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| Immulite Operating Procedure | | | | | | | |
| **Purpose** | This document provides instructions for Operation of the Siemens Immulite. Additional detail is available in the manufacturer’s [Operating Manual](file:///C:\LAB\Chemistry\Immulite%202000\I2000%20Operater's%20Guide.pdf). | | | | | | | |
| **Policy Statements** | * This procedure is intended for all Chemistry personnel responsible for testing patient samples on the Siemens Immulite analyzer. * Hours of Operation: daily from 6:30 AM until 10 PM. | | | | | | | |
| **Materials** |  | |  | |  |  | | |
|  | **Reagents** | | **Supplies** | | **Equipment** | **Media** | | |
|  | * Chemiluminescent Substrate * Probe Wash | | * Probe Cleaning Kit * Reaction Tubes (disposable) * DI H2O | | * Immulite 2000 Analyzer System: Serial number I3719 | * Daily, Weekly Immulite 2000 Maintenance Record | | |
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| **Sample** | **Collection:**  Refer to collection guidelines described in the Pre-analytic Process Procedure Manual at Children’s.  Serum (no gel) collected in red top tubes is the required sample for most tests. See individual procedures for specific sample requirements.  **Processing and Labeling:**  Centrifuge samples according to the procedure “Centrifugation of Samples” in the Pre-analytic Process Procedure Manual.  Following centrifugation, serum aliquots are transferred to properly labeled 10 x 50, 12 x 75, 13 x 75, or 16 x 75 plastic tubes for placement on the Immulite 2000.  **Volume:**  The required volume is 250 μL for dead space in addition to the volumes needed for the assays requested. Minimum required volumes are listed in each assay procedure, and the product inserts.  The Immulite 2000 can perform assays using micro sampling, requiring a minimum sample volume of 50μL in addition to the required test volumes. | | | | | | | |
| Special Safety Precautions | Refer to laboratory safety policies and procedures. | | | | | | | |
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| **Daily Maintenance** | **Step** | Action | | | | | **Related Document** | |
| 1 | Check the consumables: DI water, Substrate, Probe Wash, Reaction tubes. | | | | | Operators Guide Section 3 | |
| 2 | Empty the liquid and solid waste containers. | | | | |  | |
| 3 | Answer the Start-Up messages (2) as they appear on the monitor.   1. Would you like to delete the worklist and all the un-resulted records? (Y) 2. You may now load samples, reagents, and beads if desired. You can prime the instrument at this time. (OK) | | | | |  | |
| 4 | Prime Sample and Reagent Pipettors.   1. Instrument must be in the stop mode to open the cover 2. Select the Cover button to release the lock 3. Swivel the monitor out of the way 4. Raise the Main Cover 5. Press the green button or use the Prime button to prime the system 5-10 times. 6. Continue priming until there are no large bubbles in the DRD (Dual Resolution Dilutor) | | | | |  | |
| 5 | Prime the Water Probe and the Substrate Probe   1. Remove the Water Probe from the Bead/Tube Wash Station (the Reagent Pipettor moves away from the drain when the probe is lifted) 2. Hold the Water Probe over a flask. 3. Press and release the green prime button until there are no air bubbles in the tubing 4. Place the Water Probe back into the wash station. (Watch out for the Reagent Probe as it homes). 5. Repeat steps a-c with the Substrate Probe until there are no air bubbles in the tubing. | | | | |  | |
| 6 | Document maintenance activities on the Immulite Daily Maintenance Record stored near the instrument. | | | | |  | |
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| **Weekly Maintenance** | **Step** | Action | | | | | **Related Document** | |
|  | Refer to page 84 in the Immulite 2000 Operators Manual for the weekly maintenance procedure for Cleaning the Waste Tube. | | | | | Operators Manual pg. 84 | |
|  | Perform a Water Test to check for contamination of the source water | | | | | Operators Manual  Page 92 - 93 | |
|  | Document maintenance activities on the Immulite Maintenance Record stored near the instrument. | | | | |  | |
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| **Monthly Maintenance** | **Step** | Action | | | | | **Related Document** | |
| 1 | Refer to Section 3 in the Immulite 2000 Operators Manual for the monthly maintenance procedures listed below.   * Check the probe dispense angle of the Sample and Reagent Probes * Clean the Trackball * Clean the Fan Filter * Decontaminate the Clot Detection Transducer * Decontaminate bottles and lines * Replace Substrate | | | | | Operators Manual pg. 86  Operator’s Manual pg. 79 | |
| 2 | Document maintenance activities on the Immulite Maintenance Record stored near the instrument. | | | | |  | |
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| **Calibration** |  | Immulite 2000 assays are calibrated by the manufacturer and require an adjustment prior to use in the lab. An adjustment corrects for any variations in performance from the manufacturer’s instrument. | | | | | Operators Manual Section 4 |
|  |  | Adjustments are required when:   * A new kit is placed in use * The adjustment stability time is reached as indicated in the kit’s package insert * Quality Control fails repeatedly | | | | |  |
|  | Prepare Adjustors according to manufacturer’s instructions. | | | | |  |
|  | Remove the kit Adjustor barcode labels and label each of 2 tubes with “A” and “B” Adjustor label. Aliquot, label and store excess adjustors. | | | | |  |
|  | Transfer each Adjustor to the corresponding tube. | | | | |  |
|  | From the Home Menu, select the letter for the Sample Rack in which to load the Adjustors. | | | | |  |
|  | Open the Carousel door and pull the rack out using the finger indentations. | | | | |  |
|  | Load the Adjustor tubes in the Sample Rack with the barcodes facing outward. | | | | |  |
|  | Check samples for bubbles and splashing. | | | | |  |
|  | Slide the rack back into position and snap in place. | | | | |  |
|  | Close the Sample Carousel door. | | | | |  |
|  | Press the RUN button. | | | | |  |
|  | Once the barcodes have been scanned, select the WORKLIST button to view scanned information. | | | | |  |
|  | Enter the kit lot # in the Kit Lot # field. | | | | |  |
|  | Select ACCEPT ADJUSTOR and repeat for Adjustor “B”. | | | | |  |
| **Calibration Review** |  | Review results for acceptability once the adjustment is finished. Criteria for acceptability are:   * CV’s must be within acceptable limits for the Adjustment to be considered “Complete” * Quality Control results must be within acceptable ranges * The slope of the assay must agree within 20% of the mean slope, and 10% of previous slope for the same lot number.   The intercept must be less than the calculated mean of the instrument’s intercept. This number can be found on the Adjustment printout page. | | | | |  |
|  | If an adjustment passes the criteria, patients may be tested and results released. | | | | |  |
|  | If the adjustment fails the criteria, repeat the adjustment. If the adjustment fails a second time, consult the Technical Assistance Center. | | | | |  |
|  | Refer to the Immulite 2000 Operators Manual for a more complete description of the process, pp. 4-1 through 20. | | | | |  |
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| **Quality Control** |  | Refer to the individual assay procedures for quality control product information. | | | | |  |
|  | Load Quality Control samples in barcoded tubes in the same way as patient samples. Refer to procedural steps in the next section. | | | | |  |
|  | Assign tests to control samples:   1. Select the worklist button on the toolbar.Select the Previous or Next button to scroll to the desired control. 2. Select the TESTS button for a list of available tests. Select the tests to be run for the day. 3. Select the ACCEPT CONTROL button to save the information. The next barcode sample comes up. | | | | |  |
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| **Procedures:** | **Step** | Action | | | | | **Related Document** |
| **Operating** | 1 | Turn on the Immulite® computer monitor using the lower button on the right hand side of the monitor. | | | | |  |
| 2 | Double click the Immulite® 2000 icon found on the left side of the torques screen (diagnostics) | | | | |  |
| 3 | Touch the Run Immulite® 2000 button to begin initialization.   1. Initialization will be inhibited if doors and rotors are not seated correctly. 2. Initialization takes approximately 3 minutes. 3. All other software options are unavailable during initialization. | | | | |  |
| 4 | Perform daily maintenance. Refer to Maintenance section in this procedure. | | | | |  |
| 5 | Determine the Reagent/Bead Status (Test code, Lot number, Adjustment status, Number of tests remaining, and Wedge position are displayed)   1. Touch the red Reagent circle (home page) 2. Touch the red Bead circle (home page) 3. Determined through View Beads and Reagents on Board (tools icon) | | | | | Operators Guide Section 6 |
| 6 | Scan in 2-D barcode when loading a new kit lot number. | | | | | Operators Guide Section 4 |
| 7 | Load Reagent Wedges and Bead Packs for desired tests as needed. | | | | | Operators Guide Section 6 |
| 8 | Refer to the Calibration section in this procedure for instructions on reagent adjustments. | | | | |  |
| 9 | Load adjustors, controls, diluents, and patient samples. | | | | | Operators Guide Section 6 |
| 10 | Press the Run button to begin the sample process. (1.5 minutes to initialize) | | | | |  |
| 11 | Use the Worklist Functions button to specify which tests to run for each adjustor, control, and patient. | | | | | Operators Guide Section 7 |
| 12 | Use the Display/Edit function key of the Worklist to monitor the run status.   1. ***Waiting***- the sample is on the instrument, but the test has not started. 2. ***In-Queue***- the test is being close to being started. 3. ***No Sample***- the sample is not on the instrument 4. ***Kit Error***- there is a problem with the Bead, Reagent, or Diluent. 5. ***Sample Error-*** there is a problem with the sample (not enough or clotted) 6. ***Time*** – time remaining for the test to be completed. 7. ***Resulted***-test completed, results not sent to the LIS yet. | | | | |  |
| 13 | Add new samples   1. Lift sample lid to put the instrument into a Sample Pause. (1 minute) 2. Using the Sample Rack Detail screen select a rotor to place new samples (A-F segments) 3. Place rack back on the instrument and hit RUN 4. Go to the Worklist function and program any required fields. 5. You can monitor the run thru the Display/Edit function or the Sample Rack Detail Window. | | | | |  |
| 14 | Results will print out on the Home Screen once completed. | | | | |  |
| 15 | If results are within the reportable range, proceed to step 17. | | | | |  |
| 16 | Preparing Dilutions:   1. Appropriate dilutions are defined in the assay procedures and may be found in the instrument by selecting the KIT icon button 2. Use the proper Immulite® 2000 diluent prior to the expiration date for onboard and reflexive dilutions (AUTO) 3. Prior to use as a manual diluent the Immulite® 2000 diluent must be diluted 1 part diluent to 1.5 parts water. 4. The instrument will automatically calculate the actual concentration of the patient sample | | | | |  |
| **If** | | **Then** | | |  |
| Onboard/Auto Dilution | | 1. Place the correct diluent in a 16 x 100 mm bar-coded tube; place tube on the Sample Carousel 2. Select Worklist or Display/Edit 3. Find the patient record 4. Select the Dilution button 5. Select the assay to dilute in the Test Ordered window (highlighted blue) 6. Select the desired dilution (X5, X10, X20, X40, X100) in the Dilution Factor Window 7. Do not exceed the assay’s maximum dilution as stated in the assay procedure. 8. Select Accept Patient button 9. NOTE: Select X! button to change the dilution factor back to 1 (straight) | | | Operators Guide Section 7 |

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|  |  | **If** | | **Then** | | |  |
| Manual Dilution | | 1. Select Worklist or Display/Edit 2. Find the patient record 3. Select the Manual dilution button 4. Select the assay to dilute in the Test Ordered window (highlighted blue) 5. Type the Manual dilution 6. Select Accept Patient button 7. NOTE: Do not attempt to type in a manual dilution while the sample is IN QUE | | | Operators Guide Section 7 |
|  | **If** | | **Then** | | |  |
|  | The procedure’s maximum dilution exceeds the reportable range | | Stop making further dilutions and see Result Reporting. | | | Operators Guide Section 7 |
| **Review results** | 17 | Evaluate results of adjustments.   1. ***Controls***- controls must be within established ranges (z-score) 2. ***Slope***- slope must fall within the master slope range (0.867-1.3.01) 3. ***Slope***- slope must be within 10% of previous slope for that lot number 4. ***Intercept***- you must determine if you have a Competitive or Sandwich technique.    1. Competitive- low adjustor CPS is higher than high adjustor CPS.       1. Curve Parameter 1(kit button) times 2% equals the calculated intercept.       2. Intercept should be less than the calculated intercept.    2. Sandwich- low adjustor CPS is lower than the high adjustor CPS.       1. Master curve low adjustor CPS time 30 % equal the calculated intercept.       2. Absolute value of the intercept should be less than the calculated intercept. | | | | | Operators Guide Section 12 |
|  | 18 | Evaluate controls   1. Controls should be within previously determined acceptable ranges. 2. Report QC in Sunquest using method code IMM2 3. Use control codes C-IMM4, -IMM6 for Biorad Immunoassay Plus Control, levels 1 and 3. 4. Use control codes C-ACTH1 and ACTH2 for ACTH controls, levels 1 and 2. 5. Use the appropriate English text code for repeat tests. | | | | | [CH 2.07 Quality Control in Chemistry](http://khan.childrensmn.org/Manuals/Lab/SOP/Chem/Quality/201755.pdf) |
|  | 19 | Patient results are printed out unless hung up in Formfeed (tools icon) | | | | |  |
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| **Daily Shutdown** |  | Daily shut down of the instrument’s software.   1. Open cover and discard or store all samples 2. Shutdown the software by Logging Off (Log Off Icon) 3. Answer the question: Would you like to Log Off the Immulite® 2000 software and return to the Start-Up menu? (OK) 4. Answer the statement: You are about to delete all patient records over 62 days and control, verifier and adjustor records over 730 days. (continue) | | | | |  |
|  |  | Daily Probe Cleaning (7 minutes)   1. Double-click the Diagnostic icon on the left side of the torques screen (diagnostics) 2. Click Condensed Run Programs 3. Click Home All Motors and then Run 4. Click on Load Program 5. Click on Daily Probe Cleaning and then Run 6. Follow the prompts on the screen (place cleaning tube in appropriate spot) 7. When the program is complete, click Exit, then Quit to diagnostics. 8. Remove and discard the sample tube and remaining solution. | | | | |  |
|  |  | Restarting the software   1. Click on the windows Start button on the task bar. 2. Click Shut down. 3. Click on the Restart the Computer? Option, then click on Yes 4. Press Crtl + Alt + Delete simultaneously on the keyboard when prompted. 5. Press Enter on the keyboard at the password prompt (no password needed) 6. Turn off the power to the monitor using the lower key on the right hand side of the monitor. | | | | |  |
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| **Interpretation/ Results/ Critical Values** | Refer to the individual assay procedures for interpretive information.  Review results from the Review screen, click on “Patient” to review current results. | | | | | | | |
| **Limitations** | Heterophilic antibodies in human serum can react with the immunoglobulins included in the assay components causing interference with *in vitro* immunoassays. [See Boscato LM, Stuart MC. Heterophilic antibodies: a problem for all immunoassays. Clin Chem 1988:34:27-33.] Samples from patients routinely exposed to animals or animal serum products can demonstrate this type of interference potentially causing an anomalous result. These reagents have been formulated to minimize the risk of interference; however, potential interactions between rare sera and test components can occur. For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings. | | | | | | | |
| **Procedure Notes** | 1. The manufacturer’s procedure manual provides more detailed operating and troubleshooting information. Refer to it as needed for clarification of more complex operations. 2. Siemens Technical Service department: 1-877-229-3711, opt. 11, then opt. 3 | | | | | | | |
| Result Reporting | * Results are sent to the laboratory computer system by Selecting or Tagging all acceptable results. * Click on “Send” to release all tagged results to the LIS. * Once results are sent to the LIS, normal results will autofile with no further review. * Report results on diluted samples that are still greater than the assay range defined in each procedure, as greater than the maximum dilution factor, times the highest reportable value for the assay. | | | | | | | |
| **Computer Entry:** | OEM (online result entry)   1. In **Sunquest**, use function OEM and enter IMM2 for the Immulite 2000 method code. 2. The screen will default to the last “cup number” resulted. Enter the next cup number to continue. 3. When results are displayed on the screen, press “D” to display the previous results for comparison. 4. Press “M” to modify or remove the result (enter -), or to append a comment (- MIQ English text code.) 5. When the results are ready to be sent, press “A” to accept.  The next available result comes up for review and resulting. | | | | | | | |
|  | OEA (automated online result entry)   1. In **Sunquest**, use function OEA and enter IMM2 for the Immulite 2000 method code. 2. Press enter until the prompt ENTER CUP(S) TO BE FILED: 3. Enter a range of cups to be filed. You will see a list of the cups, the accn # and their filing status. 4. Review each cup that fails autofiling criteria.  Accept or reject, and the next failed cup presents for review | | | | | | | |
| MEM (manual result entry)   1. In Sunquest, use function MEM. 2. At the Worksheet prompt, enter IMM for the Immunoassay tests. 3. Enter patient’s accession # and results. 4. When results are displayed on the screen, press “D” to display the previous results for comparison. 5. Press “M” to modify or remove the result (enter -), or to append a comment (- MIQ English text code.) 6. When the results are ready to be sent, press “A” to accept.  The next available result comes up for review and resulting. | | | | | | | |
| **References** | 1. Siemens Immulite 2000/2500 Operator’s Manual: Document Number 600849-0001, Revision A, Version 5.xx, February 2007 2. Biorad Immunoassay Plus Control Product Insert 3. DPC End User Procedure Manual Disk #0408111; 2005 | | | | | | | |
| **Alternate Methods** | * In the event the Immulite becomes inoperable, samples may be held for up to 48 hours, with the exception of ACTH. Notify all providers of testing delay. * ACTH samples should be directed to Mayo Medical Laboratories. * In the event of prolonged instrument failure, samples should be directed to Esoterix Laboratories. * Notify Chemistry Technical Specialist and/or Medical Director | | | | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | | **Effective Date:** | **Summary of Revisions** | | |
| 1 | | L. Lichty | | 8/2001 | Replaces ACS 180:SE Operating Procedure | | |
| 2 | | L. Lichty | | 9/28/2006 | Change of quality control material | | |
| 3 | | L. Lichty | | 6/20/2007 | Revised for Autofiling | | |
| 4 | | L. Lichty/D. Helfinstine | | April 1, 2011 | New format. Deleted specific QC information. Renumbered from CH 1.01 | | |
| 5 | | L. Lichty | | January 7, 2013 | Updated, added policy statements | | |
|  | 6 | | Erin Bartos | | December 16, 2016 | Updated Daily Probe Cleaning | | |
|  | 7 | | Erin Bartos | | March 3, 2017 | Removed wedge from Daily shutdown procedure | | |
|  | 8 | | Erin Bartos | | October 4, 2017 | Changed hours of operation to Daily from 6:30am to 10pm | | |