1. Calibration Program

The *ABX MICROS 60* Calibration can be achieved in (2) different ways.
1 - Calibration is performed using a Calibrator Blood sample.

MICROS 60 OS/OT

Important: It is highly recommended that you use the *ABX MINOCAL* Calibration product when calibrating the *ABX MICROS 60* analyzer. This product is specifically designed for use with the *ABX MICROS 60* analyzer. Call your local *ABX DIAGNOSITCS Customer Service Representative* for information and ordering of this specialized product.

2 - Known Calibration Coefficients can be directly entered by selecting a Calibration Menu option.

MICROS 60 OS/OT

Important: Before performing an instrument Calibration, it is mandatory to:
1 - perform a *Concentrated Cleaning* to ensure the cleanliness of the Counting Chambers and Apertures!
2 - Run a *Blank Cycle* to assure that all the Background values are at their lowest possible limits. (See **Section 3 - Startup and Sample Run**, 1.4. Instrument Startup, (*Background Limits*).
3 - Run *Reproducibility* on a Fresh Normal patient blood sample (**10**) times and calculate the Coefficient of Variation (*CV%*) for WBC, RBC, HGB, HCT, PLT, and MPV. Note the Percent CV's in this section of the Manual.
These 3 factors will ensure a clean and precise instrument when calibrating.
If your *ABX MICROS 60* does not pass a Background or Reproducibility check, contact your local *ABX Technical Support representative!!!*

To enter into the Calibration Menu from the *Main Menu, select 3 - CALIBRATION.* The following menu will be displayed on the LCD screen as shown:

CALIBRATION	> 1- AUTO CALIBRATION
09:25	2- COEFFICIENTS

1.1. Calibration

Calibration Procedures

1 - From the Calibration Menu, *select 1 - AUTOCALIBRATION.*

2 - Select one of the (4) Operators (O.P.) which may be entered in the System Set-up menu. (See Section **5 - Instrument Configuration,** 3 - Special Functions, (*3.1. Changing Operator Identification*). After selecting one of (4) operators, press the "ENTER" key.

The LCD will display a message as indicated:

ERROR : NO SMART CARD ...	NO : ESC
INSERT NEW CARD	YES : ENTER

Press the Escape "ESC" key. This will allow you to enter into the Calibration menu and edit all the calibration information Manually.

Change Lot number

1 - Press the "ENTER" key to enter the new lot number of the calibrator material.

LOT # ? : _	EXIT : ESC
CURRENT : MCAL121	SAVE : ENTER

2 - Enter the new "Lot Number" of the current calibrator from the Assay sheet that comes with the calibration material. Use the "Up" and "Down" arrow keys to enter the Alpha characters. Use the Numeric keys to enter the Numbers. Press the "ENTER" key to save the new lot number and move to the next entry. As indicated:

LOT # : MCAL175	EXIT : ESC
CURRENT : MCAL121	SAVE : ENTER

Change Expiration date

3 - The next screen will indicate changing the Expiration date of the new calibrator.

CHANGE EXP. DATE ? (MM.DD.YY)	NO : ESC
CURRENT : 11/20/01	YES : ENTER

4 - Press the “ENTER” key, enter the new expiration date from the Calibration Assay sheet. Use the “Period” key after entering the Month. Use the “Period” key after the Day. Press the “ENTER” key to save the new expiration date and move to the next entry as indiated:

EXP. DATE : (01.20.02)	EXIT : ESC
CURRENT : 11/20/01	SAVE : ENTER

Change Target values

5 - The next screen will indicate changing the WBC Target value.

CHANGE TARGET WBC ?	NO : ESC
CURRENT : 8.2	YES : ENTER

6 - Press the “ENTER” key and enter the new target value for WBC from the Calibration Assay sheet as indicated:

TARGET WBC : 10.2	EXIT : ESC
CURRENT : 8.2	SAVE : ENTER

7 - Press the “ENTER” key to save the new target value and move to the next entry as indiated:

8 - The next screen will indicate changing the RBC Target value. Repeat Steps **6 through 8** for RBC, HGB, HCT, PLT, and MPV. When the MPV target value has been entered, the next screen that will appear will ask if you want to change the number of samples to be run for calibration.

A Calibration “Reminder”!!!

MICROS 60 OS/OT

Note: The number of samples you can run for calibration is a Minimum of (3) and a Maximum of (11). In order for the instrument to provide the best mathematical data for a good calibration, a Minimum of (**6**) sample runs is highly recommended for quality statistical calibration data!

Change Number of Calibration Samples

After all the Target values have been entered, the next screen will indicate:

CHANGE SAMPLE # ?	NO : ESC
CURRENT : 8	YES : ENTER

9 - Press the “ENTER” key to change the number of samples. The next screen will indicate entering the sample number.

SAMPLE # 10	NO : ESC
CURRENT : 8	YES : ENTER

10 - Press the “ENTER” key and enter the number of samples you wish to run for calibration or press the Escape “ESC” key if the number of samples desired is already present.

The LCD will now state, as indicated:

RUN CAL ?	NO : ESC
	YES : ENTER

11 - Press the “ENTER” key to start the calibration process. A message will be displayed on the LCD as the *ABX MICROS 60* performs a Prime cycle prior to aspirating the first sample.

RUN CAL	
10:23	PLEASE WAIT

Calibration Procedures continued:

When the cycle is complete, another message will appear stating, as indicated:

START CALIBRATION # 1 / 6
ESC TO EXIT PRESS START TO ASPIRATE

12 - Now gently and thoroughly mix the Calibrator material as indicated on the Instruction sheet that comes with the calibrator.

13 - Place the calibrator beneath the sample probe, and raise the vial upwards so that the sample probe enters into the blood.

14 - Press the “START” key on the front panel to initiate the cycle of the first sample, or press the Manual Sample Bar
The cycle will begin and the sample will be aspirated.

MICROS 60 OS/OT

Important: Wipe any excess blood from the Cap and Threads of the calibrator vial with a *Lint-free tissue* to prevent any dried blood from re-entering into the calibrator material. Dried Blood re-entering into the vial may give Error flags and reject the sample runs!

15 - Place the cap back onto the vial, gently and thoroughly mix the material for the next calibration sample run.

When the first sample is complete, the results will be displayed on the LCD screen as indicated:

WBC RBC HGB HCT PLT MPV PRESS ENTER
9.8 4.56 13.4 35.9 267 7.6 TO CONTINUE

Verify that the results are within 20% of each parameter target value indicated on the Calibrator Assay sheet.Press the “ENTER” key to continue.

16 - The next LCD display will ask you if you want to Accept or Reject the results, if and only if the results were not rejected previously.

MICROS 60 OS/OT

Important: Calibration results having Error flags such as (**$, *,** or **!** for HGB) will automatically be rejected! The system will automatically re-set itself to rerun that sample. If you acquire (3) rejects continuously on the same number sample, abort Calibration and contact your local *ABX Technical Support representative!*

The LCD display will indicate:

VALID CALIBRATION # 1 / 6
ESC TO DISCARD ENTER TO VALID

If the results are “Not” within acceptable limits, it is possible to reject the results and restart that sample run. Press the Escape ”ESC” key on the front panel to “Reject” the results. The instrument will re-start the sample at the same number.

17 - If the results are good, press the “ENTER” key to accept the first sample into the calibration data. The LCD screen will display the next sample to be run as indicated:

START CALIBRATION # 2 / 6
ESC TO EXIT PRESS START TO ASPIRATE

18 - Run the remaining calibrator samples, repeating Steps **13 through 17 for each sample**. *Remember to Gently and thoroughly mix the calibrator material between each sample run! Also Wipe the cap and threads of the vial between each run.*

When the last sample result has been validated, the *ABX MICROS 60* calculates the statistical calibration factors for each parameter.

These statistical calculations include the *Mean, Target, Coefficient of Variation, Percent difference between the Target value and the Mean, Pervious Calibration coefficients, and the New Calibration Coefficients.* The Status will indicate on the printout if a parameter has Passed or Failed Calibration.

Verify Calibration

1 - Once the calibration is complete and has Passed the Calibration criteria, Press the Escape "ESC" ket until you have returned to the Main Menu.

2 - Run the remaining Calibrator material (**3**) times as a regular patient analysis. (*Remember to gently and thoroughly mix the material between each sample run.*)

3 - When each cycle is complete, record the results in (*Table 3. Verify Calibration*) on the Minocal Assay sheet.

4 - Once all results have been entered, calculate the Total and Mean values for each parameter listed.

5 - Now compare the Mean value for each parameter to the Assay Mean values and ranges listed for the *ABX MICROS ^{2} 60.*

6 - Verify that all the calculated parameters fall within the specific parameter Ranges on the Assay sheet.

7 - If all parameters are within their specified ranges, Calibration is complete.

8 - Run Quality Control and verify that all (**3**) levels of control results are within their specified ranges. Verify that all control parameter results are without Flags (**H, L, *, $,** and **!** for HGB).

1.2. Calibration Passed

In order for *ABX MICROS 60* to "Pass" Calibration, the data must meet the statistical criteria which contain (2) conditions.

1. The Coefficient of Variations must be within their limits as indicated in the table below.
2. The difference between the "Target value" and the "Mean" for each parameter calibrated, must be less than 20%.

COEFFICIENT of Variation Limits						
Parameters	WBC	RBC	HGB	HCT	PLT	MPV
CV %	≤ 2.5	≤ 2.0	≤ 1.5	≤ 2.0	≤ 5.0	≤ 3.0

"Passed" Calibration printout is as indicated:

CALIBRATION

DATE : 01/20/2002 TIME : 09 : 48
OPERATOR : ABC
LOT # : MCAL212

RUN	WBC	RBC	HGB	HCT	PLT	MPV
1 P	10.2	4.50	14.0	38.0	242	7.6
2	9.9	4.45	14.0	37.4	246	7.9
3	9.7	4.41	14.0	37.2	237	7.7
4	10.0	4.51	14.2	37.9	251	7.7
5	9.9	4.43	14.1	37.2	254	7.5
6	9.8	4.38	14.1	36.8	248	7.5
MEAN	9.9	4.44	14.1	37.3	247	7.7
TARGET	9.9	4.54	13.5	37.2	260	7.7
C V	1.0	1.0	0.7	1.0	2.3	1.8
% CHG	0.0	2.25	4.26	0.27	5.26	0.0
OLD CAL .	1.09	0.89	1.11	1.08	1.20	0.94
CURRENT	1.09	0.91	1.07	1.08	1.26	0.94
STATUS	OK	OK	OK	OK	OK	OK

MICROS 60 OS/OT

Note: The "**P**" to the right of RUN # 1 indicates that the first calibration sample is not included in the statistical calculations. This first sample is considered as a Calibrator material "Prime"!

Once the calibration information has printer out, the screen will indicate:

```
CALIBRATION ENDED WITH NEW COEFF.
PRESS A KEY TO CONTINUE....
```

Press any key to return to the *MAIN MENU* of the *ABX MICROS 60!*

1.3. Calibration Failed

In order for *ABX MICROS 60* to "Fail" Calibration, the data must meet the statistical criteria which contain (2) conditions.

1. The Coefficient of Variations are out of thier specified limits as shown on *Page 6 in this Section.*
2. The difference between the "Target value" and the "Mean" for each parameter that failed calibration, is greater than 20%.

When *ABX MICROS 60* "Fails calibration", the results will be printed out, the Calibration coefficients are "Rejected", and the previous coefficients will remain unchanged in memory.

Once the calibration information has printed out, the screen will indicate:

```
CALIBRATION FAILED !!!
PRESS A KEY TO CONTINUE....
```

MICROS 60 OS/OT

Note: When the Calibration STATUS indicates "FAILED" on one or more parameters, even though stating "OK" on the other parameters, Calibration will not take place!

MICROS 60 OS/OT

Note: When the Calibration Fails, the operator may restart the calibration again or call your local *ABX Technical Support representative* for further instructions!

If the calibration fails and the Printer is not used, the following menu will be displayed on the LCD as indicated:

SAVED COEFF. WBC	0.97	RBC	0.88	HGB	0.95	△
REJECT. COEFF.	1.16		0.90		0.90	▽

Rejected and saved coefficients can be displayed by using the "Up" and "Down" arrow keys on the front panel. Press the Escape "ESC" key to return to the *Main Menu.*

"Failed" Calibration printout is as indicated:

CALIBRATION

DATE : 01/20/2002 TIME : 09 : 48
CALIBRATION FAILED
OPERATOR : ABC
LOT # : MCAL212

RUN	WBC	RBC	HGB	HCT	PLT	MPV
1 P	10.2	4.50	14.0	38.0	242	7.6
2	9.9	4.45	14.0	37.4	246	7.9
3	9.7	4.41	14.0	37.2	237	7.7
4	10.0	4.51	14.2	37.9	251	7.7
5	9.9	3.65	14.1	31.8	254	7.5
6	9.8	4.38	14.1	36.8	248	7.5
MEAN	9.9	4.32	14.1	36.5	247	7.7
TARGET	9.9	4.54	13.5	37.2	260	7.7
C V	1.0	7.7	0.7	6.3	2.3	1.8
% CHG	0.0	5.09	4.26	1.92	5.26	0.0
REJ. COEFF	1.09	0.89	1.11	1.08	1.20	0.94
CURRENT	1.09	1.05	1.07	1.02	1.26	0.94
STATUS	OK	FAILED	OK	FAILED	OK	OK

1.4. RDW Calibration

The RDW calibration is a separate calibration outside the Auto-calibraion menu.

MICROS 60 OS/OT

Note: The RDW calibration is normally performed by taking blood samples from (**100**) Healthy, Normal, and Drug-free individuals. These blood samples are then analyzed on a instrument that has been calibrated for RDW determination. The Mean and Standard Deviation are then calculated from that population analyzed. The same (**100**) samples are then analyzed on the *ABX MICROS 60*. A Population Mean is calculated and then compared to the known calculated Mean from the comparison instrument. The RDW calibration coefficient for the *ABX MICROS 60* is then calculated from the difference of the two Mean values.

MICROS 60 OS/OT

Note: Expected RDW values may vary with sample population and/or geographical location. It is highly recommended that each Laboratory establish its own normal ranges based on the local population!

The RDW calibration coefficient default value is normally set at (**1.00**). It can be edited by entering into the *Calibration Menu and selecting 2 - COEFFICIENTS, 1 - CALIB. COEFF.,* enter the password (**123**), or the password that has been defined by the operator in the set-up menu. See **Section 5 - Instrument Configuration,** 3 - Special functions, (*3.2. Change Password*).
The Instrument Default password is normally set to (**123**) before operator intervention. Press the "ENTER" key and the following menu will be displayed as indicated:

```
CALIB. COEFF.  >1 - WBC   <   0.97 >
10:42           2 - RBC   <   0.98 >   ▽
```

1 - Select the number (**7**) key on the key pad or use the "Down" arrow key to select the RDW coefficient as indicated on the display:

```
CALIB. COEFF. >7 - RDW  COEFF < 1.00 △
10:23          8 - PDW         < 1.00 >
```

2 - Once the RDW coefficient has been selected, press the "ENTER" key to edit the coefficient as indicated on the display:

```
RDW COEFF ? : _              EXIT  : ESC
   CURRENT  : 1.00           SAVE : ENTER
```

3 - Enter the RDW coefficient value which has been calculated from the comparison study. Press the "ENTER" key to accept the new value.

4 - Press the Escape "ESC" key until you return to the Main Menu.

▼ RDW Calibration form a Quality Control Standard

The RDW may also be calibrated by using a known Quality Control Standard.

DEFINITION: **A Quality Control Standard** is defined as a Commercial blood product which has been specifically developed and Assayed with set parameter Target values and ranges. This product is designed to precisely measure the accuracy and linearity of the analyzer.

1 - Take the *ABX Minotrol - Controls* and bring them to room temperature. Gently and thoroughly mix the control material as indicated on the instruction sheet that comes with the control kit.

2 - Run the *Normal Level control* (**6**) times, as a regular patient analysis. When the cycles are complete, note only the RDW results. Write down these result for future reference use.

3 - Calculate the Mean value for all (**6**) results and write it down for future reference use.

RDW Calibration form a Quality Control Standard continued:

4 - Take the Minotrol Assay sheet that comes with the control kit and note “Only”, the Normal Control Mean Assay value for RDW.

5 - Calculate the New RDW coefficient as followed:
• Take the Normal Control Mean Assay value for RDW,
• Divide it by the Mean value of the Normal control ran (6) times as a sample,
• Times the current RDW calibration coefficient, This will equal the New RDW Calibration coefficient.

6 - To Enter into the calibration coefficient menu, from the *Main Menu, select 3 - CALIBRATION, 2 - COEFFICIENTS, 1 - CALIB. COEFF., enter the password, and use the “Down” arrow key to 7 - RDW.*

7 - Press the “ENTER” key to enter the New coefficient for RDW. Press the “ENTER” key again to accept the New coefficient after it has been entered.

8 - Press the Escape “ESC” key until you return to the Main Menu.

9 - Now take all (3) *Levels of controls, LOW, NORMAL, HIGH,* and run them (1) time each as a regular patient analysis. When the cycles are complete, note only the RDW results and compare them to the Minotrol control Assay values for RDW, on the Assay sheet. Verify that the RDW results are somewhat close to the Mean Assay values and within the Ranges as specified for all (3) Levels.

10 - The RDW calibration is now complete. Be sure to monitor your RDW results and verify that they fall within your patient population.

Verify that Normal RDW results will be within the established ranges set in the set-up menu. See **Section 5 - Instrument Configuration,** 2 - Change Laboratory Limits, (*2.1./2.2. Result Low Limits - Result High Limits*).

MICROS 60 OS/OT

Note: Certain Pathological conditions will affect the RDW results. See **Section 1 - Specifications,** 4- Limitations, (*4.3. Known Interfering substances*)

1.5. Calibration Coefficients

Calibration may also be achieved by changing the “Calibration Coefficients” directly. From the *Mani Menu, select 3 - CALIBRATION, 2 - COEFFICIENTS.* The following menu will be displayed on the LCD screen as indicated:

COEFFICIENTS	1 - CALIB. COEFF.
10:23	2 - PRINT COEFF.

In this Menu, the operator has the option of either “Editing” the current calibration coefficients or “Printing” the current calibration coefficients.

MICROS 60 OS/OT

Important: The *ABX MICROS 60* is an accurate and reliable instrument when properly maintained. Should any variation of Quality Control results outside the Assayed ranges occur after calibration, it is Highly suggested that you contact your local *ABX Technical Support Representative* before Manually editing the calibration coefficients!!!

Changing Calibration Coefficients

When in the Coefficients menu, manually editing the calibration coefficients is performed by selecting *1 - CALIB. COEFF.* The LCD screen on the *ABX MICROS 60* will then ask for the password which allows the operator to enter into and edit the coefficients. The display will state as indicated:

PASSWORD ? :
10:24

A specific password is required to enter into the coefficients menu. Enter the password (**123**), or the password that has been defined by the operator in the set-up menu. See **Section 5 - Instrument Configuration,** 3-Special functions, (*3.2. Change Password*). The Instrument Default password is normally set to (**123**) before any operator intervention.

After entering the password, press the "ENTER" key and the following menu will be displayed as indicated:

CALIB. COEFF.	>1 - WBC	<	0.97 >	
10:42	2 - RBC	<	0.98 >	▽

To Edit any coefficient in this menu, place the cursor next the the coefficient to be edited by press the "Up"or "Down" arrow keys. Once you have selected the coefficient to be edited. follow the steps indicated.

CALIB. COEFF.	1 - WBC	<	0.97 >	
10:42	> 2 - RBC	<	0.98 >	▽

1 - Once the coefficient has been selected, press the "ENTER" key. The following menu will be displayed as indicated:

RBC	? : _	EXIT : ESC
CURRENT	: 0.98	SAVE : ENTER

2 - Enter the New coefficient derived from using the following formula, at the bottom of this page:

3 - Once New coefficient has been entered, press the "ENTER" key to accept the coefficient. The diaplay will return to the Calibrate Coefficient Menu with the new coefficient displayed as indicated:

CALIB. COEFF.	1 - WBC	<	0.97 >	
10:42	> 2 - RBC	<	1.03 >	▽

4 - Continue to use the "Up" or "Down" arrow keys to select the next coefficient to be edited. Use the same formula below to calculate the remaining coefficients.

5 - Repeat steps **1 through 3** for each remaining coefficient. Once all New coefficients have been entered, press the Escape "ESC" key until you return to the Main Menu.

MICROS 60 OS/OT

Important: After manually editing the calibration coefficients, it is Highly recommended to run Quality Control. Verify that all levels of control material are within their specified parameter ranges. Verify that there are no error flags (**H, L, *, $, !** for HGB) associated with all levels of Quality control results.

MICROS 60 OS/OT

Note: PCT and PDW are not available in the United States! These parameters are Strictly used for research and investigational purposes "Only"!

Calibration Coefficients are as listed:

WBC
RBC
HGB
HCT
PLT
MPV
RDW COEFF.
PDW COEFF.

$$\frac{\text{Parameter Target value}}{\text{Parameter Mean value}} \times \text{Current parameter coeffieicet} = \text{New parameter coefficient}$$

Print Coefficients

From the Calibration Menu, *select 2 - COEFFICIENTS, 2 - PRINT COEFF.* The current calibration coefficients will automatically printout as indicated:

COEFFICIENTS

DATE : 01/20/2002 TIME : 14:26

	WBC	RBC	HGB	HCT	PLT	MPV
CURRENT	0.97	0.88	1.13	1.08	0.95	0.92

RDW COEFF : 1.00
PDW COEFF : 1.00

MICROS 60 OS/OT

Note: PCT and PDW are not available in the United States! These parameters are Strictly used for research and investigational purposes “Only”!

Calibration Coefficient limits

After any calibration has been performed on the *ABX MICROS 60,* Verify that all parameter calibration coefficients are within their specified ranges as indicated:

Parameters	WBC	RBC	HGB	HCT	PLT	MPV	RDW	PDW
Coefficient limits								
Minimum	0.89	0.73	0.83	0.87	0.99	0.75	0.75	0.75
Target	1.09	0.89	1.11	1.08	1.20	0.94	1.00	1.00
Maximum	1.29	1.05	1.39	1.29	1.41	1.13	1.25	1.25

If any of the Calibration coefficients are out of their specified ranges after calibrating the *ABX MICROS 60,* contact your local *ABX Technical Support Representative!*

2. Quality Control Program

2.1. Quality Control Options

MICROS 60 OS/OT

Important: It is highly recommended that you use the *ABX MINOTROL* Quality Control blood product when running Q.C. on the *ABX MICROS 60* analyzer. This product is specifically designed for use with the *ABX MICROS 60* analyzers. Call your local *ABX DIAGNOSITCS Customer Service Representative* for information and ordering of this specialized product.

The *ABX MICROS 60-OS/OT* Quality Control program contains (**5**) different functions in its Menu.

1. *AUTOMATIC* - The function of this Q.C. sub-menu is to allow the operator to analyze Commercial Control blood products (MINOTROL), and store the results on the *Quality Control Smart Card.*

2. *ANALYSIS* - The function of ths Q.C. sub-menu is to allow the operator to analyze Commercial Control blood products (MINOTROL), with fixed WBC Thresholds specifically for use "Without" a Smart Card.

3. *PRINT TARGETS* - The function of this Q.C. sub-menu is to allow the operator to print the Target values of the Commercial Control blood products from the *Quality Control Smart Card "Only"!!!*

4. *STATISTICS* - The function of this Q.C. sub-menu is to allow the operator to print the cumulative statistics for the Commercial Control blood products from the *Quality Control Smart Card "Only"!!!*

5. *GRAPHS* - The function of this Q.C.sub-menu is to allow the operator to print the Levey Jennings graphs of the Commercial Control blood products from the *Quality Control Smart Card "Only"!!!*

MICROS 60 OS/OT

Caution: When running Quality Control "Without" the use of a Smart Card, pay close attention to the Result parameter Limits, if the system was programmed to print out the limits. These limits "Are not" Quality Control limits. These limits are the ones that were established in the set-up menu. See **Section 5 - Instrument Configuration,** 2-Change Laboratory Limits, (*2.1./2.2. Result Low Limits and Result High Limits*). Verify your control results with the Assay sheet that comes with the control material. Verify that each Control level parameter is within its assayed limits!!!

To enter into the Q.C. menu from the *Main Menu, select 2 - Q.C.,* then press the "ENTER" key. The menu will displayed as indicated:

Q.C.	>1 - AUTOMATIC	
09:23	2 - ANALYSIS	∇

2.2. Q.C.- Automatic

(With Q.C. Smart Card)

1 - Remove the Minotrol Quality Control blood from the refrigerator and bring it to room temperature.

2 - From the Q.C. Menu, *select 1 - AUTOMATIC.* This menu will move the operator through the automatic quality control process once the Smart Card is inserted. Operator selection, Lot # identification, Expiration date, ...etc. will be displayed between each step of the process.

3 - Insert the *Quality Control Smart Card* into the card reader with a firm push until you here it "click" into place.

Q.C.- Automatic
(With Q.C. Smart Card) continued:

The first step that takes place is that the *ABX MICROS 60* checks for the presence of a CARD READER.

If a Card Reader is not present, or if there is a technical failure with the present reader, the Q.C. PROGRAM will be aborted and the following message will appear on the LCD display as indicated:

ERROR : NO SMART CARD READER PRESS A KEY TO CONTINUE....

Once a key has been pressed, the analyzer automatically returns to the Q.C. menu because it is impossible to run Q.C. Automatic without a Smart Card Reader!

The second step that takes place is that the *ABX MICROS 60* checks for the presence of a *Quality Control Smart Card!*

If the card has not been inserted, or if the card has been inserted incorrectly, or if there is a technical failure with the present reader, the following message will appear on the LCD display as indicated:

ERROR : NO SMART CARD....	NO : ESC
INSERT NEW CARD	YES : ENTER

MICROS 60 OS/OT

Caution: The *ABX MICROS 60* will only accept the *Quality Control Smart Card* while in the Q.C. program! It will not accept:
1 - A Q.C. card that has expired!
2 - A Memory Card!
If you have the correct card and are still having the Error messages indicated above, contact your local *ABX Technical Support Representative* for further instructions regarding this issue!!!

If the Escape "ESC" key is pressed, the analyzer automatically returns to the Q.C. menu because it is impossible to run Q.C. Automatic without a Q.C.Smart Card!
If the Q.C. smart card is in the reader and the previous Error messages do not appear, the *ABX MICROS 60* will automatically read the card and display the Lot # and Expiration date of the current card as indicated:

LOT # M211 NEW Q.C.	NO : ESC
EXP DATE 01/20/02	YES : ENTER

MICROS 60 OS/OT

Caution: It is mandatory to verify that the Quality Control Smart card being used matches the Instrument Type (Micros 60), the Lot #, and Expiration date of the Quality Control material being used for this program!

Q.C.- Smart Card Messages

"NEW QC" means that this card is being used for the very first time.

"XX QC RUN" When the card already has Q.C. data on it, the display will show the next sample run for Quality control, i.e. **18 QC RUN** inplace of New QC. This number indicates the next Q.C. run after the stored runs.

For example: 1 complete QC RUN contains all (3) levels of controls, *Low, Normal, and High* analyzed 1 time each.

"QC DIFF" means that there is a difference between the QC index in the *ABX MICROS 60* and the QC index on the QC Smart card. This usually occurs when there is confusion between 2 QC Smart cards.
If the operator presses the "ENTER" key, the analyzer accepts the differences and automatically equals the indexes between the *ABX MICROS 60* and QC Smart Card.
If the operator presses the Escape "ESC" key, the analyzer requests a New Card, reads the New card information, and displays it.

"SMART CARD FULL" means that the QC Smart Card has reached its limit on stored QC data and cannot store anymore on that specific card.
A Maximum of (**33**) QC runs can be stored on QC Smart Card. 1 complete QC RUN contains all (3) levels of controls, *Low, Normal, and High,* analyzed 1 time each.
When the card is full, you must insert a New Card and press the "ENTER" key to accept the new card information!

Select Operator

Once you have accepted the QC Smart card information , the display will prompt you to select an Operator (OP.). Use the "Down" arrow key to select one of (4) operators which can be previously programmed in the system set-up menu. See **Section 5 - Instrument Configuration,** 3-Special functions, (*3.1. Change Operator*).

4 - Select one of the (4) operators and then press the "ENTER" key. A star (*) will be placed next to the chosen operator as indicated on the display:

SELECT OP	> * 1 - OP. 1	
13:22	2 - OP. 2	▽

5 - Once the operator has been select, press the "ENTER" key and the menu will be displayed.

Select Commercial Control Level

The next display to appear will ask you as to which level of commercial control you would like to analyze first. the Display is as indicated:

SELECT LEVEL	> * 1 - LOW BLOOD	
13:24	2 - NORMAL BLOOD	▽

6 - Use the "Down" arrow key to select 1 of 3 levels of commercial control to analyze, *Low, Normal, or High.* Once the selection has been made, press the "ENTER" key to accept that level.

A message "LOADING LEVEL PLEASE WAIT" will be displayed for about one half of a second. The information on the QC Smart card is read at this time. After the information is read off of the card, *ABX MICROS 60* will ask if you want to run the level of commercial control selected as indicated on the display:

M211	LOW	START QC
ESC TO EXIT	PRESS START TO ASPIRATE	

7 - Verify that the lot number on the screen matches the lot # on the Commercial control blood.

Run Commercial Control Blood

8 - Once the Control blood has equilibrated to room temperature, Gently and thoroughly mix the level of control blood indicated on the display. Follow the product instructions that come with the Minotrol control kit for proper mixing.

9 - Remove the cap and place the vial beneath the sample probe, raise the vial upwards so that the sample probe enters into the blood.

10 - Press the "START" key on the front panel to start the cycle. A brief prime cycle will occur if the *ABX MICROS 60* has not been used in the last 15 minutes. When this brief cycle is complete, the display will indicate:

M211	LOW
PRESS START TO ASPIRATE	

11 - Press the "START" key or the Manual Sample Bar, the control analysis cycle will begin.

Run Commercial Control Blood continued:

When the control analysis cycle is complete, the results are displayed as indicated:

WBC	RBC	HGB	HCT	
2.2	2.36	5.6 L	15.9	▲ ▼

12 - To view the remaining results on the display, use the “Up” and “Down” arrow keys to scroll through the results.

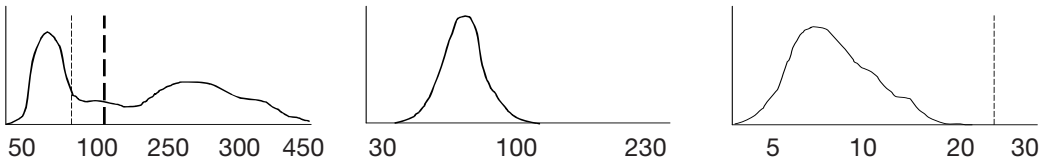
The control results are printed out as indicated:

Q. C. TIME : 09:25

DATE : 01/20/2002
LOT # : M211 LOW
EXP DATE : 02/20/2002
OPERATOR : OP. 1 Q.C. : 02
SEQ. # : 1
STARTUP PASSED

WBC	:	2.3	10^3/ mm^3	(*1.7 - 2.5*)	MCV	:	67	µm^3	(*63 - 71*)
RBC	:	2.36	10^6/ mm^3	(*2.27 - 2.57*)	MCH	:	23.6	Pg	(*23.6 - 27.6*)
HGB	:	5.6 **L**	g/dl	(*5.7 - 6.7*)	MCHC	:	35.2	g/dl	(*35.2 - 41.2*)
HCT	:	15.9	%	(*14.2 - 18.2*)	RDW	:	12.7	%	(*9.9 - 15.9*)
PLT	:	70	10^3/ mm^3	(*52 - 92*)	MPV	:	9.4	µm^3	(*7.4 - 11.4*)
DIFF	:								
%LYM	:	59.6	%	(*52.7 - 66.7*)	#LYM	:	1.3	10^3/ mm^3	(*0.9 - 1.7*)
%MON	:	14.2	%	(*7.4 - 19.4*)	#MON	:	0.3	10^3/ mm^3	(*0.1 - 0.5*)
%GRA	:	26.2	%	(*19.9 - 33.9*)	#GRA	:	0.7	10^3/ mm^3	(*0.2 - 1.0*)

WBC RBC PLT



MICROS 60 OS/OT

Note: Printed results may vary on the amount of data displayed on the printout. *Limits, LMG’s, Histograms, and Parameters* are all dependant upon the initial instrument setup. See **Section 5 - Instrument Configuration,** 1-Results Options, (*Printout, Print Limits, Print LMG’s*).

2.3. Accepting or Rejecting QC Results

The results from the control blood are compared to Assayed ranges stored on the Quality Control Smart card. If any of the parameter results are "Out of Range", an **"H"**(High) or **"L"**(Low) will be shown on the display and on the printout as well.

If a third counting sequence is initiated during the analysis cycle, and a specific parameter is in question, a Dollar sign (**$**) or a Star (*) will be shown on the display next to the parameter and the run will *Automatically be Rejected!*

If the HGB Blank is not within acceptable limits, an Exclamation (**!**) is displayed next to HGB and the run will *Automatically be Rejected!*

You "MUST" rerun the control blood if the display indicates:

RUN REJECTED PRESS A KEY TO CONTINUE....

If the results are good and the Error flags (*, **$**, **!** for HGB) do not appear on the display, press the Escape "ESC" key and the following menu will be displayed as indicated:

VALID LOW ?	NO : ESC YES : ENTER

The operator now has the option of accepting or rejecting the results.

Accepting Q.C. Results

Verify that there are No **"H"** or **"L"** flags on the display or printout before accepting your results!!!
If the operator "Accepts" the results by pressing the "ENTER" key, they will be stored on the QC Smart card and the display will return to *SELECT LEVEL* as indicated:

SELECT LEVEL > *	2 - NORMAL BLOOD
13:24	3 - HIGH BLOOD ▽

Use the "Up" or "Down" arrow keys to select the next control level for analysis.

13 - Once the next level has been selected, Press the "ENTER" key to load that control level.

14 - Gently and thoroughly mix the next control level blood. Repeat Steps **10 through 12.**

15 - After accepting the second control level results, the *ABX MICROS 60* automatically loads the last control level without returning to the *SELECT LEVEL* display.

16 - Gently and thoroughly mix the next control level blood. Repeat Steps **10 through 12.**

17 - Once the last control level has been accepted, the display will indicate:

VAILD Q.C. ?	NO : ESC YES : ENTER

18 - Press the "ENTER" key and all levels of control results will be stored on the QC Smart card as indicated on the display:

Q.C. STORED PRESS A KEY TO CONTINUE....

19 - Press the Escape "ESC" key to exit the Q.C. Menu and retrn to the Main Menu.

Rejecting Results

MICROS 60 OS/OT

Important: Error flags such as (**H, L, *, $,** and **!** for HGB) on control results are NON-valid results! The parameters with these specific flags should be reviewed and questioned before continuing with the next level of control blood!

If the operator "Rejects" the results by pressing the Escape "ESC" key, you have the option of re-running that same control level again or selecting another level. No results will be stored on the QC smart card.

Rejecting Results continued:

MICROS 60 OS/OT

Important: If a control level blood displays any Error flags (**H, L, *, $, !** for HGB) after being analyzed **Twice** in sequence for the same level,
1 - Refer to your laboratory procedures for obtaining unreliable quality control results.
2 - Perform a concentrated cleaning and rerun the control.
3 - If the results are still unreliable, ABORT Q.C. and contact your local *ABX Technical Support Representative* before continuing with Quality Control analysis!

Exiting Q.C.- Automatic

If the operator needs to Exit Q.C. at any time before all levels of control bloods are analyzed, it is possible to do so by following these simple steps:

1 - Wait until the cycle of the control level blood being analyzed is complete.

2 - Press the Escape "ESC" key and the *ABX MICROS 60* will ask you if you want to accept or reject the results as indicated on the display:

VALID	? LEVEL	NO : ESC YES : ENTER

3 - Press the escape "ESC" key and the display will return to *START QC* display as indicated:

M211	? LEVEL	START QC
ESC TO EXIT	PRESS START TO ASPIRATE	

4 - Press the Escape "ESC" key and the *ABX MICROS 60* will ask you if you want *EXIT QC ?* as indicated on the display:

EXIT QC ?	NO : ESC YES : ENTER

5 - Press the "ENTER" key and the analyzer will state that control blood results were not stored on the QC Smart card as indicated on the display:

QC NOT VALID PRESS A KEY TO CONTINUE....

After pressing any key, the analyzer returns you to the Q.C. menu as indicated on the display:

Q.C.	> 1 - AUTOMATIC	
09:23	2 - ANALYSIS	∇

Valid Q.C.

If the QC is accepted and validated, the index is increased on the QC Smart card and the *ABX MICROS 60* internal index is increased as well.

Invalid Q.C.

If the QC is rejected and not validated, the following message appears on the display:

QC NOT VALID PRESS A KEY TO CONTINUE....

Results are not stored on the QC Smart Card at the time of exit.

2.4. Q.C. Analysis
(Without Q.C. Smart Card)

1 - Remove the Minotrol Quality Control blood from the refrigerator and bring it to room temperature.

2 - From the Q.C. Menu, *select 2 - ANALYSIS.* This menu will allow the operator to run a control level blood as a normal analysis cycle "Without" the use of a Smart Card, but with specific LMG Thresholds for control level bloods. (*Independant from the Temperature*)

3 - The *ABX MICROS 60* will display a menu which will ask you for a *LOT* # and show a current lot number if any, as indicated:

LOT # :_	EXIT : ESC
CURRENT : M167	SAVE : ENTER

4 - Enter a Lot number, anywhere from **1** to **10** Alphanumeric characters. Use the Number keys to enter the numbers directly. Use the "Up" or "Down" arrow keys to select each Alpha character, pressing the "ENTER" key after each Alpha entry.

5 - Once you have entered the Lot number, press the "ENTER" key to accept it. A brief HGB Blank reference measurement is performed before the analysis cycle. a Message is displayed as indicated:

PLEASE WAIT.....

6 - When the HGB Blank reference measurement is complete, a message is displayed as indicated:

ANALYSIS
PRESS START TO ASPIRATE

7 - Once the Control blood has equilibrated to room temperature, Gently and thoroughly mix the level of control blood to be analyzed . Follow the product instructions that come with the Minotrol control kit for proper mixing.

8 - Remove the cap and place the vial beneath the sample probe, raise the vial upwards so that the sample probe enters into the blood.

9 - Press the "START" key or press the Manual Sample Bar. The control analysis cycle will begin.

10 - When the analysis cycle is complete, the results are displayed and printed out as on *Page 18 of this Section.*

11 - See Quality Control Reminder in the next column!!!

MICROS 60 OS/OT

Caution: When running Quality Control "Without" the use of a Smart Card, pay close attention to the Result parameter Limits, if the system was programmed to print out the limits. These limits "Are not" Quality Control limits. These limits are the ones that were established in the set-up menu. See **Section 5 - Instrument Configuration,** 2-Change Laboratory Limits, (*2.1./2.2. Result Low Limits and Result High Limits*). Verify your control results with the Assay sheet that comes with the control material. Verify that each Control level parameter is within its assayed limits!!!

2.5. Q.C. Print Tagrets

(Only with Q.C. Smart Card)

This Q.C. sub-menu allows you to print out the Assay ranges of all (3) levels of commercial control blood from the Q.C. Smart Card.

1 - Insert the Q.C. Smart Card into the reader with a firm push until it "clicks" into place.

2 - From the Q.C. Menu, *select 3 - PRT. TARGETS.* The display on the *ABX MICROS 60* will show the Lot # identification and Expiration date of the control blood product as indicated:

LOT # M211	NO : ESC
EXP DATE 01/20/02	YES : ENTER

3 - Press the "ENTER" key and the analyzer will load the information from the Q.C. Smart Card and print out all (3) level assay ranges. A message will appear on the display as indicated:

LOADING LEVELS	
07:16	PLEASE WAIT....

4 - The printout will show *Low limit* and *High limit* for each parameter, for each assayed level of control. *HIGH, NORMAL,and LOW.*

2.6. Q.C. Statistics (Only with Q.C. Smart Card)

This Q.C. sub-menu allows the operator to print out all the stored cumulative data for all (3) levels on the commercial control blood. The information printed out will contain all the necessary statistical data for each level. The levels can be selected individually or all at once.

MICROS 60 OS/OT

Important: It is highly recommended to print out all Quality Control Statistical data at the end of each month for hard copy verification of control data.

Each File printout contains the following information: *File Name (Blood Level), Lot # of the Control, Expiration date of the control, Date and Time of the print data request, Date and Time of each control run, Operator and Parameter results of each control run, the Reference Assay Mean, Upper, and Lower limits, the Actual Mean results of the total control runs, the 2 Standard Deviation value, and the Percent Coefficient of Variation.*

Select Statistics

1 - From the Q.C. Menu , *select 4 - STATISTICS, then press the "ENTER" key to enter into the sub-menu* as indicated on the display:

SELECT LEVEL	> * 1 - ALL
13:42	2 - LOW BLOOD

2 - Use the "Down" arrow key to select one of (3) levels to be printed out or select "ALL" to print out a (3) levels. Selection will be indicated on the display:

SELECT LEVEL	> * 3 - NORMAL BLOOD
13:56	4 - HIGH BLOOD

3 - Once your selection has been made, press the "ENTER" key to print out the statistical data. The display will state as indicated:

	LOADING LEVEL
14:06	PLEASE WAIT....

	PROCESSING RESULTS
14:06	PLEASE WAIT....

	SENDING RESULTS
14:06	PLEASE WAIT....

5 - When the statistical data has been printed out, it will state as indicated below:

6 - Maintain a copy of these results each month for Quality Control Analysis verification!

Q.C.

NORMAL
LOT # : M211 TIME : 07 : 31
EXP DATE : 02/20/02 DATE : 03/01/02

No	DATE	TIME	OP	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
1	01/03/02	09:57	OP. 2	7.4	4.58	13.6	36.3	79	29.7	37.5	279
2	01/04/02	08:23	OP. 1	7.3	4.52	13.2	35.3	78	29.2	37.4	247
3	01/05/02	10:57	OP. 3	7.3	4.47	13.4	35.2	79	29.9	38.0	254
--	---------	------	------	----	-----	-----	-----	----	-----	-----	-----
--	---------	------	------	----	-----	-----	-----	----	-----	-----	-----

ETC.....
REFERENCE :

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.4	4.52	13.4	35.7	79	29.6	37.5	249
LOW	6.8	4.34	12.8	33.7	75	27.6	34.5	219
HIGH	8.0	4.70	14.0	37.7	83	31.6	40.5	279

ACTUAL :

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.4	4.54	13.3	35.5	78	29.4	37.5	252
2SD	0.13	0.06	0.16	0.59	0.63	0.43	0.53	11.22
C V	1.70	1.37	1.18	1.67	0.80	1.46	1.40	4.45

ETC.....

2.7. Q.C. Graphs (Only with Q.C. Smart Card)

The *ABX MICROS 60* plots Levey-Jennings charts for each parameter of the Quality Control files stored on the Q.C. Smart card. Each Levey-Jennings chart will plot (**1**) data point per parameter, per control run, for every control data point stored.

Select Graphs

1 - From the Q.C. Menu, *select 5 - GRAPHS, then press the "ENTER" key* to enter into the Graphs sub-menus as indicated on the display:

SELECT LEVEL	> * 1 - ALL
13:42	2 - LOW BLOOD

2 - Use the "Down" arrow key to select one of (3) levels to be printed out or select "ALL" to print out a (3) levels. Selection will be indicated on the display:

SELECT LEVEL	> * 3 - NORMAL BLOOD
13:56	4 - HIGH BLOOD

3 - Once your selection has been made, press the "ENTER" key to print out the Levey-Jennings charts. The display will state as indicated:

	LOADING LEVEL
14:06	PLEASE WAIT....

	PROCESSING RESULTS
14:06	PLEASE WAIT....

	SENDING RESULTS
14:06	PLEASE WAIT....

4 - The parameter charts are determined by the internal software setup of the *ABX MICROS 60.* See **Section 1 - Specifications,** 1. Technical Specifications, (*1.1. Parameters*) for the parameters that are printed out on the Levey-Jennings charts.

MICROS 60 OS/OT

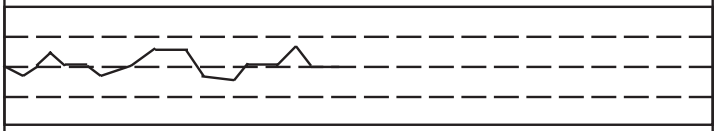
Note: Printed results may vary on the amount of data displayed on the printout. *Limits, LMG's, Histograms, and Parameters* are all dependant upon the initial instrument setup. See **Section 5 - Instrument Configuration,** 1-Results Options, (*Printout, Print Limits, Print LMG's*).

Levey-Jennings charts are printed out with the following information included: *File Name (Blood Level), Lot # of the Control, Expiration date of the control, Date and Time of the print data request, the Parameter Name, and the Parameter graph with (40) total data points.* Below each graph, *the Reference Assay Mean, Upper, and Lower limits, the Actual Mean results of the total control runs, the 2 Standard Deviation value, and the Percent Coefficient of Variation.*

Q. C.

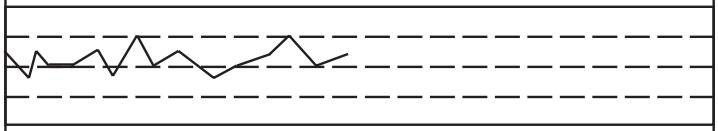
NORMAL
LOT # : M211 TIME : 10:07
EXP DATE : 02/20/02 DATE : 01/20/02

WBC



5 10 15 20 25 30 35 40
REFERENCE :
MEAN : 7.4 LOW 6.8 HIGH 8.0
ACTUAL :
MEAN : 7.4 2SD 0.13 C V 1.70

RBC



5 10 15 20 25 30 35 40
REFERENCE :
MEAN : 4.52 LOW 4.34 HIGH 4.70
ACTUAL :
MEAN : 4.54 2SD 0.06 C V 1.37

ETC.....

MICROS 60 OS/OT

Note: Q.C. Graphs will be printed out even when the parameter results are equal to zero!