QUALITY CONTROL

How to Evaluate QC and Troubleshoot Out of Control Results

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OBJECTIVES

1. Define Quality Control and its basic elements.
2. Define the criteria we use to evaluate Quality Control: Mean, Standard Deviation, and Coefficient of Variation.
3. Review basic calibration theory.
4. Provide a consistent method to troubleshoot out of control results.
5. Describe Lot-to-Lot evaluation.

QUALITY CONTROL

What should I do?

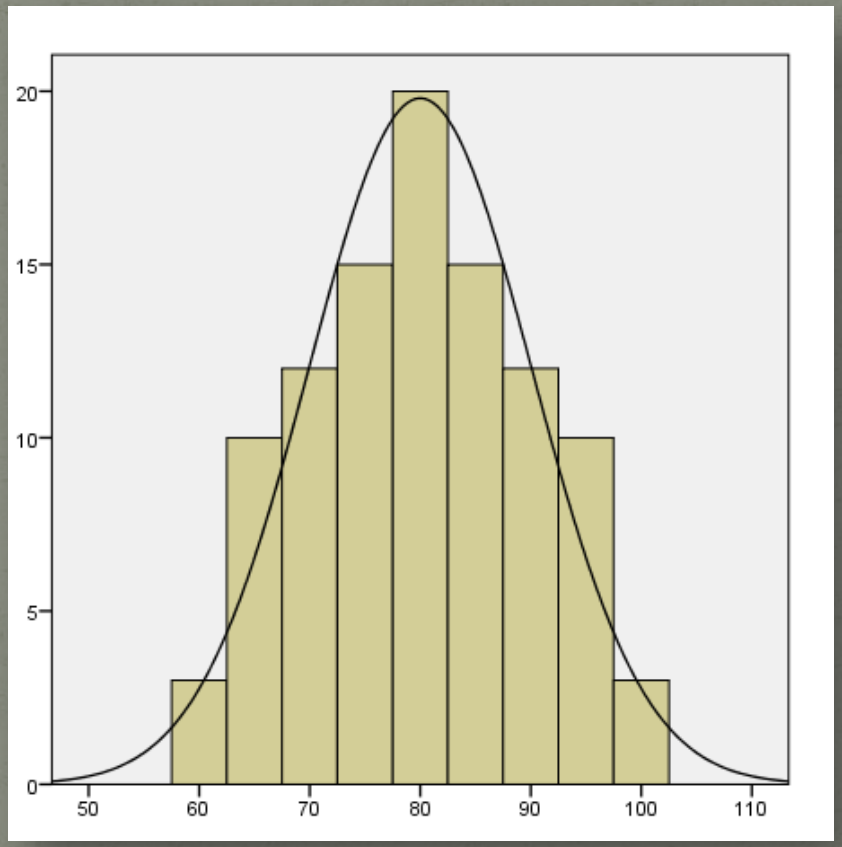
WHAT IS QUALITY CONTROL?

Statistical process that tracks the ability of reagents, instrumentation (and techs) to obtain an accurate result…

WHY DO WE RUN QC?

- Report out good results
- Detect SIGNIFICANT errors in a timely manner
- If there is an error, identify the source of the error

QC STATISTICS



QC STATISTICS

The "MEAN", or AVERAGE is a good estimate of a test's ACCURACY:

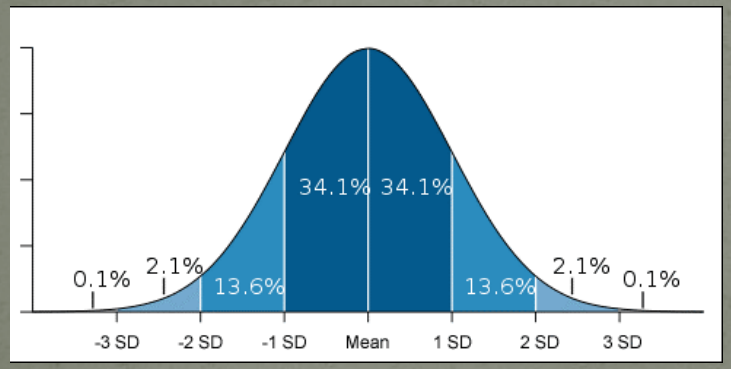
$$\overline{X} = \frac{\Sigma X}{n}$$

QC STATISTICS

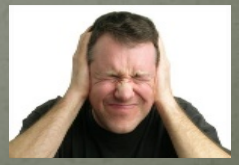
QC STATISTICS

$$SD = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

The "STANDARD DEVIATION", or SD, is a measure of PRECISION.

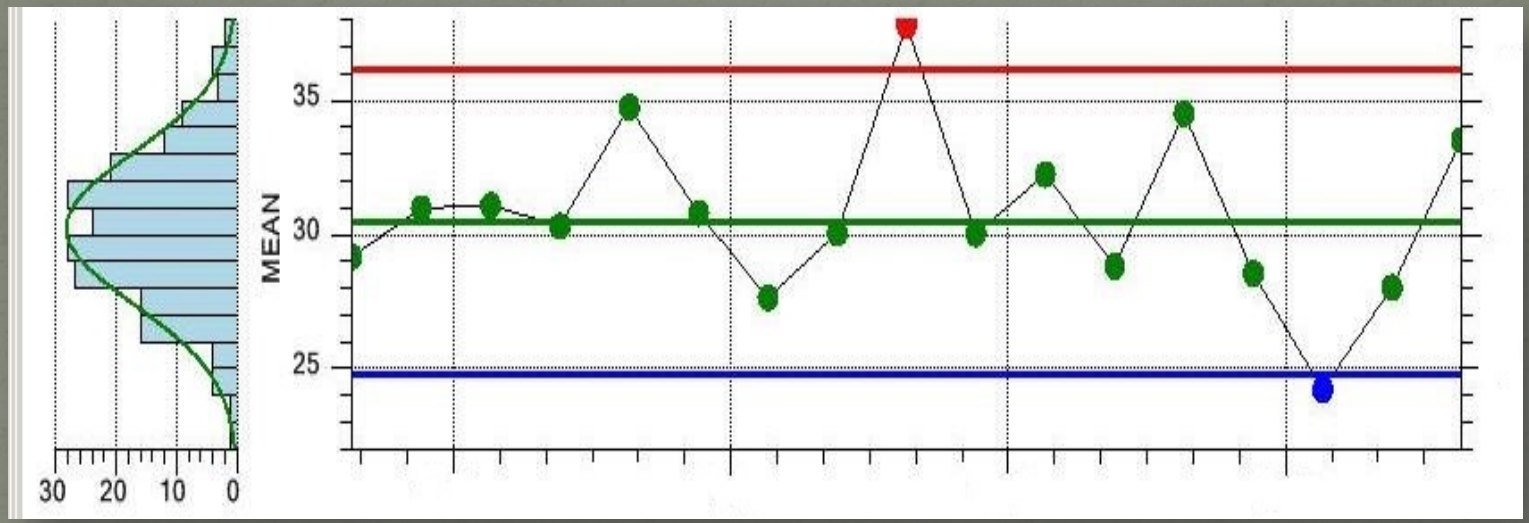


Statistically, 95% of QC points will fall within ±2SD of the mean.



QC CHARTS

QC CHARTS usually appear similar to this, with the line in the middle representing the MEAN, and lines above and below the mean representing the SDs.



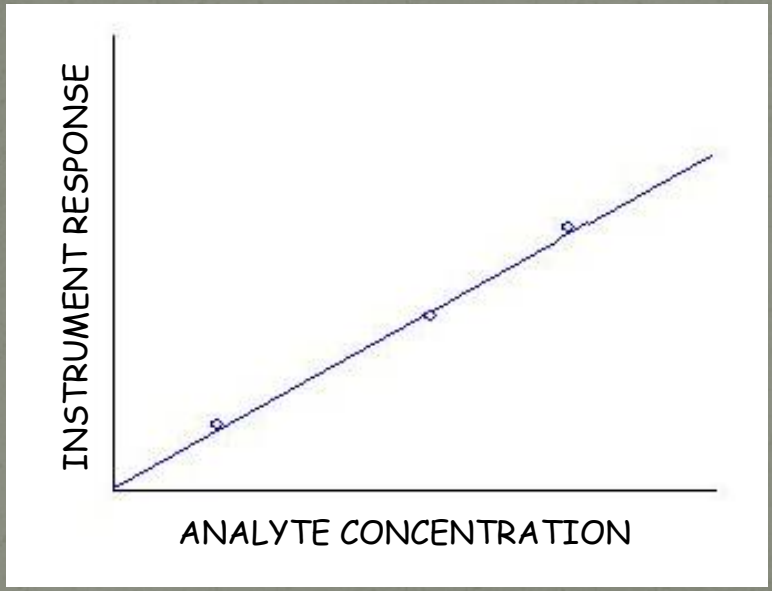
QC STATISTICS

The "COEFFICIENT OF VARIATION", or CV, is a ratio of the SD to the Mean, and is expressed as a %.

$$CV\ (\%) = \left(\frac{Standard\ deviation}{Mean}\right) \times 100$$

CALIBRATION

A calibration establishes the relationship between



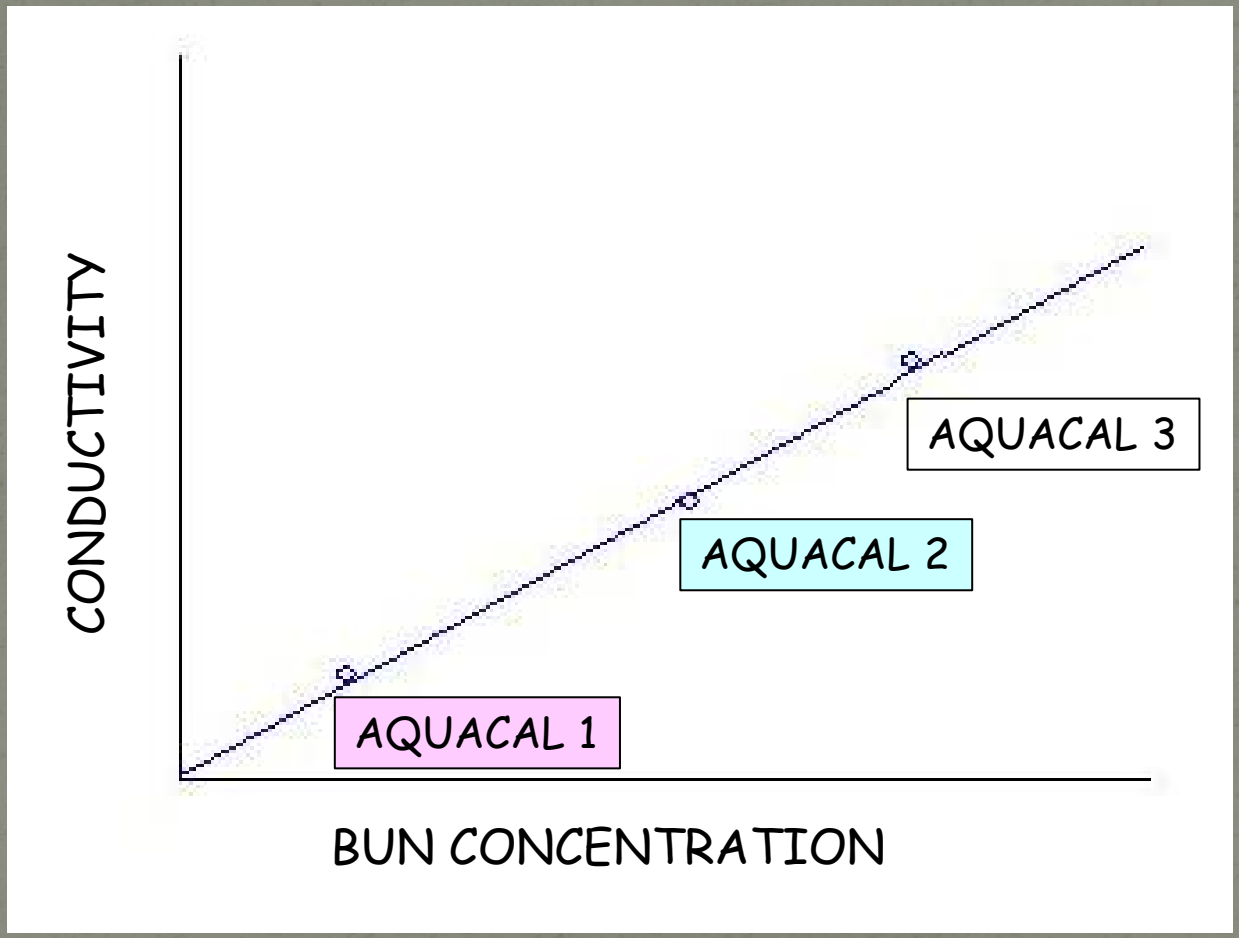
ANALYTE CONCENTRATION and INSTRUMENT RESPONSE.

CALIBRATORS

A calibrator is a sample with a **known analyte concentration**.

The "set point" on the calibration report is the calibrator value.

CALIBRATION



CALIBRATION CRITERIA

Three criteria are used to evaluate a successful calibration:

ACCURACY
PRECISION
SENSITIVITY

ACCURACY

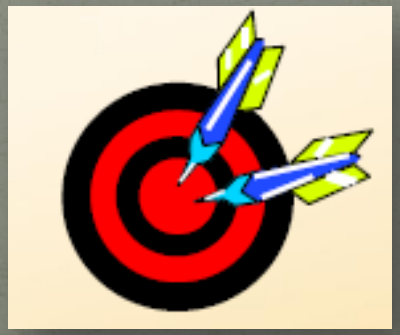
The definition of ACCURACY is recovering expected results.

The values obtained must fall between a pre-determined minimum and maximum value.

PRECISION

The definition of PRECISION is reproducibility.

The values obtained must differ by less than a predetermined amount.



SENSITIVITY

SENSITIVITY allows us to see a difference in system response with different analyte concentrations.

Without an acceptable span, the instrument may not "resolve" two close, yet different, analyte concentrations.

CALIBRATION

Successful calibration requires acceptable results for ACCURACY, PRECISION, and SPAN.

QC that's run after calibration can help you confirm that the calibration was successful.

SO, QC IS "OUT"

First, make sure your control is really "out".
Compare acceptable range in BEAKER
with the ranges in the instrument or Remisol.

CHECK THE CONTROL

- Are you using the correct control/level of control?
- Is it outdated or expired, or the end of the bottle?
- Has it been stored properly? Has it been sitting at room temperature for an extended time?
- Is it the correct lot number?
- Are there any signs of contamination or degradation?
- Is it a different shipment of control?

IF NO APPARENT ISSUES WITH THE CONTROL:

Rerun the test on a New Aliquot of Same Bottle of Control

IF THE BOTTLE OF CONTROL IS QUESTIONABLE, OR THE RERUN IS STILL OUT OF CONTROL:

Open a NEW BOTTLE of control and rerun the test.

CHECK THE REAGENT

- Was the reagent prepared properly?
- Is it close to its outdate?
- Is it due to be calibrated?
- Are there just a few tests left (say, less than 10%)?
- Is there anything going on in the instrument that could affect the reagents?

IF NO APPARENT ISSUES WITH THE REAGENT

Recalibrate the test and rerun the QC on all controls for the test.

IF THE REAGENT IS QUESTIONABLE

Prepare and/or Load new reagent before you recalibrate the test and rerun the QC on all controls for the test.

CHECK THE CALIBRATOR

Check the expiration date and open stability of the calibrator.

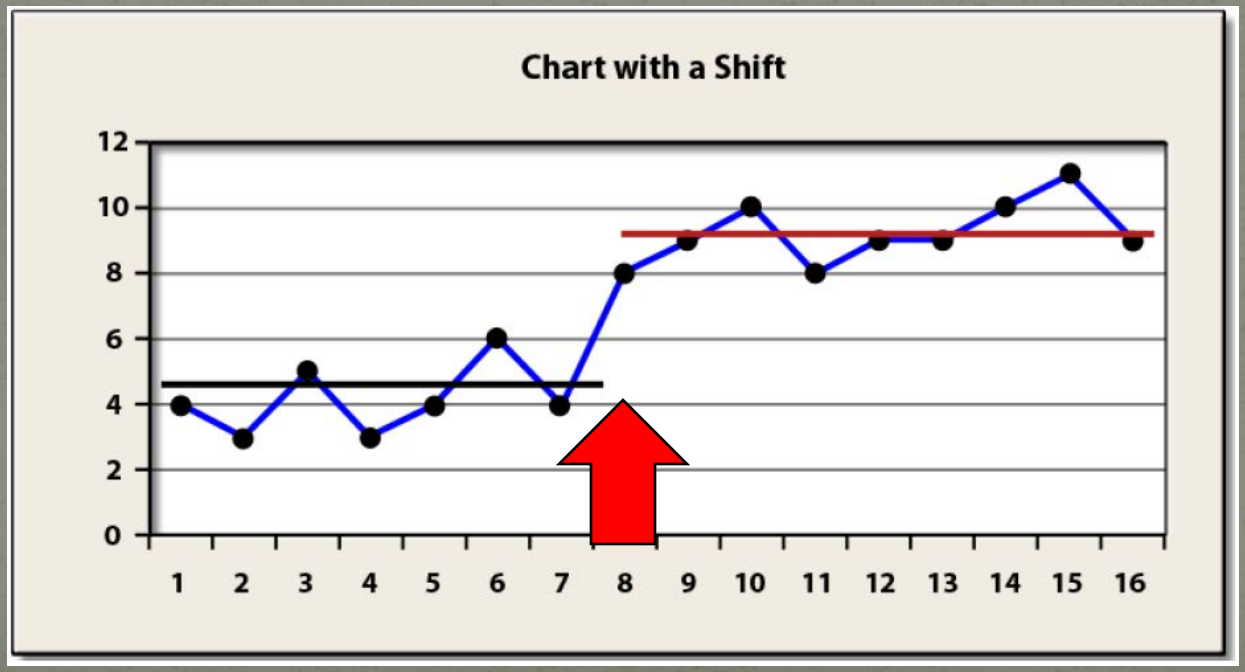
Verify correct calibrator lot number is loaded/used.

(Compare the Lot# on the calibration printout with the Lot# on the bottle of calibrator.)

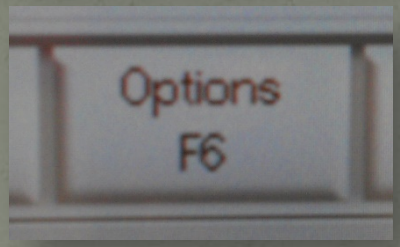
Load new calibrator data if required.

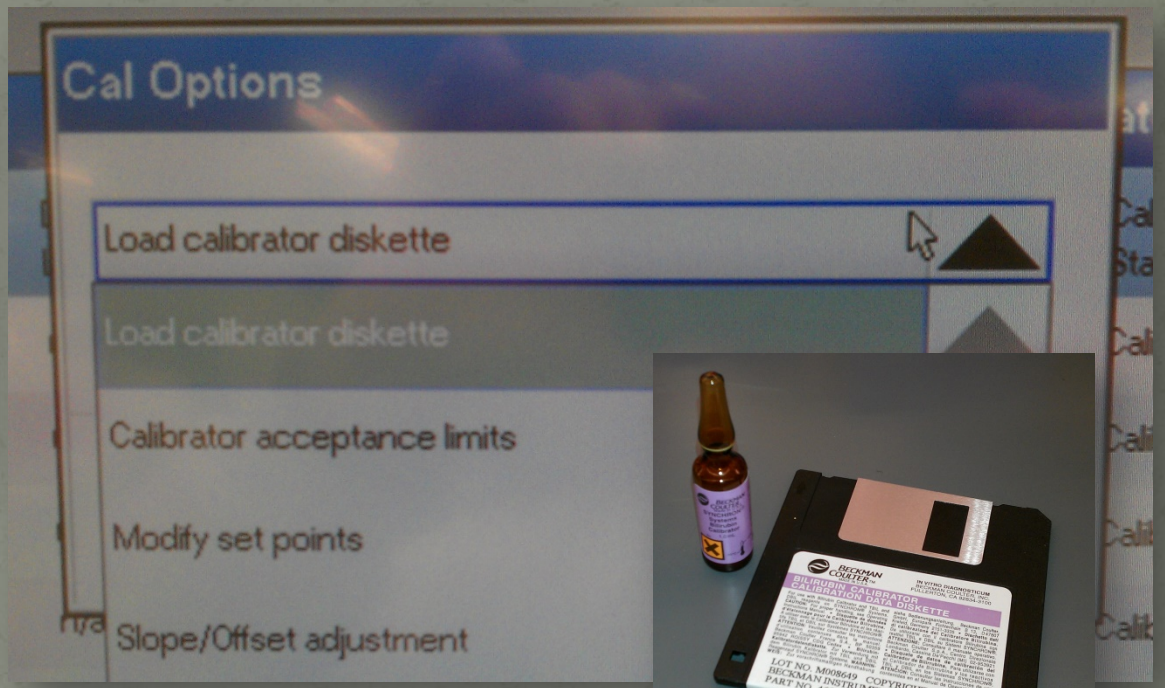
CHECK THE CALIBRATOR

Review QC charts for a "shift".



CHECK THE CALIBRATOR

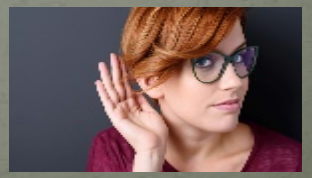




RECALIBRATE AND
RERUN CONTROLS

STILL OUT??

Now's the time to talk to a specialist or supervisor…



LOT CHANGES

Changing lots of reagent can often cause a shift in QC THAT IS NOT SEEN WITH PATIENT SAMPLES.

LOT-TO-LOT VERIFICATION

CONFIRMING THAT CHANGING LOTS OF REAGENT DOESN'T AFFECT PATIENT RESULTS IS REQUIRED BY CAP (COM.30450) AND CLIA REGULATIONS.

PATIENT SPECIMENS ARE RUN ON BOTH THE OLD AND NEW LOTS.

LOT-TO-LOT VERIFICATION

DO NOT USE THIS LOT NUMBER
NEW LOT **Record # in Log before using**
THIS LOT IS READY FOR USE

THAT MEANS WE NEED TO KEEP CLOSE TRACK OF WHICH LOTS ARE IN USE. ALWAYS.

LOT-TO-LOT VERIFICATION

WHEN A NEW LOT IS RECEIVED, ORANGE STICKERS WILL BE PLACED ON EACH BOX.

WHEN THE NEW LOT HAS BEEN VERIFIED, YELLOW STICKERS WILL BE PLACED OVER THE ORANGE STICKERS.

WHEN THE NEW LOT IS PUT IN USE, GREEN STICKERS WILL BE PLACED OVER THE YELLOW STICKERS.

NEW SHIPMENTS OF THE SAME LOT WILL GET THE SAME COLOR STICKERS.

LOT-TO-LOT VERIFICATION

TO VERIFY A NEW LOT, SELECT A NORMAL AND ABNORMAL PATIENT THAT WAS RUN ON THE OLD LOT, KEEPING SPECIMEN STABILITY IN MIND.

- TROPONIN LOT CHANGES REQUIRE AT LEAST THREE PATIENT SAMPLES: A NORMAL, AN ALERT VALUE, AND A CRITICAL VALUE.

RUN APPROPRIATE QC ON THE NEW LOT.

- EACH REAGENT WILL HAVE ACCEPTABILITY CRITERIA FOR THE PATIENT COMPARISONS.

IF THE QC IS ABOUT THE SAME AS THE PREVIOUS LOT'S QC, AND THE PATIENT RESULTS AGREE WITHIN ACCEPTABLE LIMITS, PLACE A YELLOW STICKER OVER THE ORANGE STICKER.

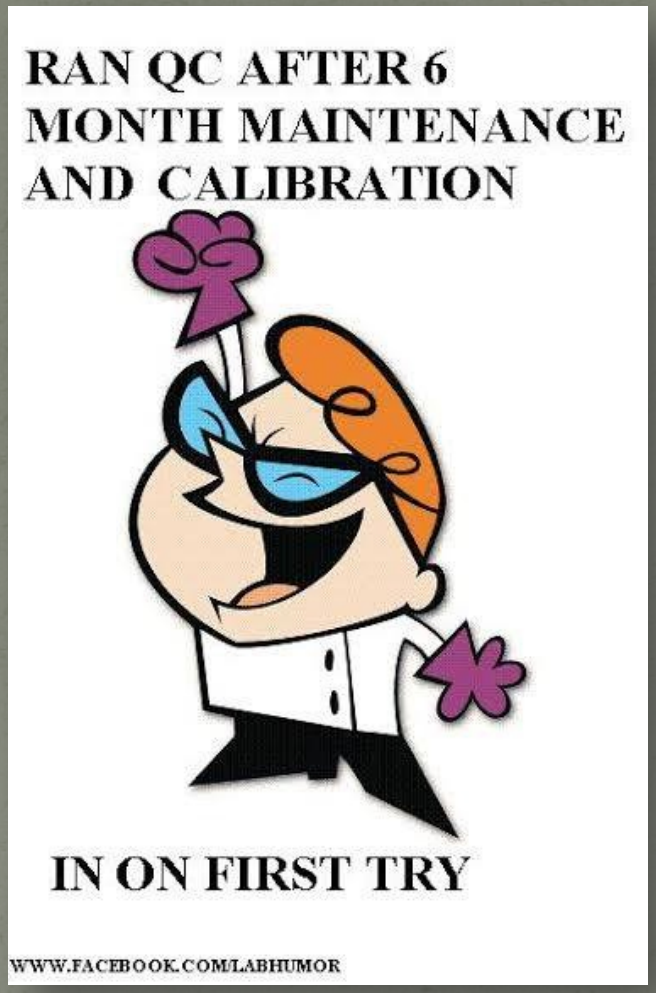
LOT-TO-LOT VERIFICATION

IF THE QC IS OUT, OR IS SIGNIFICANTLY DIFFERENT (>1 SD), BUT THE PATIENT RESULTS ARE ACCEPTABLE, NOTIFY A SPECIALIST OR SUPERVISOR. PLACE YELLOW STICKERS OVER THE ORANGE STICKERS ON THAT LOT.

IF THE PATIENT RESULTS EXCEED THE ALLOWABLE DIFFERENCE, NOTIFY A SPECIALIST OR SUPERVISOR!

HELPFUL HINTS

- DON'T RUN CONTROLS OVER AND OVER HOPING IT WILL COME IN, especially if you're getting the same result.
- Limit the time controls and calibrators are kept at room temperature to a minimum. Always.
- Check expiration dates. Always.
- Be aware of LOT#s of controls and calibrators. Always.
- Review the QC chart at the right of the Beaker results. Look for results close to the mean, and scattered fairly evenly on both sides. *Just because your control is "in", doesn't mean that you're "in control".*
- Ask for help if you need it.



It can't always be like this, but with good lab practices and everyone's help monitoring QC, running QC won't be torture…

#QC123
#DONTPANIC
#YOUCANDOIT

REFERENCES

3000 Quality Control Procedure

3001 Lot to Lot Change Procedure

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Basic QC Practices, 3rd Edition, James Westgard, Ph.D., 2010

Tietz Testbook of Clinical Chemistry, 2nd ed., Burtis, Ashwood, editors, 1998