# Changes in Grey

**Purpose:** This procedure describes the daily operation of the Siemens Atellica CH930/IM 1300 chemistry analyzer. Included in this procedure are daily operations, daily/weekly/monthly/quarterly preventative maintenance, results review, STRATUSDX interface details, troubleshooting, Calibration and Quality control.

**Principle:** The Siemens Atellica CH930/IM 1300is an integrated chemistry/Immunochemistry analyzer. Chemistry methods are performed using spectrophotometric methods and Immunochemistry is performed using enhanced chemiluminescence. Given the complex nature of this analyzer, a solid knowledge of daily operations and quality assurance is required.

**Reagents/Equipment:**

* Siemens Atellica CH/IM Analyzer
* Atellica Data Manager (ADM)
* Centrifuge
* Transfer pipets/transfer tubes
* Test specific reagents/calibrators/controls (see attached spreadsheet)
* Reaction vessels
* Chemistry reagents
* IM reagents

**Specimen Collection, Preparation and Rejection:** Bioreach Specimen Collection procedure and Bioreach Specimen stability log should be used to ensure proper specific collection and preparation requirements.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test** | **Equipment** | **Bioreach Sample Type** | **Stability Room Temp (Hours)** | **Stability Ref (Days)** | **Stability Frozen (Days)** |
| ALT | Atellica | Serum | 24 | 7 | 30 |
| Alb | Atellica | Serum | 24 | 3 | 60 |
| ALP\_2c | Atellica | Serum | 8 | 7 | 100 |
| AST | Atellica | Serum | 72 | 7 | 30 |
| TBil\_2 | Atellica | Serum | 24 | 5 | 90 |
| Ca (S,P) | Atellica | Serum | 8 | 2 | 100 |
| CO2\_c | Atellica | Serum | 24 | 3 | 60 |
| CL Multisensor | Atellica | Serum | 24 | 7 | 30 |
| Crea\_2 (S,P) | Atellica | Serum | 24 | 7 | 90 |
| GluH\_3 | Atellica | Serum | 8 | 3 | No |
| K | Atellica | Serum | 24 | 7 | 30 |
| TP | Atellica | Serum | 8 | 3 | 180 |
| NA | Atellica | Serum | 24 | 7 | 30 |
| BUN\_c | Atellica | Serum | 96 | 7 | 100 |
| Dbil\_2 | Atellica | Serum | 24 | 4 | 90 |
| GGT | Atellica | Serum | 72 | 7 | 100 |
| IP | Atellica | Serum | 8 | 4 | 100 |
| Mg | Atellica | Serum | 24 | 7 | 100 |
| Uric Acid | Atellica | Serum | 96 | 5 | 180 |
| Chol\_2 | Atellica | Serum | 8 | 2 | 30 |
| CysC | Atellica | Serum | 24 | 7 | 90 |
| HDL-C | Atellica | Serum | 24 | 8 | 30 |
| LDL-C | Atellica | Serum | 24 | 5 | 14 |
| Trig\_2 | Atellica | Serum | 24 | 7 | 30 |
| Amy | Atellica | S | 24 | 7 | 100 |
| CpS | Atellica | S | 8 | 1 | 100 |
| A1c\_E | Atellica | EDTA(WB) | 48 | 7 | 100 |
| IRI | Atellica | Serum | 8 | 1 | 100 |
| Lipase | Atellica | Serum | 24 | 7 | 100 |
| PreAlb | Atellica | Serum | 8 | 2 | 100 |
| aTG | Atellica | Serum | 8 | 2 | 100 |
| PTH | Atellica | Serum | 8 | 0.3 | 30 |
| aTPO | Atellica | Serum | 8 | 2 | 100 |
| TSH | Atellica | Serum | 24 | 2 | 30 |
| FT4 | Atellica | Serum | 8 | 2 | 100 |
| T4 | Atellica | Serum | 8 | 2 | 100 |
| FT3 | Atellica | Serum | 8 | 2 | 100 |
| T3 | Atellica | Serum | 8 | 2 | 100 |
| CK\_L | Atellica | Serum | 4 | 5 | 60 |
| hsCRP | Atellica | Serum | 8 | 3 | 100 |
| HCY | Atellica | Serum | 4 | 2 | 60 |
| LDH | Atellica | Serum | 96 | 4 | 42 |
| Lp(a) | Atellica | Serum | 24 | 14 | 100 |
| Fer | Atellica | Serum | 8 | 2 | 100 |
| Fol | Atellica | Serum | 8 | 2 | 30 |
| Iron\_2 | Atellica | Serum | 96 | 7 | 60 |
| TIBC | Atellica | Serum | 96 | 7 | 60 |
| VB12 | Atellica | Serum | 8 | 2 | 100 |
| RF | Atellica | Serum | 24 | 7 | 90 |
| AFP | Atellica | Serum | 8 | 2 | 100 |
| Andro | Atellica | Serum | 24 | 31 | 100 |
| Cor | Atellica | Serum | 8 | 2 | 30 |
| DHEAS | Atellica | Serum | 4 | 6 | 30 |
| eE2 | Atellica | Serum | 20 | 2 | 100 |
| FSH | Atellica | Serum | 8 | 2 | 100 |
| hCG | Atellica | Serum | 8 | 2 | 100 |
| LH | Atellica | Serum | 8 | 2 | 100 |
| Prge | Atellica | Serum | 8 | 2 | 100 |
| Prl | Atellica | Serum | 8 | 2 | 100 |
| PSA | Atellica | Serum | 8 | 2 | 100 |
| SHBG | Atellica | Serum | 4 | 6 | 30 |
| TST II | Atellica | Serum | 48 | 7 | 100 |
| VitD | Atellica | Serum | 24 | 7 | 100 |

**Procedure:** The complete procedural instructions for each analyte are included in the most updated package inserts/IFU’s and current analyzer onboard help guide. These include detailed test specific instructions which include limitations, calibration requirements, and specifications. Complete operation instructions for CH930/IM 1300 are contained in the onboard operators guide and quick reference guides.

**General Procedure Comments:**

1. There are 3 different modules that are part of the Atellica. The CH930 chemistry analyzer, the IM1300 immunoassay analyzer and the Sample Handler module. The CH930 and the IM1300 run independently of each other. Both require the Sample Handler to be in the Running mode for operation.
2. The Atellica Main menu provides an easily accessible on-board operators guide, which is kept current. The guide should be utilized for any detailed help needed for operation and troubleshooting.
3. The PCC Screen screen provides the Atellica operator the best access to monitoring all aspects of operations on the analyzer.
4. It is imperative that the Atellica operator know which assays need calibrations, controls and when they are due. When preparing the analyzer for the weekend or holidays, make sure that all pertinent assays are calibrated and ready.

**Daily Startup/ maintenance:** Daily start up should be performed at the start of the A.M. shift.

1. Follow the guided workflow start of shift step-by-step instructions to complete daily startup maintenance.
	1. Navigate to the guided workflow guide by clicking on the “guided workflow” tile located on the main screen of the Atellica.
	2. Click the “start of shift” workflow then click launch and follow each task step-by-step.
		1. System Status: check the health of the Atellica at a glance by viewing the system status map. The system status map shows the status of each module of the Atellica. If everything is green, then you are ready for the next step. If not, troubleshoot by clicking on the areas that are not green and follow the troubleshooting steps.
		2. Maintenance: complete all maintenance that is due. Click on the maintenance tile to view the schedule.
		3. Calibrations due: prepare calibrators for all calibrations that are due.
		4. Determine Atellica needs:
			1. Check supply needs- navigate to the “Supplies Needed” tile on the main screen.
			2. Check calibrator needs- navigate to the “Calibrations Due” tile on the main screen.
			3. check reagent needs- navigate to the navigator at the bottom left of the screen, then click “reagent overview” under the Reagents to view reagent needs.
			4. check QC needs- navigate to the “QC Needs” tile on the main screen.
		5. Load all supplies, reagents, and calibrators onto the Atellica.
		6. Reagent Overview: check reagent volumes, cal status, and QC status of all reagents.
		7. Needs Intervention: This is where the samples requiring or missing something are listed. Make sure that all samples listed here have all consumables/ diluent/ ancillary packs etc… that are needed in order for the sample to run. Check the Assay Chart located in Lab Documents on the google drive to see what is needed for each assay to run.
		8. Empty Waste
			1. The waste is located under the IM side of the analyzer. Empty the cuvette trash and the pipette trash. Remember to reset the trash waste ONLY IF YOU EMPTIED THE TRASH. IF YOU DID NOT EMPTY THE TRASH, DO NOT LIE TO THE ATELLICA.
			2. Empty tip tray trash- on the IM module screen click “waste” then click “open tip tray waste drawer.” This unlocks the drawer so the tip trays can be removed. Once removed, shut the drawer and reset the tip tray counter by answering yes when the Atellica asks if it was emptied.

**Procedural guidelines:**

1. When specimens are brought to the chemistry bench, the Atellica operator needs to ensure proper specimen requirements are met. There are two different specimen types that are run on the Atellica.
	1. Serum: Most general chemistry tests
	2. EDTA whole blood: HgbA1c
2. Any specimen not meeting specimen acceptability requirements need to be placed on the “Tests not Performed” log in the Bioreach Drive. Designated individuals on log will contact the provider to inform of the test not performed and work on recollection.
3. **Modules must be in ready/ standby status for any operation to occur**
4. Samples are placed in the input lane on the left side of Atellica (closest to the PCC screen). The output lanes are the two lanes to the right side of the machine (closest to the chemistry module).
	1. Make sure that the sample bar code label is positioned smoothly on the tube.
	2. Manually programmed tests should be placed following these steps:
		1. Navigate to patient orders
		2. Scan the sample tube barcode or manually enter a sample ID
			1. Barcode scans automatically activate the entry fields. To advance to any field, select the field or select and tab on the keyboard.
		3. Select the specimen type from the specimen type list.
		4. If applicable, enter the following information:
			1. Manual dilution factor
			2. For Study checkbox- the result will transmit to the LIS only if the operator manually selects to transmit
			3. Priority-STAT samples have the highest priority, followed by ASAP samples, and then routine samples. The priority is included in information sent to the LIS
			4. More sample information (collection/ receipt date, comments, etc.)
		5. If applicable, enter patient demographics
		6. Select add tests
		7. On the Add/Edit Tests screen, select the appropriate tests and/ or panels and then select Add Tests
		8. Make any edits to the tests ordered, dilution, replicates, analyzer, or reagent lot on which the tests will be run.
		9. Select Place Order.

**Results Review**:

1. Review any exceptions noted in the run and either rerun samples or delete exceptions using the Atellica Data Manager, ADM.
2. Results are to be reviewed in Atellica Data Manager (ADM).
	1. **Result Status:**
		1. Pending (PND): Request is created and downloaded from the LIS.
		2. Rerun (RRN): Request with results has been marked for rerun.
		3. Scheduled (SCH): Request has been downloaded to the instrument.
		4. Review (REV): Test result needs to be manually reviewed.
		5. Validated (VAL): Result has been validated by the operator or automatically.
		6. Uploaded (UPL): Result has been uploaded to the LIS
		7. Omitted (OMT): Request has been omitted and will not be uploaded to the LIS.
	2. **Sample Query Browser Overview**
		1. Searching with the sample query browser:
			1. From the Command bar, select Sample Query Browser
			2. Enter or select the appropriate parameters to narrow the search
			3. Select OK
				1. Selecting OK without entering any Sample Query information displays all samples in the database; not recommended
				2. Selecting Cancel closes the Sample Query window only if an active query session is in progress
			4. Sample list displays executed query
	3. **Sample Query Browser-Right Click Menu Options**
		1. **Unschedule Requests:** Enables operators to reroute samples for which the system never receives results.
		2. **Review and Edit:** Navigates to the review and edit window for the sample selected.
		3. **Rerun:** Targets all tests in a REV status to be rerun
		4. **Upload validated results:** Uploads validated results to the LIS. Will work if at least one request is in status Validated. Partial upload of results is possible. Select the check box included, to reupload tests that have already been transmitted to the LIS.
		5. **Report:** Allows the user to print or save a PDF of the sample's detailed information.
	4. **Review and Edit**- highlight sample and right click with your mouse to review sample.
		1. **Scroll/Validate:** The Scroll/Validate button is a dual-function button that first functions as the Scroll button until operators view all requests (within the tab page) of the current sample. After operators view all requests, the Scroll button becomes the Validate button.
		2. **Rerun, Rerun All:** Rerun enables operators to submit selected tests for repeat processing and changes the status of the tests from Review to Rerun.
		3. **Revert:** Rerun enables operators to submit selected tests for repeat processing and changes the status of the tests from Review to Rerun.
		4. **View Previous:** Enables operators to view previous samples of the patient or previous runs of the sample.
		5. **Upload All:** Enables operators to Upload All visible, Validated tests to the LIS.
		6. **Audit:** On the Review and Edit window, double-select the omitted test. The Request window displays. Select the Audit tab. The test populates the Omission note field.
		7. **Request-Options Panel:** Allows operators to view omitted results. Select the play arrow to expand the Request Options panel. On the drop-down menu Status to field, select Omitted. Select Apply.
		8. **Select dropdown menu:** Enables operators to select results be status.
	5. **Review and Edit- Right Click Menu Options**
		1. Advanced Rerun: Enables operators to configure repeat testing on tests that have already been processed at least once.
		2. Edit Result Comment: Enables operators to append a coded comment (mnemonic) to a test result.
		3. **Invalidate:** Cancels Validation (must be done before result researches status of UPL)
		4. **Omit: Enables operators to Omit test requests.**
		5. **Revert:** Enables operators to revert all requests for the selected sample to their **previous result.**
		6. **View QC:** Enables operator to investigate quality control severities by navigating from the Review and Edit tab to the QC results tab.
		7. **Unschedule:** Enables operators to reroute samples for which the system never receives results.
		8. **Set target instrument:** Allows operators to specify an instrument/analyzer to process sample orders.
	6. Review and Edit- Severity
		1. (NS) Norm Severity: Value indicating the degree to which a result is out of the normal range.
		2. (DS) Delta Severity: Value indicating the failure of a delta check.
		3. (QS) QC Severity: Value indicating the violation of QC rules.
		4. (IS) Instrument Severity: Value indicating the presence of an instrument flag.
	7. Norm Severity
		1. NS +/- 1: Abnormal result; not critical
			1. Action: result auto validate by ADM
		2. NS +/- 3: Critical result
			1. Action: Review result, comments, and instrument flags; validate or rerun
		3. NS +/- 7: Result above linearity (AMR)
			1. Action: Auto-dilution, wait for second result before validating.
		4. NS +/- 9: Result > AMR X dilution factor.
			1. Action: Result as greater than the assay's linearity range. Review comments and instrument flags; validate or rerun.
		5. DS +/- 2: Failed delta check
			1. Action: Review current and previous results. Review comments and instrument flags; validate or rerun.
		6. QS 2: Failed Westgard Rule
			1. Action: Troubleshoot, rerun QC; reset method severity if QC is in range.
		7. QS 3: Failed Westgard Rule
			1. Action: Troubleshoot, rerun QC; reset method severity if QC is in range.
		8. IS 2: Flag indicates problem with result.
			1. Action: Review instrument flags and troubleshoot.
	8. Final result status in ADM
		1. After the results are reviewed and validated, the result status will automatically change from VAL to UPL and can be finalized in the StratusDX LIS system.
	9. **StratusDX- finalizing results after reviewing in ADM**
		1. Instruments: Navigate to the Instruments tab located on the left side of the StratusDX dashboard.
			1. The instrument tab divides each department into sections. Navigate between each section tab to process results.
		2. Medical Review
			1. After the results are processed in the instrument tab, finalize results in the Medical Review tab.
		3. Medical Review Sample Status
			1. The status of each patient report is listed in the Medical Review on the right. Status options include:
				1. *Final (Review)*- a report in this status is ready to be finalized after rechecking the report: toggle to the graph icon to view result report before releasing results.
				2. *Prelim (Review)*- a report in this status means that the report is missing some results. To view missing results, toggle to the manilla folder with a plus sign icon on the right of the screen to enter results. After entering missing results click “update” to save changes.
			2. Enter Results Screen
				1. In the Enter results screen, patient results can be manually entered or overridden. To finalize a report with missing values, click “Mark Final,” this changes the result report from prelim (review) to final (review). Once in final review the report can be finalized.
				2. Report comments- can be entered in the “comments” box and will be viewable to the customer on the final report.
				3. Canceling an order- can be completed by clicking “cancel order” at the bottom of the screen.
			3. To Finalize Report
				1. Navigate to Medical Review
				2. Make sure the status of the report is Final (Review)
				3. Recheck result report
				4. Check the boxes next to each patient that needs to be finalized
				5. Click “review all results,” which is the pencil and paper icon
			4. Inbox
				1. All finalized reports will be in Inbox after being released from medical review and should have a “Final” status.

**Critical Values:** Please refer to Bioreach Critical Value Policy for complete Critical value verification and reporting details.

**Calibration:**

1. All analytes must have a current calibration.
2. All calibrations must show acceptance on the calibration report.
3. QC must be performed after each calibration.
4. See Individual IFU’s located on Bioreach Share drive for calibration material definitions, number of calibrators required, procedural steps and acceptability guidelines.
5. Calibrations are performed/programmed using the analyzer interface.
6. Any failed calibration or failed QC after calibration must have proper troubleshooting performed. See Bioreach QC policy for complete details.

**Preventative Maintenance:** To ensure proper operation of Atellica, all preventative maintenance should be performed at the proper time it is needed. By selecting the maintenance tile located on the main screen of the Atellica, the schedule of all required maintenance can be viewed, performed and documented.

**Daily Maintenance**: Daily Maintenance should be performed at the beginning of dayshift. Daily Maintenance needs to be performed on both modules of the Atellica. All modules need to be placed in the Ready status in order to perform maintenance. Daily Maintenance includes:

1. IM1300 Daily Maintenance: From the Maintenance screen select i1000sr maintenance
2. CH930 Daily Maintenance: From the Maintenance screen select c4000 maintenance
	1. SH Autocheck (10 minutes): The system automatically performs autocheck on the SH.
	2. Atellica Magline Transport Autocheck (10 minutes): The system automatically performed autocheck on the Atellica Magline Transport.
	3. IMT Daily Cleaning (4 minutes): The analyzer automatically performs IMT system cleaning daily.
	4. CH Daily Maintenance (40 minutes): The analyzer automatically performs cuvette, probe, mixer, and drain cleaning and autocheck, and the reaction ring bath refreshes daily. Requires RPC 4 and WBA.
	5. Inspecting the Washer Probes: The operator manually inspects the washer probes. See online help “inspecting washer probes” for step-by-step instructions.
	6. IM Autocheck (10 minutes): The system automatically performs autocheck.
	7. IM Daily Maintenance (20 minutes): The system automatically cleans reagent probes and wash block water lines daily. Requires 30% bottle IM cleaner #9 and cuvettes.

Weekly Maintenance:

 **Chemistry Module:**

* **Chemistry Weekly Maintenance:** The Analyzer will automatically perform cuvette, probe, and mixer cleaning, autocheck, and reaction ring bath drain and refill weekly, this will take approximately 90 minutes.
* **Check Lamp coolant:** The operator manually inspects the lamp coolant level, this can be done in diagnostics, under the Lamp section.

 **Immunology Module:**

* **IM weekly Maintenance:** The system will automatically cleans reagent probes and wash block water and wash lines weekly, this approximately takes 35 minutes.
* **Cleaning the exterior of the reagent probes:** The operator manually cleans the exterior of the reagent probe by using a lint free kimwipes, IM 9, and distilled water.
* **Inspecting and Emptying the IM water trap and Dryer:** The operator manually inspects the IM dryer and water trap and removes any condensation.

Monthly Maintenance:

**Chemistry Module:**

* **Cleaning CH Fan:** The operator manually cleans the Fan filters. There is one fan located behind each module (1 total). The filter will be rinsed off with DI water and any debris will be removed, allow the filter to fully dry before putting it back, or place clean filters if multiple sets are available.
* **Inspect/clean probe wash stations:** The operator manually inspects and cleans the wash probe stations. To clean the stations use an alcohol wipe and wipe the area.
* **Inspect/clean probes and mixer impellers:** The operator manually inspects and cleans the exterior of the CH probes and mixer impellers.

**Immunology Module:**

* **Clean the exterior of the aspirate probes:** the operator manually cleans the exterior of the aspirate probes monthly to remove residue by using a lint free kimwipes, IM 9 and distilled water.
* **Cleaning IM Fan:** The operator manually cleans the Fan filters. There is one fan located behind each module (1 total). The filter will be rinsed off with DI water and any debris will be removed, allow the filter to fully dry before putting it back, or place clean filters if multiple sets are available.

As needed Maintenance:

**Note:** all procedures may be found on ONLINE help located on the Atellica, each procedure should be followed step by step to ensure the maintenance is done correctly.

 **SH Module:**

* **Cleaning the SH drawer and Racks:** The operator manually cleans the SH sampler drawers and racks with an alcohol wipe.
* **Inspecting/Replacing the SH robot Gripper O-rings:** The operator replaces the robot gripper rings, refer to online help for step to step procedure.

**Chemistry Module:**

* **Cleaning Reagent Loader:** The operator manually cleans the reagent loader
* **Cleaning system fluids drawer:** The operator manually cleans the system fluid drawers
* **Cleaning the washer probes:** The operator manually cleans the washer probes
* **Replacing the Dilution/Reaction Ring cuvette Segments:** The operator manually replaces the dilution/reaction ring cuvettes every 4 months.
* **Replacing Reagent Mixer and sample mixer Impeller:** The operator manually replaces the reagent mixer and sampler mixer impeller.
* **Replacing the Dilution Mixer impeller, probe, wash probe 1-3, reaction wash probe 1-6:** The operator manually replaces Dilution Mixer impeller, probe, wash probe 1-3, reaction wash probe 1-6.
* **Replacing the reagent probe 1 or 2 and sample probe:** The operator manually replaces reagent probe 1 or 2 and sample probe.
* **Replacing IMT Peristaltic pump tubing:** The operator manually replaces the IMT peristaltic pump tubing yearly/ 50,000 cycles.
* **Replacing the source lamp:** the operator manually replaces the source lamp based on lamp intensity.

**Immunology Module:**

* **Cleaning the IM Sample Tip Drip Tray:** The operator must inspect the sample drip tray and clean as needed.
* **Cleaning Cuvette waste Area:** The operator manually removes liners and cleans the waste bins.
* **Cleaning reagent drawer:** The operator manually cleans the reagent drawer to remove residues.
* **Cleaning reagent probe rinse stations:** the operator manually cleans the reagent probe rinse stations to remove residue with cotton free kimwipes.
* **Cleaning sample Tips waste area:** The operator manually removes liners and cleans the waste bins.
* **Cleaning system fluids Drawer:** The operator manually cleans the system fluids drawer to remove residue.
* **Replacing the reagent probes 1,2, or 3:** The operator manually replaces reagent probe 1,2, or 3.
* **Replacing the aspirate probe 1,2,3 or 4:** The operator manually replaces aspirate probe 1,2,3, or 4.

**Troubleshooting**

1. **Operator Event Log:**
	1. Displays system events as the events occur (read from the bottom up to figure out the cause of the issue)
	2. An event can be selected, the detailed information will display at the bottom of the workspace
	3. Online Help enables you to review the event, possible causes, corrective actions, and corrective action procedures.
2. **Service Support Request: T**he service support request feature can be utilized by selecting the headphone icon in the status bar.
	1. Allows the operator to contact the local technical support provider through an encrypted connection to ensure patient data privacy
	2. Can be used to ask a question, request information, or troubleshoot issues
	3. The local technical support provider will call the operator by phone or text chat
3. **Operator Diagnostics Screen:** Allows the operator to perform diagnostic activities for maintenance and troubleshooting.
4. **IMT Troubleshooting:** Allows the operator to perform IMT diagnostic activities for maintenance or troubleshooting. This DOES NOT require the operator to “Enter Diagnostics” to perform these activities.
5. **Software Lockup:**
	1. When the system displays a blue screen, wait for the display to restore. In most occurrences, the system requires 1-3 minutes to repair itself.
	2. Wait for the system to automatically complete the repairs for the full 10 minutes to avoid canceling or interrupting all patient testing.
	3. If the system does not restart after 10 minutes, the PCC automatically reboots. The system logs an event after a successful reboot.
6. **Restart the PCC: f**ollow the instructions EXACTLY in online help to perform an instrument restart.
7. **Shutting down and powering off an analyzer within the system:** follow the instructions EXACTLY in online help to perform an instrument shutdown.
8. **Full System Shutdown:** Only should be completed if suggested by service. Follow the instructions EXACTLY in online help to perform a complete system shutdown.
9. **Starting the system:**  Follow the instructions in Online Help to restart the system.
10. Call the Siemens Hotline for troubleshooting guidance 1-877-229-3711

**Resources:**

1. Online Help
2. PEP Connect

**Quality Control:** Quality Control needs to be run on each analyte per day of use. Please refer to the Analyte spreadsheet for correct QC material.

1. Any value greater than 2 sd needs to be reviewed.
2. Values greater than 2 sd should be reviewed to determine if repeat testing should be performed.
3. BioRad Unity data should be utilized for any QC troubleshooting issue and any new parallel QC implementation.

**Determining QC Needs**

1. QC Needs tile- Located on the Atellica Dashboard, The QC needs tiles provides a list of the QC materials the system requires for the operator-defined day based on the QC Schedule. The tile body displays the number or required QC materials.
2. When a QC need exists, an alert displays in the QC Needs tile on the Dashboard:
	1. Red: A QC order exists and the QC material is either not onboard, low, or expired
	2. Green: No analyzer has an immediate need for QC material
3. QC material is required if it is low, expired, or not onboard AND one of the following applies:
	1. The QC scheduler is set up to create an order before the end of the operator-defined day
	2. There is a pending QC order in the Worklist

**Printing QR Barcodes:**

1. In the search Navigator search QC definitions
2. Highlight (check) the QC and click print barcode

\*Note All samples loaded on the sample Handler require a barcode label.

**Cal-QC Storage Inventory-** is used to review the status of material stored in the CAL-QC storage area.

1. Use the Filter section to find specific QC material
2. Select the checkbox next to the QC material name to view the assays and individual expiration associated with that QC material.
3. A refrigerated space that allows for prolonged storage for up to 60 sample containers containing calibrator or QC material
4. The following types of tubes can be stored in the Cal-QC storage area:
	1. Calibrator or QC materials in 12 X 75-mm round-bottom glass or polypropylene sample containers
	2. QC materials in Sample containers provided by Bio-Rad Laboratories, Inc.

**Creating QC Orders**

1. In the system navigator, search for QC orders
2. Select the appropriate filters for the analyte that needs QC
3. Select QC material
4. click next
5. place order

**Analyzing QC results:** All QC results will be reviewed in ADM (Atellica Data Manager), please see the ADM procedure for guidance.

**Assay Limitations:**

|  |  |
| --- | --- |
| **Assay** | **Limitations** |
| A1c | (Hbf) fetal hemoglobin causes significant interference. A1c values are invalid in patients with known hereditary persistence of HbF. Hemolytic anemia, other hemolytic diseases, pregnancy or recent significant blood loss will cause false decreased HgbA1c results. DO NOT use sodium fluoride/ potassium oxalate tubes as they interfere with the assay. |
| ALB | No limitations |
| ALP | No limitations |
| ALT | Venipucture should occur prior to sulfasalazine administration due to the potential for falsely depressed results.  |
| AMY | No limitations |
| AST | Hemolyzed samples will falsely increase AST levels due to high AST levels found in RBCs. Ensure Hemolysis comment is present on report. |
| Ca | No limitations |
| Chol\_2 | Venipuncture should occur prior to N-acetyl Cysteine or Metamizole administration due to the potential for falsely depressed results  |
| CK | Hemolyzed samples cause significant interference. Ensure Hemolysis comment is present on report. |
| CO2 | No limitations |
| Creatinine | Do not use/report on grossly hemolyzed samples. Hemolysed samples will falsely increase creatinine. Ensure Hemolysis comment is present on report. Unconjugated bilirubin at 15 mg/dL fasely decreases results. Glucose at 332 mg/dL will cause falsely increases results. Total protein at 12.0 mg/dL will cause fasely increases results. |
| cysc\_2 | No limitations |
| GGT | No limitations |
| Gluc | No limitations |
| hCG | Serum samples containing heterophilic antibodies can falsely increase the result. |
| HDL | Venipuncture should occur prior to metamizole administration due to the potential for falsely depressed results.  |
| hsCRP | As with all immunoassays, there is a potential that heterophilic antibodies may interfere with this method. The presence of heterophilic antibodies could result in an anomalous result. |
| IP | Blood samples from some patients with monoclonal gammopathies (abnormal proteins in the blood) may produce falsely elevated results. |
| Iron | Do NOT use hemolyzed samples. The use of hemolyzed samples may cause a significant interference. Ensure Hemolysis comment is present on report. |
| LDH | Do not use hemolyzed samples. Ensure Hemolysis comment is present on report. To avoid falsely elevated results due to high red blood cell LD levels, separate specimens from the clot ASAP. |
| LDLC | Venipuncture should occur prior to metamizole administration due to the potential for falsely depressed results.  |
| Lip | No limitations |
| LP(a) | No limitations |
| Mg | Hemolyzed samples will falsely elevate results. Ensure Hemolysis comment is present on report. Hgb concentrations above 500 mg/dL may result in a positive bias in specimens. Hgb at 750 mg/dL falsely increases results. EDTA at 25 mg/dL falsely decreases results. Zinc at 0.5 mg/dL falsely increases results. |
| Na, K, Cl | Avoid Hemolyzed samples for potassium. Hemolyzed samples result in a falsely increases potassium result. Ensure Hemolysis comment is present on report. Iron at 1 g/dLfalsely increases the potassium result. Salicylate at 50 mg/dL falsely increases the chloride result. |
| Prealb | No limitations |
| RF | Do not use hemolyzed samples. Ensure Hemolysis comment is present on report. A hgb of 200 mg/dL may cause falsely decreased results. |
| Tbil | No limitations |
| TIBC | No limitations |
| TP | Dextran (a drug taken to expand blood volume) may cause falsely elevated results. |
| Trig | Do not use hemolyzed samples as they cause significant interference. Ensure Hemolysis comment is present on report. |
| UA | Venipuncture should occur prior to N-acetyl Cysteine or Metamizole administration due to the potential for falsely depressed results  |
| UN | Hgb at 250 mg/dL falsely inreases results. Conjugated bilirubin at 30 mg/dL falsely decreases results. |
| AFP | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| Androstenedione | Patient samples may demonstrate falsely elevated results in the presence of biotin > 500 ng/mL. |
|  | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| aTG | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| aTPO | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| DHEA-S | Patient samples may demonstrate falsely elevated results in the presence of biotin > 5 mg/day. |
|  | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| PTH | Patient samples may containheterophilic antibodies that could react in immunoassays to give falsely elevated or depressed ressults. This assay is designed to minimize heterophilic antibody interference. The Atellica IM PTH assay will detect non-intact PTH, such as PTH fragment (7-84) which may cause falsely elevated PTH results in pateints with abnormal renal function. |
| CPS | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| Ee2 | The Drug Fulvestrant (Faslodex) may cause falsely elevated estradiol results in immunoassays. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| Fer | Serum Ferritin values are elevated in the presence of the following conditions and do not reflect actual body iron stores: inflammation, significant tissue destruction, liver disease, malignancies such as acute leukemia and Hodgkin's disease, and therapy with iron supplements. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| Fol | Hemolysis significantly increases folate values in serum due to the high folate concentrations found in red blood cells. Methotrexate and leucovorin interfere with folate measurement because these drugs cross-react with folate-binding proteins. Biotin concentrations greater than 50 ng/mL may lead to falsely elevated results for patient samples.  |
| FT4 | The Anticonvulsant drug phenytoin may interfere with total and FT4 levels due to competition for TBG-binding carbamazepine. FT4 values may be decreased in patients with non-thyroidal conditions and in patients taking carbamazepine. Thyroid autoantibodies in human serum may interfere and cause falsely elevated FT4 results. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. In rare conditions associated with extreme variations in the albumin-binding capacity, such as familial dysalbuminemic hyperthyroxinemia, direct free thyroid hormone assays may yield misleading results.  |
| FT3 | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. In rare conditions associated with extreme variations in the albumin-binding capacity, such as familial dysalbuminemic hyperthyroxinemia, direct free thyroid hormone assays may yield misleading results. |
| FSH | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| HCY | Patients taking methotrexate, nicotinic acid, theophylline, nitrous oxide, or L-dopa can have falsely elevated serum or plasma HCY levels. Individuals taking S-adenosyl-methionine (anti-depressant) may show falsely elevated levels of HCY. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| IRI | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. Insulin autoantibodies in human seroum may interfere and cause discordant results.  |
| LH | Administration of gonadotropin-releaseing hormone, compiphene citrate, human menopausal gonadotropin, estorgens, or testosterone can result in elevated or depressed endogenous values. |
| PRGE | The supplement dehydroepiandrosteone (DHEA) may cause falsely elevated results. New steroid-based medications with similar chemical structures to progesterone making the possibility for cross-reactivity possible. The cross-activity can cause falsely elevated results. Patient samples may contain heterophilic antibodies that may give falsely elevated or depressed results.  |
| PRL | Pregnancy, lactation, and the administration of oral contraceptives can increase results. Patient samples may contain heterophilic antibodies that could react in immunossays to give falsely elevated or depressed results. |
| PSA | Patients undergoing prostate manipulation may show falsely elevated results. Patients wtih cancer may exhibit increased levels of PSA. Patient samples may contain heterophilic antibodies that could react and give falsely elevated results. |
| SHBG | For patients receiving therapy with a high dose of biotin (> 5 mg/day), no sample should be taken until at least 8 hrs after the last biotin administration. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| TSTII | Samples with conjugated bilirubin concentrations >15 mg/dL will cause erroneous results. Samples with unconjugated bilirubin concentrations > 20 mg/dL will cause erroneous results. DO NOT use samples from patients that are receiving nandrolone decanoate, 11B-hydroxytestosterone, and 11-keto-testosterone as a strong interaction was found. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| TSH3-UL | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. Do not use samples that contain fluorescein. Fluorescein levels > 0.24 ug/mL may decrease results in assay.  |
| ThCG | All in vitro assays can generate erroneous results. Persistent serum hCG results in the range of 10.0-100.0 MIU/mL over several months suggests the patients blood my contain interfering substances such as: Plasma components, serum proteins (rheumatoid factor), Heterophile and human anti-animal antibodies. Drugs, drug metabolites, and cross - reacting substances also may cause interference. |
| T4 | The anticonvulsant drug phenytoin may interefere with test due to competition for TBG binding sites. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| T3 | Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| VitB12 | Excessive exposure of sample to light may alter results. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |
| VitD | Do NOT use hemolyzed samples, hemolyzed samples will cause falsely depressed values. Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. |

**Proficiency Testing:**

* Proficiency test material will be obtained from an approved source
* Proficiency test material will be handled and documented in the same manner as a patient specimen
* The Laboratory Director/Designee will review all proficiency test results

**QA Measurements:** As per Bioreach Laboratory Quality Assurance policy, QC is reviewed on a monthly basis. All Quality Assurance issues are discussed at Lab Meetings and reviewed by staff and the Laboratory Director/designee.

**Quality Improvement Plan/Performance Improvement**: Repeat Chemistry/Immunoassay problems/issues should be considered as a potential Quality Improvement/Performance Improvement item. Please refer to the Bioreach Performance Improvement Policy for additional information.

**Reference:** Siemens Atellica Instructions for use Version 1.26

StratusDx Instructions for use

Bio-Rad Quality Control Unity data