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| Title: | ACL TOP Quality Control | | |
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| Approver(s): | CLIA Director | | |
| Location/Region/Division: | Baylor Scott & White System | | |
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# sCOPE

This document applies to employees that perform coagulation studies within the Baylor Scott and White Health System.

# DEFINITIONS

*When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.*

**CLSI CLRW:** Clinical Laboratory Reagent Water as defined by the Clinical and Laboratory Standards Institute.

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| method/Utility |
| The purpose of this procedure is to provide instructions on how to run quality control specimens on the ACL TOP. |

# PROCEDURE

Controls are run using two different levels of control material each eight hours of patient testing, each time new new reagent vials are loaded on the analyzer,and to verify calibration standard curve.

**Before performing QC, the following conditions must be met:**

1. QC materials must be placed in the appropriate positions on the analyzer using the original bottles on the appropriate rack. If using sample cup see Programming QC from the Sample Rack Detail Screen section below.
2. Program QC from the QC Test Status List
   1. Select QC from the Menu bar then Test Status List from the drop down menu
   2. Double-click on the appropriate test or select the test and select the QC Statistics Icon
   3. Select the material for the test by clicking on it the Test->Material definition tree (on the left side of the screen).
      1. You can toggle the display between Test->Material and Material->Test by clicking the Material->Test Tree View Icon.
      2. Clicking the checkbox on the main test in the tree selects all QC related to the Material->Test and adds it to the Program QC List.
      3. Clicking the Checkbox again will deselect the tests related to the material selected.
      4. Also, using the Clear QC Selection icon in the toolbar will remove any previous selections
      5. Ensure all tests (master and paired) are feasible before initiating the run
         1. If the master test is not feasible and the paired test is feasible, the master test will not be run, and the paired test will run but fail.
         2. If the master test is feasible and the paired test is not feasible, the master test will be run and produce results, but the paired test will not be run.
3. Select the Program QC icon to start running the QC tests.
4. When the QC tests are completed, the QC Statistics screen for each material/test combination is updated with the result information.
5. Check that QC has been performed and passed. Document as per facility requirements.

***Note:*** If the QC fails there is an audible alarm and a flashing red “!” in the QC Alarms tab found at the bottom of the screen in the System Alarms Status area. QC will fail when the result is above or below laboratory established criteria.

**Programming QC from the Sample Rack Details Screen**

Use this method of performing QC when you are working with a QC material that is placed in a sample container in a sample rack.

***Note:*** If this method is used to program QC you will not be able to use bar codes and the following material tracking features will be lost volume warning, on-board stability tracking, and expiration date tracking.

***Follow either option “A’’ or “B’’***

***Option A:***

1. Select the Sample Area icon or select **Analysis** >**Sample Area** from the menu bar.
2. Place the **QC** control into sample cupon the sample rack
3. Insert the sample rack onto the analyzer
4. With the focus on the rack with the QC controls, select the **Rack Details** icon to open the Rack Details screen.
5. Select the desired position within the rack and select Quality Control from the Sample Type drop down list.
6. Select the appropriate material name from the Sample ID drop down list.
7. If lot management is enabled, select either the Active lot or Alternate lot button.
8. Select the Add/Remove Tests icon to open the Tests and Profiles dialog box.
9. Select the appropriate tests by clicking on them to populate the Rack Detail screen.
10. Select the **Run** icon in the toolbar.
11. When the QC tests are completed, the QC Statistics screen for each material/test combination is updated with the result information.
12. Check that QC has been performed and passed. Document as per facility requirements.

***Option B:***

1. Select the Sample Area icon or select **Analysis** >**Sample Area** from the menu bar.
2. Place the **QC** control into sample cupon the sample rack
3. Click **sample rack** icon show on the **sample Area** to open the Rack Details screen.
4. Select the desired position within the rack (where the QC sample cup loaded) and select Quality Control from the Sample Type drop down list.
5. Select the appropriate material name from the Sample ID drop down list.
6. If lot management is enabled, select either the Active lot or Alternate lot button.
7. Select the Add/Remove Tests icon to open the Tests and Profiles dialog box.
8. Select the appropriate tests by clicking on them to populate the Rack Detail screen.
9. Click **Insert Rack** icon in the toolbar
10. Insert the sample rack
11. Select the **Run** icon in the toolbar.
12. When the QC tests are completed, the QC Statistics screen for each material/test combination is updated with the result information.
13. Check that QC has been performed and passed. Document as per facility requirements.

***Note:*** If the QC fails there is an audible alarm and a flashing red “!” in the QC Alarms tab found at the bottom of the screen in the System Alarms Status area. QC will fail when the result is above or below laboratory established criteria.

***Caution:*** When loading sample, diluent or reagent racks, the racks must be pulled all the way out before loading.   Pulling out racks partially while loading or changing bottles, tubes, or sample cups may result in incorrect identification of the rack contents.

**Automatic QC**

If automatic QC has been enabled for a test, the system will automatically perform QC once the user-defined frequency has expired.  To enable automatic QC, See:  [QC Setup Definition](mk:@MSITStore:D:\ACL-TOP_MINI_EN.chm::/QCSetupDefinition.html) on the instrument’s help screen.

Before the scheduled time, make sure that there is a sufficient quantity of Quality Control material to run all assays needing that level QC. This can be determined by using the TOP Test Feasibility icon. When in the Sample or Reagent area, it can be found in Toolbar as an operational icon.

1. QC results can be reviewed by selecting QC from the Menu Bar and selecting Test Status List from the drop-down menu.
2. Double click in the far-left column and the QC Statistics screen will be displayed
3. Select the QC filter from the Toolbar and choose the desired timeframe
4. From the QC tree on the left, highlight each QC to review the QC result with date and time performed

***Note:*** If the QC fails there is an audible alarm and a flashing red “!” in the QC Alarms tab found at the bottom of the screen in the System Alarms Status area. QC will fail when the result is above or below laboratory established criteria.

Lyophilized controls require reconstitution with CLSI CLRW type water or NERL water. All unopened controls are stable until the expiration date shown on the vial when kept at 2-8°C (Refer to facility Appendices).

**Troubleshooting Failed QC**

* All unacceptable QC results must be documented, along with any corrective action steps taken. Perform the following steps, in order, until QC passes.
  1. Repeat QC using the same vial of QC.
  2. Repeat QC using a new vial of QC.
  3. Replace all reagents for that assay and repeat QC.

Notify section leadership, if applicable per facility workflow. Troubleshooting steps may include recalibration, additional maintenance, and/or contacting IL technical support for further guidance.

***QC Troubleshooting Notes***

* + The results of quality control are reviewed for acceptability before reporting results. If QC is not acceptable, patient results are not reported.
  + Extended troubleshooting, including repeating of previously resulted samples, may be performed at the discretion of responsible personnel.

***Note:*** Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

**QC Statistics**

* QC statistics should be reviewed by appropriate supervisory personnel or designee on at least a monthly basis.
* The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed. Investigate QC flags and document actions taken if appropriate.
* To access the QC Statistics on the IL:
  1. Select QC from the Menu bar.
  2. Select Test Status List.
  3. Double click on far-left column to open results and stats screen.
  4. Filter QC results based by date range needed.
  5. Levey-Jennings charts with statistic mean lines and trend lines can be viewed from this screen.
* Monthly the total number, interval statistc mean, and interval 1 SD for each QC material is submitted to *AccuTrak.*
  + ***Note:***The report needs to be submitted by the 10th of every month to be included in the peer group comparisons.
* *AccuTrak* is IL’s inter-laboratory quality control program.
  + Peer group comparisons are used for managing laboratory quality, as well as laboratory accuracy and precision.
* Reports are generated for reviewing instrument performance.

# ATTACHMENTS

None.

# RELATED DOCUMENTS

ACL TOP Analytes (BSWH.LAB.CG.403.R)

Facility Specific ACL TOP Appendices

# REFERENCES

1. IL ACL TOP Instrument Manual, Instrumentation Laboratory, 12/2011.

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| Revision History |  |

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| --- | --- | --- | --- | --- |
| **Version #** | **Effective Date** | **Description of Change** | **Revised By** | **Removed Date** |
| V2 | See Signatures | Added appropriate frequency of QC testing and how it is used to verify the standard curve. | Hematology Sub-Council | NA |
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