Beckman Coulter
Remisol Middleware **Technical Procedure #1530.t**

Purpose

The Beckman Coulter Remisol Data Manager collects and manages data and workflow for the three LH780 instruments and the two ACL TOP analyzers. It also connects to the host LIS system. It provides data management capabilities such as automatic results validation, delta checking, results editing, and archiving and restoring of patient results and scatterplots. In addition the Hematology Remisol contains a diffpad to perform manual or scan differentials and morphology reporting directly into the Remisol software allowing for alternate storage of the complete CBC report. Because of these storage capabilities previous results for each patient will be displayed alongside current results allowing for easy "look back" functions for previous samples.

Systems Description

A. Remisol Menus

1 Environment: contains the setup functions and some maintenance for the Remisol. Only a few choices need to be accessed for troubleshooting purposes. The remainder of functions contain information and instructions only to be accessed by setup operators.

   a. Instrument setup: For each instrument (LH780-1-Shemp, LH780-2-Moe, LH780-3-Larry, ACL TOP-1, ACL TOP-2, Cellavision and DIFFPAD) the baud rates and data bits etc are set. For transmission and communication to occur the "not connected" box must be unchecked.
   b. Host Setup: The interface type must be set on "ASTMH" for proper transmission to occur. Again the "not connected" box must be unchecked.
   c. Reset Communications: Instrument (LH780-1, LH780-2, LH780-3, ACL TOP-1, ACL TOP-2, Cellavision and Diffpad) and interface (ASTMH) communication can be reset from this screen.
   d. Communication Event Log: This is the only screen added to the desktop display from the environment menu. Click on communication event log to add it to the display screen.

2 Desk: The Desk menu contains functions for creating and working with patient requests and samples currently being processed. This menu is used to add lists to the desktop instead of icons.

3 Archives: The Archives menu contains functions for archiving current patient requests and searching for previous samples. Archived requests are available for viewing, printing, and comparing to current requests, but cannot be modified.

4 Configuration: The Configuration menu contains functions for configuring parameters, profiles, comments, writing rules, etc. Nothing is done in this menu on a routine basis.
5 Quality Control, Window, and Keyboard are not used at this time.
6 Help: contains the help information and the information on the software version etc.

B. Remisol Icons

1. Sample List: Is added to the desktop with this icon and contains sample information for samples to be run or rerun: Patient ID, Name, Medical Record etc. Four tabs sort results into All Heme, All Coag, Rerun Heme (samples retrieved from the stockyard for reruns on instrument, Batch Coag (those samples with extra tests). The following flags may be seen.
    a. The test tube will be red for STATs.
    b. Symbol in first column
        i. ?: No response from instrument
        ii. T: Downloaded
        iii. B: Instrument is busy
        iv. E: Transmission error occurred
    c. Symbol in second column
        v. R: Result received from instrument
    d. Symbol in third column
        vi. P: Awaiting rerun results from instrument
        vii. R: Rerun results received from instrument
    e. Symbol in fourth column
        viii. M: Sample id changed manually
    f. Sample List must be cleared daily of excess samples including those run at the Cancer Center.

2 Request List: The results list is added to the desktop with this icon and contains a list samples that have been run: the results, a number of flags, sample ID, patient name and medical record number, order location, and cassette position. The patient results are sorted under eleven tabs (on the Command Central station computer) and are from left to right: 1) Held Heme- these are samples that failed to pass all of the rules that were not autovalidated and must be dealt with. 2) Uploaded Heme-those samples that autovalidated completely and will be automatically archived and disappear automatically within 10 seconds. 3) Running Coag-Those coags running on the analyzers or downloaded to a particular analyzer. 4) Problem Coags-those coags that failed to pass all of the rules which do not autovalidate and must be dealt with. Note: Maintenance overdue on the ACL TOP's is an error that will cause the failure of autovalidation until maintenance is done and the

error is cleared. All batched tests will go to the problem coag tab for manual validation. 5) Uploaded Coags-those coags autovalidated by the Remisol. These samples will automatically archive after 10 seconds and disappear. 6) Tagged- Those samples tagged manually by the operator are held in this tab. Samples must be tagged AND saved in order to be stored in this area. 7) Slide review- those samples which require slide review for manual or scan diffs, platelet flags, cellular interference flags etc. Operators performing differentials will utilize this tab. 8) All Heme- all heme samples that have not been archived will appear under this tab. Samples may not archive due to lack of matching barcode ID, partial validation, or other reasons. 9) STAT- all Hemo samples requested as STAT will be contained in this tab. 10) All Coag samples that have not been archived will appear under this tab. Samples may not archive due to lack of matching barcode ID, partial validation, or other reasons. 11) Cellavision- every sample that has been placed on the Cellavision with a readable barcode will show under this tab to separate them from the main slide review list. The other work stations will show different combinations of tabs depending on their position and function in the lab.

a. Symbols in the request list include:
   i. Symbol in first column
      a) S=STAT
   ii. Symbol in second column
      a) O=Out of Validation Range
   iii. Symbol in third column
      a) P=Pending
      b) C=Complete
   iv. Symbol in fourth column
      a) R=Received and not opened for review yet. These samples must be dealt with (even if it is just tagged for later) before closing the screen as the sample will be removed from the Held Heme tab once opened regardless of which tab it is originally opened from.

3 Previous Results Icon: Searches in archived samples for previous results and stored scatterplots.
4 Search Function finds previous results in archived samples.
5 View previous and next sample icons display request list in sequence.
6 Thumbs up (or down) validates or invalidates a sample manually and sends results to LIS.

7 Host transmission Icon transmits data to host (LIS) computer.
8 Microscope Icon opens the diffpad to perform manual differentials and enter morphology.

Using the Remisol for Hematology

A. To look at an individual sample double click on the desired sample in the request list. There are three sections to each report:

1 Patient demographic and Scatterplot column: Displays the histograms and scatterplots on one tab for Hematology samples and patient demographic information on the second tab.
2 The Comments section or middle column: All instrument suspect flags, comments and Remisol generated rule flags and conditions will be displayed here. Any morphology added at the diffpad or on Cellavision will also be displayed here.
3 Parameter column or third column: Displays the parameter name followed by the numeric values for each sample. A code column follows which shows calculated values (C), manual entry (M), delta checks (X) etc. Lastly previous results for each patient will be displayed with the most recent displayed on the left.

B. To manually validate results on the Remisol:

1 Highlight the results to be validated by clicking on the result(s) you wish to validate (i.e. the red cell parameters on a cellular interference flag, or the blood count on a problem diff, etc.).
2 Hit the "thumbs up" button.
3 To validate an entire sample, click on the date and time button on top to highlight everything and then the thumbs up button.
4 Results will transmit to LIS and an "H" (sent to host) will appear to the right of the "v" symbol.

C. To manually rerun and edit a sample (Lipemic/Icteric cold agglutinin, corrections, etc):

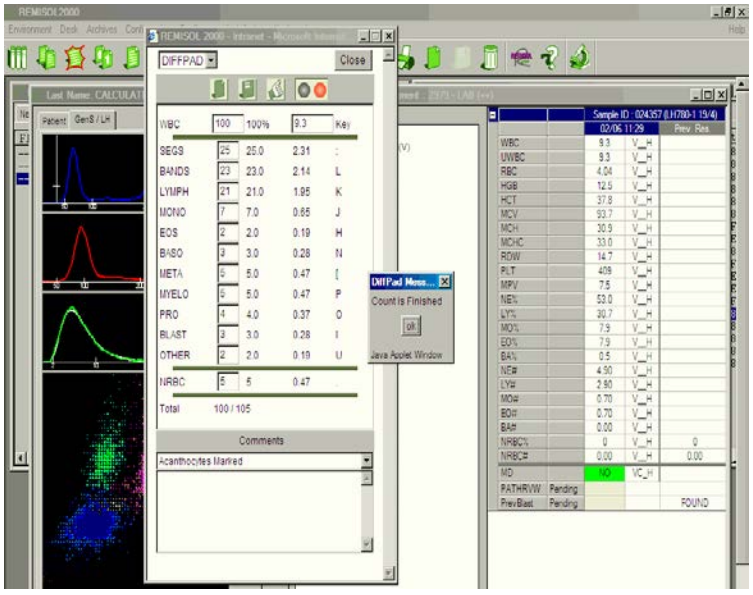
1 Under sample ID on the analyzer, enter the original barcode number and run pump and dump sample or warmed sample etc. through the instrument. The original rule that flagged the sample will prevent the autovalidation of the pump and dump results.
2 Since rerun samples from Cancer Center have no prior original result in the Remisol do not use the barcode number for these samples as the pump and dump results will autovalidate as whole untreated blood if barcode is used.
3 The dilution tube and dilution factor do not function in the Hematology mode
4 The rerun sample results appear to the left of the original sample.

5 Calculate your new values, edit original result by clicking on result, and hand entering and saving new results.
6 Once you are satisfied with the results, highlight the BC or CBC results and give the sample a thumbs up to validate.
7 Comments (corrected for icterous or lipemia, run at 37^{o},etc) must be entered at the LIS level under specimen comments until such time as comments are available in Remisol for Hematology.
8 NOTE: Critical values will not autoverify and cannot be manually validated in the Remisol alone. All documentation and final verification must be performed in the LIS.
9 Priority One called comments will have to be entered manually in the LIS after the fact under specimen comments.
10 Coag reruns and repeats will be frontloaded on the instrument. Coag batched samples (anything other than PT,APTT, FIB, and XDP) will require manual validation.

Using the Diffpad Function

D. Select the desired sample and open from request list.

1 To enter the diffpad, click on the microscope symbol.
2 Select DIFFPAD or SCANDIFF from pull down menu at the top left of the diffpad screen.
3 DIFFPAD is used for manual differentials and morphology
4 SCANDIFF is used for adding morphology and scan comments without having to perform a 100 cell manual differential. Nucleated red cells can be added from this screen.



5 The diffpad keyboard will be customized for your login during training when you receive your password.
6 Perform 100 cell differential. Or change the number of WBC counted to less if you cannot perform a 100 cell differential. When count is finished, select OK.
7 If you are not satisfied with your diff, hit the red light and the diffpad will reset. Note previous results will be lost so do a print screen if you wish to save results to enter later.
8 Diffpad numbers can be added as whole numbers to each cell type for faster entry to reenter a differential later on.
9 Perform morphology additions before validating or closing the sample.
    a. Morphology is added through the use of pulldown screens in the comments section. To move down the alphabetical morphology, click on the pull down arrow, then hit the first letter of the desired morphology and click on desired entry (P for poikilocytosis, etc.).
    b. Plt estimates and left shift comments are added here as well.
    c. You may only choose one comment per morphology (only slight aniso, or moderate aniso but not both). The last answer will overwrite the earlier answers.
    d. Move through the pull downs until all of the desired morphology is present.
    e. Platelet Estimates and Platelet morphology have been separated into different tests because of the choice of one option only.
    f. For platelet estimates the choices all start with the word Platelet and include:
        i. Platelet Estimate Appears Adequate
        ii. Platelet Estimate Appears Decreased
        iii. Platelet Estimate Appears Marked Decreased
        iv. Platelet Estimate Appears Increased
        v. Platelet Estimate Appears Marked Increased
        vi. Platelet Clumps Present. Number Appears Adequate
        vii. Platelet Clumps Present. Number Appears Decreased
        viii. Platelet Clumps Present. Number appears Increased
        ix. Platelet Clumps present. Unable to estimate quantity
    g. The platelet morphology choices are preceded by PLT and include:
        x. PLT Large platelets noted on scan
        xi. PLT Giant Platelets noted on scan
        xii. PLT Platelet satellitism noted
        xiii. PLT Hypogranular platelets noted on scan
        xiv. PLT Bizarre platelets noted on scan
        xv. PLT Large and giant platelets noted on scan
        xvi. PLT Agranular platelets seen on scan
    h. WBC Morphology comments will also need to be added through the diffpad in a newly created WBC morphology test:

i. Hypersegmented neutrophils, reactive lymphs, left shift present or not, and toxic granulation all have individual tests in the LIS so those comments do not apply to this field. They can be accessed through the pulldown morphology menu.
j. The following are comments available in the WBC morphology field:
   xvii. WBC Auer Rods Present
   xviii. WBC Smudge Cells noted on Scan
   xix. WBC Plasmacytoid Lymphs noted on scan
   xx. WBC Hypogranular eosinophils noted on scan
   xxi. WBC Toxic vacuoles noted in neutrophils
   xxii. WBC Dysplastic neutrophils noted
   xxiii. WBC Hypogranular neutrophils noted on scan
   xxiv. WBC Atypical lymphocytes noted
   xxv. WBC Pelger Huet-like morphology noted in neutrophils.
k. Comments can still be added in the LIS, but must be added after the diffpad results are validated and sent to the LIS.

10 Once manual differential has been performed and all morphology has been added…..
11 Give the "thumbs up" sign
12 The computer will take a few seconds to add the differential to the original results screen and the diffpad will close.
13 The manual differential will have been added in a new column in the request list and the morphology comments now show in the rules comments section.
14 Note the lowercase v indicating manual validation and the M for manually entered results. An H will show as soon as results are transmitted to the host (usually a few seconds after the diff pops up).

Troubleshooting Remisol

A. The main server and backup server are located under the Cellavision bench. The main server is the one under the Cellavision and the backup failsafe under the microscope. The username to log on is sysadm and the password session.

B. Monitor Icons

1 Along the bottom of each Remisol screen is seven greenish or aqua indicator lights corresponding to each analyzer (the three LH's, the two TOPs, one Cellavision and one ASTMH-LIS connection).
2 Hover the cursor over each button and it will identify the instrument.
3 The light will flash light green while transmitting data back and forth.
4 When the light is red the connection is broken and data transmission has stopped. The first step in that case is to reset communications as stated below and failing that look at physical connections at both instrument and server level.
5 If physical connections are intact, shut down the remisol software on all terminals and power down the server computer to reset the system.

C. If the main server crashes the mirror imaged backup failsafe computer must be brought up in order to continue transmission.

1 Unplug the main server from the network at the back of the computer (labelled 4 port cable).
2 Stop ALL Remisol stations that are connected to the main server (Command Central, Cellavision, Coag, Fluids).
3 Manually switch the LIS connection, the mouse and the keyboard to the backup server.
4 On backup server execute Swap SERVER.cmd.
5 Reboot ALL Remisol stations.
6 The backup server now becomes the only server operational.
7 Contact Beckman to repair and reconnect original server.

D. Reset Communications:

1 Instrument (LH780-1, LH780-2, LH780-3, ACL TOP-1, ACL TOP-2, Cellavision and Diffpad) and interface (ASTMH) communication can be reset from the reset communication screen on the environment tab on the Remisol by highlighting the appropriate choices followed by the green check mark.

2 The communications can also be reset at the server (near Cellavision) using the RADV monitor.

a. Click on the RADV monitor in the lower left corner (Double Zero or owl-eyes icon)
b. User is sysadm and password is session.
c. The Remisol tab (computer icon) resets the R2000.
d. The Instrument tab resets the remisol connection to individual analyzers.
e. The LIS computer tower resets the ASTMH connection.
f. Click on the icon to enter the individual reset areas.
g. Highlight the instrument or connection on the left then click on STOP on the right.
h. A message pops up that “The module is stopping”, then “The module is stopped”
i. Click on START on the right.
j. A message pops up that “The module is starting” then “The module has started”
k. DO NOT use the reset button, use the start and stop described above.

References

1. DL2000 Operations Guide, Beckman Coulter, June 2005

2. DL2000 Hematology Operations Guide, Beckman Coulter, June 2005

3. CAP Lab General checklist for autoverification, Sept 27, 2007

4. Dale J. Duca, Autoverification in a Laboratory Information System, Laboratory Medicine January 2002, Number 1, Volume 33, 21-25

5. Crolla, L and Westgard, J, Evaluation of Rule-based Autoverification Protocols, Clinical Leadership and Management Review, 2003

6. CLSI Guideline AUTO10-A Autoverification of Clinical Laboratory Results, Volume 26 Number 32, October 2006

Procedure History

Date	Written/Revised By	Revision	Approved Date	Approved By
April 2009	L Freeman	New		
August 2010	L Freeman	Revised for Remisol	8/29/10	M Chen MD
		Biannual Review	8/24/12	D Dwyre MD
		Biannual Review	10/1/14	D Dwyre MD
April 2015	L Freeman	Added failsafe and troubleshooting	5/5/15	D Dwyre MD