
pSMILE
SAFETY·QUALITY·RESULTS
Internal Quality Control (IQC)
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Overview

- How to establish laboratory means, QC ranges, and Historical CV
- Levey-Jennings Charts
- Review Westgard Rules
- Troubleshooting QC failures
- Retaining Patient Controls
- XB Moving Averages
- Systematic Error vs Random Error

Internal Quality Control Includes

- Daily control specimen
  - Commercial Control- lasts 1-3 months
  - Patient Control - daily
- XB Analysis – Moving Average
- Correlation/Comparison System- Back-up instruments
- Policy- QC and Troubleshooting

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With hematology you have several choices to use for internal quality control. They can be used alone or in combinations.

- Daily control specimen can have Commercial
- Another type of daily control you can have with hematology are patient control.
- XB analysis or moving average – for hematology only -If you are able to use this you can see within 100 samples that you may have an instrument problem.
- Along with these other controls you should have some type of Correlation/comparison system- back-up instruments
- And of course with all of these you will need policy for both acceptability of controls and if they are out troubleshooting for problems.

Factors to Consider with IQC

- Type of instrument – if fully automated.
- The size of the lab.
- The level of training of your staff.
- The number of specimens handled each day.
- Dayshift vs 24 hour laboratory.
- Country's own regulations.
- Accreditation requirements.

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Of course the amount of internal quality control depends on several factors.
It will depend the,

- type of instrument,
- the size of the lab,
- the level of training of your staff,
- the number of specimens handled each day
- your country's own regulations
- Any accreditation requirements

Commercial Controls

- Assayed vs Non-assayed
- Introducing New QC Lot
- Establishing QC Ranges

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- Most regulatory agencies have standards for how many and how often controls should be run. Usually it is at least two levels run in a 24 hour period or on days instrument is used. Typically for hematology there are three levels of controls. Again the number of time they are run will depend on a number of factors -one being the number of specimens processed and the time frame over when they are run. If you only run around 50 per day then once a day may be enough, but if you run 1000 samples then multiple times would be better. You don't want to find out after running 500 samples that a problem has occurred. That would be a lot of patients results you would have to re-confirm.
- For commercial controls there are two types you can get the assayed – with already established means and ranges and the Non-assayed where you will establish you own. I strongly suggest to go with the assayed.
- Ideally when you get a new lot you will still have your old lot to run in parallel.
- After the initial parallel running and the controls are now in use, each laboratory should establish their own means and ranges. The values stated on the assay sheet provided by the manufacturer should be used only as guides in setting the initial

control limits for testing the new lot. The observed mean should fall within the range published but does not have to match it perfectly. I will also go over a simplified version on how to establish your own ranges.

Establishing New QC Ranges (Parallel QC Testing)

1. Set up new QC files for each control level of the new lot.
2. Verify the new lot by running each level of control three times in its respective file.
3. Ensure that the mean values of the control runs fall within the ranges published on the manufacturer assay.
4. Run each level at least twice a day for 3-5 days (minimum 20x) to provide enough data to calculate new mean values for each analyte.
5. Compare the calculated mean values for each level to the range specified on the manufacturer assay sheet.
6. Calculate new means and experimental SDs for each analyte
7. The mean should be within range of the manufacturer assay sheet.

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Here are the steps:
#1 This is where you can use the mean and range that came in the package insert of controls- either in your instrument or in your LIS or both.
#3 They don't have to match exactly just be in the range. So why do we do this first? You want to ensure that the new lot is good. If they fall outside the range first you would try a different vial but if that one is out too you will need to figure out if there is an instrument problem or a sample problem. If it is a sample you will need to contact your supplier and get a new set sent to you.
#4 once you have seen that the controls are usable you will. Should get a minimum of 20 data points. Should be looking at the data as you get it to ensure there are no trends which is six data points in one direction either increase or decrease
#5 compare CV to manufacturer's recommendation. The CV should be within the acceptable manufacturer's recommendation. The CV should be found in the instrument or method documentation.
#6 Calculate new means and experimental SDs. Use a software or Excel to perform the calculations.
#7 Compare the mean to the assay mean and SD should be within the assay range. You can use this calculated mean and SD to create your QC range but I suggest using the SD calculated with your instrument historical CV. I will go over this in the next

slides.

Establishing Means and Standard Deviations

1. Analyze the control(s) a minimum of 20 times across several days.
2. Take the average of these runs.
3. The average should be within the range stated on the assay sheet.
4. Calculate a two Standard Deviation range from your results.
5. Incorporate this SD range around your new mean and monitor.
6. The mean and SD values should be periodically recalculated during the life of the new lot- especially for Hematology.

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So once your are ready to switch from the old QC to the new lot you will first use the mean established in your lot-to-lot.
This will be your starting point to establish your own mean and standard deviation
Here are the steps.

This mean will be considered as the “new Mean”

Most hematology instruments have quality control files that will calculate these means and ranges automatically.

Historical CV (CV_h)

- CV = Coefficient of Variation- a statistical measure of the relative dispersion of data points in a data series around the mean - monitors precision.
- %CV is the ratio of the standard deviation to the mean.
- SD/Mean X 100 = %CV
- Historical CV (CV_h) is derived from CV values from previous lot number.
- If don't have previous CV can use current CV as the CV_h.
- Need to increase this value by 1-2%

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- CV monitors you instrument precision.
- Best established over several lots- 3 or more is best.
- Can either be the average CV or more preferable the highest acceptable CV over that period. The number of previous CVs used will need to be put into a policy such as "The last 5 lot number CVs are used to create the Historical CV%. The policy will also state whether it is an average of them or the highest acceptable. Also should state needs to be within the manufacturer's state CV for that analyte.
- CVs obtained during times of instrument malfunctions or significantly higher than the average CV should not be used in the calculation. Again that should be stated in your policy. Any CV higher than normal should be investigated
- If you don't have previous CV values- you can use the new one until get more new lots
- To make sure QC range not too narrow need to add 1-2 % to the CV- so it 3.5- make it 5% to start with.

Manufacturer's CVs and Peer CVs

- Compare to instrument manufacturer CVs.
- Compare to Peer CVs

Calcium - mg/dL	CHM-01				CHM-02				CHM-03				CHM-04				CHM-	
METHOD/INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN
ALL METHOD PRINCIPLES ALL INSTRUMENTS**	5736	9.339	0.257	2.7	5742	6.161	0.250	4.1	5740	12.844	0.338	2.6	5748	10.302	0.254	2.5	5751	10.315

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- Important to compare your CVh and parallel testing to both the manufacture's and peer CVs. If the CV is too large the QC range will be too wide and won't warn you of problems. Too small and the range will be too narrow and will cause more QC errors wasting material and time unnecessarily.
- The first CV to compare is of course your manufacturer's claims. Usually can find the instrument CV claims in the instrument manual or method documentation. If yours is higher then service needs to be called.
- Another CV you can compare yours to is to your peer group. You can use your latest EQA evaluation to do this. Find In the PSR each sample has a CV. You can either average the samples CV or use the highest CV - again this needs to be stated in a policy. Ideally lab should be less than the EQA CV. If not then should investigate why your system is unable to recover the precision of yours peers.
- Another source to compare your CV is a QC companies peer group program. In these programs you submit your mean, SD and CV to the company and then the company compiles the data with other labs using the same QC material, instrument and method and publishes the data. Allows you to judge your instrument's performance on a monthly basis. You want your CV to be less than the peer's CV.

Establishing QC Range with CV_h

- Calculate the CV and SD from the new control parallel testing
- SD Formula $s = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N}(x_i - \bar{x})^2}$
- New CV must be comparable to manufacturer's instrument-method CV and approximate the CV_h
- Calculate new range using new mean and CV_h in the following formula:
  - $SD=CV_h/100$ X mean

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- So now we are ready to use our CVh to calculate a new QC range.
- From the data created by the parallel testing with your new control you have calculated the CV and SD. Just to review here is he formula for Standard Deviation. You can use a program such as Excel to calculate this and most instruments QC files calculate it.
- Your new CV for this lot should compare within the manufacturer's and previous CVs. If not then there is an instrument precision problem.
- If you use the SD calculated from new lot to establish QC ranges may be too narrow since limited number of data points. Not enough variation in the points.
- The CVh will help to accommodate lot-to-lot variation.
- To calculate the new SD using the CVh we will use this formula.
- QC ranges calculated using this method will be more sensitive to changes and will alert lab personnel when there are changes in a testing system. Goal is to detect changes before becomes clinically significant and affect patient results.
- By tracking the CV from lot-to-lot and month-to-month alert you to instrument problems. Precision is a very good indicator of the overall function of the instrument. Increase CV should be corrected through maintenance and service. Service might ask what your CV is and if not over manufacture's claim might not come but lab maybe able to correct problems.

Chemistry Example

- Package insert normal control mean range Glucose = 80-92 mg/dL
- Lab's new mean = 85
- Manufacturer's Glucose CV = 4.0%
- Labs last three CVs were 2.2, 1.8 and 2.5
- CV from parallel testing = 2.4
- EQA peer group CV = 3.1
- Vendor peer group CV = 2.7
- Historic average CV is 2.2 and the highest historic is 2.5
- So this is a successful CV history and Glucose is falling within Manufacturer, EQA peer group and Vendor peer group ranges.

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- Here is an example for establishing a glucose QC range on new lot.
- So first you want to run at least 20 points for several days by different techs. The package range is and you new mean is
- Your mean is within the manufacturer's so that is good.
- The manufacturer's CV for glucose is
- This lab's policy is to use the last three lot numbers CV for the CVh which are –
- These compare well with manufacturer's CV. All of these are under their claim.
- In addition this lab monitors their EQA peer group CV. The last survey CV result was-
- They also participate in a vendor peer group program. This result was -
- So once again depending on the policy can either average the last three or use the highest as long as below the highest CV in the comparison
- The policy is to use the highest CV as long as below the highest comparison which in this example would be 2.5

SD Calculation

SD = $\underline{CV_h}$ X mean/100

SD = 2.5 X 85 /100 = 2.1

Range = Mean +/- 2(SD)

Internal Established QC Range = 85.0 +/- 4.2 = 80.8 - 89.2 mg/dL

Package insert normal control mean range Glucose = 80-92

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- So using this formula can figure out our range
- Use 2sd for our range. This is close to the assay range of 80-92. Just a little narrower.
- As you run more QC you can monitor and adjust as needed.
- Must record all changes to the settings

Hematology Factors

- Some hematology parameters, such as MCV, Platelets and RBC will start to change over time.
- MCV will increase.
- RBC values can decrease.
- Platelets values will increase.
- Mean, SD, and CV should be evaluated monthly.
- XB is helpful here as cellular debris breaks down –used only for RBC and RBC indices.

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- Due to the make up of hematology controls over time there will be normal breakdown of cells that will show up particularly in the MCV, RBC and Platelets.

- The RBC will start to take on fluid so you will see the MCV increasing over time by as much as 2 units.
- Another things that can occur is the actual rupture of the RBC due to the swelling. In this case you will see a decrease in your RBC.
- Because you now will have RBC fragments they can be counted as Platelets so the values will increase.
- Your QC should be evaluated monthly to ensure continued acceptable performance. When adjusting QC it is important to include all valid data collected since the material was put into use. Only omit data points caused by know operator or instrument error. Don't delete points if just outside your range (2SD). If you eliminate them you are excluding true variability of controls. If the mean changes significantly, such as more than 1 SD than you should check the calibration and adjust as needed.

MCV Range

- Initial MCV mean – 84 fl
- SD= 2.0 fl
- 2 SD = +/- 4 fl
- Know variation of mean 2 fl
- Use half known variation accommodate change
  - 1 fl
- What should the mean be?
  - 85
- Established range – 81-89 fl
- Cumulative mean at end of product life should be 85.

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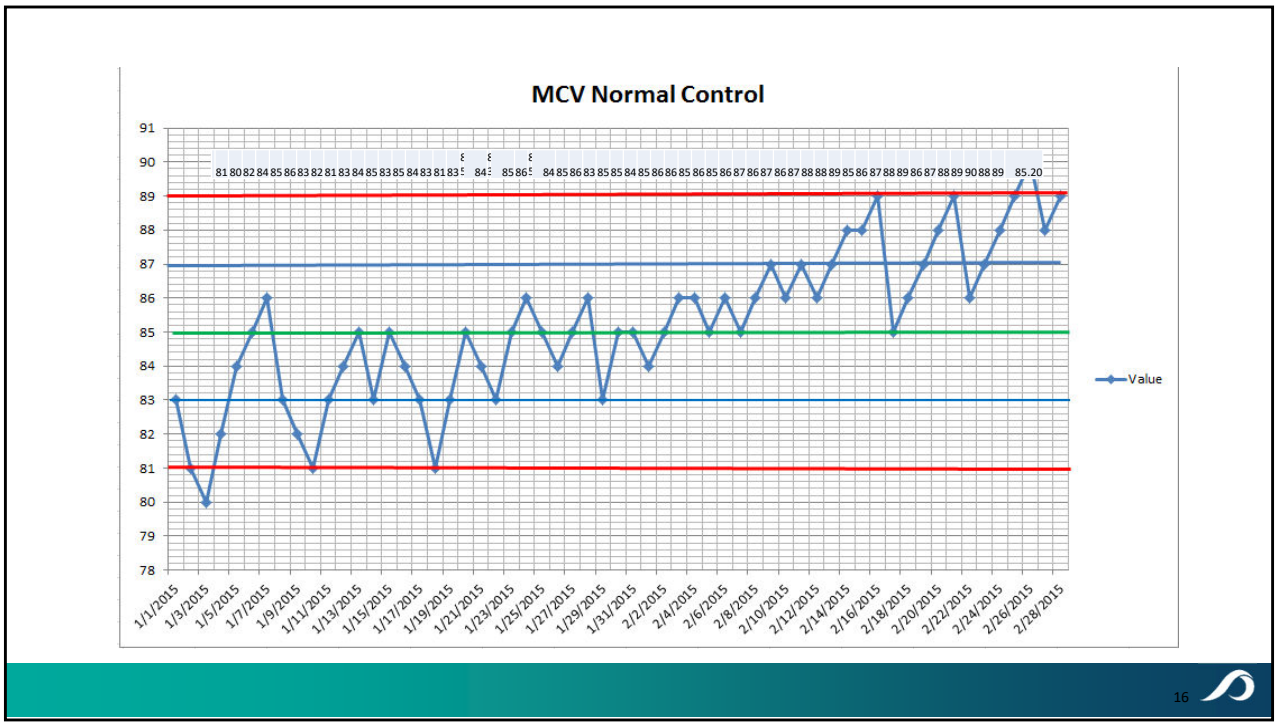
- So you can use the same process as I did with the glucose to create your lab QC ranges with hematology using a your CVh.
- For these three analytes, MCV, RBC, and Platelets you can take their variation into consideration to accommodate them into your mean and range.
- So after doing our parallel testing our initial mean is 84.
- So using the same steps as we did with the glucose can calculate the new SD using the CVh.
- The SD calculated using the CVh is 2.0 fl
- 2 SD range of +/- 4 fl.
- Through using historical data on previous controls you can established how much the normal swelling of the RBC can increase the MCV. Look at beginning runs and end runs and substract change. Can average it over several lot numbers
- In my example it is established that the MCV increases 2 fl through the running period of our control. So to compensate for this increase it is acceptable to raise the mean by half this change to accommodate this known rise. So if your initial mean was 84 what can we set our compensated mean to 85
- Using our 2 SD what would our range come out to be: 81-89.
- With this range our values will start below the mean then rise through it and finishing above the mean.

- At the end of the product life the cumulative mean (mean calculated with all the data points run) should be around 85. If start seeing this average above then could indicate instrument problem such as calibration needed.
- Again by using historical data for RBC and Platelets changes you can establish the means using their variation over time. For RBCs their numbers can show a gradual decrease due to rupture. Onto the calculated mean you would want to start the mean half of the variation below the mean. For platelets due to RBC fragments they will increase so add half variation above the initial mean. As the cells fragment the RBC will start to fall while the Platelets value rises. Again by the end of the product life your cumulative mean should be close to the original calculated mean.



Here we have an example of what the LJ chart might look like with our previous exercise. The cumulative mean will be 85
So now I will show you parallel testing results for RBC

RBC Range

- Manufacturer RBC mean – 2.29 x 10^6
- Manufacturer RBC Range – 2.18-2.40 x 10^6
- Calculated RBC mean – 2.35 x 10^6
- Is this mean valid?
- Yes because within the manufacturer's range.
- Our 2SD = +/- 0.15 x 10^6
- Calculated RBC range – 2.20-2.50 x 10^6

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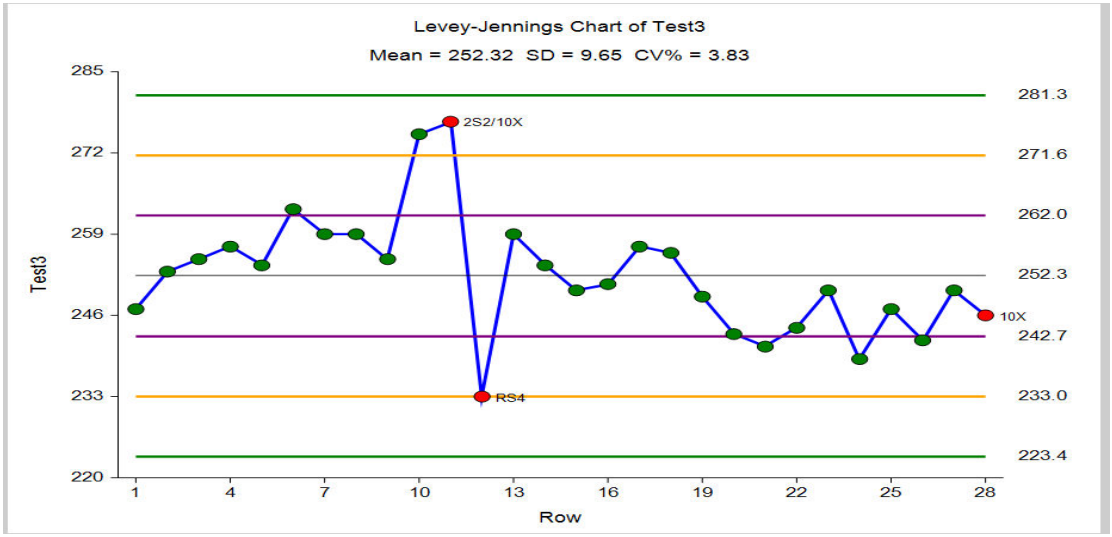
So here is the manufacturer's RBC mean and the range from the package insert.
We perform out testing to establish our own mean.
Is it a valid mean? Yes within the range.
After using the historical CV we calculated our 2 SD and it is 0.15
So what is the range?
So can we use this range? Yes as long as our mean is within manufacturer's range does not matter if our range is exact.
This analyte will decrease over time so if you have figured out this change can subtract it from your mean.

So we have done the calculations to create our means and ranges how will we monitor them?

Levey-Jennings QC Charts



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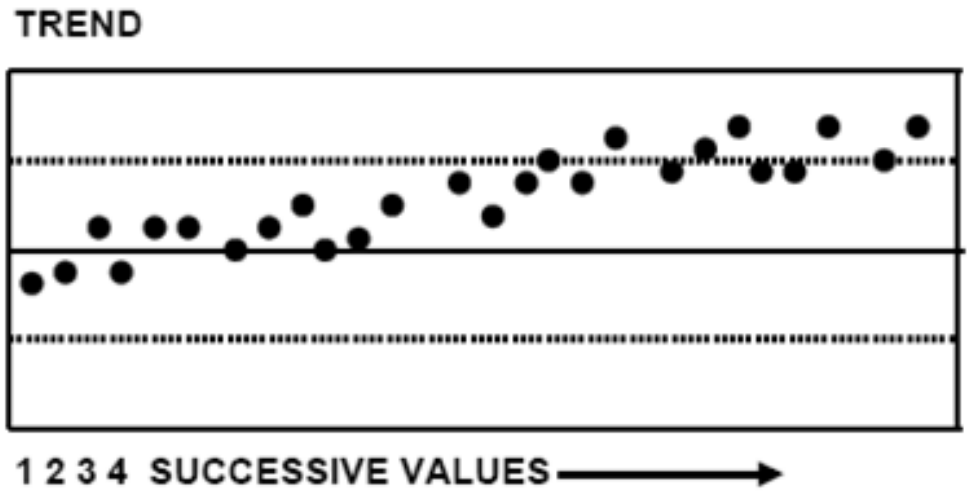
- The Levey-Jennings QC Chart is the most commonly used chart used to show the results of a control for a specified period in a graphic form. The chart depicts the position of data points relative to the assigned mean and SD. Here we see 1 and 2SD range. Also you can see the outliners.
- What are **Outliners - Outliers** are discrepant values which do not agree with the pattern of the rest of the points. They may be due to mistakes or they may be a significant finding.
- On this chart we see a big jump above and below the mean. Statistically 1 out of 20 points outside the limit is normal. Usually rerunning the sample the result will be in this time so you can assume that it was just a normal outliner. It is when you start seeing patterns that you have to worried about it. We will look at three patterns you may get with your LJ charts

Trend



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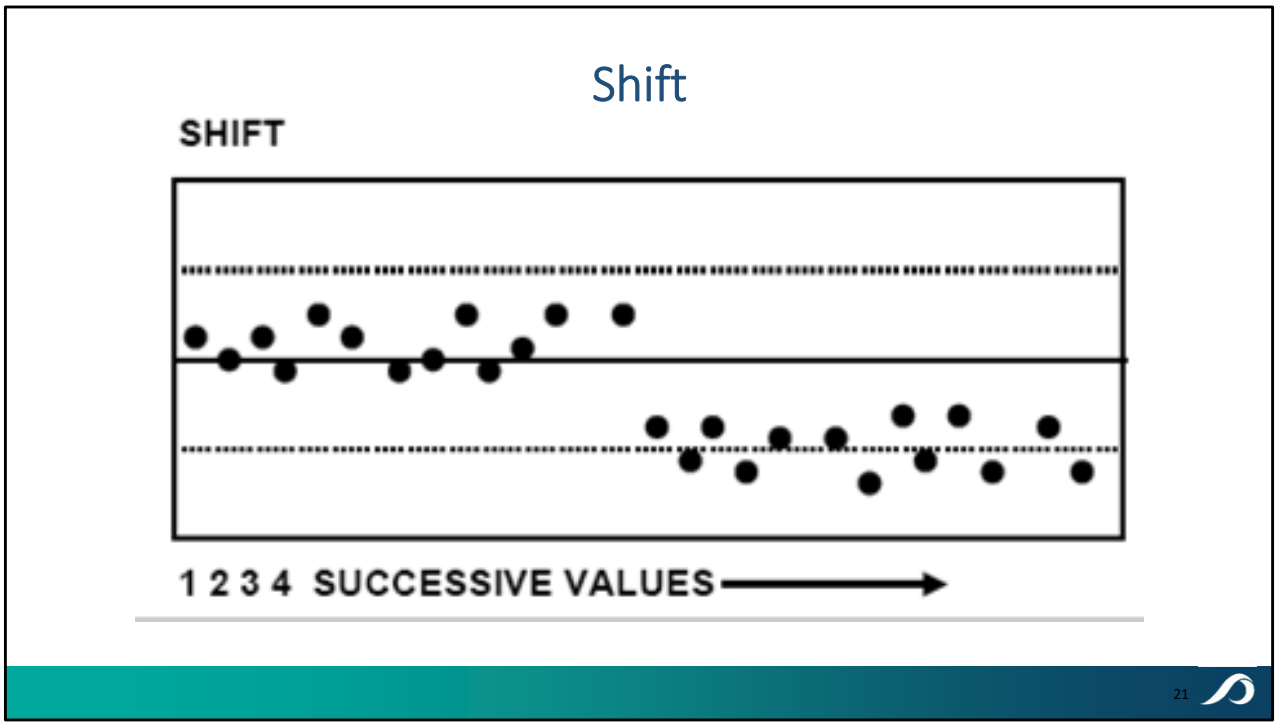
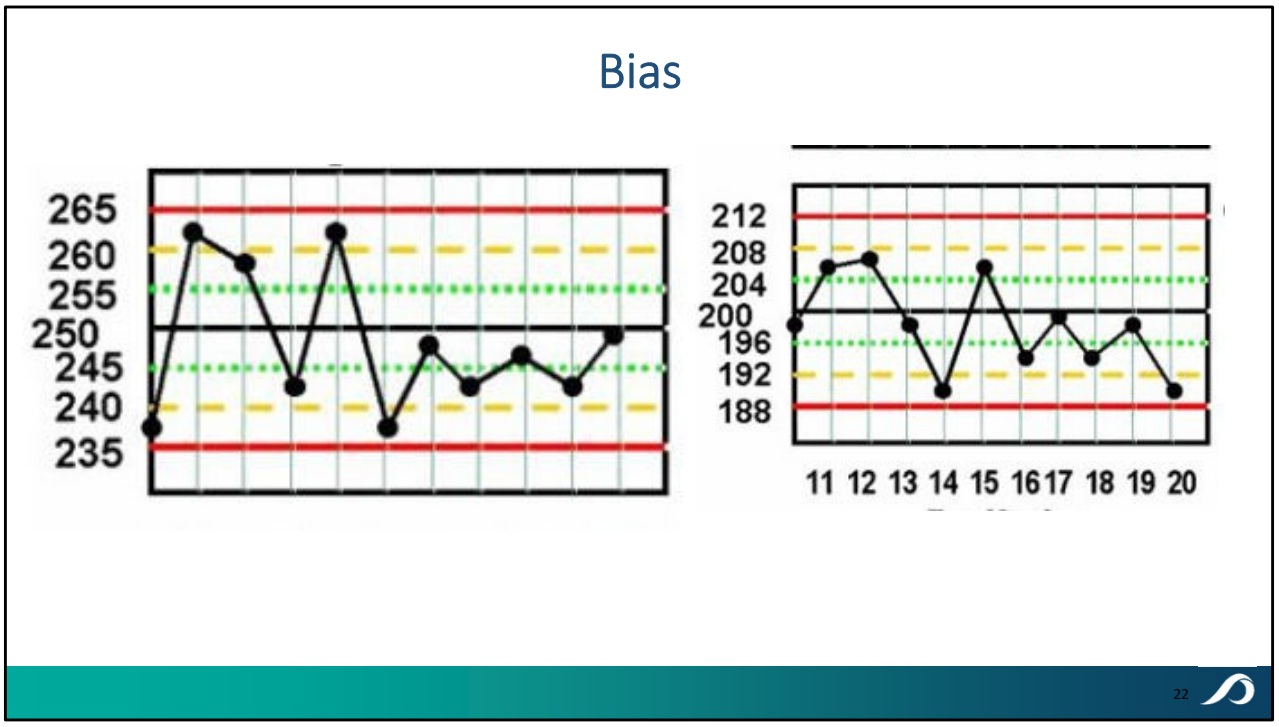
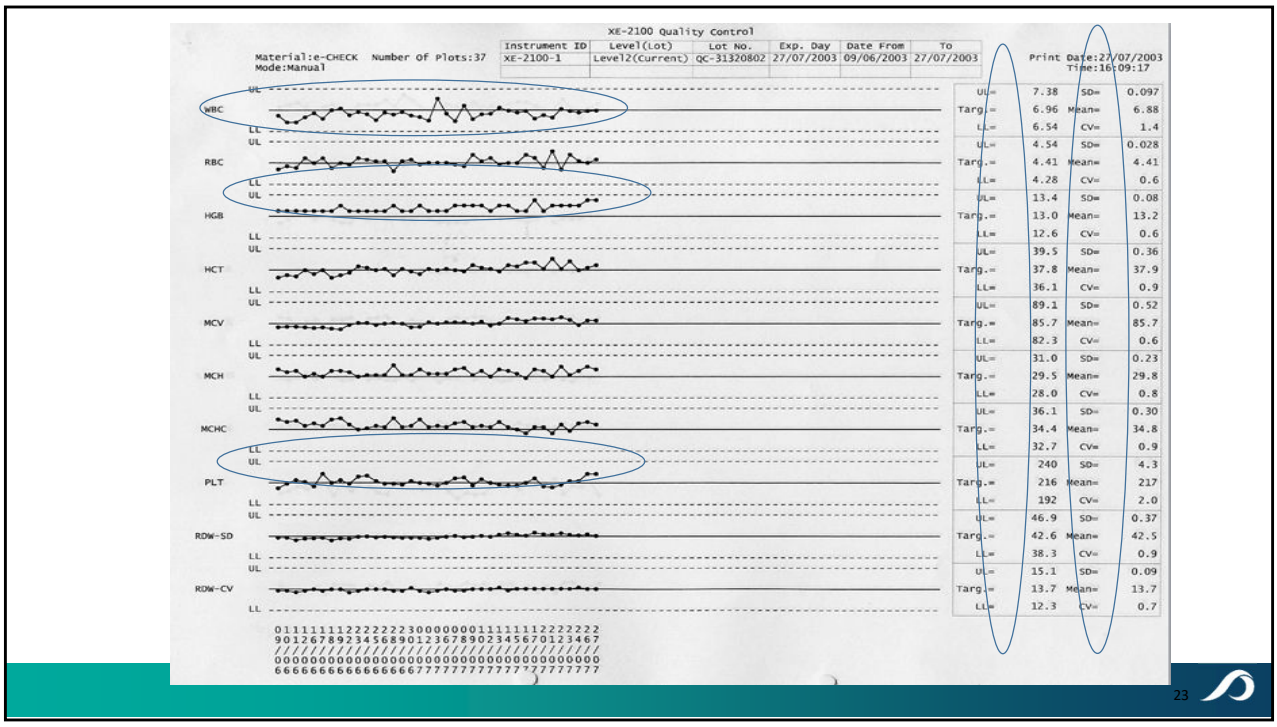
First we will look at a Trend. A trend occurs when six or more values show a gradual increase or decrease. The values do not have to be out of your acceptable range but this pattern can indicate that a problem exists. Because hematology controls are cell-based, some trending in sizing parameters can be expected as I said previously for the MCV, RBC and platelets. What you are looking for is excessive trending. Another reason for trending could be that a light source is going bad. If a trend can't be justified then it needs to be investigated.



Next we have a Shift. This is when there is a sudden change in control results from one run or day to the next. A shift does not always mean that a problem exists. Some reason you might get a shift are the Instrument was just calibrated. There was service performed on it.



Finally we have a bias. A bias is when your control starts running on one side of the mean. It can occur with just one or all of your controls. If it is only one of your control can indicate a problem with just that level. It may be a bad vial. Another reason could be that there is a new lot number in the frig and the tech grab the new one and ran in the old file. If it is across all the controls than can indicate an instrument problem or the need to calibrate.



Here we have a typical LJ chart for a hematology instrument.

We have the original means and upper and lower ranges.
Here we have the cumulative range.
Let's look at a couple of the analytes.
If we look at the WBC we see that the cumulative shows a slight negative bias.
Here with the Hgb we see that the whole time there was a positive bias.
And with the platelet it starts slightly below the mean, on the mean and toward the end above

QC Policy

- Each laboratory should adopt QC rules.
- Establish policy/corrective action for controls that are “Out”.
  - Do not run patients.
  - Documentation is important.
- Establish policy for trends, bias and shifts.
- Establish when calibration is required.

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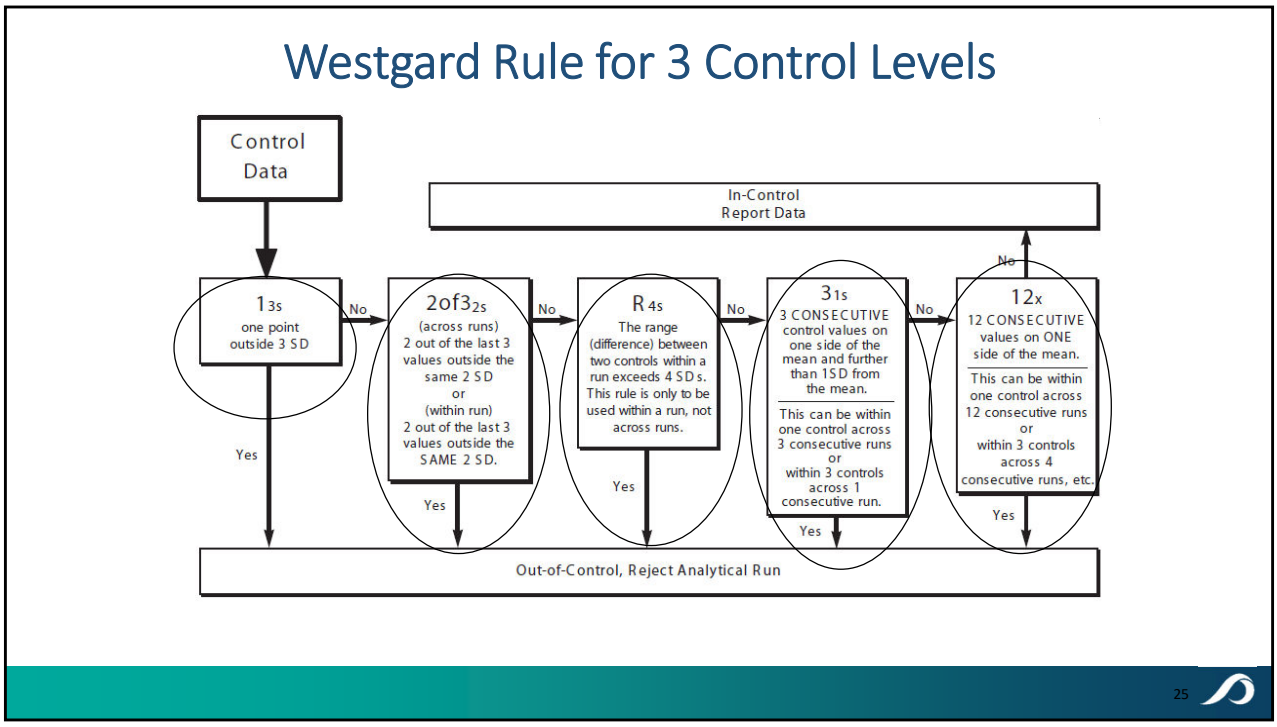
- With all Quality Control you need to create policies for acceptable and unacceptable results.. Of course the ones that most of us know are the Westgard rules. I will show you two typical ones in our next slides.

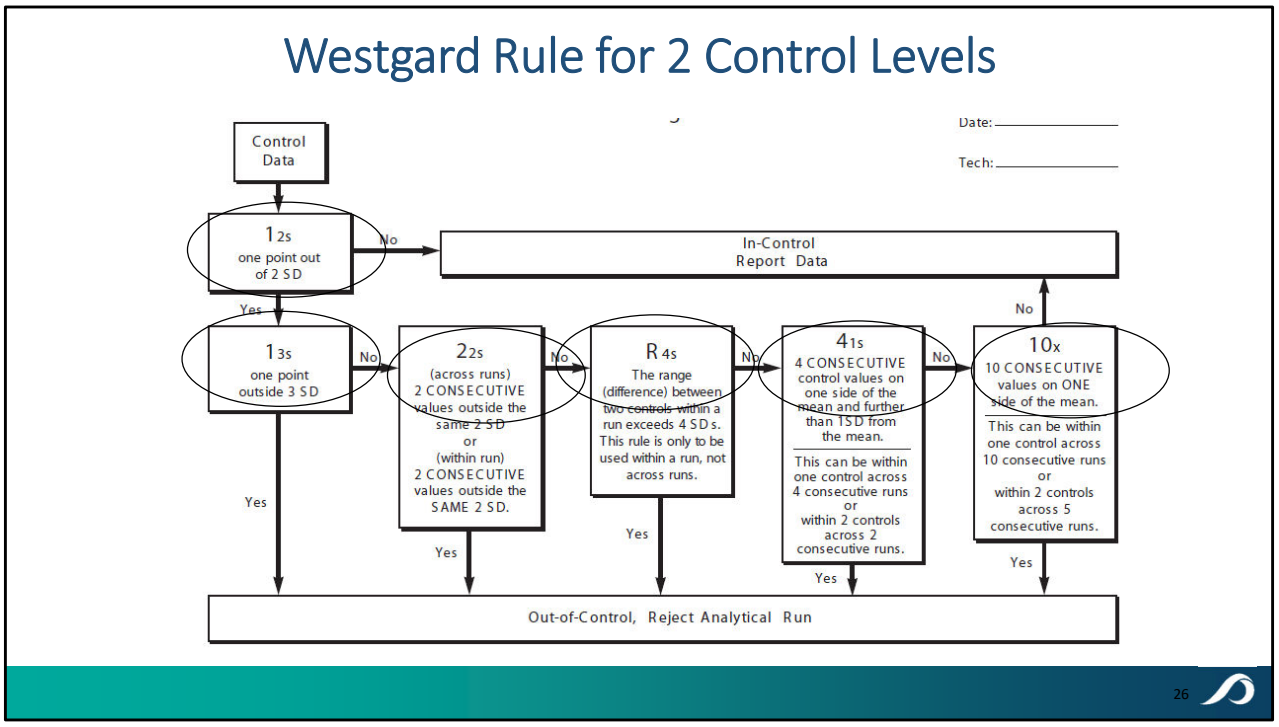
- What do you do if the control is “Out” – Beyond your established range. If control is “out” first rule would be - **Do not run any patient samples until determining what caused the control to be out**, Second everything should be documented such as the date of occurrence, what is out such as WBC low control, the lot# and expiration date. What action performed such as rerunning and repeat in range. Should include initials of person performing the corrective action. All of these occurrences need to be reviewed by the supervisor.
- Your policy will include what to do for Trends, bias, and shifts
- When to calibrate instrument
- Usually with hematology instrument unless there is major service done the calibration is very stable and usually done every 6 months. When you are deciding if a calibration is needed you look at all levels of QC. If each level is showing the same consist problem such as all running a bias below the mean could indicate the need to re-calibrate. Depending on the instrument you may be able to perform the calibration yourself or it may require a service call.

- For Chemistry instrument it can depend on the analyte, the type of instrument and reagent how often a calibration is needed. Once again you need to develop a policy.



Here is a diagram showing the typical Westgard rule chart that can used for 3 control levels. It uses a combination of decision criteria, usually these 5 different control rules to judge the acceptability of an analytical run. You will see the difference with a 3 control vs a two control run is that this one does not have the 1 2SD rule. This rule is usually used as a warning to trigger careful inspection of the control data. If there is one 2SD outliner it would not be looked at as a problem with this Westgard rule. You are allowed to report out patients with it.

The 1 3s and R4s are more sensitive to random error while the 2 of 3-2S, 3 1s and 12x are sensitive to systematic error.



Here is another Westgard combination. It is usually used with 2 controls such as in chemistry.
As you can see if you get this rule then you need to get at least one of the other rules to reject the run. As I said previous statistics show that there can be at least one outliner for every 20 runs.

The 1 2s, 1 3S and R4s are more sensitive to random error while the 2 2S, 4 1S and 10x are sensitive to systematic error.

Westgard Multi-rules are used to reduce costs while maintaining a high level of certainty that your analytical process is functioning properly. It helps to decrease the number of false rejection without compromising quality.

Policy Example

- If control out +/-2SD and a second Westgard rule is also seen
  - ➢Rerun the control.
  - ➢If another vial of control is available use it.
  - ➢No more than 2 control reruns from same vial or new vial should be made.
  - ➢If control still out begin troubleshooting do not report patient results.
    - ✓Check maintenance log
    - ✓Check reagent
    - ✓Check calibration date

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Here is an example of a QC policy

Troubleshooting Guideline

- Should have a policy on how to perform trouble shooting for out of range results.
  - ➢Instrument vs sample problem
  - ➢Resolve problem before running patients
- Can create a checklist .
- Can also include a Corrective Action Flowchart .

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In addition to your QC policy every laboratory should create policy on how to perform troubleshooting when their QC is out of range.

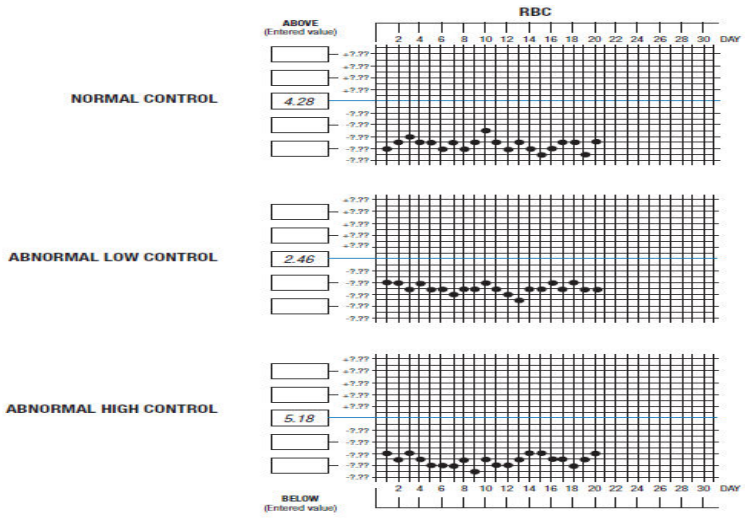
Part of your investigation will be establishing whether it is a sample problem vs an instrument problem.
If only one instrument than can try opening a new vial and running to see if the results differ or are the same.

Should troubleshoot the problem and remedy the situation prior to running patient samples.

It is good to have a checklist for your techs to follow..

Another helpful item could be a flowchart.

LJ Example



See a bias on all three. We see that the points are being reproduced showing the instrument precision is good however the results are not accurate.
They are all on the low side of the assigned values, a negative bias.
What would be some things to look at?

- Check for correct lot number? Did someone get into the new lot number or use the wrong files on the instrument.
- When was instrument last calibrated?
- When was last service?
- Has maintenance been performed?

In most heme instrument there are required maintenance that needs to be done such as bleaching of the aperture to prevent buildup of protein. The protein buildup can decrease the flow through the aperture which can lead to lower RBC values.
Check to see if maintenance has been done.
For chemistry could be a lamp problem where it is starting to dim

Another type of Internal QC that can be use to help extend your commercial controls

Retained Patient Control

- Two-three patient samples with specific parameters –ex. Low/high plt count, high HCG value, high HgbA1C.
- Can possibly be used over a 24 hour period- refrigerate samples
- Cost efficient.
- Can be used to detect systematic error.
- Transferable between instruments and modes.

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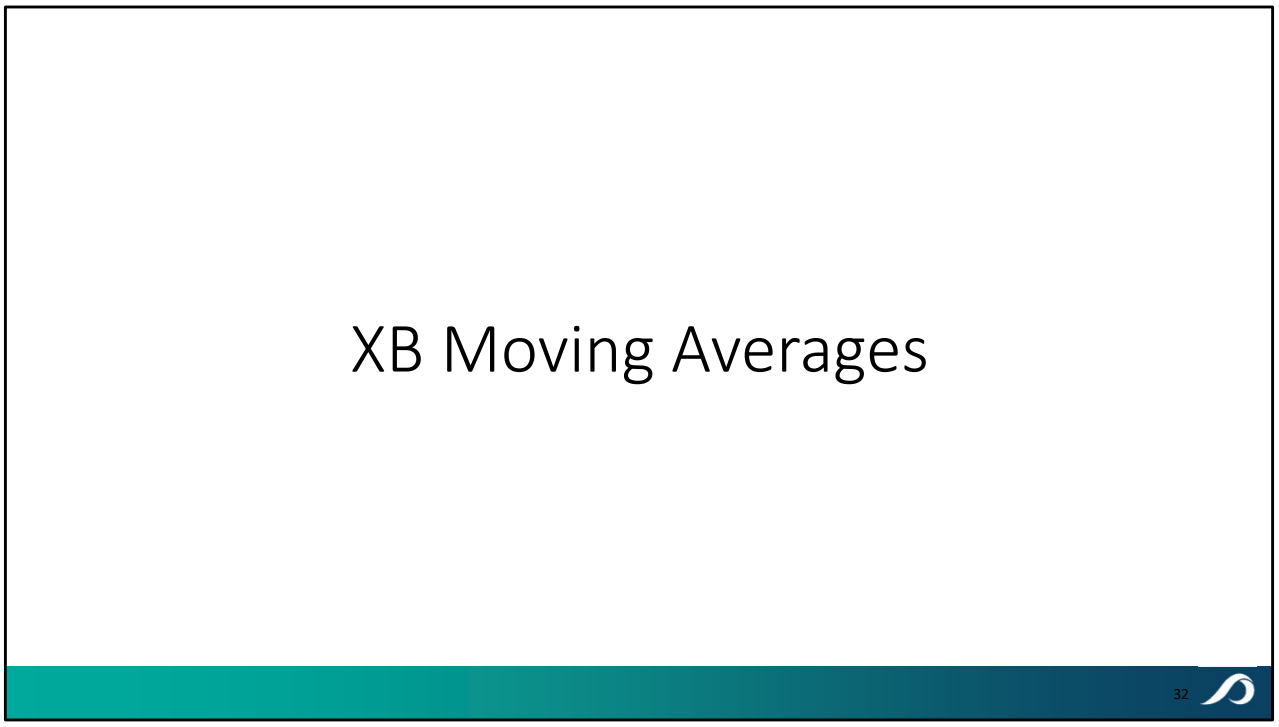
What is it?

- Usually consist of 2 -3 patient specimens pick from morning run. Preferably newly drawn blood, not sitting around for a long time. Should be a full draw because will be running it several times maybe on different instruments and/or modes throughout the day.
- Can be used over a 24 hour period. There is no significant changes in major parameters for 24 is properly stored

Why use them?

- Cost efficient. Can be run at closer intervals than commercial controls. Will allow you to have smaller batches of samples to repeat if find there are instrument problems.
- They can detect systematic errors

- Good way to correlate between different instruments and modes. Once again cost efficient.



Another type of Internal QC that can be use to help extend your commercial controls

XB – Moving Averages

- Cost effective quality control method.
- Allows for continuous monitoring of system performance.
- Uses patient samples in conjunction with other controls.
- Created by Brian S Bull.
- Algorithm evaluates RBC indices.
- Must run either 100/day or 400/week

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Last Internal QC will talk about is XB – Moving Averages

How many use these on their instrument?

XB analysis is another cost effective quality control method
allows for continuous monitoring of system performance
using patient samples in conjunction with commercial and patient controls.

Created by Brian S Bull. It uses a complex algorithm that evaluates RBC indices which are typically stable for a individual patient, from day to day, and stable for patient population over time.

They are considered as an added support to a lab's QC program being very effective if the lab has a volume of > 100 samples/day or 400 per week. It uses small batches of 20 samples to calculate a point for each parameter.

How to Set Target Values

- Start with Bull's values:
  - MCV = 89.5, MCH=30.5, MCHC=34.0
- Run 400 bloods or one week's worth ~ if less this may not be best way to monitor for your laboratory.
- Calculate the mean (target value), SD and %CV
- %CV has to be </= 1.5%
- Target value should be within 3% of Bull's
- The values must be physiologically possible
- Upper and lower range set at 5% of target

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First set to Bull's values

Next run either 400 bloods or a week's worth. Again you need to run at least 100 per day or 400 /week

Want to calculate your own values.

Need to make sure the %CV is </= 1.5%. When monitoring your QC - CV% monitors your instrument precision. It has a little different use with XB, if your CV is higher than 1.5 it means you don't have a random enough population.
You need to look back through your runs. Did you have a big batch of specific patients such as babies, oncology patients, renal patients. Depending on if this will be your usual population of samples it may mean you can't use XB to monitor your instrument. If it was an unusual batch of specimens the you can these results and try calculating your values again but remember you still need to have at least 100/day or 400/week.
Your target values should be within 3% of Bull's target values
And most important of course it has to be values have to be physiologically possible.
In beginning can set the upper and lower range at 5%. After using it for several

months re-evaluate to see if you can decrease it down to 3%.

Reason Why Moving Average to be Out

- Non-random population – oncology patients with abnormal values, children, renal disease patients.
- Instrument problem – chamber needs cleaning, laser issues etc.
- Calibration – You just calibrated and need to reset your target values.

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Example would be got a large batch of bloods from specific clinic such as oncology, renal or even children

Actually problem with the instrument. Later we will go over some examples. I have included a SOP and flow diagram for you to follow.

Last you had to calibrate your instrument and this could have changed the target values. You would have to run evaluated the target value like you did in the beginning.

XB Troubleshooting Policy

- Moving Average Acceptability

If	Then
Moving average parameters agree within the established limits set	Proceed with test of patient samples.
If 5-6 batches fall outside the limit set and cannot be explained	Hold testing of patient samples and run on backup until investigation complete

- Investigation

Step	Action	
1	Run 10-12 patients on both instruments (if available) and compare results.	
2	Check Internal Quality Control for any trends and/or bias.	
	If	**Then**
	Internal QC shows no trends/bias and patient result match between instruments	continue to use instrument and monitor
	If moving average still out	See flow chart and call Service Tech Hotline as needed, run on back-up instrument.
	Internal controls shows trends/bias and /or patient results do not match	See flow chart and call Service Tech Hotline as needed. Run patients on backup instrument.

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Here are examples of XB troubleshooting policy

Systematic vs. Random Error

Definition

- Systematic error
  - It is a consistent or proportional difference between the observed and true values.
  - Affects the accuracy of a measurement or how close to the true value.
- Random error
  - It is a chance difference between the observed and true values.
  - Mainly affects precision of the instrument.

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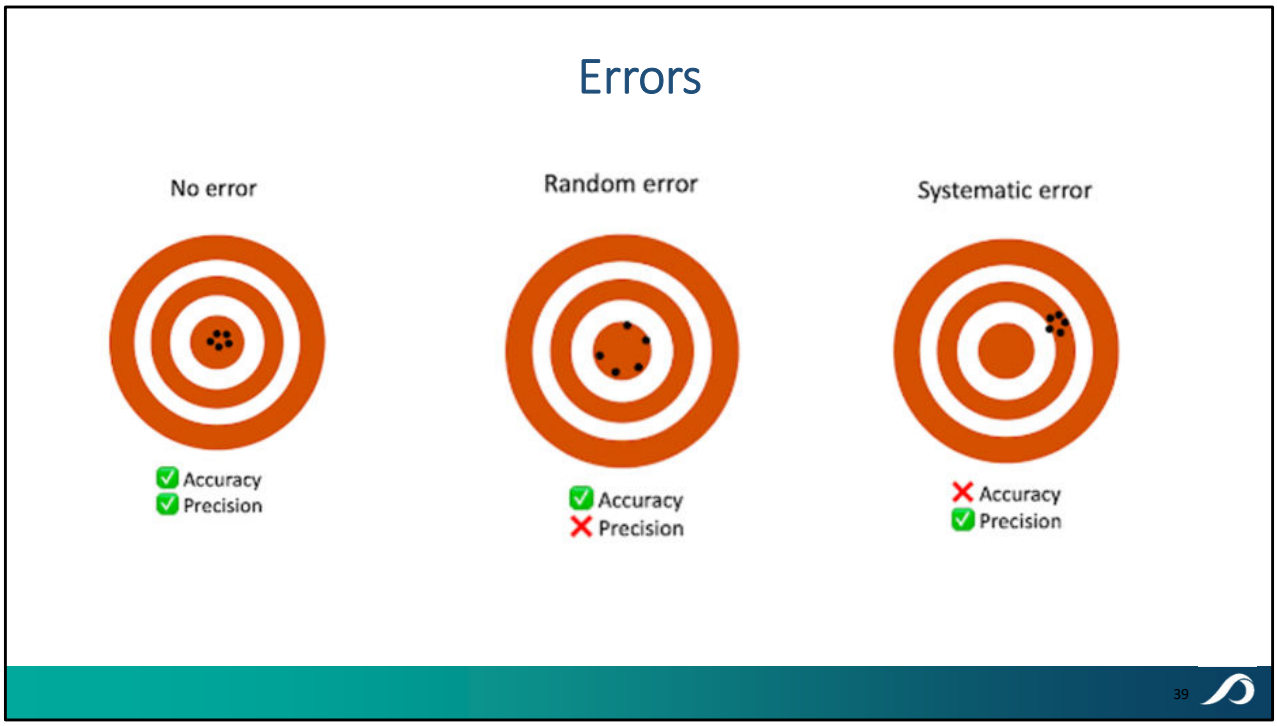
It affects accuracy The average variation is biased, because all measurements are affect in the same way. Systematic errors are generally the bigger problem. Random error affect precision. isn't necessarily a mistake but a natural part of measurement. There is always some variability in measurements even when you measure the same sample repeatedly, because of fluctuations in the environment, the instrument, or your own interpretations. Precision - The average of all difference of measurement from the true value



Here we have three possible outcomes when running a sample We can have one that shows both accuracy and precision. The points are very close together close to the true value

The middle shows random error where the points are within range of the true value but not very precise

The last show systematic error where the points are precise but far beyond the true value. Systematic errors can skew your data to lead to false results. If you have systematic error your measurements will be biased away from the true values.

Systematic Error VS. Random Error

- Consistent and repeatable
- Flawed experiment
- Same direction
- Reagent lot issues
- Faulty equipment – sampling issues, mechanical problems, dirty cuvettes/chambers, light source/laser breakdown.

- No pattern
- Unpredictable
- Unavoidable
- Cannot be replicated
- To be expected

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So to conclude Systematic errors are:
Random error are:
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IQC Recommendations

- A three level commercial control along with a retained patient control.
- If patient numbers permits add XB to IQC
- Commercial controls
  - ➢Two levels at beginning, middle and end of shift
- Retained Patient Controls
  - ➢At equal times between commercial controls

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If your laboratory only has a dayshift then recommend
3 level QC with retained patient
If patient numbers permit add the XB
Suggestion for running the commercial controls.
Suggestion for running patient controls.

Questions?

References

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