HEMOCHRON®

Whole Blood Coagulation Systems

Low Range Activated Clotting Time (ACT-LR) Cuvette
Correlation Protocol for HEMOCHRON®
Microcoagulation Instruments

MSIG: 48 10/06

Dear Medical Professional:

Thank you for your interest in evaluating the HEMOCHRON® Jr. Microcoagulation system for your near patient coagulation testing needs. The HEMOCHRON Jr. offers a simple, one-step procedure using fresh whole blood samples to evaluate essential coagulation parameters: the ACT+, ACT-LR, APTT and PT. Test results are reported in plasma equivalent values and INR for PT, plasma equivalent values for APTT and in celite ACT equivalent values when performing the ACT+ or ACT-LR. By converting whole blood results into traditional, laboratory test value form, the HEMOCHRON Jr. delivers results in familiar clinical parameters facilitating accurate clinical data interpretation. In this way, near-patient testing can truly become an extension of the clinical laboratory.

Because of the varying sensitivities of different manufacturer's ACT reagents, and because of different methodologies used on coagulation instrumentation, results obtained using various systems will differ. Studies have shown that in the majority of instances clinical interpretation of test results is similar even if the actual results are not identical. The inherent value of point-of-care hemostasis monitoring, namely timeliness of test results, must be supplemented by determination of correlation with your current method.

While no two coagulation instrument/reagent systems produce results that match exactly, systems can be correlated to provide statistically acceptable results so as not to alter the overall clinical interpretation of the test results. To perform a correlation between two systems, ideally, samples are tested simultaneously on each system using the same blood sample.

ITC suggests the attached recommended correlation protocol and data collection form to minimize the data collection variables when performing a correlation between whole blood coagulation systems. The protocol is segmented into parts to allow the user to become familiar with the HEMOCHRON Jr. test procedures prior to actual data collection for correlation. Obtaining a good correlation between the two systems requires that the operator be proficient at both procedures prior to beginning data collection, and that strict adherence to the guidelines be followed.

We recommend that you fax us a copy of your correlation data once you have completed the protocol. Often, upon examination of the data, we find the correlation between the two systems can be improved (i.e. by performing a few more tests in a sensitivity range where there may not be many data points). Together, we are certain that a good correlation can be obtained between the HEMOCHRON Jr. and your laboratory system.

If at any time during the correlation process you require assistance, do not hesitate to contact our in-house Technical Service staff at 1-800-631-5945.

Thank you for your interest in evaluating our point-of-care analyzers. We are certain you will find them to be an important supplement to the diagnostic protocols you currently employ.

HEMOCHRON® Jr. ACT-LR Clinical Correlation Protocol

Prior to initiating the Clinical Correlation, review all package inserts and the HEMOCHRON® Jr. Operator's Manual for complete instructions. Review this entire protocol before beginning a test. The HEMOCHRON Jr. ACT-LR test cuvette can be used with any model HEMOCHRON Jr. Microcoagulation Systems.

Patient Population:

1.   A sufficient number of samples must be obtained to span the entire normal and therapeutic range.

2.   The table at the bottom of the attached data collection forms indicates the breakdown of the number of paired samples required in each sensitivity range.

3.   The normal range samples (volunteer normal donors) should be done first, prior to collected specimens from anticoagulated patients.

Material Preparation:

1.   Bring all cuvettes to room temperature. This may require up to 1 hour.

2.   Perform instrument quality control (as per the appropriate HEMOCHRON Jr. Instrument Operator's Manual) using the HEMOCHRON Jr. EQC test cartridges, or *direct*CHECK® Quality Control test products.

Test Procedure:

1.   Insert the cuvette into the analyzer. The instrument will display a number of messages (i.e. pump warming...) while performing a series of internal tests. **Do not** collect any blood sample until the analyzer display reads "ADD SAMPLE... PRESS START". Once displayed, you have 5 minutes to collect the fresh whole blood sample and add it to the cuvette.

Blood Collection:

1.   Collect 2 mL of fresh whole blood. (When using a 2 syringe technique, make sure to use the second draw.)

2.   Using the collection syringe, **immediately** add the blood sample to the center well of the HEMOCHRON Jr. cuvette. Fill the center well of the cuvette flush to the top (if a large dome forms on top of the well, push it over into the outer well).

   Note: If the blood sample is collected and added to the cuvette prior to the analyzer being ready, a fault message will most likely be displayed, and the result will be invalid. If sample collection exceeds the 5 minute time limit, the analyzer will display a "START TIMEOUT" message, and you will need to discard the cuvette and replace it with a new cuvette, according to the package insert instructions.

3.   Depress the START button on the analyzer.

4.   When comparing the HEMOCHRON Jr. system to another HEMOCHRON system, **immediately** fill the appropriate HEMOCHRON ACT tube or cuvette using the blood sample remaining in the syringe. Conduct the test immediately.

        When comparing the HEMOCHRON Jr. to another manufacturer's ACT test follow that manufacturer's recommended procedure to complete the comparison.

5.   Record the HEMOCHRON Jr. ACT-LR result upon completion of the test (indicated by an audible beep).

6.   Record the result of the comparison test.

Recording Results:

        Record all information on attached data sheets.

1.   Record time specimen is drawn.

2.   Record HEMOCHRON Jr. results: celite ACT equivalent time

3.   Record the corresponding ACT-LR test result generated by the HEMOCHRON or an alternative manufacturer's instrument.

4.   Once a minimum of 30 sets of data points distributed over the desired clinical range have been collected, call ITC Technical Service (800-631-5945) to review the data.

5.   The Technical Service Department will request that you fax your results to them for analysis. Once analysis is complete, Technical Services will contact you to discuss whether your correlation is acceptable, or whether additional data is required.

Interpretation of results:

Clinical correlations demonstrate the statistical similarity of the two test systems. Data is analyzed using a linear regression model. The correlation coefficient (r) indicates the degree to which data points deviate from the line of best fit. A perfect correlation of 1.0 indicates each data point is matched to the "control" method, measured against a line of best fit. The slope of the regression line indicates a bias in either test method. In order to have two tests be identical, both the correlation coefficient (r) and the slope of the regression line must be 1.0. Correlations of HEMOCHRON whole blood assays to standard methods are generally 0.88 or greater. This indicates the tests are statistically similar, yet actual differences of individual data points are expected.

HEMOCHRON Jr. ACT-LR CORRELATION PROTOCOL DATA SHEET

Hospital	Date:
Investigator	Title:
Address	Phone:
Jr. ACT-LR Cuvette lot number:	Jr. model/serial number:

Patient #	Draw Time	Reference ACT Value	Test Time	HEMOCHRON Jr.	Comments/ Indicate if patient is on heparin
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
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26					
27					
28					
29					
30					
31					
32					
33					
34					
35					

Sensitivity Range

Reference ACT	Number of Patients
Normal	10
Heparinized	min. of 20