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DIMENSION OPERATING PROCEDURE

I. PRINCIPLE

Dimension Clinical Chemistry System is a discrete, random-access clinical chemistry analyzer. It uses Siemens Flex multiple test reagent cartridges, disposable reaction cuvettes, and integrated multi-sensor technology (IMT) to provide rapid, accurate, and precise test results. The heterogeneous immunoassay (HM) module and the LOCI® module are added features for processing. The Dimension Clinical Chemistry systems are floor-model, microprocessor-controlled, integrated instrument/chemistry systems that measure a variety of analytes, including enzyme activities, in body fluids and has the ability to check for clots during sample aspiration.

II. SPECIMEN

A. The Dimension Analyzer can process serum, plasma, urine, body fluid and CSF.
B. The IMT can be used to process serum, plasma, urine or other body fluid samples.
C. Sample volume: 2 µl – 60 µl dependent upon the test performed.
D. Refer to Chemistry Summary sheet for specific volumes and sample requirements for each test.
E. Interfering Substances: Refer to Dimension Interference's Sheet

III. REAGENT

A. Reagents:
   1. All reagents are supplied by Siemens, unless otherwise noted.
   2. The reagents are stored at 2° to 8 °C until stated expiration date, unless otherwise noted.
   3. The test reagents come packaged in a Flex® reagent cartridge.
   4. No reagent prep is required.
   5. After reagent cartridge is placed on analyzer the expiration date depends on that reagent's stability.
   6. The number of days the reagent is stable on the analyzer is automatically tracked by the analyzer.
   7. Refer to Reagent Stability in this procedure for additional data on expiration dates.

B. Reagent List:
   1. Chemistry Wash:
      a. This reagent consists of HEPES Buffer.
      b. The reagent is stored at room temperature until stated expiration date.
      c. No reagent preparation is required.
      d. Indications of Possible Deterioration: Cloudiness, haze on particulate matter in reagent. Any container which is suspect should not be used.
      e. Stability: The instrument will prompt the user when this reagent needs to be replaced.
   2. Sample Probe Cleaner:
      a. This reagent consists of 2.63% Sodium Hypochlorite.
      b. Store at room temp. Caution: IRRITANT. May cause eye and skin irritation. Flush skin with water after contact. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

c. No preparation is required.
d. Indications of Possible Deterioration: Cloudiness or particulate matter in reagent. Any container which is suspect should not be used.
e. Stability: The instrument will prompt the user when this reagent needs to be replaced.

3. Reagent Probe Cleaner:
   a. Caution: Contains 0.1 N Sodium Hydroxide. May cause eye and skin irritation. Flush skin with water after contact. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.
   b. Store at room temperature.
   c. Ready to use.
   d. Indications of Possible Deterioration: Cloudiness or particulate matter in reagent.
   e. Stability: The instrument will prompt the user when this reagent needs to be replaced.
4. QuikLYTE Standard A:
   a. Contains 14.0 mmol/L of Na, 0.4 mmol/L of K, 11.3 mmol/L of Cl and 2.5mmol/L of CO_2.
   b. Store at room temperature.
   c. Ready to use.
   d. Stability: Good until stated expiration date. After opening, the reagent is good for 21 days on the analyzer. The instrument will prompt the user when this reagent needs to be replaced.
5. QuikLYTE Standard B:
   a. Contains 5.0 mmol/L of Na, 2.2 mmol/L of K, 5.0 mmol/L of Cl and 1.0 mmol/L of CO_2.
   b. Store at room temperature.
   c. Ready to use.
   d. Stability: Good until stated expiration date. After opening, the reagent is good for 21 days on the analyzer. The instrument will prompt the user when this reagent needs to be replaced.
6. Flush Solution:
   a. Contains 14.0 mmol/L of Na, 0.4 mmol/L of K, 10.6 mmol/L of Cl and 1.8 mmol/L of CO_2.
   b. Store at room temperature.
   c. Ready to use.
   d. Stability: Good until stated expiration date. After opening, the reagent is good for 21 days on the analyzer. The instrument will prompt the user when this reagent needs to be replaced.
7. Enzyme Diluent:
   a. Contains bovine albumin to be used as a diluent for patient sera with elevated enzyme activity. Not to be used to dilute samples for lipase measurement or CKMB.
   b. Store refrigerated until ready for use.
   c. To prepare:
      1) Remove vial from refrigerator.
      2) Remove stopper and volumetrically add 10.0 ml of DI Water.

3) Replace stopper and invert gently 10 times.
4) Let vials stand on bench top for 15 minutes, then invert gently 20 times.
5) Let vials stand on bench top an additional 15 minutes. Then invert 10 times and swirl gently.
6) Use immediately or refrigerate at 2-8 C.

d. Before use, allow product to come to room temp, then invert 10 times and swirl gently.
e. Stability: Good until stated expiration date before reconstitution. After reconstitution, product is stable for 7 days.
f. If visible turbidity appears, discard product.

8. Salt Bridge Solution:
   a. Contains 1.2 mol/L of KCL.
   b. Store at room temperature.
   c. Ready for use.
   d. Stability: Good until stated expiration date.
9. QuikLYTE Sample Diluent:
   a. Contains 500 ml of Buffer.
   b. Store at room temperature.
   c. Ready to use.
   d. Stability: Good until stated expiration date.
10. HM Heterogeneous Immunoassay Module Sample Diluent:
   a. Horse serum based preserved liquid, 50ml
   b. Ready for use .
   c. Store at 2 - 8^{0}C.
   d. Stability: Good until expiration date.
11. Multi 2 SDIL:
   a. Preserved liquid bovine serum albumin based product used to dilute samples that exceed AMR of LOCI module (TSHL).
   b. Ready for use.
   c. Store at 2 - 8^{0}C.
   d. Stability: Open: 30 days, unopened good until stated expiration date.

C. Non Reagent Supplies:
1. Cuvette Cartridge: Store at room temp.
2. RXL Reaction Vessels: Store at room temp.
3. QuikLYTE IMT Cartridges:
   a. Store at 2° to 8°C.
   b. Stable for 5 days or 1000 samples on the instrument.
   c. Stability: Good until stated expiration date. The instrument will prompt user when this reagent needs to be replaced.
4. Maintenance Replacement Items: Filters, tubing, etc.

IV. CALIBRATION

A. Calibrations: Calibrations are performed when:
1. Starting a new test method.
2. Any new lot number of analyte.

3. QC and troubleshooting for QC discrepancies and failures.
4. The calibration expires, usually 30 days to 90 days after initial calibration.
5. Indicated by the analyzer for calibration / verification.
6. A major part, such as the pump, photometer, or source lamp, is replaced. The procedure manual will list which analytes need to be recalibrated. See RXL Calibration Procedure for instructions and methods.

B. Calibration / Verification:
   1. A Calibration / Verification is performed at least twice a year
   2. The calibrators are supplied by Siemens.

C. AMR (Analytical Measurement Range):
   1. AMR is verified at least twice a year with Siemens reagent calibrations, the CAP Calibration / Linearity survey, Bio-Rad Linearity Kit for HB1C,or Main Standards Kits for IMT linearity.
   2. These AMR Verifications are recorded on the Calibration Sheet and are reviewed and signed by a supervisor.
   3. If using our reagent calibration for AMR, refer to the Calibration Sheet for acceptability criteria. If using the CAP Calibration / Linearity survey, use CAP's acceptability criteria for evaluation.

V. QUALITY CONTROL

A. Quality Control (QC) is run every 24 hours for the analytes being tested within this time frame. See RXL QC Procedure for instructions and specific QC material used.

VI. PROCEDURE:

A. REAGENT LOADING:
   1. Reagent Cartridge Inventory:
      a. The Reagent Cartridge Inventory contains all the information for each Flex reagent cartridge currently in the reagent tray.
      b. To access the Reagent cartridge inventory, PRESS F4: SYSTEM PREP in the Operating menu Screen and F1: INVENTORY or use ALT/I key combination.
      c. Using the Reagent Cartridge Inventory screen, press a test key on the keyboard to move to that method in the listing.
      d. PRESS F1: INVENTORY or use the ALT/I key combination the following information is shown for each reagent cartridge.
         1) Method: Method name abbreviation.
         2) Lot Number: The six character manufacturing lot number found in the barcode label on the reagent cartridge.
         3) Sequence #: The five digit number for each cartridge found in the barcode label on the reagent cartridge.
         4) Tests Left: The number of test equivalents of reagent remaining in the cartridge.

5) Calib Exp Date: The date that the calibration for that lot expires.
6) System Exp Date: The date after which the cartridge will not be used by the system and must be discarded (on board stability outdate).
7) In Use: The cartridge is currently being hydrated or is being used by the system to process a test.
8) Note: Also posted on the reagent inventory screen is a reagent manager icon with the number of open slots available for use.

2. Front Loading Reagent Cartridges
   a. Reagent cartridges can be placed into the instrument using the automatic loader on the front of the analyzer. Place the reagent cartridge in the loader with the narrow end of the flex facing into the analyzer. The Dimension will read the information on the bar code label and then move the cartridge in to the reagent tray.
   b. Warning: Do not add any reagent cartridge that has exceeded its on-system expiration date or has exceeded its shelf life date.
3. Loading Reagent Cartridges on the RMS (Reagent Management System)
   a. Reagent cartridges are placed onto the load tray. The load tray can hold 18 cartridges.
   b. Press the "Flex Load" key which is located on the front of the load tray.
   c. The cartridges are pushed onto the elevator and the bar code is read.
   d. The elevator lowers the reagent cartridges from the load tray to the turntable which moves the cartridges from place to place within the RMS.
4. Adding a 3rd lot number of a method. The analyzer can only hold a maximum of two lots for a method. The third lot is found under HOLD. You will need to go into the inventory 3rd lots screen to replace one of the other lots:
   a. F4: System Prep>F1:Inventory> F1: Show Hold> F1: Show 3rd Lot.
   b. Move cursor to reagent lot Press F1: Replace Lot.
   c. This permanently removes a previous lot – "New lot would replace calibrated lot. Do you approve?" Press "y" to confirm removal or "n" if you do not want to replace this lot.
5. Loading IMT Reagents From the Operating Menu:
   a. Press F4: SYSTEM PREP
   b. Press F3: IMT
   c. Press F1: CHANGE CONSUM
   d. Press any of the function keys to replace the reagent associated with any given function key. Enter the lot number of the reagent on the screen.
   e. Press F8: STORE CHANGES

B. REMOVING REAGENT CARTRIDGES:
1. RMS Removal - Automatic Mode
   a. Empty or expired reagent cartridges are removed from the system and deposited into the RMS waste container.

b. The Dimension® system tracks the number of cartridges in the waste and will indicate when to empty the waste container.
c. Empty the RMS Waste container into Hazardous waste.
d. Indicate in the Dimension® the waste is empty by:
e. Going to the Operator Menu and press:
F4: System Prep
F6: Sys Counters
F7: RMS Counters
Highlight Flexes in Waste box on right
Enter
F1: Store Changes

2. Front Flex loader (light is blinking): Automatic Mode
   a. Remove the cartridge from the loader
   b. Place flex into Hazardous waste.
3. Manual Mode:
   a. To remove a specific reagent cartridge,
      1) Go to the Inventory Screen (ALT I), move the cursor to the cartridge to be removed
      2) Press F3: REMOVE REAG.
      3) When the red loader light begins blinking, remove the reagent cartridge from the loader.
      4) Press F1: CONFIRM REMOVE
   b. To remove all empty cartridges
      1) Press F7: REMOVE ZERO'D.
      2) Remove the empty reagent cartridges from the instrument as they are removed from the reagent tray.
   c. To remove all reagent cartridges
      1) Press F8: REMOVE ALL.
      2) Remove the reagent cartridges from the loader as they are removed from the reagent tray.
4. Removing old lots and their Calibrations:
   a. From the Operating Menu:, Press F5:PROCESS CONTROL
   b. Press F1: CALIBRATION
   c. Press F1: STATUS LIST
   d. Press F2: OFFBOARD LOTS
   e. Select the lot you want to permanently remove from the instrument memory and move the cursor to that lot number
   f. Press F3: DELETE and y for Yes to confirm deletion. Be sure to check method lot number first. The calibration will be deleted.
   g. Repeat this step for each lot to be removed from the instrument memory.

C. TESTING: SAMPLE SET-UP :

1. Preparing Samples:
    a. Whichever type of sample container is used, ensure that the sample quality is acceptable for processing before loading it into a segment.
    b. The sample should be free of clots, fibrin strands, and other impurities that may affect metering fluids through the instrument.
    c. There should be no air bubbles in the sample container.
2. Types of Containers
    a. The following types of sample containers can be used on the Dimension:
        1) Sample cups with lids
        2) SSC containers, (small sample cup containers).
        3) Uncapped 5-ml, 7-ml, and 10-ml sample tubes
        4) Pediatric tubes of various sizes and capacities.
    b. Label secondary containers such as sample cups or SSC's that are used for short volume and diluted specimens with the patient's initials, the last four numbers of the accession number or patient's DOB. Be sure to verify patient identifiers on the aliquot label to the original tube information.
    c. The Mode on the EXL/RXL must specify "sample cup" or "SSC" for correct depth sampling of the specimen when put into these containers..
    d. Using Sample Cups:
        1) When using sample cups, snap the lid on the sample cup down securely so it does not interfere with the sample probe.
        2) Ensure that prior to processing a sample cup, sufficient sample is present in the cup to allow for any possible automatic rerun of tests from that sample cup.
        3) Sample cups must be placed into an adapter to load them into a segment.
        4) Push the sample cup completely down onto the adapter.
        5) The Siemens sample cup will hold a maximum of 1.5 ml of sample with a dead volume of 50ul.
    e. Using Primary Sample Tubes:
        1) When using primary sample tubes and pediatric tubes, use an appropriate adapter, if necessary, to load the tube into the sample area.
        2) The sample probe maximum depth alignment was performed for each type of tube used.
    f. Using SSC (Small Sample Containers)
        1) The SSC allows the operator to run short samples in bar-coded tubes.
        2) The SSC should be used when a short sample is detected in a sample tube which is bar-coded.
        3) The SSC will hold a maximum of 1 ml of sample with a dead volume of 50 µl.

4) The SSC must be placed on a barcoded sample tube and be labeled.

3. Sample Volume Required for Processing
   a. The Dimension determines whether there is enough volume of fluid in the container to process the tests requested by performing a "level sense" on sample tubes.
   b. Only a "level detect" for the presence of sample is performed on sample cups and SSC containers
   c. Neither a "level detect" or a "level sense" is performed when the Limited Cup-No Level Sense mode is selected.
   d. If there is not enough fluid present, the short sample icon will appear.
   e. The short sample situation must be resolved before the sample will be processed.
   f. Warning: If there is no sample in the sample cup after processing is complete, the test results must be carefully reviewed to determine if test results are reportable. To help determine which results are valid, view the test results in their sampled order sequence.
      1) Go to the test results screen for that sample and
      2) Press F7: SMP ON/OFF until a message appears that indicates that the order of the tests on the screen is the sampled order.
      3) Tests at the top of this screen were processed first.
         Tests at the bottom of the screen were processed last.
      4) There may or may not be a test report message associated with an erroneous result from short-sample problems.
      5) Retest any methods that could be short sampled (QNS) to obtain accurate results.

D. LIS LOADLIST BI-DIRECTIONAL FROM INTERFACE
   1. With the Sunquest Interface, the LIS system will automatically download all patient demographics and test requests to the Dimension for the barcode on the tube.
   2. After the specimen has been collected and received, place the bar-coded sample in a segmented carrier and place on the instrument.
   3. Press RUN.
   4. The instrument should read the bar-code and process the test(s).
   5. Patient with multiples tests may have multiple accession barcodes. Check the labels carefully.
   6. If the instrument cannot read the barcode label or if the interface is down, manually order the test(s).

E. Manual Order Testing: For certain test methods, specimen types or when the LIS is not interfaced (downtimes), manual ordering may be used.
   1. From the operating menu press F1: ENTER DATA. Using the ENTER DATA screen, enter the information in the following operator-assigned fields.

a. Position -- Enter the segment letter and position
b. Patient Name -- Enter the patient name
c. Sample # -- Enter the barcode # (CID#)
d. Tests -- Use the test keys or panel keys

2. Check the information in the following fields. If necessary, change the information as shown.
   a. Mode -- F7: Next Mode
   b. Priority -- F4: Next Priority
   c. Fluid -- F8: Next Fluid
   d. Dilution (optional) – keyboard
   e. Location (optional) – keyboard
3. Press F1: NEW SAMPLE to confirm the sample information and open fields for the next entry.
4. Repeat steps 1 to 3 to enter more samples.
5. When the last sample is entered, press the LOADLIST function key to ensure that the sample(s) entered will be run.
6. Other Fluids:
   a. All Body Fluid Tests: (Thoracentesis, Abdominal, etc.). Unless otherwise specified should be tested using Serum as NEXT FLUID choice.
   b. Hb1C testing is tested using the SSC Mode and CSF/Blood for the Fluid.
   c. Urine Tests: When the urine mode is chosen some analytes, will be subjected to dilution using a preset factor, prior to analysis. The results are pre-calculated and final unless accompanied by an error flag. Refer to the Dilution chart in the Dimension Procedure Manual.
7. Dilutions:
   a. The dilution field identifies the dilution factor for a manual dilution. It is used to correct the result calculation; so that the printed result is the final answer, providing the linear range of the assay is not exceeded.
   b. When a dilution factor is entered, that sample will not be auto-diluted by the instrument. Refer to the AMR/CRR Dilutions Table in this manual for diluents, dilution factors, and Clinically Reportable Range used.
   c. When manually programming a diluted sample on the analyzer, do not use the original CID number for the sample ID. Techs should double check the result before it goes across the interface.

F. Loading Samples:
1. Ensure that any lids on sample cups are snapped down completely and that all stoppers have been removed from the sample tubes.
2. Ensure that the correct sample container is loaded in the correct segment.

3. Primary tube containers must be loaded in the correct segments with the barcode labels positioned so that the barcode is visible in the opening of the segment. This allows the barcode scanner to read the barcode.
4. SSC containers must be loaded in the yellow or orange colored segments with the barcode label also positioned so that the barcode is visible in the opening of the segment and can be read by the barcode scanners.
5. Sample cups must be loaded in segments that have the proper adaptor.
6. The sample container must be completely seated in its segment position.
7. Do not load samples/segments into the sample area if:
    a. The segment's status box is red in color.
    b. The moving wheel light is it.
    c. The message "Moving Wheel" is in the photometric sampler status box.
8. Place the segments in the sample area.

G. Processing Samples:
1. When the samples, (Bar-coded & Non-bar-coded) in their proper sample container and correct segments have been loaded into the sample area, begin processing by selecting the appropriate option below. Samples that have had their sample information downloaded to the Dimension will be run when the instrument reads the bar code during a scanning of the sample segments.
2. To start the testing, select any of the three options below.
    a. Press F2: PROCESS SINGLE if you are processing a single sample from the Enter Sample Data screen.
    b. Press F4: RUN if you are processing a group of samples from the load list screen.
    c. Press the RUN key.

H. Adding Samples While the System is processing
1. While the instrument is processing, you can load additional ordered barcoded sample containers into any segment open positions. Do not switch tubes in a given segment position.
2. You can also load segments into empty segment areas or any segment position that has a green "finished" status box by removing that segment and inserting the new segment in its place.
3. Press the RUN key after adding samples and/or segments.

I. System Needs
1. Before the system begins processing samples, it checks to see if it needs any reagents or supplies, or needs any process control functions to be performed. System needs include:
    a. Adding reagent cartridges
    b. IMT consumables
    c. Cuvette film cartridge
    d. Calibration/Verification on Photometric methods and the IMT system

e. Quality control

2. If no system needs are required, the system will begin processing.
3. If system needs are required, the Check Needs icon turns red.
4. Satisfy the system needs listed or choose to ignore these needs.
5. If you choose to ignore system needs, tests that require those needs will not be processed. Tests will still be processed and reported if you ignore QC needs, but QC must be run and acceptable before patient results may be reported.
6. When the Check Needs icon is red, press the ALT/N key combination to go directly to the System Needs screen.
7. To fill a specific need, press its function key to see a list of what is needed.
8. If after filling a system need, other system needs are still required, the System Needs screen will reappear and allow you to press another function key and fill another need.
9. If no additional system needs are required, the system will begin processing the samples.

J. Resolving a Short Sample Detected:
   1. When the short sample icon appears the instrument will also sound its alarm. This indicates that there is not enough sample in the sample container to perform all the tests requested.
   2. Go to the Load list screen and press F2: NEXT SAMPLE STATUS to change the status to Short Samples and see a list of the samples that do not have enough fluid. You may choose any of the following four options to rectify the problem.
      a. Add more of the same sample to the sample container.
      b. Reduce the number of tests on the sample.
      c. Transfer the sample to a smaller sample container (SSC)
      d. If the sample is already in a sample cup, change the mode to Limited Cup-No Level Sense.
   3. Follow the following steps to resolve the short sample situation:
      a. Tube (with bar code):
         1) Transfer the sample into an SSC.
         2) Place the SSC on top of the same tube
         3) Place the tube in the same segment position.
         4) Press F6: CHANGE TO SSC and say Y to prompt.
      b. Sample Cup: Press F7: NO LEVEL/CUP and answer the prompt that appears with a "Y". This sample cup will be changed to the Limited Cup-no level sense mode.
      c. Limited Cup: There is nothing you can do to this sample except add more sample or reduce tests.
   4. When you have resolved all short samples, press F4: RUN or the Run Key.

K. Resolving a Clot Check message:
   1. The clot check feature detects a clotted sample, flushes it down the IMT port drain and performs a clot check recovery sequence.

2. Follow the ALT/M troubleshooting steps in the Dimension software for the error codes and suggested action. There are five codes included in the clot check function. The instrument attempts an automatic recovery and if this does not correct the issue, the operator must perform further action.
3. Once the clot check issue is resolved the sample should be retested.
4. If the clot check transducer board has failed, the transducer can be bypassed until the Field Service Representative arrives to replace it. See "Installing Clot Bypass Sample Tubing" procedure in the Clot Check supplement book.

L. Determining the Status of Samples:
   1. The Sample Status program enables you to check the progress of samples through the instrument. There are three screens that allow you to determine the status of your samples and segments:
      a. Sample Status
      b. Segment Status On Board
      c. Segment Status All
   2. Sample Status Screen:
      a. The Sample Status Screen can contain the last 500 sample requests entered into instrument memory. A sample appears on this screen until it is automatically discarded when the 500 sample or 5000-test result limits is exceeded, whichever occurs first. When the list is full, samples are discarded on a first-in, first-out basis.
      b. Viewing Sample Status From the Sample Status screen, check that the sample status category you want to view appears in the brackets in the upper right-hand corner of the screen. If this is not the status category you want to view, press F2: NEXT STATUS until the status category desired appears. The Status and meaning are as follows:
         1) Entered: This sample's data has been entered into the load list, but you have not requested the system to run this sample yet. This sample's data can still be edited before processing.
         2) Ready: This sample's data has been entered into a loadlist, the sample has been loaded into the sample area, and the system was asked to run this sample. This sample's data can still be edited before processing.
         3) Begun: The system has begun to process tests for the sample; some test results may be available. You can see any completed tests by moving the cursor to the sample and pressing F8: TEST RESULTS. Additional tests can be added to the sample even though processing has already begun.
         4) Done: All tests for the sample have been processed; all test results are available. You can see these results by moving the cursor to the samples and pressing F8: TEST RESULTS. This sample can

be edited and rerun, if the sample segment has not been moved or removed.

5) Printed: All tests for the sample have been processed; all test results have been sent to the printer. This sample can be edited and rerun, if the sample has not been moved or removed.
6) Report: All tests for the sample have been processed; all test results have been sent to LIS. This sample can be edited and rerun if the sample has not been moved or removed.
7) All: This is a comprehensive list of all samples currently in instrument memory.

3. Segment Status - On Board Segments:
   a. You can view the position assignments status of segments appearing in the segment status area of the screen by selected F8 Segment Status from the operating menu or by pressing the ALT/S key combination at any time.
      1) One can view the processing status of segment positions for all segments at any time by pressing the ALT/S key combination and then pressing F1: SEE ALL.
      2) Check the option keys.
   b. The On Board Segments screen shows each segment position and the sample ID of the sample that is assigned to that position. The segment ID uses the information in the sample number field from the sample's Enter Sample Data screen.
   c. If the words NO DATA appear in a field, there isn't data available either in system memory or from the LIS for this sample.
4. Segment Status – All:
   a. One can view the processing status of segment positions for all segments at any time by pressing the ALT/S key combination and then pressing F!: SEE ALL. Check the option keys.
   b. Use F1: On Board to go back to the On Board segments.
   c. Use F3: DELETE SEG to clear segments by entering its letter or by entering an asterisk for all on board segments or by entering an exclamation point for all segments.
   d. Use F4: DELETE SAMPLE to delete individual samples from the segment. Just press F4 and follow the prompts.
   e. Meaning of letters used for status of sample.

B	**BEGUN**
D	**DONE**
E	**ENTERED**
R	**READY**

R	**REPORTED**
P	**PRINTED**

M. Alert keys on the touchscreen: The five Alert Keys on the touchscreen can change color to warn you of operating conditions requiring a quick response.
   1. STAT Status: This status key can inform the operator of two important and useful options. Touch the STAT key and the amount of test time remaining will be displayed next to the patient name. The alert key turns red to inform the operator of processing errors on the sample.
   2. Sample Alert: The Sample Alert key lets the operator know if a specimen is rerunning because of a processing error. Touch the Sample Alert key to find the patient name, Sample ID, position, reason for rerunning, method, and amount of time the sample will be available in.
   3. Supplies: The Supplies Alert key turns yellow when the available number of tests on the instrument reaches the 'Alert At' number. This number is pre-set to allow the operator the option of when to retrieve another flex. Touch the alert key to determine which test method flexes to obtain.
   4. QC Alert: The QC Alert appears yellow when a QC result is out of range or if QC is expired or will expire in 30 minutes. Touching the QC Alert key will inform the operator to see the method(s) affected.
   5. Calibration Alert: The Calibration alert key changes color when a calibrated lot number approaches or reaches its expiration date. When the Calib Alert key is yellow, press it to display the Calibration Alert screen. This will tell you the method, lot number and the amount of time before the calibration expires. You can also perform several tasks from this screen by pressing the appropriate function key, such as Set Up and Run, Calibration Review, Grouping cals (this groups methods by the Calibration Product), Configuring the alerts, and Defining a Calibration Product.

VII. CALCULATION:

A. No calculations are required except when a sample is manually diluted.
B. The printed result must be multiplied by the appropriate dilution factor and results manually entered in LIS. Do not use the original CID number when programming diluted specimens on the analyzer. Techs should verify the result instead of letting it autoverify.
C. If the dilution factor was entered in the analyzer prior to running the test, the printed result is final and the result in collation can be used as is, if there are no test messages attached.
D. Special Calculations:

A/G Ratio =	Albumin divided by (TP-ALB)
AGAP =	Na - (Cl + Carb)
IBIL =	TBil - Dbil

LDL = [Chol - (HDL + VLDL)]
VLDL = Trig/5
%SAT = IRON/IBCT X 100

E. These special calculations are on line in the LIS.
F. If LIS fails, these formulas may be used to calculate the above parameters.

VIII. REPORTING RESULTS

A. Reviewing Results:
   1. Reportable Test Results:
      a. Test results which contain Hi, Lo, or Diluted test report messages may be reported.
      b. Results with any other message must not be reported until the message is investigated.
      c. Critical or panic test results are not automatically repeated by the chemistry analyzer. Be sure to check the sample and analyzer for errors.
   2. Test Report Messages:
      a. See "Understanding Test Report Messages" in the Operator Guide for information on messages and what action to be taken.
      b. Above Assay range, HIL interference, abnormal assay and other messages will keep sample results from autovalidation in the LIS. These issues must be addressed with the sample and the result status in the computer by the tech.
      c. Dilutions:
         1) The dilution field identifies the dilution factor for a manual dilution. It is used to correct the result calculation; so that the printed result is the final answer, providing the linear range of the assay is not exceeded. Do not use the original CID number for the sample.
         2) When a dilution factor is entered, that sample will not be auto-diluted by the instrument. Refer to the AMR/CRR Dilutions Table in this manual for diluents, dilution factors, and Clinically Reportable Range used.
      d. Below assay range messages will be resolved after these points have been addressed:
         1) Does the sample have sufficient usable sample?
         2) Was the sample placed in the appropriate segment and cup position?
         3) Is the instrument functioning appropriately?
         4) Is the result consistent with the clinical information?
         5) Is the result consistent with prior tests?

6) If the questions are yes, no further testing is required and results may be turned out with the appropriate linear range values.

e. HBIC error messages: View error messages by selecting Sample Status(F2), scroll to patient and choose Test Results (F3). At the bottom of the screen there will be a yellow area that will indicate the parameter with the flag (ie. HB, HbA1c , or HbA1c%).

1) HB1C: Glycosylated Hemoglobin, Assay Range Flag. If the instrument throws an assay range flag, perform a 1:2 dilution with CLR water. Do NOT use a dilution factor because the instrument measures % of Hemoglobin B1C to total red cells.

2) HB1C: Glycoslyted Hemoglobin, Abnormal Assay Flag. If the instrument throws an abnormal assay flag (due to increased lipemia), perform a plasma replacement with CLR water. Do NOT use a dilution factor because the instrument measures % of Hemoglobin B1C to total red cells.

3. Analyzer troubleshooting issues must be resolved before reporting patient results. If you need assistance call Siemens Technical Solutions Center at 1-800-441-9250 and enter the Functional Location number for the analyzer. The Functional Location number is found on the analyzer screen. Complete a Troubleshooting document (UPPK RXL-0308.01) for each issue for the lead to review. See Chemistry Anayzer Troubleshooting Guide"

B. LIS Procedure:

1. Refer to UPPK-LIS 0627 Result Entry in Sunquest
2. Refer to UPPK GEN 0257 Result Review, Verification and Correction Policy.
3. Refer to UPPK GEN 0621 Detection and Correction of Errors.

IX. LINEAR RANGE:

A. For Analytical Measurement Range and Clinically Reportable Range and to dilute, follow UPPK-CH-0567 AMR and Maximum Dilution policy and chart.

X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. For Hemolysis, Icterus & Lipemia (HIL): Refer to UPPK-RXL-0488 HIL Evaluation.
B. For non HIL Interfering Substances on the Dimension, refer to the Product Insert Sheet.

XI. REFERENCES

A. Siemens Dimension RXL Clinical Chemistry System, Operators Guide SIEMENS International Inc., Newark, DE, 19714.
B. Siemens Dimension RXL/EXL Method Sheets SIEMENS International Inc., Newark, DE, 19714.

C. Bio-Rad Liquichek Cardiac Markers Control Instruction Sheet, Bio-Rad Laboratories, Irvine, CA 92618
D. Bio-Rad Liquichek Urine Chem Control Instruction Sheet, Bio-Rad Laboratories, Irvine, CA 92618
E. Bio-Rad Liquichek Ethanol/Ammonia Control Instruction Sheet,Bio-Rad, Irvine CA 92618
F. Bio-Rad Liquichek Multiqual Instruction Sheet,Bio-Rad, Irvine, CA 92618)
G. Bio-Rad Lyphochek Immunology Plus Control, Bio-Rad, Irvine , CA 92618.
H. Bio-Rad Liquichek Immunoassay Plus Control Instruction Sheet, Bio-Rad, Irvine CA 92618.
I. Bio-Rad Lyphochek Diabetes Control Instruction Sheet, Irvine, CA 92618.
J. Bio-Rad Liquichek Spinal Fluid Control Instruction sheet, Bio-Rad, Irvine CA 92618.

POLICY CREATION :		***Date***
Author:	***Steve Watkins, MT (ASCP)***	***07/01/1999***
Medical Director:	***Kathryn O. Kramer, MD***	***07/01/1999***

MEDICAL DIRECTOR		
DATE		SIGNATURE
4/02/19	Lori Ruesch, DO	

1	Reporting Below assay range results, Resolving clot check message, SQ infor	Suzanne Behle	03/27/19