We expect QC materials to provide information about what is occurring with the measurement procedure. In other words, we expect the performance of the QC materials to mirror the same effects as what is occurring to our patient samples. To do this, QC materials should: [i]

1. Mimic the matrix and viscosity of the patient samples being tested
   1. Matrix—the base from which control materials are prepared in addition to the preservatives added for stability
   2. Matrix effect – the influence of the control material’s matrix, other than the concentration of the analyte, on the measurement procedure to produce differing results when compared to other methods while still producing consistent results on patient samples
2. Be both physically and chemically sensitive to changes in the measurement procedure as patient samples
3. Contain concentrations of analytes at or near medical decision points
4. Be available in one lot number that is stable for an extended period of time
5. Be available at different concentration levels to assess the measuring range of the method
6. Remain stable before and after opening a vial as indicated by the manufacturer
7. Produce minimal vial-to-vial variability

[i] Brooks, Zoe (2003). Quality Control – from Data to Decisions. Basic Concepts (Section 2, Topic 2)

In addition to the above stated qualities, other considerations should be weighed for your specific site, such as:

1. Use of lyophilized (freeze-dried) controls
   1. Usually less costly per box than liquid
   2. Require a special diluent or deionized Type I water
   3. Require availability of clean Class A Volumetric pipets and pipetting bulbs
   4. Require staff that is capable of
      1. Accurately pipetting manually
      2. Strictly adhering to reconstitution and mixing instructions provided by the manufacturer
   5. May experience more vial-to-vial variability (increase imprecision) especially if improper handling and reconstitution occurs
   6. Frequently has a shorter opened vial expiry interval
      1. May result in discarding unused portion (hidden cost consideration)
2. Use of liquid controls
   1. Usually more costly per box than lyophilized
   2. Eliminates many of the handling and reconstitution errors
   3. Influence of matrix effect may be greater with the method you use
   4. Frequently has a longer opened vial expiry interval
      1. May discard less or none of the product if consumed within opened expiry date
3. Frequency of lot number changes
   1. Performing parallel testing takes time and money (costs of performing testing on QC materials)
   2. With each QC material lot number change, lose access to summary or cumulative data
   3. Recommend to purchase a year supply of the same lot number, when possible
      1. Desired expiration date should be specified at time of purchase
      2. Storage issues
      3. Difficulties encounter with setting up a standing order with the vendor
4. Vendor considerations
   1. Availability of an inter-laboratory comparison program
   2. Provide troubleshooting support
   3. Ability to accommodate standing orders
   4. Ability to sequester specified lot number and automatically ship and bill as outlined in the purchase agreement