

How to Establish a QC Range for Aqueous Controls

LifeHealth recommends the following method for establishing tentative aqueous QC ranges for the IRMA analyzer.

Test Method:

- Store the controls where the quality control testing will be performed, (i.e. the designated Point-Of-Care area), to minimize the effects of temperature variation on aqueous control results. Follow the package insert for equilibration time if controls are stored in a refrigerator. Record the daily room temperature to document temperature variation in the control testing/storage area.
- Conduct testing with multiple users to address any sample handling variations between different operators.
- Conduct testing over a minimum 5-day period to take into account any variations in room temperature, barometric pressure, and operator technique.
- Analyze, at a minimum, 10-20 samples per control level.

Aqueous Control Sample Handling and Timing:

1. Before sampling, shake the control ampule per package insert. Hold the ampule by the top to avoid transfer of body heat to the contents of the ampule.
2. Restore liquid to the bottom of the ampule with gentle tapping. If foam or small bubbles are present, **set the ampule down and allow to stand until these have come to the surface.**
3. Insert a cartridge into the IRMA analyzer and wait until **calibration has completed**; then, with fingers protected, carefully snap open the control ampule.
4. The ampule contents should be sampled as soon as the ampule is opened. It is necessary to transfer the liquid from the ampule to a syringe. Use an **18 or 20 gauge needle** with a **1 to 3 mL non-heparinized** syringe. Insert the needle to the bottom of the ampule and slowly draw the liquid into the syringe. Draw approximately 1 mL into a 1 mL syringe, or all but the last bit of ampule contents into a 2 mL or 3 mL syringe. Immediately remove the needle. **DO NOT** remove any bubbles or invert the syringe, remove the cartridge cap and firmly attach the syringe to the cartridge luer port. Hold the syringe in a stopwatch like hold and using your thumb, in one single, quick, controlled motion inject all but the last bit of syringe contents into the cartridge, taking care not to inject an air bubble into the cartridge.
5. Make sure that there are no bubbles over the sensors and that the gel has been completely displaced, then press **test**.

Data Analysis

1. Determine the **mean (X)** for each control analyte (e.g., pH, pCO₂, pO₂) for each control level.

$$X = \frac{\sum xi}{n}$$

where: Σ is the "sum of"; xi is each data point; n is the number of data points

Your mean should fall within the range on the package insert.

2. Assign tentative ranges by applying the following criteria:

Analyte	Range Limits
pH	mean \pm 0.03 (levels 1,2,3)
pCO ₂ (mmHg)	mean \pm 8 (level 1) mean \pm 5 (levels 2,3)
pO ₂ (mmHg)	mean \pm 10 (levels 1,2,3)
Na ⁺ (mM)	mean \pm 5 (levels 1,2,3)
K ⁺ (mM)	mean \pm 0.5 (levels 1,2,3)
iCa (mM)	mean \pm 0.1 (levels 1,2,3)
Cl ⁻ (mM)	mean \pm 5 (levels 1,2,3)
BUN (mg/dL)	mean \pm 3 (level 1) mean \pm 5 (level 2) mean \pm 8 (level 3)
Glucose (mg/dL)	mean \pm 15 (level 1) mean \pm 20 (level 2) mean \pm 30 (level 3)
Creatinine (mg/dL)	mean \pm 0.3 (level 1) mean \pm 1.2 (level 2)
Lactate (mg/dL)	mean \pm 0.3 (level 1) mean \pm 0.5 (level 2) mean \pm 1.5 (level 3)
Hct (%)	mean \pm 3 (levels 1,2,3)

Example: The level 1 pH mean was calculated to be 7.145.

$$7.145 - 0.03 = 7.115 \text{ (lower limit)} \quad 7.145 + 0.03 = 7.175 \text{ (upper limit)}$$

Note: Due to the small number of observations, initial quality control limits should be established using the range limits above. Once a minimum of 100 points per level have been collected, standard deviations may be used to establish limits.

3. To determine the **standard deviation (SD)**, use the formula below and the mean calculated in step 1.

$$SD = \frac{\sqrt{\sum (X - xi)^2}}{n - 1}$$

where: Σ is the “sum of”; X is the mean; xi is the result of each data point; n is the number of data points

4. Eliminate any values that fall outside of ± 3 SD of the mean (these results may be due to poor sample handling, etc.).
5. Recalculate the mean with the remaining values.
6. Recalculate the standard deviation.
- Approximately **68%** of all determinations should fall within **± 1 SD** of the mean value.
 - Approximately **95%** of all determinations should fall within **± 2 SD** of the mean value.
 - Approximately **99.7%** of all determinations should fall within **± 3 SD** of the mean value.

Laboratories commonly set control limits at either two or three standard deviations. If two standard deviations are chosen, the laboratory can predict that under these conditions, only one out of 20 determinations will exceed the limits as a result of chance. If a second result exceeds two standard deviations, it is then suspect of not meeting the conditions originally used in determining the mean. If a result exceeds three standard deviations, this result is genuinely suspect since this could occur by chance only three times in one thousand.

Data should be reviewed monthly after the range is established to verify that the range is still representative of conditions originally used in determining the mean.

Acceptance and Rejection Criteria for Daily Quality Control:

Follow the protocols established for your facility. The following suggestions may be used to establish a protocol for evaluating QC results.

- If all values are within range, the system is ready for patient testing.
- If a value is out of the range:
 1. Verify that the QC range used to evaluate results is for QC lot being tested.
 2. Verify that the sample has been correctly handled and injected into the cartridge.

3. Have the same operator repeat the testing with another ampule of control. This will help determine whether sample-handling by an individual operator is a possible source of error.
4. If test results are still out of range, have a different operator repeat the test with a different ampule.
5. If test results are still out of range, check the room temperature of testing area for temperature shifts. For every 1°C change in temperature, a 1% change in gas value will be seen.
6. If test results are still out of range, contact LifeHealth Technical Service.
7. Document all actions taken to resolve the problem.

Note: If a QC result is just outside of the range, follow the established protocol for your facility. This may be to accept the value and allow patient testing to continue while the next quality control results are monitored.