A QC protocol (plan) describes how the analytical staff routinely performs QC and responds to QC data.

1. Define the statistical QC rule to be applied and its frequency.
2. Define how the control materials will be analyzed.
3. Define how to interpret the rules.
4. Define what troubleshooting actions should be taken, including documentation.

**Example QC Protocol for XYZ Analyzer**

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| Statistical QC Rules | 1:3s  1:2.5s  1:3s/2:2s/R:4s/4:1s | ALT, AST, Bili-Tot, Creat  TP, CK  Glucose |
| Analysis of Control Material | Analyze one sample of the Precinorm Normal and one sample of the Precinorm Abnormal controls for a total of 2 control measurements in each analytical run | |
| Interpretation of Results | 1. Scan the chart for any measurement greater than ± 2SD. If no measurement is found, then accept the run and report patient results. 2. If a measurement is found, inspect the control data using the specified QC rejection rule for the analyte.    1. Within current run inspection       * apply the 1:3s from each material       * apply the 1:2.5s from each material       * apply the 2:2s and R:4s rules across materials    2. Across-run inspection       * apply the 2:2s rule within each material across the last two runs       * apply the 4:1s rule within each material across the last 4 runs       * apply the 4:1s from the last two runs and the two measurements on each material 3. If none of the rules from Step 2 are violated when applying the specified rejection rule for the analyte, accept the run and report patient test results. If a rule for an analyte is violated in Step 2, reject the run and do not report patient test results for that analyte. | |
| Troubleshooting Actions | 1. Circle the analytical run number to indicate the run was rejected 2. Complete a *Daily QC Investigation Report* to identify the type of error occurring and the possible causes for the error. 3. Refer to the troubleshooting section of the operator’s manual as needed. 4. Take corrective action based on the investigational report. 5. File the investigational report in the instrument’s log under the corrective action section. | |