COAG.1500.1.0   SYSMEX CA-1500 ROUTINE OPERATION

PRINCIPLE
The Sysmex CA-1500 is a computerized coagulation analyzer with automated sample preparation. Two of the approved methods of coagulation detection are utilized for coagulation studies.

The coagulation method measures the change in scattered light intensity caused by the change in turbidity during the coagulation process at 660 nm. A curve is calculated and the coagulation time determined using the percentage detection method. PT, APTT, Fibrinogen, TCT and several factor assays are determined using this method.

The chromogenic method measures the change in transmitted light absorbance of a color change reaction at 405 nm. Several special coagulation tests utilize this method.

OWNERS
Manager, Regional Hematology Laboratory

SPECIMEN
Refer to individual CA-1500 assay procedures.

REAGENTS
A.   **Dade 1500 Clean I Solution** (50mL order # B4265-1)
        Stable until expiration date on bottle when stored at 2-8 C or 30 days when stored at room temperature. 48 hour expiration when on board instrument. .

B.   **Dade 1500 Clean II Solution** (500mL box order #GSZ-500A)
        Stable when stored at room temperature until labeled expiration unopened. Open expiration is two months from open date. 48 hour expiration when on board instrument.

C.   **Clinical Laboratory Reagent Water (CLRW)**

D.   Refer to individual CA-1500 assay procedures for test specific reagents.

EQUIPMENT
A.   Sysmex CA-1500
B.   Graphic Printer with paper
C.   Sysmex CA-1500 sample racks
D.   1500 Sample Plates 2500/pk (order # B4263-1)
E.   Sysmex Reaction Tubes 3000/pk (order# B4262-10)
F.   Sysmex 1500 Push Vials 10/pk (order# 02D3 U-10)
G.   Fisher Brand Disposable 4mL Autoanalyzer Cups 1000/pk (22-020748)

CALIBRATION
Refer to Sysmex CA-1500 LED CALS COAG.1500.2.0

QUALITY CONTROLS

Refer to individual Sysmex CA-1500 assay procedures for quality control materials and usage procedures.

PROCEDURE

A.   LCD SCREEN AND TOUCH PANEL

Analysis results, instrument status messages and other information are displayed on the CA-1500 LCD touch screen. Lightly pressing the keys on the touch panel activates the key function. The screen consists of three areas:

1.   System Status: Displays the Sysmex key, error messages, analysis status, and peripheral equipment status.

a.   Sysmex key:
   - Screen Print to print the current screen.
   - Error Log displays the error history.
   - Auto QC displays the window for selection of automatically performed QC parameters.

b.   Error Messages

Displays current error message. Check the Error Log to view two or more errors that occur simultaneously.

c.   Analysis Status

Displays the current analysis status of the instrument such as "Ready", "Dispensing" and "Waiting".

d.   Status of Peripheral Equipment:

Displays the status of connections with peripheral equipment such as **HC** (host computer), **GP** (graphic printer), and **HD** (hard disk). See chapter 9 "Troubleshooting" of CA-1500 Operators Manual for related error messages.

e.   STAT key

See "Sample Processing – STAT Sample Analysis" section.

f.   Lid Signal

Lid (backlit in green) indicates the light shield lid can be opened.

Lid (backlit in red) indicates the light shield lid should not be opened.

g.   Start key

Select to start and interrupt analysis. The start key display varies from [start] to [interrupt] to [resume] depending on the instrument status.

h.   Data printer next sample ID number

Displays the sample ID of the next results to print.

2.   Data Processing: Displays the progress of analysis (i.e. Main Menu), work list, stored data list, coagulation curve, quality control data, standard curve data and current instrument settings.

3.   Menu: Displays menus that are used to select functions.

B.   LOADING REAGENTS

1.   From the Main Menu select [SET REAGENTS]. The CONSUMABLES screen will appear.

Each position in the reagent tray is identified with a letter and number combination. Each key on the consumables screen corresponds with an identical position in the reagent tray. The reagent volume and reagent name are also defined on each key where a reagent has been assigned. Reagent positions backlit in green indicate a sufficient amount of reagent on board. Those backlit in red indicate an insufficient amount of reagent to perform testing.
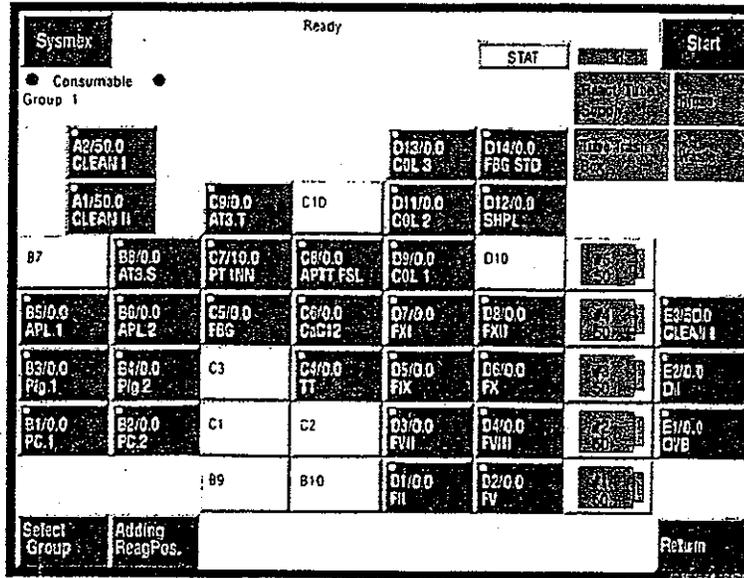
Picture of consumable screen

2. Confirm that the "lid" signal (status) is green. Open the light shield lid.
3. Load reagents in the appropriate positions on the reagent tray. Adapters may be used to ensure proper placement of reagent in the tray. If there is a gap between the reagent bottle and the reagent holder then select an adapter that is appropriate for the vial size and reagent position to be used.
4. Load each reagent by selecting the specific reagent key. The Volume keypad will be displayed.
5. Verify the lot number of the reagent displayed. To change the lot number press [LOT#]. Key in the correct lot number and [ENTER]
6. Verify the expiration date of the reagent displayed. To change the expiration date press [EXP DATE]. Key in the date using the mm/dd/yy format and [ENTER].
7. Verify the correct vial type is displayed. To change the vial type press [VIAL] and select the correct type using the arrow keys [OK]. See table below.
8. Verify the reagent volume displayed. To update volume press the corresponding numeric keys on the volume keypad and [ENTER]. Short sampling of reagent will occur if programmed reagent volume is greater than the actual capacity of the reagent vial.
9. Select vial type and reagent volume based upon the test volume per 24 hours.
10. [RETURN] to exit Consumables screen back to Main Menu.
11. Close the lid to the reagent tray compartment.

12. Replace all reagents at least every 24 hours and clean reusable vials with Clinical Laboratory Reagent Water (CLRW).
13. If the prompt "Update Settings?" is displayed then press [SET].

VIAL TYPE	DEAD VOLUME	REAGENT	SUGGESTED USES (Select vials based on 24hr reagent usage.)
2mL cup	0.1mL		
4mL cup	0.1mL	Dade FSL Actin, Innovin, CaCl, Thrombin	Low volume testing.
Attached (50mL bottles)	3.0mL	Dade Clean I Solution	Aliquot Clean I Solution from refrigerated working vial.
PV-10 (10mL push vial)	0.9mL	Dade Clean II Solution	Aliquot Dade Clean II from 5L box for low volume testing.
GW15	1.2mL	Dade FSL Actin, Innovin, CaCl, Thrombin, Owens Buffer	Push vials (PV-10) or 4mL cups may be used for reagents in areas where test volume is low. Reagent bottles (GW15) may be used for high volume testing.
GW5	0.6mL	Dade Citrol controls	Use 4mL cups instead of Citrol vials to lessen dead volume.

C. LOADING CONSUMABLE SUPPLIES
   1. Sample Plates
      The sample plates are used for onboard sampling where plasma is delivered to the wells and the amount required for testing is pipetted into the reaction tubes for testing. The status of the sample plate inventory is displayed on the right hand side of the Consumable screen. Five positions are available on the reagent tray to hold the 50 well sample plates. The LED next to each plate indicates the status of that plate.
         LED is green (green on Consumables screen) indicates an unused plate with 50 clean wells available.
         LED is red (yellow on Consumables screen) indicates the well is in use with some clean wells available.
         LED is flashing red indicates the plate is completely used with no clean wells available.
      a. Confirm that the instrument is not operating.
      b. Remove used sample plate from reagent tray.
      c. Load new sample plate. The sample plates are keyed for loading in one direction only.
      d. When the sample plate is replaced the software is automatically updated. The LED will change to green and green will appear on the Consumable screen.

CAUTION: Do not load partially used sample plates. The instrument does not recognize partially used wells.

2.   Reaction Tubes
        The reaction tube hopper will hold 300 reaction tubes. The reaction tubes can be replenished at any time during operation. The alarm sounds when the volume is low.
        a.   Press on front part of hopper cover to pop open the hopper lid.
        b.   Fill hopper with reaction tubes up to the red line. Do not overfill hopper.
        c.   Close the reaction tube hopper lid.
3.   Rinse Solution (CLRW)
        Replace the rinse solution as needed.
        a.   Confirm that the instrument is not operating.
        b.   Unscrew cap and carefully lift tubing and float switch out of the water box.
        c.   Avoid touching the float switch as incorrect results may occur due to contamination of the rinse solution.

WARNING:
Avoid injury. Do not open the light shield lid or place hands inside instrument during analysis.

CAUTION:

Permanent damage to the instrument may result if power is turned off during analysis. Turn power off only when the analyzer status is

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D.   CONTROL PROCESSING
        Controls may be run from the sample rack or from a predefined reagent holder position.
        1.   Controls run from the sample rack:
                a.   Press [WORKLIST] from the Main Menu.
                b.   Advance the rack numbers to the next available rack by pressing [NEXT] until the screen background color has changed from blue to white. The empty Workload List will be displayed.
                c.   Press [ID NO. ENTRY].
                d.   Press [QC][ENTER] on the numeric keypad followed by the level of quality control [ENTER]. Example: [QC] [ENTER] [01] [ENTER]. The work list will display the ID as a quality control file number (i.e. QC01).
                e.   Press [C] [ENTER] to clear any data entry errors on the numeric keypad.
                f.   Press [QUIT] to remove the numeric keypad display.
                g.   Select the tests to be run for the assigned control. With the control name highlighted press individual test keys to select the tests for that control. The

symbol "O" under the test name indicates that the test has been selected. A "—" indicates that the test has not been selected.

    h.   Aliquot the control into a sample tube and place the tube in the sample rack.

    i.   Complete programming of other QC material then press [START] or [REGISTER MORE] if instrument is already running to begin control processing.

2.   Controls run from a predefined reagent holder position:

    a.   Press [SET REAGENTS] from the Main Menu.

    b.   Confirm that the "lid" signal (status) is green. Open the light shield lid.

    c.   Verify that the reagent Group 1 displayed on the Consumables screen contains the control holder position key. If the Reagent Position key is displayed in pink on the Consumable screen verify that the reagent position contains the correct reagent.

    d.   Press [desired control] reagent holder position key to display the numeric keypad and control information.

    e.   Verify that the correct lot number is displayed. Change the lot number if required. Press [Lot#] to display the alphanumeric keypad. Key in the correct lot number [ENTER].

    f.   Verify that the correct expiration date is displayed. Change the expiration date if required. Press [Exp Date]. Key in the correct date using the mm/dd/yy format [ENTER].

    g.   Verify that the correct vial type is displayed. Change the vial type if required. Press [VIAL] to display vial selection. Use the arrow keys to select the correct type [OK].

    h.   Verify that the correct volume is displayed. Change the volume if required. Key in the correct volume [ENTER]. The display will return to the Consumables screen.

    i.   Pour the control material into a 2ml or 4ml analyzer cup.

    j.   Label the cup with the control expiration date and time.

    k.   Place cup into the assigned reagent holder position. The assigned position is displayed as D_ (i.e. D9, D10).

    l.   [RETURN] to exit the Consumables screen and return to the Main Menu.

    m.   Press [WORKLIST].

    n.   Press [REAGENT HOLDER] to display the Reagent Holder Worklist.

    o.   Select a control using the arrow keys until the desired control is highlighted.

    p.   Select the tests to be run for the assigned control. With the control name highlighted press individual test keys to select the tests for that control. The symbol "O" under the test name indicates that the test has been selected. A "—" indicates that the test has not been selected.

    q.   Press [START] to initiate control run or [REGISTER MORE] if instrument is already running to begin control processing.

E.   SAMPLE PROCESSING

Samples that are in a rack or on a work list that have not yet been processed can be changed or cancelled by interrupting analysis. Once analysis has been started on an individual rack or work list that rack or work list cannot be altered. Specimens are processed in the following order:

STAT holder, STAT in sample rack, samples in reagent holder and samples in sample rack. Analysis of samples in STAT holders and reagent holders are executed in order beginning with the smallest numbered holder.

1. Bar Coded Specimens in Sample Rack
    a. Verify "READY" is displayed in the status area of the screen.
    b. Remove caps from specimens and insert specimen tubes into the sample rack. *Tube adapters are available to accommodate different tube sizes. Use the appropriate adapter in the sample rack to assure the tube is firmly seated in the rack.*
    c. Verify the barcode labels are facing out toward the barcode reader.
    d. Place sample rack on the input tray so that the groove on the sample rack fits on to the lip of the input tray.
    e. Press [START] or [REGISTER MORE] if instrument is already running to begin specimen processing.

2. Non Bar Coded Specimens (Manual Work list) in Sample Rack
    a. Verify "READY" is displayed in the status area of the screen.
    b. Remove caps from specimens and insert specimen tubes into the sample rack. *Tube adapters are available to accommodate different tube sizes. Use the appropriate adapter in the sample rack to assure the tube is firmly seated in the rack.*
    c. Press [WORKLIST] from the Main Menu.
    d. Verify <REGISTER RACK> is displayed above the parameter keys.
    e. Press [RACK] if register rack is not displayed.
    f. Press [NEXT] to advance to the next available.
    g. Verify "next available" rack is displayed (white background).
    h. Select the desired sample rack position using the [↑] and [↓] arrow keys.
    i. Press [ID ENTRY] to display the numeric keypad for the highlighted rack position.
    j. Key in sample identification [ENTER].
    k. Press [QUIT] on the numeric keypad when all specimens have been assigned a position.
    l. Select the tests to be run for each specimen. With the specimen ID highlighted press individual test keys to select the tests for that specimen. The symbol "O" under the test name indicates that the test has been selected. A "—" indicates that the test has not been selected.
    m. Press [ENTER] when test selection is complete and to advance to the next specimen on the work list.
    n. Repeat test selection until all specimens in the rack have assigned tests.
    o. Place sample rack on the input tray so that the groove on the sample rack fits on to the lip of the input tray.
    p. Press [START] or [REGISTER MORE] if instrument is already running to begin specimen processing.
    q. Repeat steps {f} through {o} to continue testing with additional racks.

    IMPORTANT! If LIS is completely nonfunctional then [REGISTER MORE] must be selected to process additional racks while the instrument is running.

3. Micro Sample Mode
Micro sample mode is used when a minimal sample volume is available. The sample is not dispensed into a sample plate but is directly dispensed into the reaction tube and analyzed. Subsequent dilutions will utilize the sample plate. When micro sample is selected automatic reanalysis will not be performed.

   a. Follow steps described in "Non Bar Coded Specimens (Manual Worklist)" through step "l".

   b. Press [MICRO]. The "O" symbol will be displayed on the Micro key. Samples programmed in micro mode will display a "M" in the "opt" column, \for that sample, on the Worklist screen. OR

   c. Run bar coded specimens in Micro mode by using the [↑] and [↓] arrow keys to highlight the position on the rack where micro sampling is required. Press [MICRO]. *Note: When running bar coded specimens from the sample rack the work list will contain no information. Highlight the position number even though no sample identifier is listed. Notice that after selecting [MICRO] an "M" will be displayed for that position indicating that micro sample mode has been selected.*

4. STAT Sample Analysis
STAT samples are given priority over all other samples. STAT specimens are sampled from the STAT sample holder located inside the instrument. Five positions are available in the STAT sample holder. Both sample cups and specimen tubes may be used in the STAT sample holder. Bar codes are not read when specimens are in the STAT sample holder. Manual ID entry is required. STAT test orders cannot be cancelled after the [START] or [RESUME] has been selected.

   a. Press [STAT]. The STAT Sample Setting Position Selection window will appear.

   b. Press [STAT Holder]. The run in progress will stop and the message "Being Interrupted" will appear.

   c. Press [OK] at the "Set STAT Samples" prompt. The Work Load List for the STAT sample holder will be displayed.

   d. Press [ID ENTRY] to display the numeric keypad for the highlighted tube position.

   e. Key in sample identification [ENTER].

   f. Press [QUIT] on the numeric keypad when STAT specimen has been assigned a position.

   g. Select the tests to be run for each specimen. With the specimen ID highlighted press individual test keys to select the tests for that specimen. The symbol "O" under the test name indicates that the test has been selected. A "—" indicates that the test has not been selected.

   h. Verify that the lid LED is green.

CAUTION:

If the LED is red do not try to open the door. **Forcing the door open may cause permanent instrument damage.**

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      i.   Push the STAT sample door in until it locks into an open position.

      j.   Place specimen into STAT holder making sure all caps have been removed.

      k.   Press the white button located on the left inside of the sample door to close the door.

      l.   Press [START] or [RESUME] to begin STAT sample analysis. Routine work that may have been interrupted will automatically be processed following the STAT sample.

      m.   Verify that the lid LED is green before opening the sample door. If the LED is red then press [STAT]. The STAT Sample Setting Position Selection window will appear.

      n.   Press [Remove STAT tube]. The run in progress will stop and the message "Being Interrupted" will appear. Press [OK] when prompted.

      o.   Remove STAT tubes when the lid LED is green. Press [RESUME].

2. Interrupting Sample Analysis
Interruption of sample analysis may be required to replenish reagents. Change workload lists that have not yet been processed by interrupting sample analysis. See "STAT Sample Analysis" to interrupt operation to run a STAT specimen.

      a.   Press [INTERRUPT]. The Interrupt Analysis screen will be displayed.

      b.   Select either [ORDER CHANGE] or [REAGENT SUPPLY] from the Interrupt Analysis display.

      c.   Change order information or reagents after the message "Being Interrupted" has disappeared and the status area at the top of the screen displays "Waiting".

      d.   Press [RESUME] to continue with sample analysis.

F. ERROR MESSAGES
The CA-1500 records every error as it occurs and can store up to 189 error messages. Errors include instrument/accessories/ software malfunctions and data analysis errors. Access the error log to review errors. When an error occurs the error message will appear at the top of the screen, the alarm will sound and sample analysis will stop. When the alarm sounds the [SYSMEX] key turns red and displays [ALARM RESET]. Error flags attached to sample results are displayed under Stored Data on the Analysis Result screen.

Calculation Parameter Flags are displayed instead of a result. These flags may accompany analysis errors or instrument errors.

      ***.*   Analysis data not obtained due to error *(May need to view Stored Data to obtain a 50% reading. See error table.)*

      - - -. -   Could not calculate parameter

      +++.+   Value exceeded displayable range

      / / /. /   Could not calculate the mean

Abnormal Value Flags are displayed with the result. These flags are displayed either on the right or left of the abnormal result.

Displayed on the left:
- ***** disparity between replicates
- **!** sample performed on dilution
- **<** result exceeded the lower reportable limit
- **>** result exceeded the upper reportable limit

Displayed on the right:
- **--** result exceeded the lower mark limit
- **+** result exceeded the upper mark limit
- **x** calculation parameter could not be calculated

1. Instrument Errors
   a. Press [ALARM RESET] to turn the alarm off.
   b. See the Sysmex CA-1500 Operators Manual, Section 9 to troubleshoot by error message.
   c. Press [SYSMEX] located in the upper left corner of screen to view the error log.
   d. Press [ERROR LOG]. 21 errors are displayed per page on the screen.
   e. Press [PAGE UP] or [PAGE DOWN] to view another page.
   f. Use the [↑] and [↓] arrow keys to select an individual error message.
   g. Press [INFO] to display the Detailed Information screen.
   h. Press [QUIT] to return to the Error Log screen.
   i. Press [QUIT] to exit the Error Log screen.
2. Analysis Errors

   Analysis errors pertain either to the sample coagulation curve (clotting assays) or optical density graph (chromogenic assays). An error occurs when the coagulation curve deviates from a normal curve for the assay. See "Normal Coagulation curve" in Section G below. Every analysis error code has a descriptive name and a numeric code. The error description can be viewed by pressing the red {ERR} button on the graphic display of the sample. Analysis data errors are not displayed in the Error Log but appear with sample results in the Stored Data display. See table below for analysis errors. Also refer to the Sysmex CA-1500 Operators Manual, chapter 9, Troubleshooting.

ANALYSIS ERRORS TABLE				
Error Code	Message	Result	Probable Cause	Corrective Action
ERR001	Temperature Error		Temperature error occurred during analysis of the sample.	See "Temp Errors" Operators Manual
ERR002	Slight Coagulation	12.5*	Detected reaction is extremely small.	- Check sample for contaminants. - Verify delivery of the sample and reagents.

				(Low fibrinogen, reagent problem, factor deficiencies or presence of inhibitors.	• Reanalyze the sample. • If results are equivalent (+/10.0%) and the coagulation curves, in Stored Data, are acceptable then the mean of the results may be reported.
ERR004	Analysis Time Over	***.*	Analysis not completed within the normal detection time. (No plateau is established on the coagulation curve.) Occurs when testing samples with prolonged clotting times or if <u>cold</u> Owens buffer is used for fibrinogen.	• Check sample for contaminants. • Verify delivery of sample and reagents. • Reanalyze sample. If the repeat results do not have an asterisk * then repeat result may be reported. If an asterisk is present the sample may not be capable of clot formation.	
ERR008	Coagulation Curve Error	***.*	Coagulation curve abnormalities most commonly due to air bubbles in the reaction tube or reagent. Sample may also be abnormal.	• Make sure buffer has been equilibrated to room temperature. • Check sample, reagent volume and integrity. • Reanalyze sample. If the repeat results does not have an asterisk * then repeat result may be reported. • Reanalyze the sample. If repeat result has an * then compare results <u>and</u> acceptability of curves. Access the curves in Stored Data. If the curves and curve data are	

				acceptable and the repeat results are equivalent (agree +/-10.0%) with the initial results at the 50% coagulation detection point then the mean (in seconds at 50%) of the two samples may be reported. • Print report if this data is utilized in patient result reporting.
ERR016	Overflow (Turbidity Level Over)	***.*	Turbidity is too high for analyzer to read. (Specimen contaminants such as lipemia or icterus).	• Reanalyze fibrinogens with 1:2 autodilution. • PT/PTT: If unable to obtain results specimen must be reanalyzed using an electromechanical method (Start 4).

ERR032	No Coagulation	***.*	Analyzer is unable to detect a clot or a weak clot was detected. Abnormal sample or reagent problems are probable cause. An NC error does not necessarily mean the specimen is unable to form a clot.	NC with dH$\geq$ 10 - Check sample for contaminants - Verify delivery of sample and reagents. - Review the Analysis Data Format for smooth progression, of clot formation, in seconds. Print report if this data is utilized in patient result reporting. - Reanalyze the sample. - Access the coagulation data curves in Stored Data. If the curves and curve data are acceptable and the repeat results are equivalent (agree +/- 10.0%) with the initial results at the 50% coagulation detection point then the mean (in seconds at 50%) of the two samples may be reported. - Print report if this data is utilized in patient result reporting. *Note: APTT results: Observe the time at the 2% position of the analysis data format printout. If the result, in seconds, is < 15 seconds then an early reaction may have occurred. Do not report results.*

				NC with dH< 10 • Check sample for contaminants • Verify delivery of sample and reagents. • Review the original graph to see if clotting occurred. Note: The Analysis Data format will not print if the dH<10. Coagulation curve will basically appear as a flat line due to rise of <10. • Reanalyze the specimen. If no * then report results. • If * reoccurs then specimen must be tested on Start 4 / 8 analyzer.

ERR0064	No absolute result can be obtained. Generally a system operation error.	***.*	Prescribed time passed after sample was pipetted to the sample plate.	Reanalyze sample.
ERR0100	No absolute result can be obtained	***.*	Analysis result outside reportable range.	Fibrinogen: "Redilution required". PT/APTT: " Range Over" See Results Reporting Sections for individual test procedure for reporting protocol.

G.   COAGULATION CURVES
Three key elements must be present in a valid clot curve: a baseline, a delta H, and a plateau. Several readings are taken to determine the **baseline** before the clotting process begins and is displayed as a flat line at the beginning of the curve. In the example below the baseline reading for PT=170 and APTT= 190 seconds.

The **delta H** is the time period between the baseline and the plateau, in seconds, in which clot formation occurs. In the example below the dH for PT=106 and APTT =329 seconds.

The **plateau** is displayed as a flat line following the completion of clot formation where significant changes in clot formation are no longer occurring.

NORMAL CLOT CURVE FORMATION

X axis=% clot formation
Y axis= coagulation time in seconds

```
Final  Valid
PT         < 1/ 1>            APTT        < 1/ 1>
|x4              12.0  sec    |                    42.3  sec
|                     (50)    |                         (50)
|     ___/‾‾‾‾                |      ___/‾‾‾‾
|  _/                         |    _/
|_/                           |__/
0          60    1.17  INR    0          120

bH  170 dH  106              bH  190 dH  329
CH NO.     3                 CH NO.     4
ERR        0                 ERR        0
```
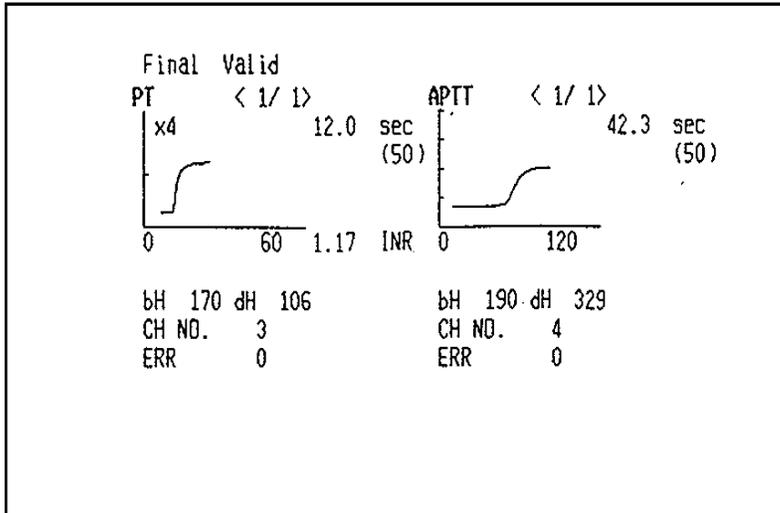
bH *baseline*
dH *change between baseline and plataue baseline and plateau*
CH NO *channel in which test is performed*
ERR *error codes if any*

Some sample analysis errors can be resolved by viewing the clot formation results when clotting is 50% completed. Coagulation results read at the 50% point in the coagulation process can be obtained by viewing the coagulation curve. See "Corrective Action" column of "Analysis Errors Table" for indications for use. Coagulation curves can be accessed in the Stored Data function.

1.   To view the coagulation curve on the instrument display select STORED DATA from the Main Menu.
2.   Use the [↑] and [↓] arrow keys to highlight the sample to be displayed.
3.   Select GRAPH.
4.   Select CHANGE SCALE to increase the size of the graph for easier viewing.
5.   The time in seconds at 50% coagulation is displayed. See example below. 50% coagulation equals 36.4 sec.
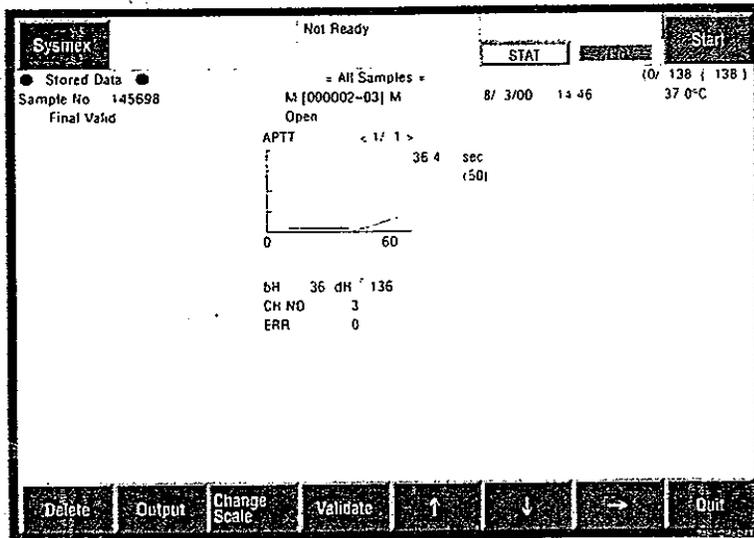
Coagulation curve picture

6. To print a copy of the coagulation curve select STORED DATA from the Main Menu.
7. Use the [↑] and [↓] arrow keys to highlight the sample to be displayed.
8. Select MARK. A yellow block will appear on the left side of the screen indicating selected sample.
9. Select CURRENT and QUIT
10. Select OUTPUT
11. Select MARKED
12. Select GP GRAPH. Coagulation curve for the marked patient will print. QUIT to exit function.
13. To "unmark" selected samples select MARK and ALL CLEAR. The yellow blocks will be removed.

H. ANALYSIS FORMAT DATA
    The Analysis Data format displays the time in seconds beginning at 2% and continuing at 2% increments through 100% clot detection. The time in seconds at 50% clot detection can be determined from this display as well as the coagulation curve. A smooth progression in seconds should be observed during clot formation in a normal specimen. Sporadic and large increases in progression of seconds would indicate a specimen abnormality. Print report if this data is utilized in patient result reporting.

NORMAL SAMPLE ANALYSIS DATA FORMAT

```
NORMAL SAMPLE ANALYSIS DATA FORMAT


Final  Valid
                        Analysis
PT        < 1/ 1>
                 2 %    11.1 sec   32 %   11.7 sec   62 %   12.3 sec
                 4 %    11.2 sec   34 %   11.7 sec   64 %   12.4 sec
                 6 %    11.3 sec   36 %   11.8 sec   66 %   12.5 sec
                 8 %    11.3 sec   38 %   11.8 sec   68 %   12.6 sec
0          60   10 %    11.4 sec   40 %   11.8 sec   70 %   12.7 sec
                12 %    11.4 sec   42 %   11.9 sec   72 %   12.7 sec
     12.0  sec  14 %    11.4 sec   44 %   11.9 sec   74 %   12.8 sec
        (50)    16 %    11.4 sec   46 %   12.0 sec   76 %   13.0 sec
                18 %    11.5 sec   48 %   12.0 sec   78 %   13.1 sec
                20 %    11.5 sec   50 % ->  12.0 sec  80 %   13.3 sec
     1.17  INR  22 %    11.5 sec   52 %   12.0 sec
                24 %    11.5 sec   54 %   12.1 sec
bH  170 dH  106 26 %    11.6 sec   56 %   12.1 sec
CH NO.    3     28 %    11.6 sec   58 %   12.2 sec
ERR       0     30 %    11.7 sec   60 %   12.3 sec
```

To change the printer setting to print an Analysis Data format:
1.	Press [SETTINTGS] from the Main Menu.
2.	Press [I/O SETTINGS].
3.	Press [GP].
4.	Press [SERVICE].
5.	Press [SET] to update the printer settings.
6.	Press [RETURN].
7.	Press [RETURN] to display the Main Menu.

To print the Analysis Data format for a specimen:
1.	Press [STORED DATA] from the Main Menu.
2.	Use the [↑] and [↓] keys to select specimen.
3.	Press [MARK].
4.	Press [CURRENT].
5.	Press [QUIT].
6.	From Stored Data press [OUTPUT].
7.	Press [MARKED].
8.	Press [GP GRAPH].
9.	Change printer settings back to [LIST] after report has printed.

I.	STORED DATA
1.	The Stored Data function includes:
- Sample information including patient ID, rack number and sequence number.
- Result information including coagulation curves, means, patient results, QC results and standards results.
- Result printing capability.
- Resending results to the host computer.

SYSMEX CA-1500 ROUTINE OPERATION

- • Recalculation of results.
- • Displays of coagulation curves.
- • Searching and sorting of results.

2. Select STORED DATA from the Main Menu. Up to 20 samples are displayed per screen. The Stored Data screen is displayed in two or more pages. The first page is the sample information screen and the second page is the analysis result screen. Select either [←] or [→] to move back and forth between the two pages. Select PREV or NEXT to scroll through the pages. Use the[↑] and [↓] arrow keys to select an individual sample line.
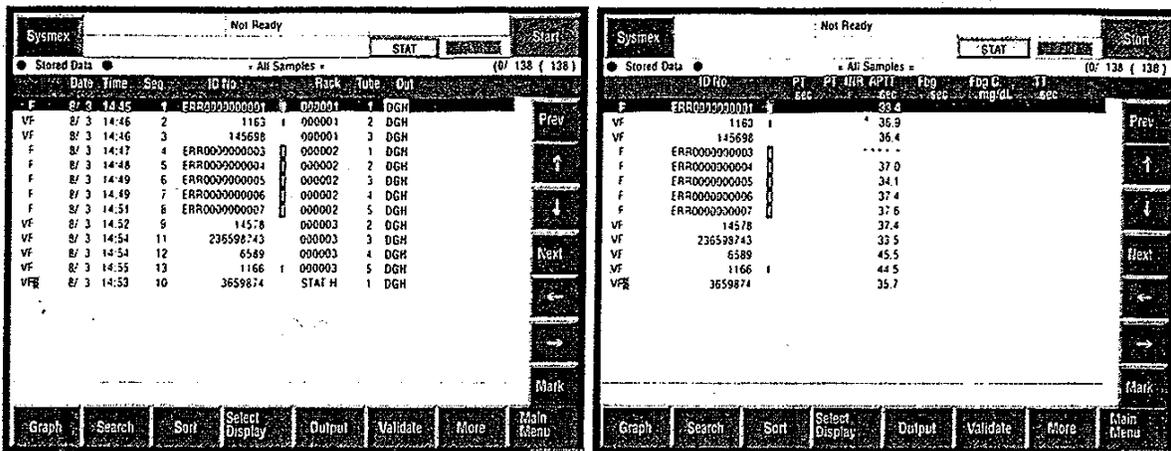
Stored data picture

3. Sample Information Screen
The sample information screen shows detail about the sample.
   a. The date and time analysis was performed.
   b. The sequence in the day the analysis was performed.
   c. Symbols indicating specific information about the sample.
      M Mean data when replication analysis is executed
      F Data for final report
      V Data has been validated
      S STAT analysis sample
      R Data is from a reanalysis
      * After sample ID indicates an identical sample ID exists with the same data
      I Sample ID was read with the barcode reader (backlit in red when read error occurs)
      D Data output flag indicating that data was sent to data printer
      G Data output flag indicating that data was sent to graphics printer
      H Data output flag indicating that data was sent to host computer
      C Concentration of sample due to redilution.

4. Moving and sorting stored data can be performed for viewing of specific samples. Select SEARCH , SORT or SELECT DISPLAY from the Stored Data screen. Options for grouping data are given after selecting a function.

5. Display Sample Graph
    a. Select appropriate sample from the Stored Data screen.
    b. Press [GRAPH].

6. Delete a Sample
    a. Select appropriate sample from the Stored Data screen.
    b. Press [MORE]
    c. Press [DELETE]
    d. Press [QUIT]

7. Recalculate a Sample
    (Applicable for ratio reported results only.)
    a. Press [MORE] from the Stored Data screen.
    b. Press [RECALC].
    c. Select one of the following:
        [Current Data] to recalculate data at the cursor position.
        [Marked Data] to recalculate data that has been marked.
        [Not Calc Data] to calculate all data that has not been calculated.
    d. Select [QUIT] to stop the procedure.

8. Output/ Print from Stored Data
    a. Select Stored Data from the Main Menu.
    b. Use the arrow keys to select the appropriate data.
    c. Press [OUTPUT].
    d. Select one of the following from the Select Sample Menu:
        [Current] to output the data in the current position.
        [Marked] to output data that is marked.
        [All] to output all stored data.
        [Output cancel] to stop the data output.
    e. Select one of the following output devices:
        [DP] to send the data to the data printer.
        [GP Graph] to send the coagulation graph to the graphics printer.
        [GP List] to send a list of data to the graphics printer.
        [HC] to send the data to the host computer.
        [FD] to send the data to a diskette.

9. Resend Data to the Host Computer
    (For use following LIS downtime.)
    a. Select Stored Data from the Main Menu.
    b. Select SELECT DISPLAY.
    c. Select NOT YET OUTPUT.
    d. Select HC and OK.
    e. Select OUTPUT.
    f. Select ALL.
    g. Select HC.
    h. Select SELECT DISPLAY to reset the Stored Data display.

i.   Select ALL.
j.   Select MAIN MENU to exit Stored Data.

RESULTS REPORTING
See individual test procedures

LIMITATIONS
See individual test procedures

REFERENCES
A.   Sysmex® CA-1500 Operators Manual. Sysmex Corporation. Revised 8/2000.
B.   Sysmex® CA-1500 automated Coagulation Analyzer Training Guidebook. Dade Behring
        Document CT61, Effective 1/7/02.
C.   Dade Behring Procedure: Prothrombin Time-Sysmex® CA-1500 Innovin®. PTINN1500.
D.   Dade Behring Procedure: Activated Partial Thromboplastin Time-Sysmex® CA-1500 Actin® FSL
        Activated PTT Reagent. APTTFSL1500.

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IMPLEMENTATION DATE (Pre-SharePoint):   July 2002