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From: Adam Rosendorff
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[CL QIO-00020 Quality Control Guidelines.docx](#)

Dear CLIA

Please refer to the following QC policies.

Thanks,

Adam

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|  | SOP | Document Number: CL-QOP-00020 Revision: A |
| | Quality Control Rules | Effective Date: 1/15/2014 |
| Quality Control Policies | | |

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1. DAILY QC

- 1.1 Run at least two and preferably 3 controls**
- 1.2 If any of the controls are out of the range stated in the manufacturer's package insert (usually the mean of the manufacturer's runs $\pm 2SD$), repeat the QC for the controls.**
- 1.3 Ensure the QC material is not beyond the manufacturer's expiration date.**
- 1.4 If any of the 3 controls are still out of the range stated in the manufacturer's package insert, redo calibration for the analyte.**
- 1.5 Repeat QC**
- 1.6 If QC passes, proceed with patient testing**
- 1.7 If QC fails again, consult technical support for the analyzer in question**

2. CONTINUOUS QC

- 2.1 Ongoing QC should be monitored for any of the following failures:**
- 2.2 1_{2S} : If one control is greater than $\pm 2SD$ s is used as a warning rule that initiates testing of control data by the other control rules**
- 2.3 1_{3S} : QC "Flyers": One control exceeding $\pm 3SD$ results in QC failure for that control: such failures are usually the result of random error**
- 2.4 2_{2S} : Two (2) consecutive control observations exceeding $\pm 2SD$ results in QC failure for that control observation: such failures may indicate systematic error**
- 2.5 R_{4S} : One observation exceeding the mean $+2SD$ and another exceeding the mean $-2SD$ is a rejection rule. Observations can come from the same QC run with different control levels. S_U failure usually indicates random error.**
- 2.6 4_{1S} : Four Consecutive observations on the same side of the 1SD line**
- 2.7 10_x : Ten consecutive observations on the same side of the mean line.**
- 2.8 For a detailed description of the application of Westgard rules, refer to Tietz. Et. al. (4th Edition), pgs 504-506**

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3. EDISON QC

3.1 ESTABLISHING QC RANGES

- 3.1.1 Assay all control levels as you would patient samples (3 EDISONS per RUN) over 10 days
- 3.1.2 Calculate the mean for each level
- 3.1.3 Calculate the SD for each level
- 3.1.4 Acceptable low QC range is the mean – 2SD
- 3.1.5 Acceptable high QC range is the mean + 2SD

3.2 EDISON DAILY QC

- 3.2.1 Run at least 2 and preferably levels. Ensure QC material is not outdated/expired.
- 3.2.2 If all pass run patient samples
- 3.2.3 If QC fails (defined as a failure of one or more levels) repeat QC
- 3.2.4 If QC still fails recalibrate instruments
- 3.2.5 If QC passes run patient specimens
- 3.2.6 If QC still fails → STOP and consult with Theranos technical support.