HEMOCHRON®

Whole Blood Coagulation Systems

Citrated Activated Partial Thromboplastin Time (APTT) Cuvette

Correlation Protocol for HEMOCHRON®
Microcoagulation Instruments

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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 whole blood samples to evaluate essential coagulation parameters. Test results are reported in plasma equivalent values and INR for PTs: plasma equivalent values for APTTs. 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 brands and lots of plasma based APTT reagents, and because of different methodologies used on coagulation instrumentation, results obtained using various combinations of instrument/reagent 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 would be tested simultaneously on each system using the same blood sample. Logistically, this becomes difficult when one system performs tests using a whole blood sample at the bedside, and the other system uses a plasma based sample and is performed in the laboratory.

ITC suggests the attached correlation protocol and data collection form be used to minimize the data collection variables (such as time elapsed between blood sample collection and test performance) when performing a correlation between whole blood and plasma-based 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 or email 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 Department at 1-800-631-5945 or by email at techservice@itcmed.com.

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. Citrate APTT Clinical Correlation Protocol

Prior to clinical use, a correlation study comparing the HEMOCHRON Jr. Citrate APTT test and standard laboratory assay will assist in determining any necessary target time adjustments. Prior to initiating the Clinical Correlation, review all package inserts and the HEMOCHRON Jr. instrument operator's manual for complete instructions. Review this entire protocol before beginning a test.

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 form 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 collecting 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 instrument Operator's Manual) using the HEMOCHRON Jr. EQC test cartridges, or *direct*CHECK® Quality Control test products.

Blood Collection:

1. a. Collect 2 tubes of citrated blood

OR

b. Alternatively, a single citrated tube may be used. After mixing, a small (< 1 ml) sample can be removed from tube with a syringe and tested on the JR. instrument.

Note: Either 3.2% or 3.8% sodium citrate tubes may be employed. However, differences exist between laboratory test results with each citrate concentration. It is therefore critical that only one concentration be used by a single medical facility.

2. **Immediately** label the citrated blood sample with "STAT CORRELATION STUDY" and patient ID and immediately transport to the clinical laboratory.
3. 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). Depress the START button on the analyzer.

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.

4. Record the HEMOCHRON Jr. results upon completion of the test (indicated by an audible beep).

5. The comparative plasma test is to be performed using the standard lab procedure.

   The laboratory assay must be performed within 60 minutes of specimen collection.

Recording Results:

Record all information on attached data sheets.

1. Record specimen draw time and time that laboratory result was obtained.
2. Record HEMOCHRON Jr. results
3. Record the corresponding laboratory plasma APTT result.
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) and arrange to have the collected data faxed or emailed for review and analysis.
5. 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 laboratory method generally result in a correlation coefficient of 0.88 or greater. This indicates the tests are statistically similar, yet actual differences of individual data points are expected.

HEMOCHRON Jr. Citrated APTT CORRELATION PROTOCOL DATA SHEET

Hospital:	Date:
Investigator:	Title:
Address:	Phone:
Jr. Citrate APTT Cuvette lot number:	Jr. model/serial number:

Patient #	Draw Time	HEMOCHRON Jr.		Time tested in lab	Lab Plasma Value	Comments/ Indicate if patient is on heparin
		Whole Blood Result	Plasma Equiv. Result			
1						
2						
3						
4						
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Sensitivity Range

Target Plasma APTT Range	Number of Patients
Normal	min. of 9
35 - 54	min. of 8
55 - 74	min. of 7
75 - 95	min. of 6