	6.86	-0.52
16+56#	245	219	8	8.3	3.8	232	465	19.9	8.6	-0.6	219	8	8.3	3.8	231	538	20.0	8.7	-0.6
CD19%	12.4	12.7	8	0.36	2.85	12.6	788	0.73	5.76	0.12	12.7	8	0.36	2.85	12.6	893	0.73	5.81	0.14
CD19#	282	291	8	9.9	3.4	292	476	30.2	10.3	0.0	291	8	9.9	3.4	292	557	29.1	10.0	0.0
45#LY	2,224	2,272	11	50.4	2.2	2,324	155	84.5	3.6	-0.6	2,272	11	50.4	2.2	2,309	201	87.2	3.8	-0.4

Important Notes

1. This report reflects the same units of measure for each parameter as listed on the product assay.
2. A graph will not be included on reported parameters in which data contains only one data point and for submissions which consist of summary data.
3. The presence of an asterisk (*) indicates that there are less than 10 unique instruments submitting data for the current month's reports.
4. The presence of dashes (----) indicates there were no values to calculate or report.
5. SDI values greater than 2.0 or less than -2.0 are displayed in white on a dark background.

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Lot Number: 9021

Due: 3/15/2019

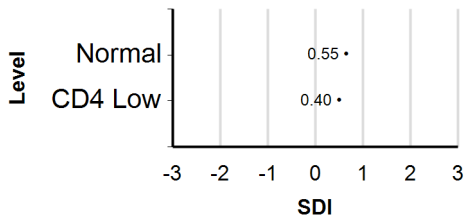
Submitted: 3/7/2019

From: 2/1/2019

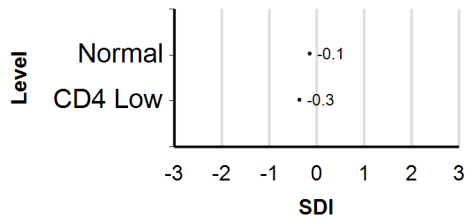
To: 2/28/2019

S.D.I. Reports

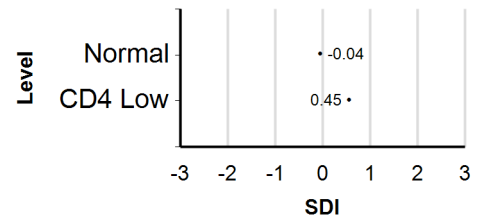
CD3%



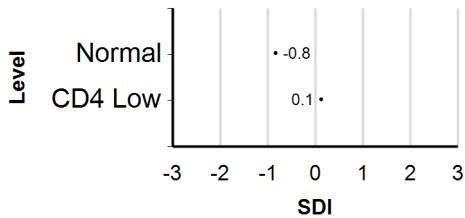
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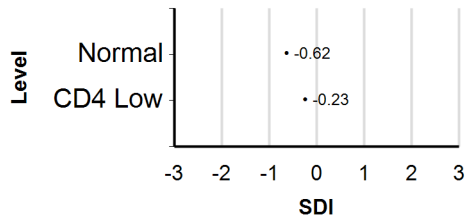
CD4%



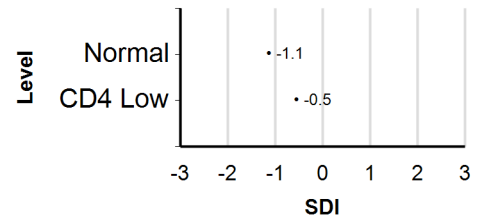
CD4#



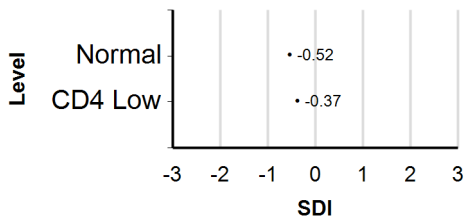
CD8%



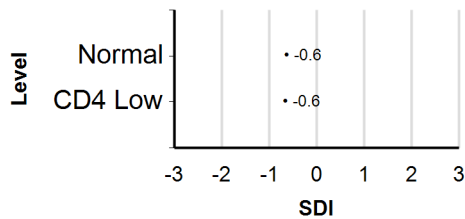
CD8#



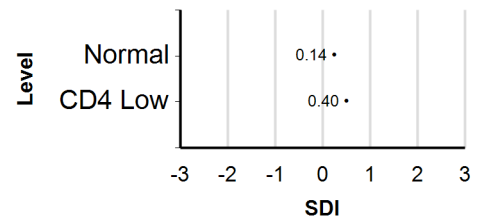
16+56%



16+56#



CD19%



CD-Chex Plus®

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1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

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Lot Number: 9021

Due: 3/15/2019

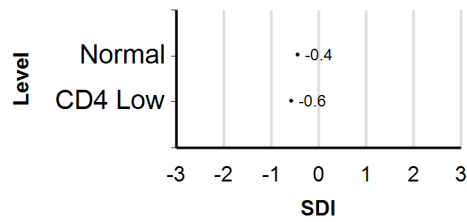
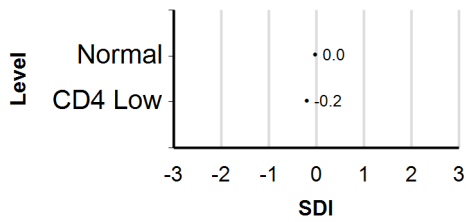
Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

CD19#

45#LY



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1234 MAIN STREET

ANYTOWN, NE 12345 US

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Lot Number: 9021

Due: 3/15/2019

Submitted: 3/7/2019

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Historical Data Comparison Report - Last Six Months

CD4 Low

SD

Due Date	9/15/2018	10/15/2018	11/15/2018	12/15/2018	1/15/2019	2/15/2019	3/15/2019								
Lot #'s	8162	8218	8218	8218	8274	8274	8274	8330	8330	8330	9021				
CD3%	1.17	1.30	0.77	0.83	0.88	0.77	1.05	0.70	1.09	1.16	1.02				
CD3#	30.2	21.3	33.3	20.1	24.8	28.7	21.6	23.1	18.2	31.5	15.8				
CD4%	0.41	0.18	0.44	0.41	0.53	0.38	0.44	0.45	0.47	0.41	0.78				
CD4#	7.2	4.6	10.0	6.8	10.9	6.8	8.0	8.3	8.3	8.1	11.2				
CD8%	0.78	0.27	0.50	0.79	1.47	0.99	1.00	1.02	1.01	0.63	0.78				
CD8#	16.1	10.3	28.1	20.2	5.4	16.5	18.1	19.5	18.9	20.7	12.8				
16+56%	0.55	0.67	0.33	0.63	0.62	0.71	0.70	0.51	0.64	0.86	0.58				
16+56#	10.2	8.8	10.0	12.1	15.5	11.6	11.3	7.5	9.8	14.0	10.3				
CD19%	0.68	1.03	0.64	0.71	1.02	0.55	0.63	0.43	0.67	0.38	0.75				
CD19#	10.7	20.7	14.7	17.4	12.2	12.3	12.5	9.1	12.2	9.2	13.5				
45#LY	43.7	26.4	53.6	37.0	33.1	38.4	30.9	32.4	26.8	40.6	33.5				

Historical

SD 2 SD

1.00	2.01
25.7	51.4
0.45	0.89
8.0	16.0
0.86	1.72
18.7	37.5
0.64	1.28
11.1	22.2
0.66	1.32
13.3	26.5
37.8	75.7

CV

Due Date	9/15/2018	10/15/2018	11/15/2018	12/15/2018	1/15/2019	2/15/2019	3/15/2019								
Lot #'s	8162	8218	8218	8218	8274	8274	8274	8330	8330	8330	9021				
CD3%	1.88	2.20	1.30	1.40	1.43	1.27	1.71	1.10	1.70	1.82	1.61				
CD3#	3.7	2.3	3.7	2.2	3.0	3.4	2.6	2.8	2.3	3.9	2.2				
CD4%	3.20	1.73	4.31	4.12	4.31	3.11	3.65	3.40	3.63	3.15	5.27				
CD4#	4.3	3.0	6.4	4.4	6.5	4.0	4.8	4.9	5.1	5.0	6.6				
CD8%	1.82	0.60	1.13	1.79	3.37	2.27	2.31	2.38	2.33	1.44	1.84				
CD8#	2.9	1.5	4.1	3.0	0.9	2.7	3.0	3.6	3.5	3.8	2.7				
16+56%	3.18	3.98	1.94	3.70	3.48	4.12	4.07	3.02	3.81	5.10	3.68				
16+56#	4.4	3.4	3.8	4.6	6.3	4.9	4.8	3.4	4.6	6.5	5.8				
CD19%	3.41	4.54	2.86	3.17	5.17	2.66	3.06	2.27	3.63	2.11	3.69				
CD19#	4.1	5.9	4.3	5.0	4.5	4.3	4.4	3.7	5.2	4.0	5.9				
45#LY	3.3	1.7	3.5	2.4	2.4	2.8	2.2	2.5	2.1	3.2	3.0				

Historical

CV

1.63
3.1
3.66
4.9
1.98
3.2
3.74
4.7
3.24
4.7
2.8

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SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 4/20/2019

Lot Number: 9021

Due: 3/15/2019

Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

Normal

SD

Due Date	9/15/2018		10/15/2018		11/15/2018		12/15/2018		1/15/2019		2/15/2019		3/15/2019	
Lot #'s	8162	8218	8218	8218	8274	8274	8274	8330	8330	8330	9021			
CD3%	0.40	0.46	0.62	0.67	0.70	0.60	0.94	0.52	0.47	0.62	0.47			
CD3#	47.2	44.8	65.5	29.4	24.0	38.0	48.2	32.4	47.5	40.1	36.4			
CD4%	0.57	0.30	0.74	0.56	0.47	0.60	0.64	0.62	0.50	0.68	0.42			
CD4#	34.3	23.2	29.6	37.6	32.8	29.7	33.1	24.4	24.7	28.7	37.3			
CD8%	0.59	0.40	0.69	0.55	0.29	0.68	0.55	0.35	0.49	0.52	0.49			
CD8#	22.5	14.0	18.7	20.3	12.2	23.6	17.7	15.8	16.0	18.7	20.5			
16+56%	0.31	0.28	0.36	0.41	0.43	0.44	0.65	0.29	0.22	0.47	0.31			
16+56#	12.0	6.4	16.0	10.9	12.2	13.2	15.3	9.1	8.9	12.5	8.3			
CD19%	0.32	0.31	0.26	0.45	0.38	0.37	0.37	0.51	0.35	0.48	0.36			
CD19#	8.4	8.8	16.0	12.1	8.9	10.7	10.7	11.9	10.2	14.5	9.9			
45#LY	60.7	57.0	96.2	37.0	17.8	48.5	57.9	40.0	60.8	49.8	50.4			

Historical

SD 2 SD

0.60	1.20
43.6	87.3
0.58	1.16
31.1	62.3
0.55	1.11
19.3	38.7
0.40	0.80
12.0	24.0
0.38	0.76
11.4	22.7
56.8	113.7

CV

Due Date	9/15/2018		10/15/2018		11/15/2018		12/15/2018		1/15/2019		2/15/2019		3/15/2019	
Lot #'s	8162	8218	8218	8218	8274	8274	8274	8330	8330	8330	9021			
CD3%	0.52	0.60	0.80	0.87	0.90	0.77	1.22	0.68	0.61	0.80	0.60			
CD3#	2.6	2.4	3.7	1.6	1.4	2.2	2.8	1.8	2.7	2.3	2.1			
CD4%	1.19	0.60	1.51	1.15	0.95	1.22	1.32	1.31	1.07	1.44	0.84			
CD4#	3.0	2.0	2.6	3.3	3.0	2.8	3.0	2.2	2.4	2.7	3.4			
CD8%	2.43	1.64	2.78	2.25	1.20	2.78	2.21	1.39	1.95	2.07	2.06			
CD8#	3.9	2.4	3.2	3.5	2.3	4.4	3.2	2.7	2.9	3.3	3.8			
16+56%	2.89	2.94	3.76	4.22	4.30	4.35	6.56	2.73	2.11	4.43	3.21			
16+56#	4.8	2.8	7.1	4.8	5.5	5.9	6.9	3.7	3.7	5.2	3.8			
CD19%	2.51	2.41	2.03	3.53	3.22	3.02	2.98	4.21	2.86	4.05	2.85			
CD19#	2.8	2.9	5.3	4.0	3.3	3.9	3.8	4.3	3.7	5.4	3.4			
45#LY	2.6	2.4	4.1	1.6	0.8	2.2	2.6	1.7	2.7	2.2	2.2			

Historical

CV

0.78
2.5
1.21
2.8
2.24
3.4
3.96
5.1
3.06
4.0
2.5

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SAMPLE LAB REPORT

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ANYTOWN, NE 12345 US

Shift: 1

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Due: 3/15/2019

Submitted: 3/7/2019

From: 2/1/2019

To: 2/28/2019

Customer Data Submitted

0.00 Values with a horizontal strike-through are determined to be outliers and were excluded.

0.00 Values with a diagonal strike-through are duplicate data that were excluded.

CD4 Low 90210072

	CD3%	CD3#	CD4%	CD4#	CD8%	CD8#	16+56%	16+56#	CD19%	CD19#	45#LY
Summary	62.9	707	14.9	169	42.6	483	15.9	178	20.2	229	1,124

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Normal 90210071

	CD3%	CD3#	CD4%	CD4#	CD8%	CD8#	16+56%	16+56#	CD19%	CD19#	45#LY
Summary	77.2	1,754	49.6	1,103	23.9	533	9.6	219	12.7	291	2,272