HemataSTAT®

Sample Quarterly and Daily Quality Control Procedures

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Form 489
Rev 4-1-10

I. PURPOSE:

A. The purpose of this procedure is to offer guidance to users of the HemataSTAT® Microhematocrit Centrifuge in the development of quality control procedures.

B. This procedure is not a requirement of the manufacturer. A facility should establish its own acceptance procedure in accordance with local, state, and federal regulations to assure proper operation of the equipment.

II. SCOPE:

A. The quarterly Quality Control should be performed when the centrifuge is first placed into service, after repairs to the centrifuge and on a quarterly basis.

B. The daily Quality Control should be performed prior to routine use of the unit for determining hematocrit values.

III. REFERENCE DOCUMENTS AND FORMS:

A. Reference Documents

1. HemataSTAT® Operators Manual
2. HemataCHEK® insert sheet

B. Forms:

1. HemataSTAT Quarterly Quality Control Log – Appendix A
2. HemataSTAT Daily Quality Control Log – Appendix B

IV. EQUIPMENT AND MATERIALS:

A. HemataSTAT Microhematocrit Centrifuge
B. Capillary Tubes
C. HemataCHEK
D. Calibrated Stopwatch
E. Calibrated Tachometer
F. Tube Sealant

V. QUARTERLY QUALITY CONTROL:

A. Timer Accuracy:

1. Press the run button on the centrifuge. Start timing with a calibrated stopwatch when "RUNNING WAIT 60 SEC" is displayed on the LCD.
2. Stop the stopwatch when the motor shuts off. Record the elapsed time on the stopwatch in seconds and the stopwatch identification number on Appendix A.
3. If the reading does not fall within 60 ± 3 seconds, repeat the time measurement in duplicate and record the results on Appendix A – Repeat Timer Reading.
4. Decide whether the HemataSTAT centrifuge is accepted or rejected using the criteria below:
   a. If the initial time falls within the specified range, accept the centrifuge.
   b. If both repeat times fall within the specified range, accept the centrifuge.
   c. If one or both repeat times fall outside the range, reject the centrifuge.
5. Document and initial the decision on Appendix A.

B. RPM Accuracy:

1. Place six tube holders with tubes into the rotor. Place a piece of white tape on top of the rotor.

2. Close and lock the lid, then press the start button.
3. The message “ACCELERATING” appears momentarily.
4. At 50 SEC the message changes to “RPM=XXXX WAIT XX SEC”.
5. Take the tachometer reading at this point, record both the tachometer reading and the RPM reading. Record the values and the tachometer identification number on Appendix A.
6. If the RPM reading on the tachometer differs more than ± 2% of the related LCD display or if the RPM value on the LCD is less than 5,670 or greater than 6,930, repeat the failed measurement in duplicate. Record the values on Appendix A under Repeat RPM Reading.
7. Decide whether the HemataSTAT centrifuge is accepted or rejected using the criteria below:
    a. If the initial tachometer and displayed RPM values are within the range, accept the centrifuge.
    b. If both repeats fall within the range, accept the centrifuge.
    c. If one or both repeats fall outside the range, reject the centrifuge.
8. Document and initial the decision on Appendix A.

C. Reading Accuracy/Overall Performance Testing Low Controls:

Upon initiation of testing, fill in the proper information on the Quarterly Quality Control Log – Appendix A. When a new vial of HemataCHEK Blood Control is opened, cross out the manufacturer’s date on the vial; fill in the date opened and the new expiration date. (Note: The new expiration date is based on 31 days from when the vial is initially opened.)

1. Use the low liquid reference control (HemataCHEK, Separation Technology, Inc.). Record the following information on the Reading Accuracy section of Appendix A:
    a. Lot Number
    b. Expiration Date
    c. Date Vial Opened
    d. Open Vial Expiration Date
    e. Expected Value Range
2. Test two replicates of the low liquid control on the HemataSTAT Centrifuge. See the HemataCHEK insert sheet and HemataSTAT manual for proper use of the controls.
    a. Centrifuge the two samples at the same time.
    b. Record the values as Readings 1 and 2 – Appendix A.
    c. Compare each of the values to the manufacturer’s printed expected values (range). If the reading falls:
        i. Within the acceptable range, mark Y (Yes) on Appendix A.
        ii. Outside the acceptable range, mark N (No) on Appendix A.

    Note: Unacceptable test results may be a result of improper mixing of the controls before use.

3. If one of the values of the low control is out of the manufacturer’s expected value range, repeat the test in duplicate. Record the results on Appendix A under Repeat Test.
4. Decide whether the HemataSTAT Centrifuge is accepted or rejected using the following criteria.
    a. If both initial results of the normal control level fall within the expected range, accept the centrifuge.
    b. If both initial results are out of range, reject the centrifuge.
    c. If both repeat values fall within the range, accept the centrifuge.
    d. If both repeat values fall outside the range reject the centrifuge.
5. Document and initial your decision on Appendix A.

D. Reading Accuracy/Overall Performance Testing Normal Controls:

1. Use the normal liquid reference control (HemataCHEK, Separation Technology, Inc.). Record the following information on the Reading Accuracy section of Appendix A:
   a. Lot Number
   b. Expiration Date
   c. Date Vial Opened
   d. Open Vial Expiration Date
   e. Expected Value Range

2. Test two replicates of the normal liquid control on the HemataSTAT Centrifuge. See the HemataCHEK insert sheet and HemataSTAT manual for proper use of the controls.
   a. Centrifuge the two samples at the same time.
   b. Record the values as Readings 1 and 2 – Appendix A
   c. Compare each of the values to the manufacturer's printed expected values (range). If the reading falls:
      i. Within the acceptable range, mark Y (Yes) on Appendix A.
      ii. Outside the acceptable range, mark N (No) on Appendix A.

   Note: Unacceptable test results may be a result of improper mixing of the controls before use.

3. If one of the values of the normal control is out of the manufacturer's expected value range, repeat the test in duplicate. Record the results on Appendix A under Repeat Test.

4. Decide whether the HemataSTAT Centrifuge is accepted or rejected using the following criteria.
   a. If both initial results of the normal control level fall within the expected range, accept the centrifuge.
   b. If both initial results are out of range, reject the centrifuge.
   c. If both repeat values fall within the range, accept the centrifuge.
   d. If both repeat values fall outside the range reject the centrifuge.

5. Document and initial your decision on Appendix A.

E. Reading Accuracy/Overall Performance Testing High Controls:

1. Use the high liquid reference control (HemataCHEK, Separation Technology, Inc.). Record the following information on the Reading Accuracy section of Appendix A:
   a. Lot Number
   b. Expiration Date
   c. Date Vial Opened
   d. Open Vial Expiration Date
   e. Expected Value Range

2. Test two replicates of the high liquid control on the HemataSTAT Centrifuge. See the HemataCHEK insert sheet and HemataSTAT manual for proper use of the controls.
   a. Centrifuge the two samples at the same time.
   b. Record the values as Readings 1 and 2 – Appendix A.
   c. Compare each of the values to the manufacturer's printed expected values (range). If the reading falls:
      i. Within the acceptable range, mark Y (Yes) on Appendix A.
      ii. Outside the acceptable range, mark N (No) on Appendix A.

   Note: Unacceptable test results may be a result of improper mixing of the controls before use.

3. If one of the values of the high control is out of the manufacturer's expected value range, repeat the test in duplicate. Record the results on Appendix A under Repeat Test.

4. Decide whether the HemataSTAT Centrifuge is accepted or rejected using the following criteria.

    a. If both initial results of the high control level fall within the expected range, accept the centrifuge.
    b. If both initial results are out of range, reject the centrifuge.
    c. If both repeat values fall within the range, accept the centrifuge.
    d. If both repeat values fall outside the range reject the centrifuge.

5. Document and initial your decision on Appendix A.

F. User Acceptance Review:

1. If the testing is successfully completed, route Appendix A for signatures by the appropriate personnel.

G. User Rejection Review:

1. If the centrifuge is rejected, route Appendix A for signature and tag or mark the instrument as “DO NOT USE”.
2. Contact Separation Technology for assistance or repair. Document this action on the HemataSTAT Quarterly Quality Control Log. Initial and date the entry.

VI. DAILY QUALITY CONTROL:

Upon initiation of testing, fill in the proper information on the Daily Quality Control Log – Appendix B. When a new vial of HemataCHEK Blood Control is opened, cross out the manufacturer’s date on the vial; fill in the date opened and the new expiration date. (Note: The new expiration date is based on 31 days from when the vial is initially opened.)

A. Centrifuge all three samples at one time.
B. Read the tubes and record the results on the Daily Quality Control Log – Appendix B.
C. Compare each of the results to the manufacturer’s printed acceptable values (range).
D. If the results are within the acceptable ranges, the centrifuge may be accepted for use.
E. If any of the results are out of the acceptable ranges, assure proper mixing of the vial(s) and retest the out of range level(s) in duplicate.
F. If the repeat test results are within the acceptable range the centrifuge may be accepted for use.
G. If any of the repeat results are not within the acceptable range the unit should be labeled out of service and the manufacturer should be contacted. (Note: Test results may be confirmed by repeating the process with a new vial of HemataCHEK.)
H. Submit the completed log to the supervisor for review.

APPENDIX A

QUARTERLY QUALITY CONTROL LOG

Centrifuge ID #: _____
Capillary Tube Size:_____

Timer Accuracy

Initial Timer Reading		**Repeat Timer Reading**		
Reading #1	Stopwatch ID#	Reading #1	Reading #2	Stopwatch ID #

Acceptable Range: 60 ±3 seconds

HemataSTAT Centrifuge: Accepted: ____ Rejected: ____ Initials/Date: _____

RPM Accuracy

Initial RPM Reading			**Repeat RPM Reading**				
Tach Reading #1*	LCD Display #1**	Tach ID #	Tach Reading #1*	LCD Display #1**	Tach Reading #2*	LCD Display #2**	Tach ID #

*Acceptable Tolerance: ± 2% of LCD display ** Acceptable Range: 5670 – 6930 (6300 ± 10%)

HemataSTAT Centrifuge: Accepted: ____ Rejected: ____ Initials/Date: _____

Reading Accuracy

HemataCHEK Controls	**Low**	**Normal**	**High**
Lot Number			
Expiration Date			
Date Vial Opened			
Open Vial Expiration Date			
Expected Value Range			

Initial Test

Low				**Normal**				**High**			
Reading #1%	Accept Y/N	Reading #2%	Accept Y/N	Reading #1%	Accept Y/N	Reading #2%	Accept Y/N	Reading #1%	Accept Y/N	Reading #2%	Accept Y/N

Repeat Test

Low				**Normal**				**High**			
Reading #1%	Accept Y/N	Reading #2%	Accept Y/N	Reading #1%	Accept Y/N	Reading #2%	Accept Y/N	Reading #1%	Accept Y/N	Reading #2%	Accept Y/N

See Table above for expected value range.

HemataSTAT Centrifuge: Accepted: ____ Rejected: ____ Initials/Date: _____

Comments:_____
_____

User Acceptance Review:
The attached results have been reviewed and the instrument is: Accepted_____ Rejected_____

_____ _____
Signature Date

Appendix B

HemataSTAT
Daily Quality Control Log

Centrifuge ID # _____		Low Lot #: _____ Date Opened: _____ Exp. Date: _____ Range: _____		Normal Lot #: _____ Date Opened: _____ Exp. Date: _____ Range: _____		High Lot #: _____ Date Opened: _____ Exp. Date: _____ Range: _____		Capillary Tube Type: _____ Size: _____	
#	Date	HCT	*S/U	HCT	*S/U	HCT	*S/U	Initials	Reviewer
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
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31									

*S = Satisfactory/U = Unsatisfactory

Supervisor Review: _____ Date: _____