

CD-Chex Plus®

Instrument/Serial Number: BD FACSCanto™ II V0000000001

Lab Acct Number: 00100

SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 12/26/2020

Lot Number: 0272

Due: 12/15/2020

Submitted: 12/2/2020

From: 11/4/2020

To: 11/30/2020

INTERPRETIVE COMMENTS

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

REVIEWED BY: _____

DATE: _____

DUE DATE FOR NEXT SUBMISSION: 01/15/2021

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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CD4 Low 02720072

Current Submission - Number of Instruments: 118

Cumulative Submissions

Total Number of Instruments: 126

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%	59.6	59.1	13	1.19	2.01	58.4	2204	1.34	2.30	0.51	59.1	28	1.01	1.71	58.5	2834	1.42	2.44	0.47
CD3#	836	833	13	43.0	5.2	820	1722	44.9	5.5	0.3	859	28	60.7	7.1	821	2227	47.1	5.7	0.8
CD4%	12.1	11.9	13	0.56	4.72	11.9	2139	0.66	5.53	-0.05	11.9	28	0.52	4.37	11.9	2748	0.66	5.57	0.03
CD4#	178	167	13	10.7	6.4	167	1685	12.2	7.3	0.0	173	28	13.6	7.9	167	2159	12.7	7.6	0.5
CD8%	42.9	42.3	13	1.23	2.91	43.0	2080	1.71	3.98	-0.39	42.4	28	1.23	2.90	43.1	2688	1.74	4.03	-0.38
CD8#	621	597	13	37.9	6.4	604	1649	37.7	6.2	-0.2	616	28	50.8	8.2	605	2143	39.8	6.6	0.3
16+56%	19.7	19.7	11	0.96	4.84	20.0	1359	0.92	4.61	-0.30	19.5	19	0.80	4.11	20.0	1778	0.95	4.77	-0.46
16+56#	301	279	11	23.4	8.4	281	1124	19.7	7.0	-0.1	280	19	19.4	7.0	281	1465	21.2	7.6	-0.1
CD19%	19.6	20.4	11	0.87	4.25	19.8	1400	0.90	4.57	0.61	20.6	19	0.85	4.11	19.9	1824	0.97	4.88	0.76
CD19#	293	287	11	19.4	6.7	280	1148	20.3	7.2	0.4	295	19	19.2	6.5	280	1495	21.0	7.5	0.7
LYM#	1,458	1,410	13	71.5	5.1	1,411	138	72.0	5.1	0.0	1,453	28	95.3	6.6	1,395	255	91.2	6.5	0.6

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Normal 02720071

Current Submission - Number of Instruments: 129

Cumulative Submissions

Total Number of Instruments: 137

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%	76.3	75.4	12	0.79	1.04	75.2	2298	1.30	1.73	0.10	75.9	26	1.05	1.38	75.3	2974	1.31	1.75	0.47
CD3#	1,657	1,688	12	94.5	5.6	1,631	1732	95.5	5.9	0.6	1,707	25	86.6	5.1	1,635	2226	94.6	5.8	0.8
CD4%	48.7	48.7	12	1.03	2.11	48.2	2223	1.22	2.53	0.41	48.9	26	1.02	2.09	48.2	2878	1.21	2.51	0.52
CD4#	1,050	1,091	12	72.8	6.7	1,047	1676	65.4	6.2	0.7	1,101	25	60.5	5.5	1,049	2162	64.7	6.2	0.8
CD8%	25.3	24.6	12	2.38	9.66	25.3	2164	1.41	5.58	-0.49	24.5	26	1.62	6.63	25.4	2817	1.50	5.91	-0.59
CD8#	539	549	12	43.9	8.0	549	1645	42.8	7.8	0.0	553	26	39.3	7.1	553	2129	44.8	8.1	0.0
16+56%	11.3	11.7	9	0.78	6.64	11.5	1442	0.74	6.42	0.31	11.3	17	0.89	7.84	11.5	1855	0.75	6.50	-0.22
16+56#	268	264	10	25.5	9.7	251	1187	20.2	8.0	0.6	261	18	31.9	12.2	251	1515	21.1	8.4	0.5
CD19%	11.9	12.2	10	0.49	3.98	12.1	1612	0.67	5.54	0.10	12.2	18	0.61	5.01	12.2	2103	0.69	5.70	0.08
CD19#	283	274	10	19.7	7.2	266	1224	22.2	8.3	0.3	282	18	30.5	10.8	267	1571	22.7	8.5	0.6
LYM#	2,222	2,231	11	129.3	5.8	2,153	234	209.3	9.7	0.4	2,246	24	106.6	4.7	2,157	372	196.2	9.1	0.5

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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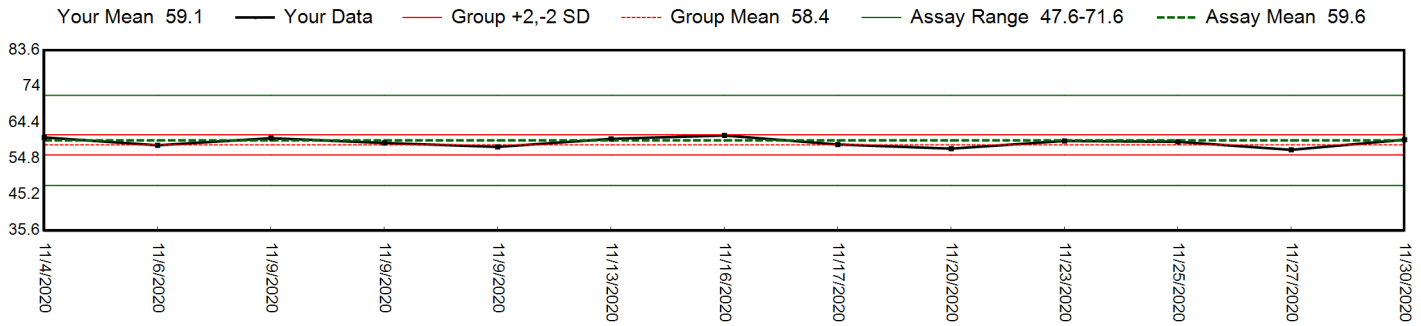
Submitted: 12/2/2020

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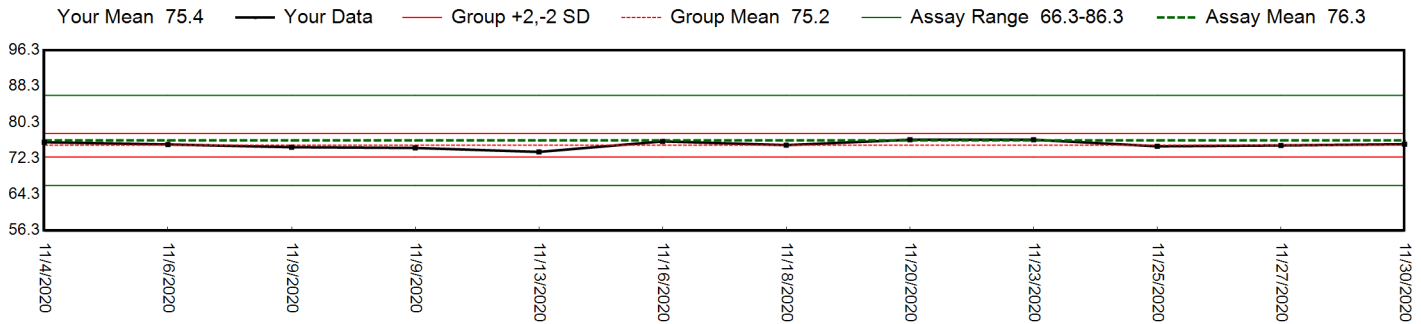
Levey-Jennings Graphs CD4 Low CD3%

Only values with RunDates are displayed.



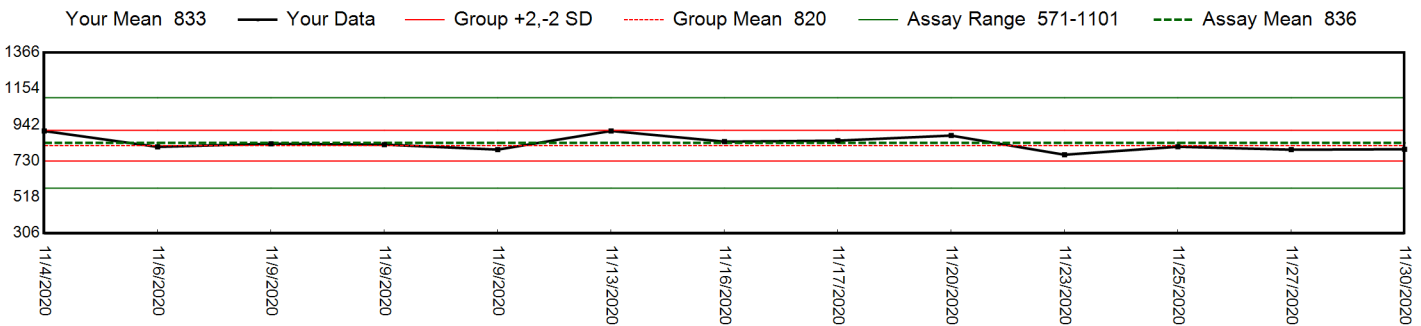
Normal CD3%

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CD4 Low CD3#

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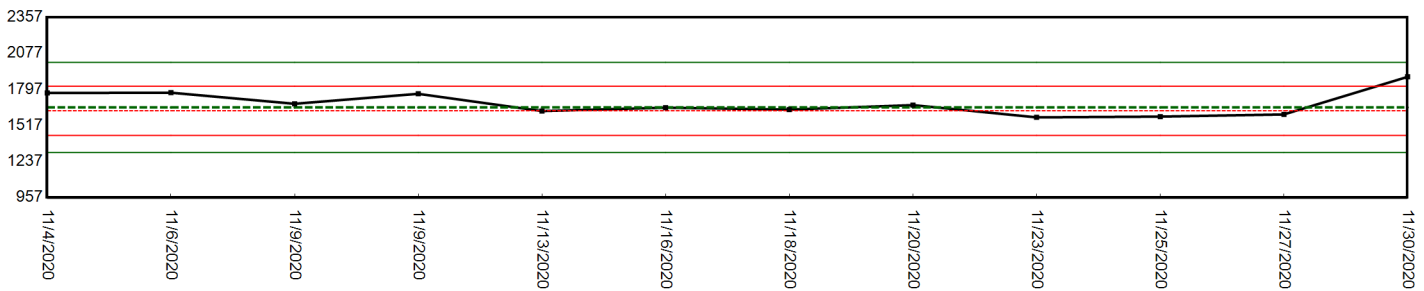
From: 11/4/2020

To: 11/30/2020

Normal CD3#

Only values with RunDates are displayed.

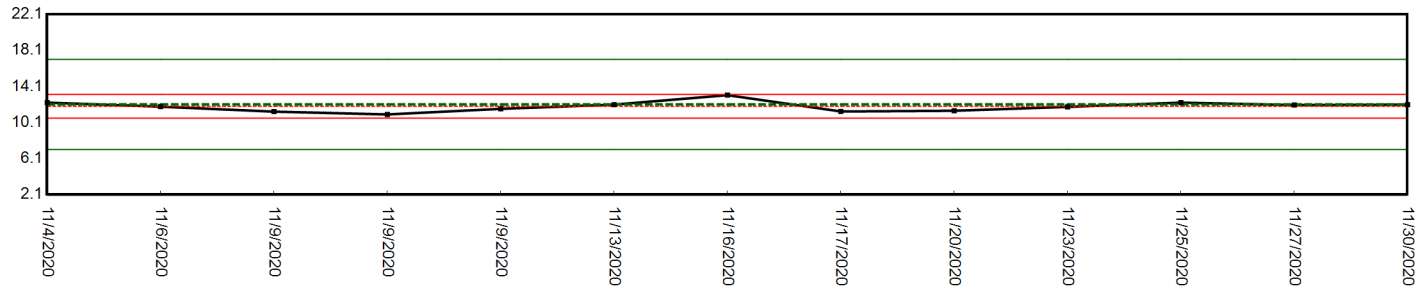
Your Mean 1688 — Your Data — Group +2,-2 SD - - - Group Mean 1631 — Assay Range 1307-2007 - - - Assay Mean 1657



CD4 Low CD4%

Only values with RunDates are displayed.

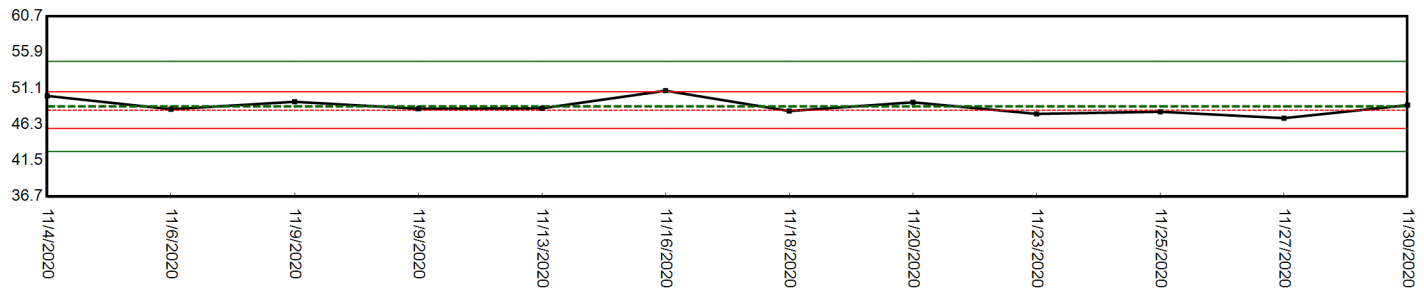
Your Mean 11.9 — Your Data — Group +2,-2 SD - - - Group Mean 11.9 — Assay Range 7.1-17.1 - - - Assay Mean 12.1



Normal CD4%

Only values with RunDates are displayed.

Your Mean 48.7 — Your Data — Group +2,-2 SD - - - Group Mean 48.2 — Assay Range 42.7-54.7 - - - Assay Mean 48.7



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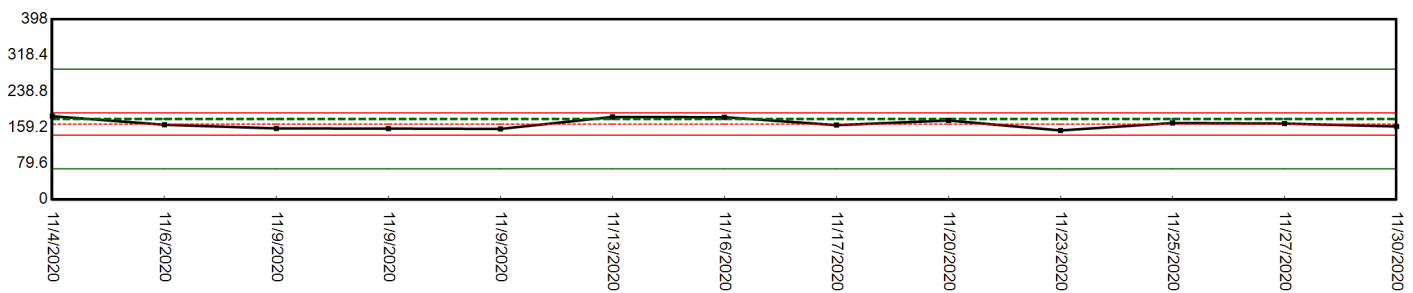
From: 11/4/2020

To: 11/30/2020

CD4 Low CD4#

Only values with RunDates are displayed.

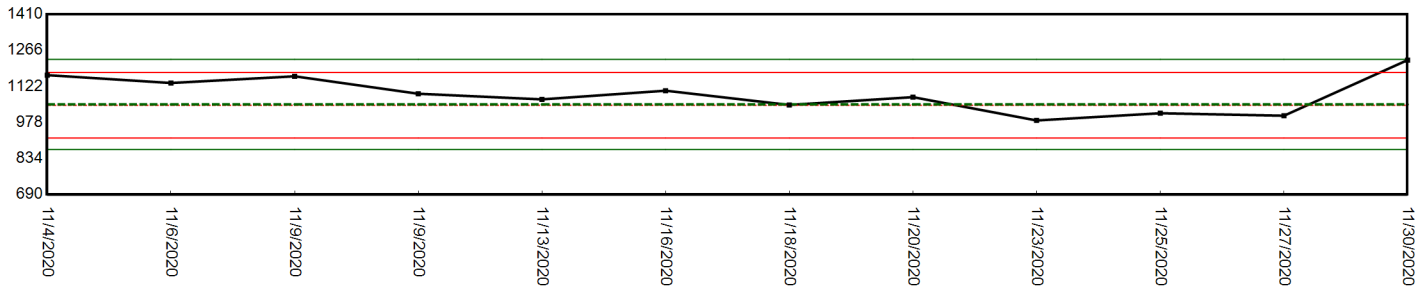
Your Mean 167 Your Data Group +2,-2 SD Group Mean 167 Assay Range 68-288 Assay Mean 178



Normal CD4#

Only values with RunDates are displayed.

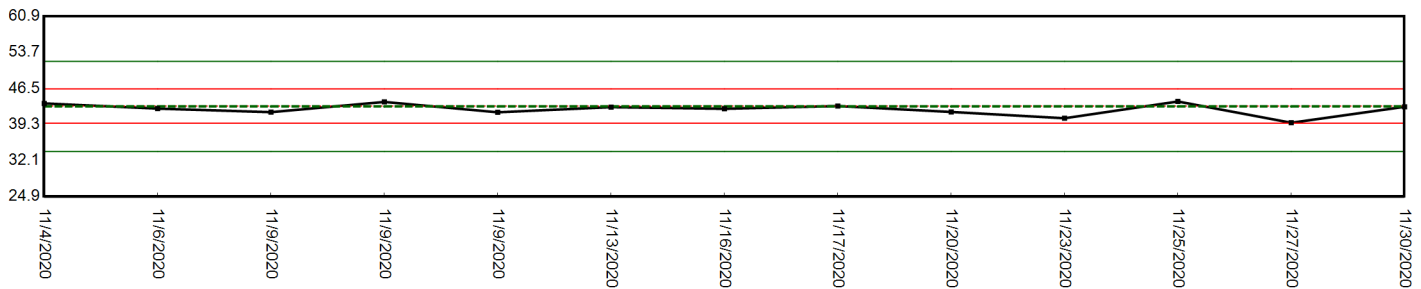
Your Mean 1091 Your Data Group +2,-2 SD Group Mean 1047 Assay Range 870-1230 Assay Mean 1050



CD4 Low CD8%

Only values with RunDates are displayed.

Your Mean 42.3 Your Data Group +2,-2 SD Group Mean 43.0 Assay Range 33.9-51.9 Assay Mean 42.9



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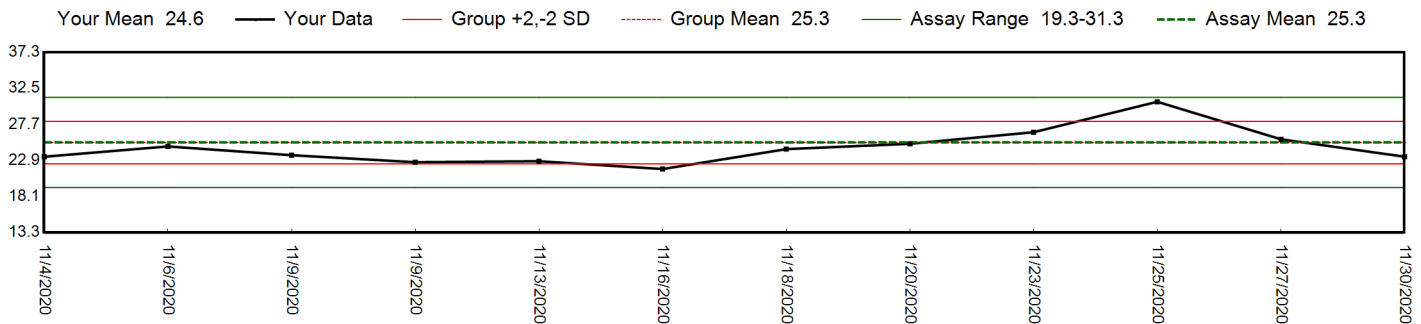
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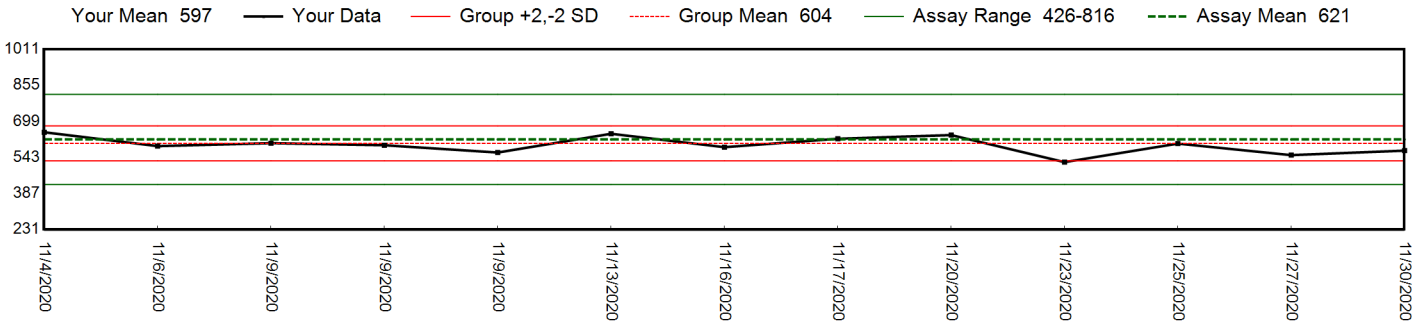
Normal CD8%

Only values with RunDates are displayed.



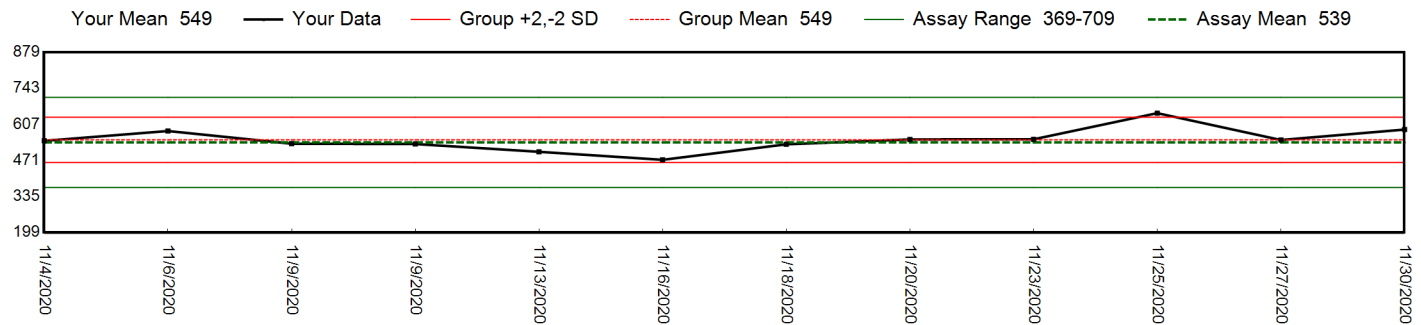
CD4 Low CD8#

Only values with RunDates are displayed.



Normal CD8#

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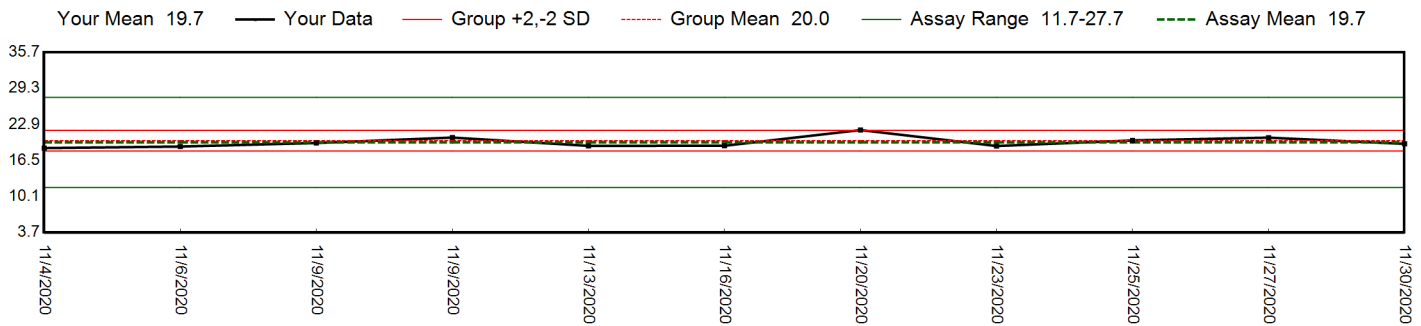
Submitted: 12/2/2020

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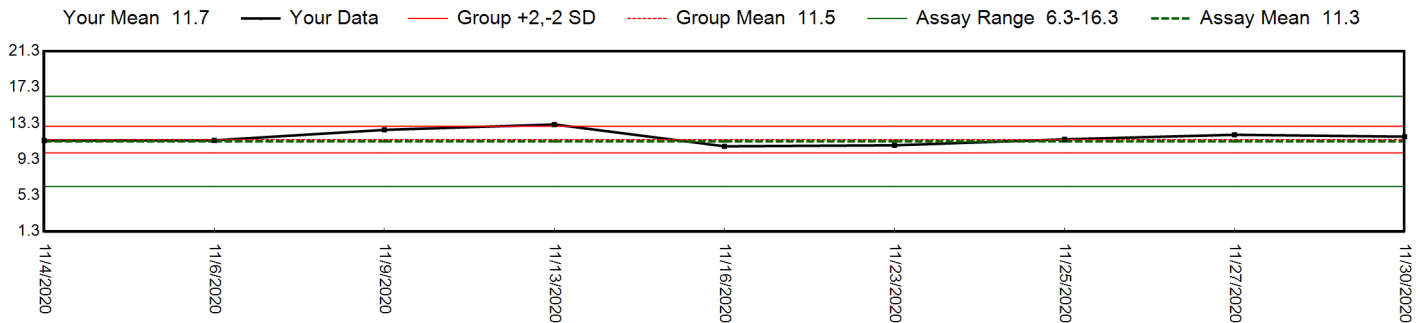
CD4 Low 16+56%

Only values with RunDates are displayed.



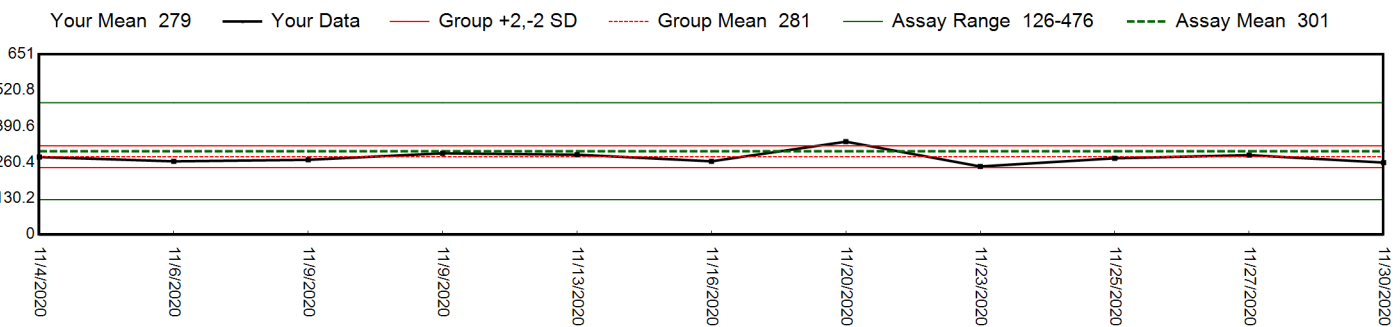
Normal 16+56%

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CD4 Low 16+56#

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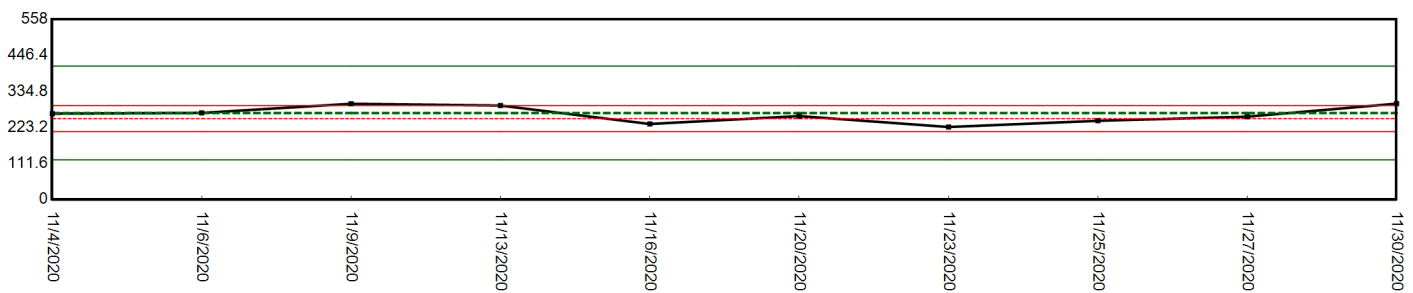
From: 11/4/2020

To: 11/30/2020

Normal 16+56#

Only values with RunDates are displayed.

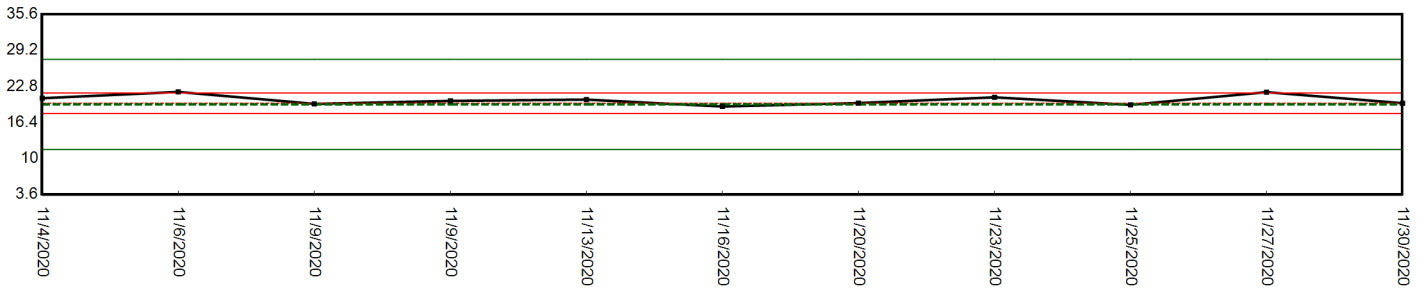
Your Mean 264 — Your Data — Group +2,-2 SD - - - Group Mean 251 — Assay Range 123-413 - - - Assay Mean 268



CD4 Low CD19%

Only values with RunDates are displayed.

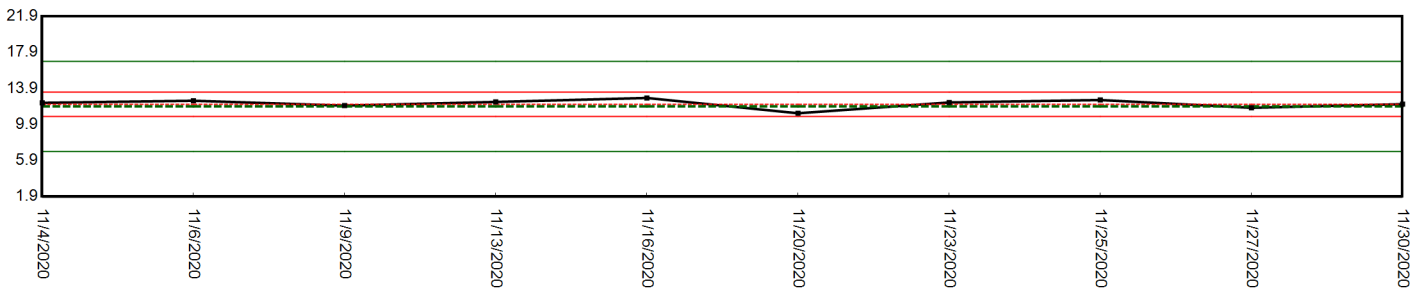
Your Mean 20.4 — Your Data — Group +2,-2 SD - - - Group Mean 19.8 — Assay Range 11.6-27.6 - - - Assay Mean 19.6



Normal CD19%

Only values with RunDates are displayed.

Your Mean 12.2 — Your Data — Group +2,-2 SD - - - Group Mean 12.1 — Assay Range 6.9-16.9 - - - Assay Mean 11.9



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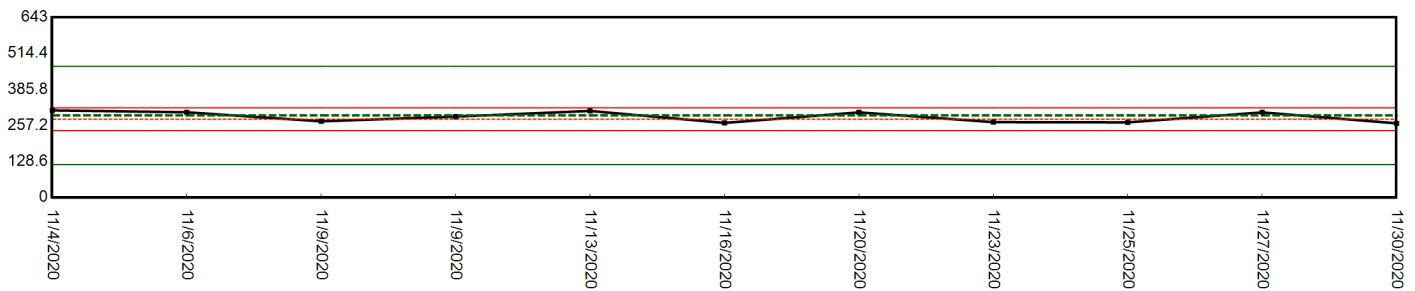
From: 11/4/2020

To: 11/30/2020

CD4 Low CD19#

Only values with RunDates are displayed.

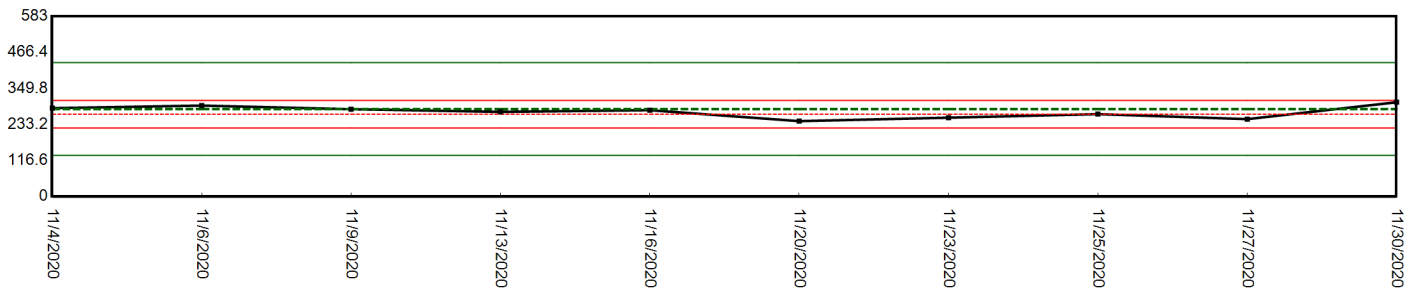
Your Mean 287 Your Data Group +2,-2 SD Group Mean 280 Assay Range 118-468 Assay Mean 293



Normal CD19#

Only values with RunDates are displayed.

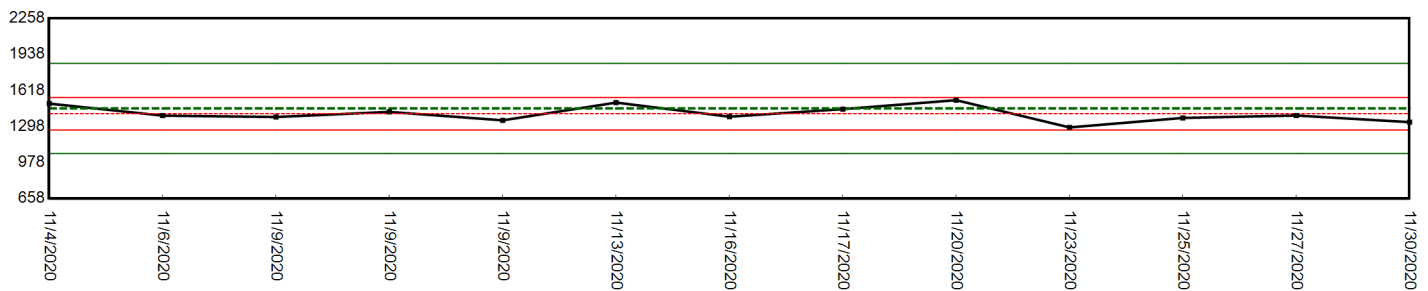
Your Mean 274 Your Data Group +2,-2 SD Group Mean 266 Assay Range 133-433 Assay Mean 283



CD4 Low LYM#

Only values with RunDates are displayed.

Your Mean 1410 Your Data Group +2,-2 SD Group Mean 1411 Assay Range 1058-1858 Assay Mean 1458



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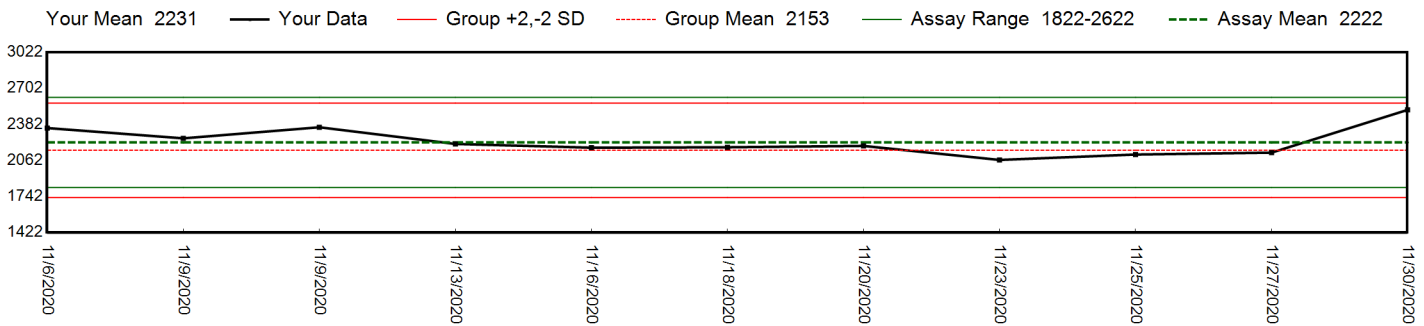
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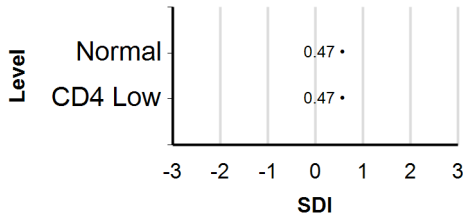
Submitted: 12/2/2020

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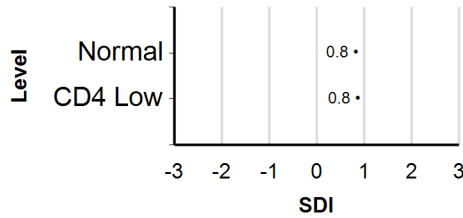
To: 11/30/2020

S.D.I. Reports

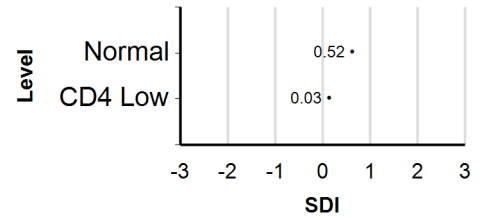
CD3%



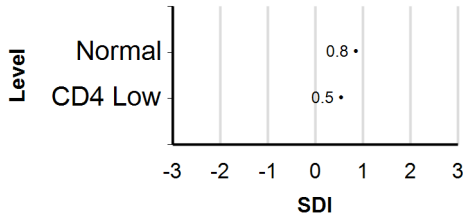
CD3#



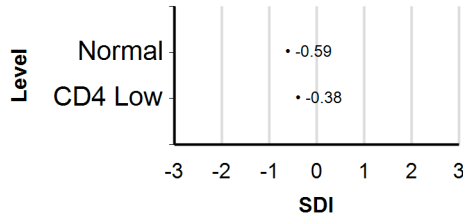
CD4%



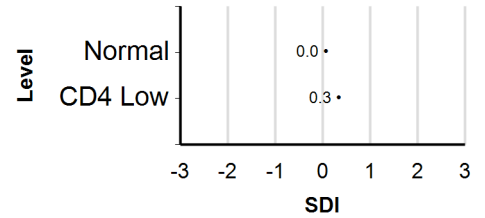
CD4#



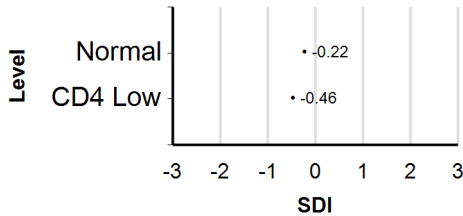
CD8%



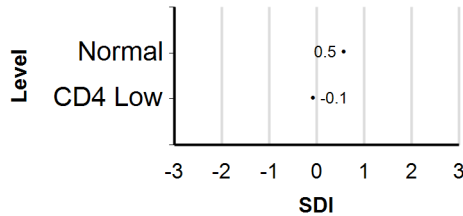
CD8#



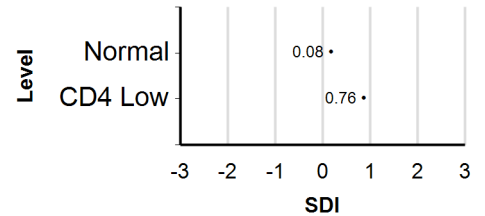
16+56%



16+56#



CD19%



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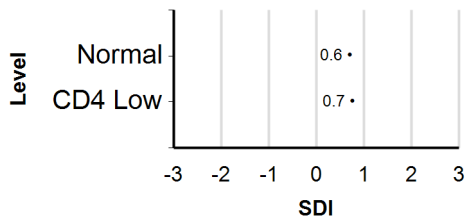
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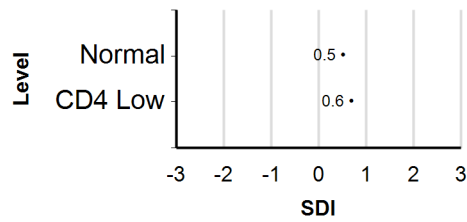
From: 11/4/2020

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CD19#



LYM#



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Historical Data Comparison Report - Last Six Months

CD4 Low

SD

Due Date	8/15/2020		9/15/2020		10/15/2020		11/15/2020		12/15/2020	
Lot #'s	0104	0160	0160	0216	0216	0216	0272	0272	0272	0272
CD3%	0.77	0.92	1.05	0.09	1.02	1.38	0.86	1.19		
CD3#	30.4	83.0	52.0	33.6	36.9	49.2	65.9	43.0		
CD4%	0.65	0.80	0.74	0.12	0.71	0.74	0.50	0.56		
CD4#	11.3	22.6	10.8	4.4	12.6	15.3	14.1	10.7		
CD8%	1.11	1.16	1.10	0.40	1.10	1.51	1.26	1.23		
CD8#	23.3	58.5	44.1	17.4	32.0	38.8	55.6	37.9		
16+56%	0.71	0.46	0.85	0.00	0.90	0.86	0.44	0.96		
16+56#	17.9	37.0	17.1	0.0	16.0	16.2	13.5	23.4		
CD19%	0.47	0.88	1.19	0.00	0.73	0.79	0.74	0.87		
CD19#	12.4	31.1	19.6	0.0	13.3	17.4	13.7	19.4		
LYM#	46.5	140.8	87.9	52.9	57.6	69.8	99.8	71.5		

Historical

SD 2 SD

1.06	2.11
55.4	110.8
0.69	1.37
15.3	30.5
1.29	2.59
43.5	87.0
0.74	1.49
22.9	45.9
0.80	1.60
20.1	40.2
91.6	183.2

CV

Due Date	8/15/2020		9/15/2020		10/15/2020		11/15/2020		12/15/2020	
Lot #'s	0104	0160	0160	0216	0216	0216	0272	0272	0272	0272
CD3%	1.28	1.54	1.75	0.15	1.66	2.25	1.46	2.01		
CD3#	3.0	10.3	6.9	4.0	4.0	5.3	7.5	5.2		
CD4%	6.03	6.34	6.00	1.03	6.11	6.67	4.17	4.72		
CD4#	6.3	13.3	7.0	2.7	7.2	9.1	7.9	6.4		
CD8%	2.54	2.69	2.57	0.92	2.48	3.33	2.98	2.91		
CD8#	3.2	10.1	8.1	2.9	4.8	5.7	8.8	6.4		
16+56%	3.90	2.23	4.19	0.00	5.31	4.93	2.27	4.84		
16+56#	5.9	13.3	6.6	0.0	6.3	6.1	4.8	8.4		
CD19%	2.34	4.71	6.47	0.00	3.63	3.92	3.51	4.25		
CD19#	3.7	12.2	8.4	0.0	4.4	5.6	4.5	6.7		
LYM#	2.8	10.5	6.9	3.8	3.8	4.6	6.7	5.1		

Historical

CV

1.75
6.2
5.95
8.9
2.97
6.7
3.96
8.2
3.99
6.6
6.1

CD-Chex Plus®

Instrument/Serial Number: **BD FACSCanto™ II V0000000001**

Lab Acct Number: 00100
SAMPLE LAB REPORT
 1234 MAIN STREET
 ANYTOWN, NE 12345 US

Shift: 1
Due: 12/15/2020
Lot Exp: 12/26/2020
Submitted: 12/2/2020
Lot Number: 0272
From: 11/4/2020
To: 11/30/2020

Normal

SD

Due Date	8/15/2020		9/15/2020		10/15/2020		11/15/2020		12/15/2020	
Lot #'s	0104	0160	0160	0216	0216	0216	0272	0272	0272	0272
CD3%	0.97	0.98	0.75	0.08	0.86	1.03	1.06	0.79		
CD3#	50.9	160.9	155.1	195.2	106.7	59.0	77.8	94.5		
CD4%	0.89	0.94	0.73	0.05	0.89	0.87	1.03	1.03		
CD4#	34.3	107.3	104.4	127.4	66.2	39.3	47.7	72.8		
CD8%	0.80	0.93	0.85	0.04	0.92	1.57	0.53	2.38		
CD8#	27.2	63.7	48.0	60.1	40.4	40.5	36.0	43.9		
16+56%	0.46	0.45	0.53	0.00	0.80	0.45	0.78	0.78		
16+56#	14.2	43.7	54.4	0.0	25.8	12.6	40.3	25.5		
CD19%	0.35	0.66	0.94	0.00	0.43	0.77	0.78	0.49		
CD19#	15.1	40.2	42.1	0.0	20.2	19.7	39.5	19.7		
LYM#	78.7	196.5	214.0	252.7	146.1	67.6	86.5	129.3		

Historical

SD 2 SD

0.92	1.85
109.8	219.6
0.86	1.73
72.6	145.2
1.20	2.41
45.6	91.2
0.62	1.24
30.9	61.8
0.62	1.25
27.5	55.1
141.9	283.8

CV

Due Date	8/15/2020		9/15/2020		10/15/2020		11/15/2020		12/15/2020	
Lot #'s	0104	0160	0160	0216	0216	0216	0272	0272	0272	0272
CD3%	1.26	1.26	0.97	0.11	1.10	1.32	1.39	1.04		
CD3#	2.6	8.5	8.6	11.3	5.7	3.2	4.5	5.6		
CD4%	1.80	1.80	1.41	0.10	1.76	1.71	2.10	2.11		
CD4#	2.7	8.5	8.6	11.3	5.4	3.2	4.3	6.7		
CD8%	3.25	3.94	3.65	0.15	3.78	6.34	2.18	9.66		
CD8#	4.3	11.3	8.8	11.3	6.9	6.8	6.5	8.0		
16+56%	4.63	4.16	4.73	0.00	8.36	4.83	7.17	6.64		
16+56#	5.6	16.7	22.2	0.0	11.1	5.6	15.6	9.7		
CD19%	2.94	6.21	8.56	0.00	3.63	6.52	6.36	3.98		
CD19#	4.9	15.7	17.8	0.0	7.0	7.0	13.6	7.2		
LYM#	3.0	8.1	9.2	11.4	6.1	2.8	3.8	5.8		

Historical

CV

1.20
5.8
1.71
5.9
4.99
7.7
5.95
12.2
5.31
9.6
5.8

CD-Chex Plus®

Instrument/Serial Number: BD FACSCanto™ II V0000000001

Lab Acct Number: 00100

SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 12/26/2020

Lot Number: 0272

Due: 12/15/2020

Submitted: 12/2/2020

From: 11/4/2020

To: 11/30/2020

Customer Data Submitted

9-00 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 02720072

	CD3%	CD3#	CD4%	CD4#	CD8%	CD8#	16+56%	16+56#	CD19%	CD19#	LYM#
11/4/2020	60.4	906	12.3	184	43.5	652	18.7	280	20.7	311	1,501
11/6/2020	58.3	813	11.9	165	42.5	592	19.0	265	21.8	304	1,394
11/9/2020	58.9	797	11.6	157	41.7	564					1,353
11/9/2020	57.9	826	11.0	157	41.8	596	20.6	293	20.2	289	1,427
11/9/2020	60.2	831	11.3	156	43.8	605	19.6	270	19.7	272	1,382
11/13/2020	60.0	906	12.1	182	42.8	646	19.1	288	20.5	309	1,510
11/16/2020	60.9	844	13.1	182	42.4	588	19.1	265	19.2	266	1,385
11/17/2020	58.5	850	11.3	164	43.0	624					1,452
11/20/2020	57.4	879	11.4	175	41.8	640	21.9	335	19.9	304	1,531
11/23/2020	59.5	767	11.8	153	40.5	523	19.1	246	20.9	269	1,290
11/25/2020	59.2	814	12.3	169	43.9	603	20.1	276	19.5	268	1,374
11/27/2020	57.1	797	12.0	168	39.6	553	20.6	287	21.8	304	1,395
11/30/2020	59.8	799	12.1	161	42.8	572	19.5	260	19.8	265	1,336

CD-Chex Plus®

Instrument/Serial Number: BD FACSCanto™ II V0000000001

Lab Acct Number: 00100

SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 12/26/2020

Lot Number: 0272

Due: 12/15/2020

Submitted: 12/2/2020

From: 11/4/2020

To: 11/30/2020

Normal 02720071

	CD3%	CD3#	CD4%	CD4#	CD8%	CD8#	16+56%	16+56#	CD19%	CD19#	LYM#
11/4/2020	75.9	1,769	50.1	1,167	23.4	545	11.4	266	12.3	286	
11/6/2020	75.4	1,772	48.3	1,136	24.8	582	11.4	268	12.5	294	2,350
11/9/2020	74.6	1,685	48.4	1,093	23.6	533					2,258
11/9/2020	74.8	1,763	49.3	1,162	22.7	534	12.6	297	12.0	283	2,357
11/13/2020	73.8	1,629	48.5	1,070	22.8	504	13.2	291	12.4	274	2,209
11/16/2020	76.1	1,655	50.8	1,105	21.8	473	10.8	234	12.8	279	2,175
11/18/2020	75.3	1,640	48.1	1,048	24.4	532					2,179
11/20/2020	76.5	1,675	49.3	1,079	25.1	550		258	11.1	244	2,191
11/23/2020	76.5	1,580	47.7	986	26.7	551	10.9	225	12.3	255	2,067
11/25/2020	75.0	1,586	48.0	1,015	30.7	649	11.5	244	12.6	267	2,115
11/27/2020	75.2	1,603	47.1	1,005	25.7	548	12.0	257	11.8	250	2,132
11/30/2020	75.5	1,895	48.9	1,227	23.4	588	11.8	297	12.2	305	2,511