

A1c-Cellular®

Instrument/Serial Number: Tosoh G8 000001

Lab Acct Number: 00100

SAMPLE LAB REPORT

1234 MAIN STREET

ANYTOWN, NE 12345 US

Shift: 1

Lot Exp: 1/4/2021

Lot Number: 0181

Due: 12/1/2020

Submitted: 12/1/2020

From: 11/1/2020

To: 12/1/2020

INTERPRETIVE COMMENTS

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

REVIEWED BY: _____

DATE: _____

DUE DATE FOR NEXT SUBMISSION: 01/01/2021

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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1234 MAIN STREET	Lot Number: 0181	From: 11/1/2020
ANYTOWN, NE 12345 US		To: 12/1/2020

Level 1 01810416

Current Submission - Number of Instruments: 16

**Cumulative Submissions
Total Number of Instruments: 19**

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.
HbA1c	5.1	5.1	20	0.07	1.47	5.1	390	0.11	2.12	0.29	5.0	111	0.07	1.30	5.1	1191	0.09	1.85	-0.25

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Level 2 01810417

Current Submission - Number of Instruments: 16

Cumulative Submissions

Total Number of Instruments: 19

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.
HbA1c	9.6	9.8	20	0.08	0.77	9.8	392	0.20	2.06	0.10	9.9	109	0.19	1.93	9.9	1190	0.21	2.14	0.01

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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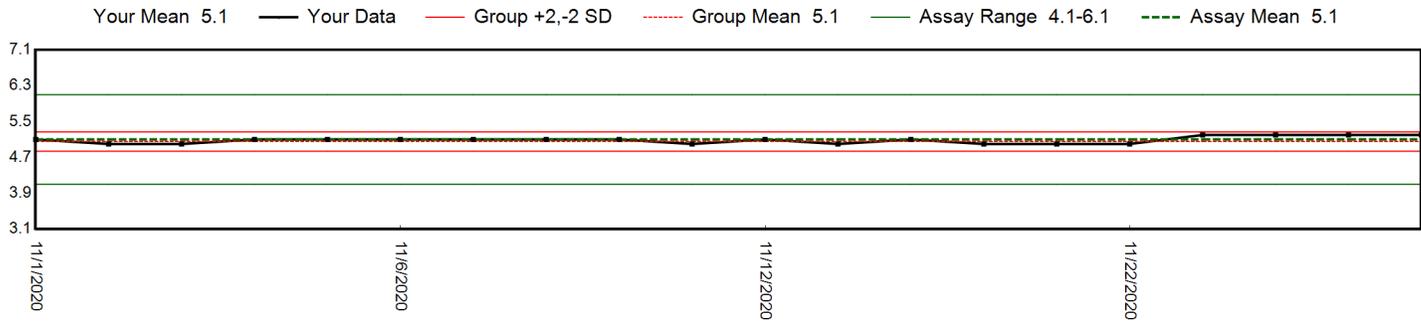
Submitted: 12/1/2020

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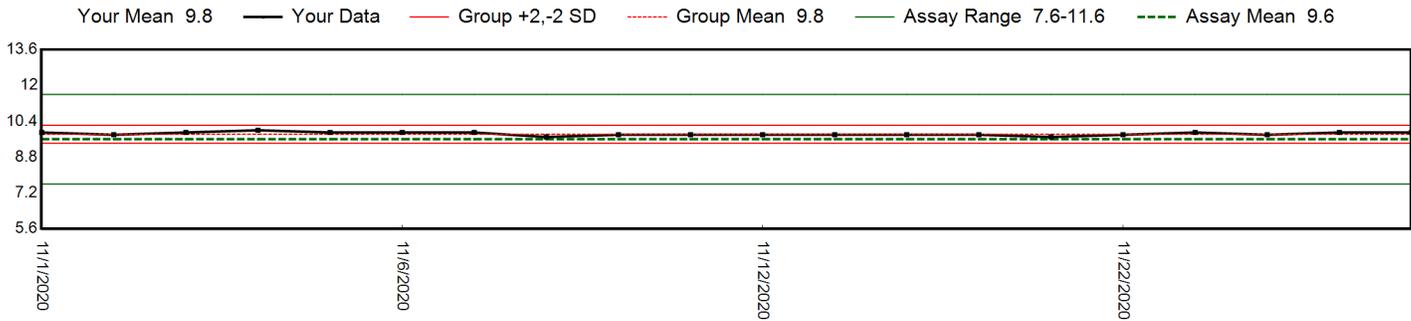
Levey-Jennings Graphs Level 1 HbA1c

Only values with RunDates are displayed.



Level 2 HbA1c

Only values with RunDates are displayed.



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Instrument/Serial Number: Tosoh G8 0000001

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Lot Exp: 1/4/2021

Lot Number: 0181

Due: 12/1/2020

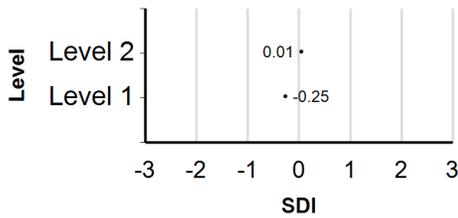
Submitted: 12/1/2020

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S.D.I. Reports

HbA1c



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Historical Data Comparison Report - Last Six Months

Level 1

SD

Due Date	7/1/2020	8/1/2020	9/1/2020	10/1/2020	11/1/2020	12/1/2020
Lot #'s	0013	0013	0181	0181	0181	0181
HbA1c	0.06	0.05	0.08	0.06	0.05	0.05

Historical

SD 2 SD

0.06	0.12
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CV

Due Date	7/1/2020	8/1/2020	9/1/2020	10/1/2020	11/1/2020	12/1/2020
Lot #'s	0013	0013	0181	0181	0181	0181
HbA1c	1.17	0.96	1.67	1.15	1.04	1.09

Historical

CV

1.19

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Level 2

SD

Due Date	7/1/2020	8/1/2020	9/1/2020	10/1/2020	11/1/2020	12/1/2020
Lot #'s	0013	0013	0181	0181	0181	0181
HbA1c	0.09	0.08	0.09	0.23	0.08	0.09

Historical

SD 2 SD

0.12	0.24
------	------

CV

Due Date	7/1/2020	8/1/2020	9/1/2020	10/1/2020	11/1/2020	12/1/2020
Lot #'s	0013	0013	0181	0181	0181	0181
HbA1c	0.82	0.74	0.87	2.27	0.85	0.95

Historical

CV

1.21

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Customer Data Submitted

~~9.00~~ Values with a horizontal strike-through are determined to be outliers and were excluded.

~~6.00~~ Values with a diagonal strike-through are duplicate data that were excluded.

Level 1 01810416

	HbA1c
11/1/2020	5.1
11/2/2020	5.0
11/3/2020	5.0
11/4/2020	5.1
11/5/2020	5.1
11/6/2020	5.1
11/7/2020	5.1
11/9/2020	5.1
11/10/2020	5.1
11/11/2020	5.0
11/12/2020	5.1
11/13/2020	5.0
11/16/2020	5.1
11/19/2020	5.0
11/20/2020	5.0
11/22/2020	5.0
11/25/2020	5.2
11/27/2020	5.2
11/29/2020	5.2
12/1/2020	5.2

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Level 2 01810417

	HbA1c
11/1/2020	9.9
11/2/2020	9.8
11/3/2020	9.9
11/4/2020	10.0
11/5/2020	9.9
11/6/2020	9.9
11/7/2020	9.9
11/9/2020	9.7
11/10/2020	9.8
11/11/2020	9.8
11/12/2020	9.8
11/13/2020	9.8
11/16/2020	9.8
11/19/2020	9.8
11/20/2020	9.7
11/22/2020	9.8
11/25/2020	9.9
11/27/2020	9.8
11/29/2020	9.9
12/1/2020	9.9