



- Controls
 - Accuracy
 - Precision
 - Reliability
- Define terms used to describe quality control measures used in the clinical laboratory such as:
 - Dispersion
 - Trend
 - Shift
- Describe quality controls standards used to determine reliable results.
 - Control Files
 - Histograms
 - Levy Jennings Graphs
 - and Control Rules



- Quality Control (or QC) is a process that monitors the accuracy and reproducibility of results through use of control materials.
 - Ensures excellence in performance by monitoring the functions of the lab instruments and their reagents.
 - So, instead of running a patient sample, whose value is unknown to us, we run a test on a ‘Control’, which is a sample whose value we do know.
 - Then we see how close the analyzer comes to the correct value.



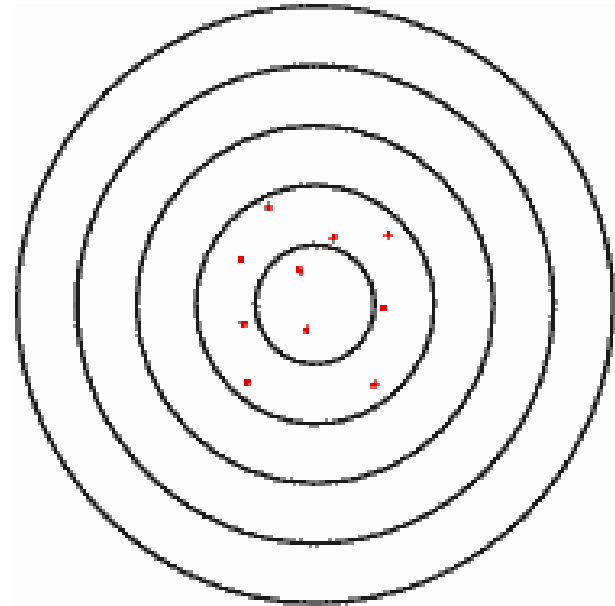
LABORATORY TERMINOLOGY

- **Control:** *A solution with a known value used to verify the **accuracy** and **precision** of the equipment.*



Controls

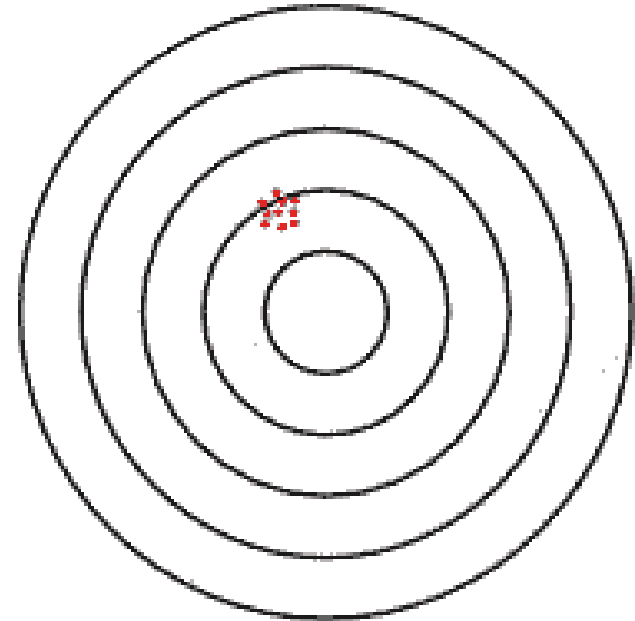
- Accuracy is how close the measured value is to the actual value and implies freedom from error.





Controls

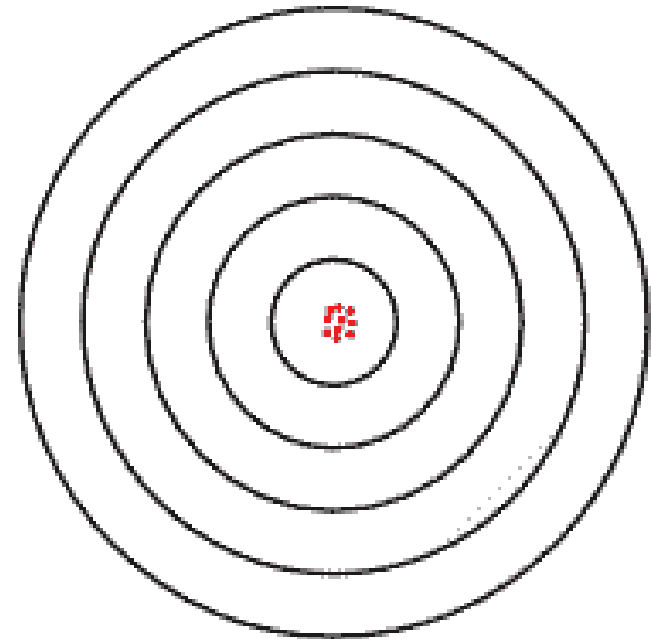
- **Precision** is how well the instrument reproduces the same result and implies freedom from variation.





Controls

- *An instrument is said to be **RELIABLE** when it is both *Accurate* and *Precise*.*
- Now, as I mentioned earlier, we know what the value of the control material is supposed to be, so every time we run a ‘Control’, we record the results and monitor them.





A good QC program is instrumental in:

- Detecting increases in the frequency of both high and low acceptable control values, which is known as **dispersion**.
- Detecting any progressive drift of control values to one side of the mean or the other for at least 5 consecutive results is referred to as a **trend**.
 - The 'mean' is the expected average.
- Detecting an abrupt change in at least 5 consecutive results all above or below the mean is referred to as a **shift**.



Control Files

- Clinical labs use tables and graphs to help evaluate the collected control material results.
- The tables are called ‘control files’ and the graphs are called ‘Levy-Jennings’ graphs.



Control Files

- Below is a control file; it is a table that tracks the results of all our Control material.
- Every time we run a control, the results are loaded into this control file spreadsheet or database (depending on your software).
- Below we have a control file with the last four control results (or Runs) for a WBC count and a RBC count.
- The mean is the average of the four results and 2SD stands for 2 standard deviations, which basically means +/- 2%.

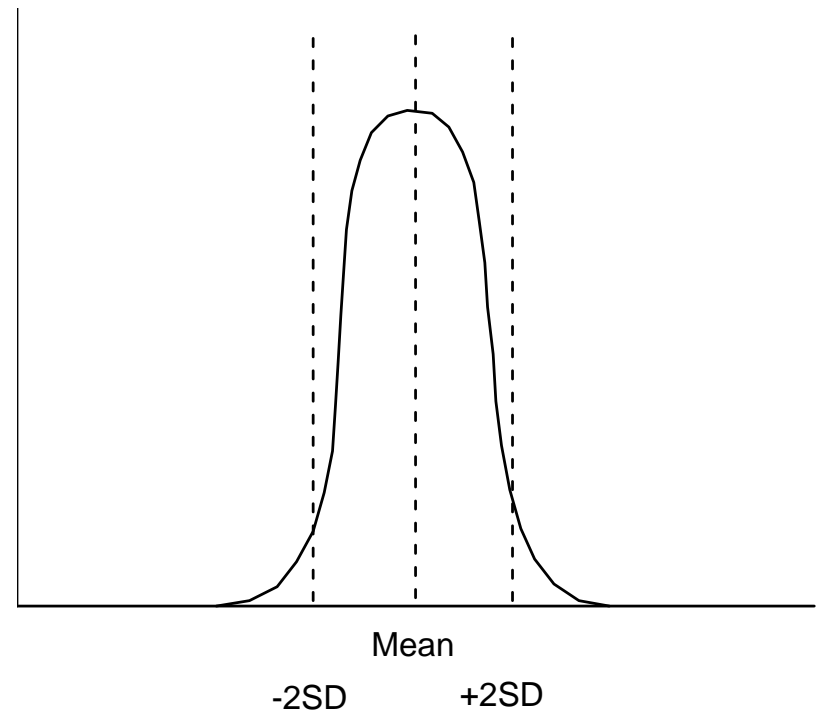
Run	<u>WBC</u>	<u>RBC</u>
1	8000	4500000
2	8050	4500500
3	7925	4600000
4	8015	4800000
Mean	7997	4600125
2SD	160	92000



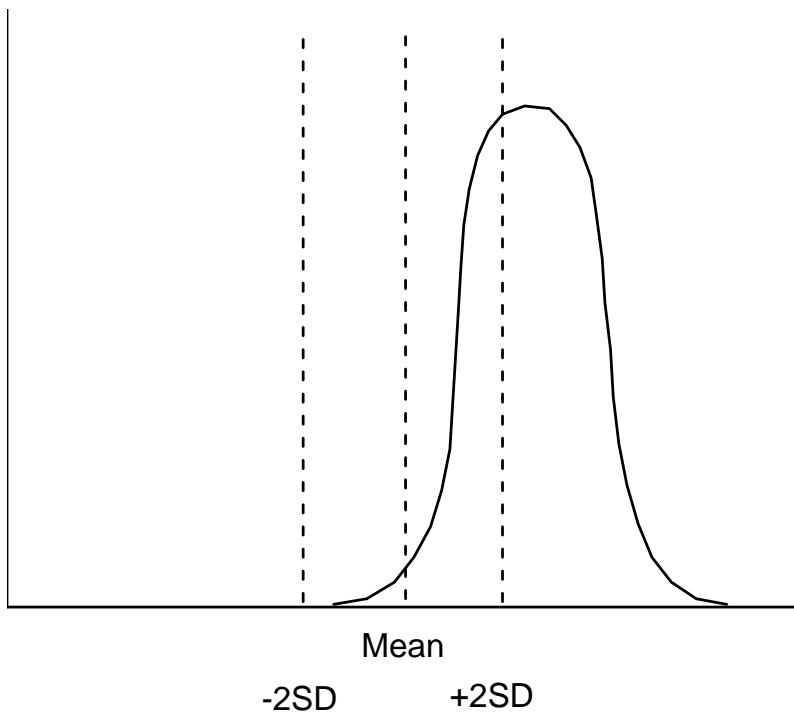
Now, the graphical representation of this control data is called a **histogram**; you may know it as a bell curve.

The vertical axis is the number of times a result has appeared, and the horizontal axis shows our mean results $\pm 2SD$.

- This histogram shows nearly no errors.
 - The center of the bell curve is aligned with the expected mean, meaning our average results were what we were supposed to get, and
 - almost all the results fall within $\pm 2SD$ of the mean.
 - Very infrequently did our control results fall outside the $2SD$ of the mean.
 - This analyzer has good reliability (accuracy and precision).

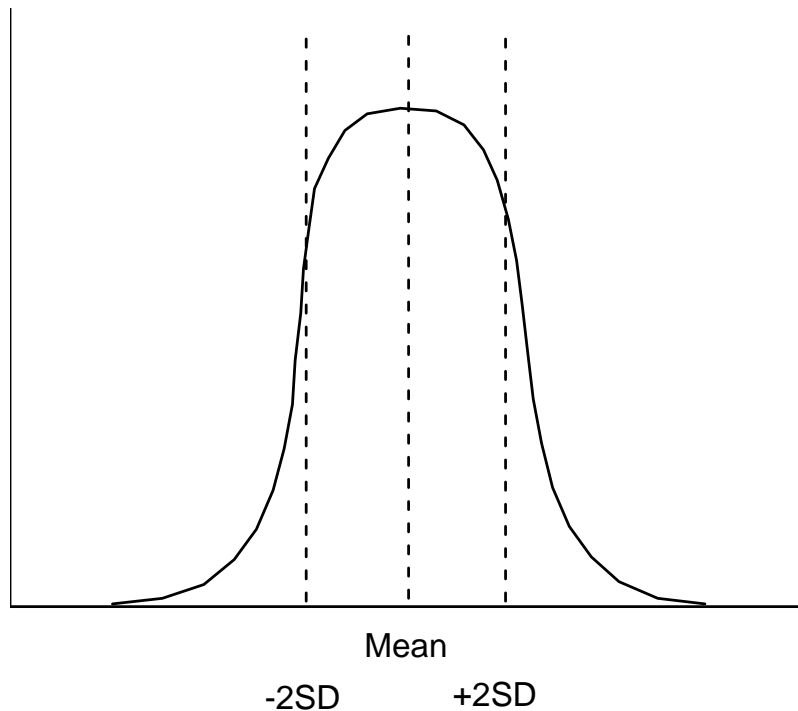


Histograms



- This histogram shows a **shift** or **trend**; the results of our Controls are all above the expected mean.
 - Now, notice that my histogram is still relatively thin (narrow dispersion); so all of our control results are close to each other (about the same).
 - This means we still have precision (we're getting close to the same result over and over again, but they are all outside the 2SD, meaning we have poor accuracy).

Histograms

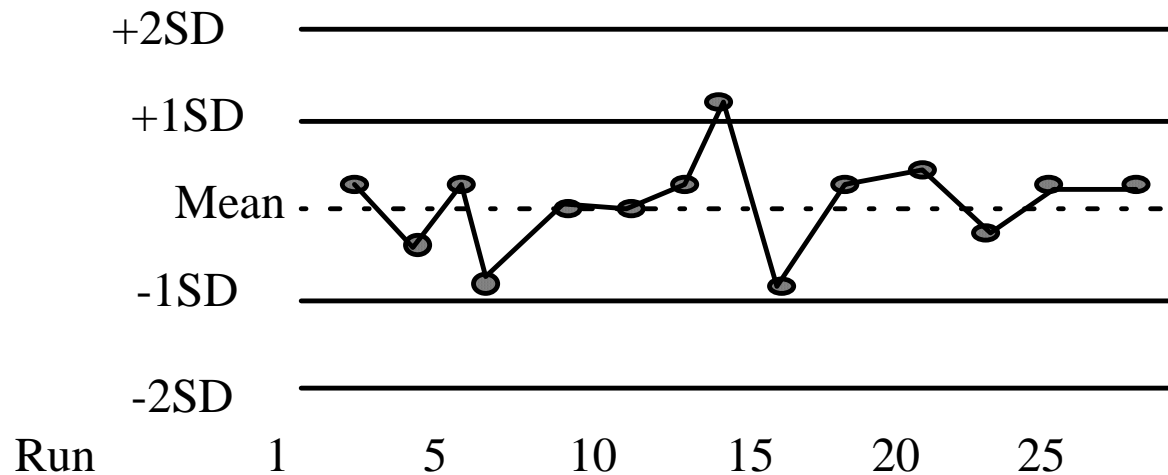


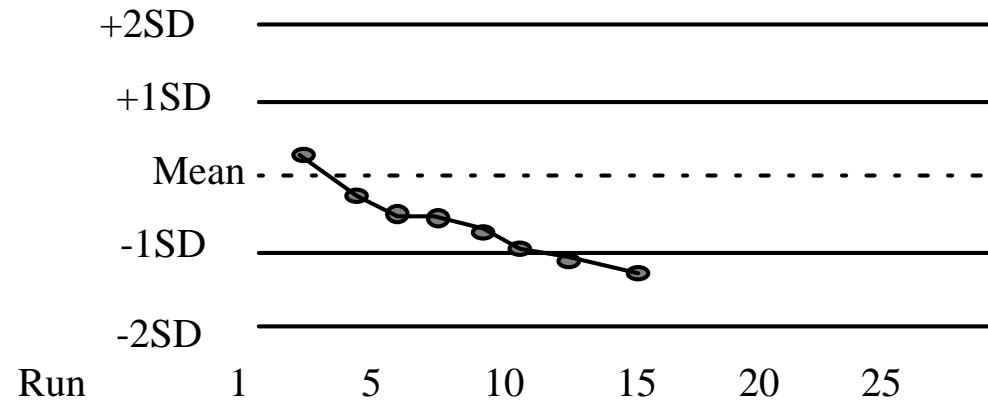
- This histogram shows an increase in the range of our control results (**dispersion**).
 - Notice how the bell curve is getting wider.
 - Here, we have neither accuracy nor precision.



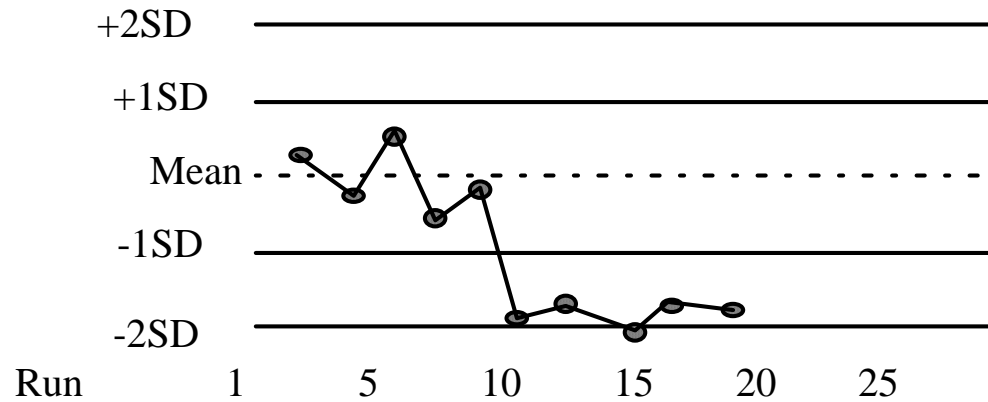
LEVY JENNINGS GRAPH

- The Levy Jennings graph is the traditional graphic display for quality control results.
- It allows for easy detection of **in control** and **out of control** samples and for subtle developing problems.



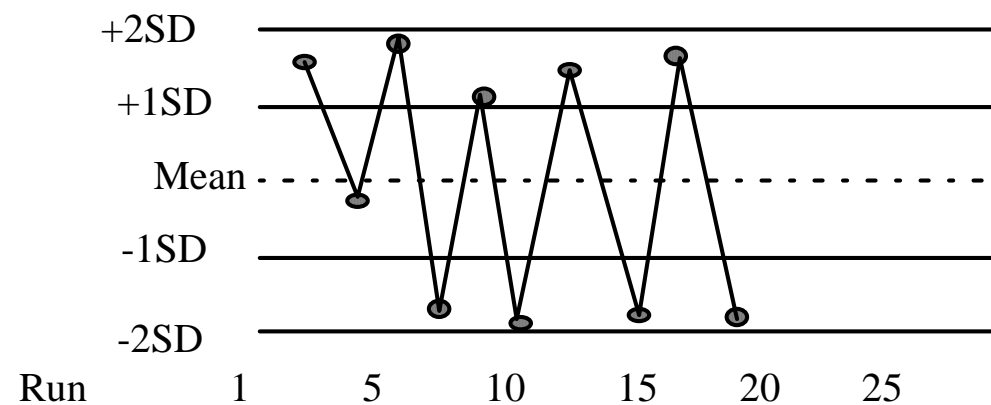


- Trend: A **trend** is a gradual change in 5 consecutive control results with all the results going upward or downward on the graph.
 - This systematic drift, or trend, in control values suggests a deterioration of a reagent or control material.
 - It's also important to note that each individual result by itself appears fine; they are all within 2SD; it's not until we track the results that we see a possible problem taking place.



- Shift: A **shift** is a sudden or abrupt change in 5 consecutive results all above or below the mean (usually due to a malfunction of the instrument or an error in technique).
 - Again, note, that even after the shift, our results are still within 2SD; but obviously something changed between the 9th and 10th run.
 - While precision is still excellent, accuracy is not.

LEVY JENNINGS GRAPH



- Random Error (or Dispersion): A **random error** is one that is present in all observations deviating the values above and below the mean.



Okay, so we have these charts; when do we stop what we're doing and say 'hey, this is a problem'?

Well, the lab has what are called 'Control Rules'.

A **Control Rule** is used to determine if the results of an analytical run represents acceptable accuracy and precision by comparing them to defined limits.

- Now, many Control Rules can apply; some popular standards are to reject a QC run when . . .
 - the control samples exceed the +/- 2SD limits just once.
 - two consecutive control observations exceed the +/- 2SD limits.
 - four consecutive control observations exceed the +/- 1SD limits.
 - ten consecutive control observations are on the same side of the mean.