



i-STAT 1 SYSTEM TECHNICAL BULLETIN

ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration

BACKGROUND

The Activated Clotting Time (ACT) test has been in existence for over 30 years. It is the most popular test for measuring the effect of heparin administered during an interventional procedure. By placing an activator in the test chamber, the blood sample is “activated” to promote clotting. When heparin is present in the sample, the clotting is delayed in proportion to the amount of “anticoagulation” effect of the heparin.

Since its inception, numerous changes have taken place to ACT tests, including increased automation and decreased sample volume. Today, there are many new, fully automated, low blood volume ACT tests on the market, in addition to the older, macro blood volume, semi-automated tube-based systems (*i.e.*, Hemochron, Actalyke™). The micro sample ACT systems typically employ test cartridges or cards (instead of tubes), and all have incorporated an automatic test cycle prewarming step that brings the ACT testing chamber to 37 °C prior to initiating the clotting reaction. As blood clotting is an enzymatic process, the temperature at which the clotting cycle takes place has a marked impact on the rate at which the blood clot forms. The ACT tests that incorporate a prewarming step allow the entire clotting reaction to take place at 37 °C. ACT tests that do not use a prewarming step are subject to a delay before the blood specimen reaches (and stabilizes at) 37 °C; the actual time needed to reach 37 °C is dependant on the starting temperature of the sample test tube. For example, a 30 °C blood sample placed into a (non-prewarmed) 25 °C ACT tube will take a few minutes before the test environment (blood, reagent, tube) stabilizes at 37 °C. The result of this thermal delay is an increase in the reported ACT clot time that will depend on sample tube temperature.

ACT Instruments <u>WITH</u> an automatic prewarming step	ACT Instruments <u>WITHOUT</u> an automatic prewarming step
Medtronic ACT Plus	Hemochron 801/401/8000/Response
Medtronic HMS Plus	Actalyke
Bayer/TAS HMT	
Roche ACT	
Hemochron Jr. (Signature/PCL)	
i-STAT 1	

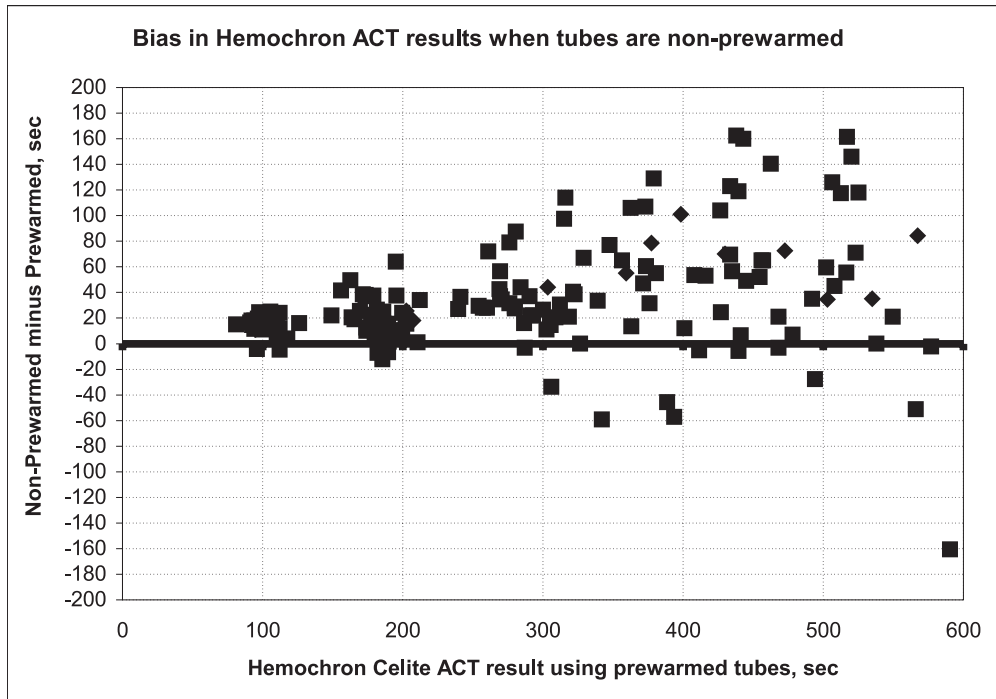
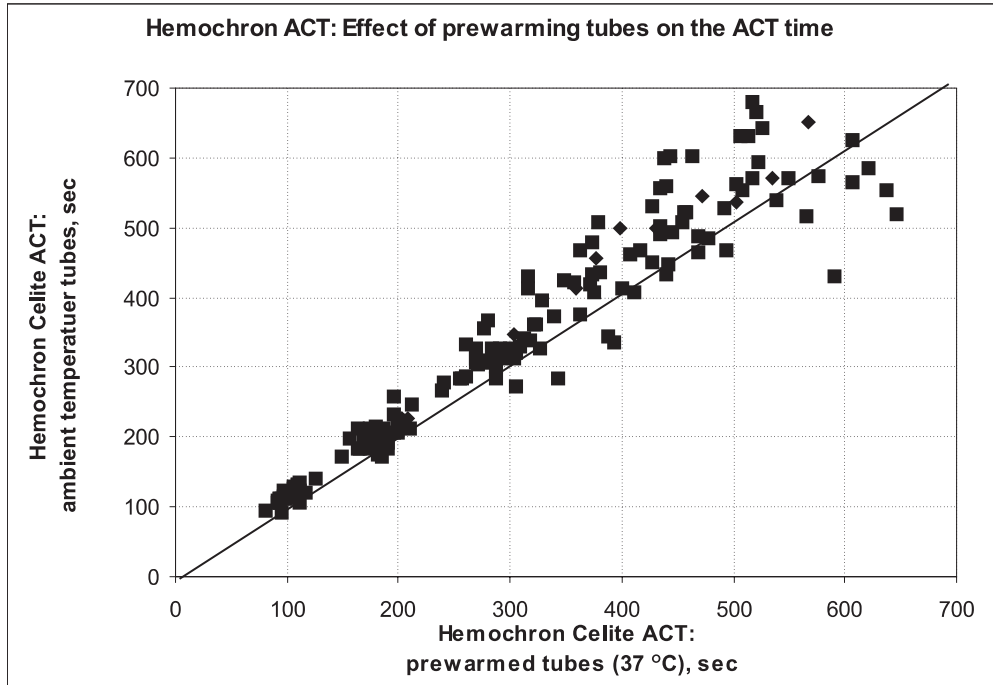
i-STAT ACT CALIBRATION

Currently, the i-STAT Celite ACT and i-STAT Kaolin ACT tests are factory calibrated by mathematically adjusting the raw i-STAT “clot time” to match the Hemochron Celite tube result. This calibration is performed by testing cartridges and Hemochron Celite tubes side by side, using a range of heparinized, non-hemodiluted whole blood samples, and using **Hemochron tubes prewarmed to 37 °C**.

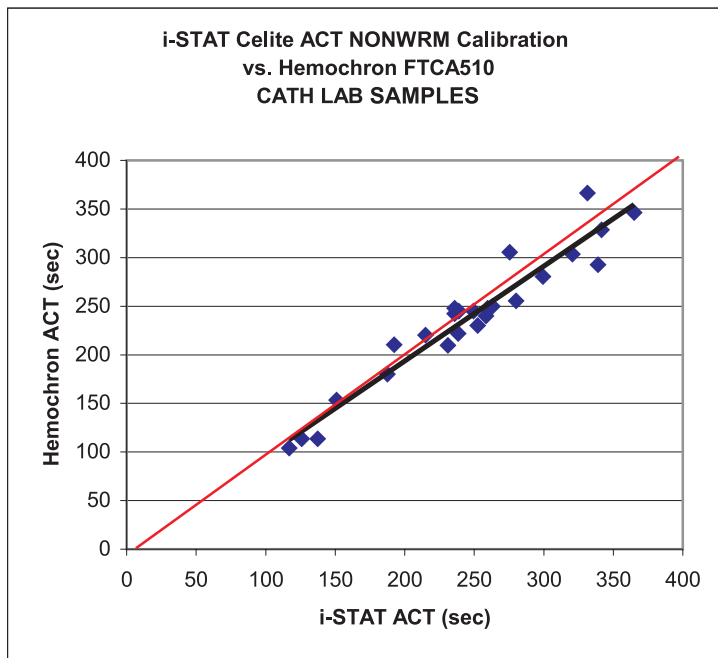
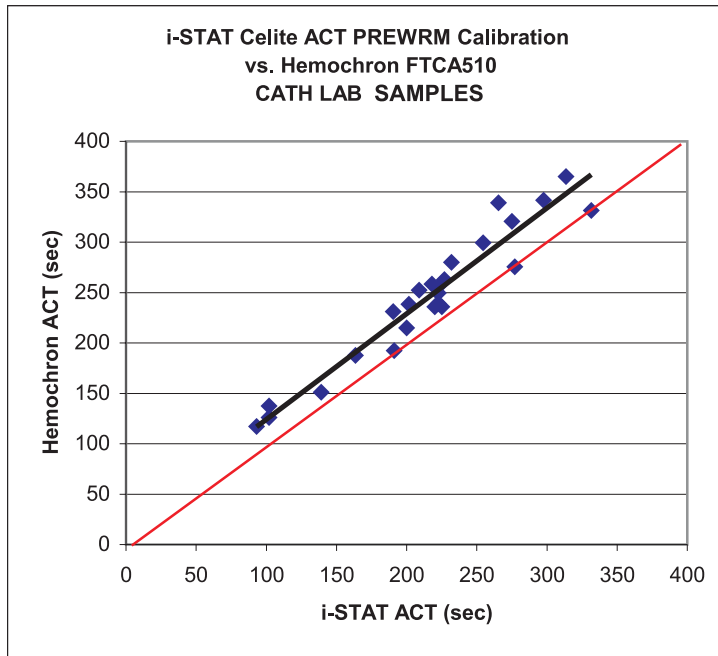
Customers who are familiar with macro-sample ACT methods like Hemochron and Actalyke™, and who do not preheat their tubes prior to each test, have found that the bias in results between their previous ACT method and the i-STAT ACT may require changing familiar clotting time target values. In order to ease the changeover to the i-STAT ACT method under these circumstances, i-STAT now provides a choice between the current 37 °C result calibration and a new “non-prewarm” (or ambient temperature) result calibration. The additional calibration mode allows an i-STAT ACT cartridge to deliver results that will be a closer match for those users who are familiar with macro-sample methods without automatic prewarming cycles, and should reduce the need to make large changes to ACT target times or ranges. Since micro-sample methods (Medtronic HR-ACT, Hemochron Jr. ACT+) already incorporate preheating of the test cuvettes, users with ACT target times and ranges based on these methods should continue to use their current i-STAT 37 °C calibration.

REPRESENTATIVE DATA

Effect of Sample Tube Temperature on Hemochron ACT Results using Paired Samples: prewarmed sample tubes vs. non-prewarmed sample tubes.

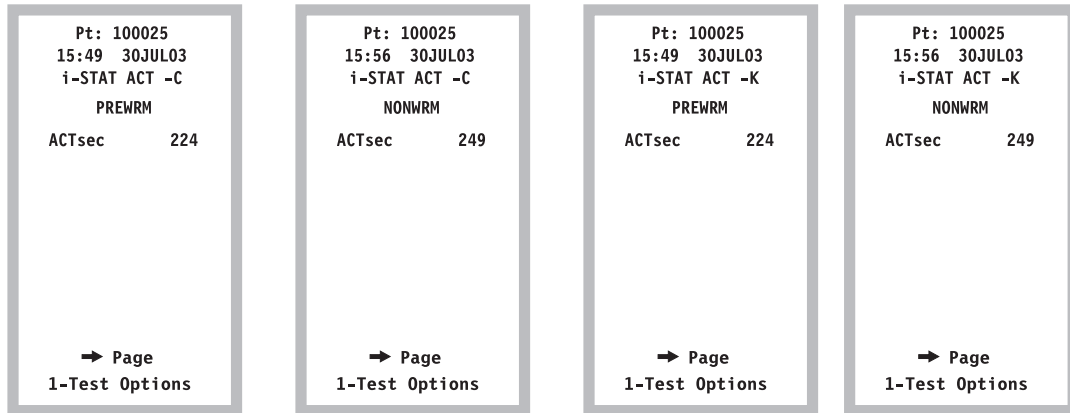


i-STAT Celite ACT vs. Room Temperature Hemochron FTCA510: prewarmed (**PREWRM**) vs. non-prewarmed (**NONWRM**) calibration modes.



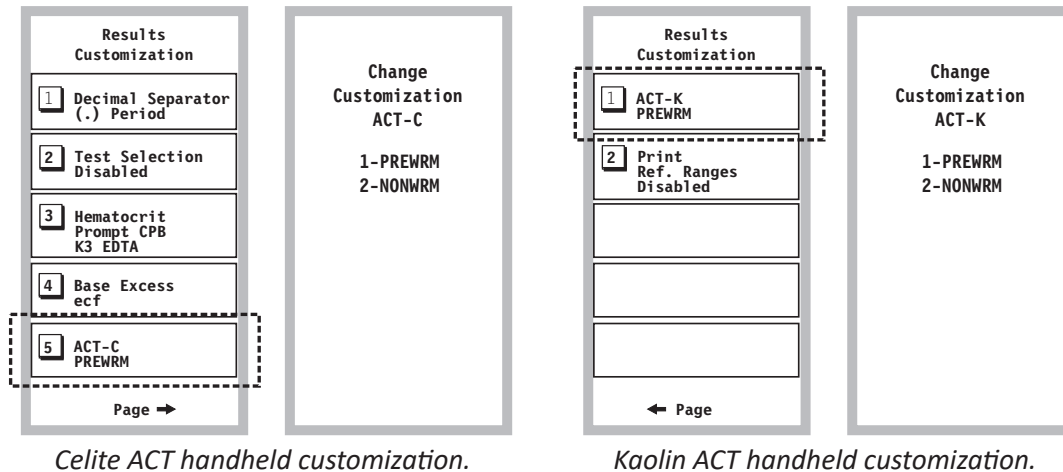
i-STAT 1 ANALYZER DISPLAY

The ACT test results displayed on the i-STAT 1 Analyzer show the calibration setting that was used to perform the ACT calculations.



CUSTOMIZATION

- The i-STAT 1 Analyzer is capable of offering both the **NONWRM** and **PREWRM** ACT customization settings. These customizations can be viewed, selected and changed via the RESULTS CUSTOMIZATION section on the i-STAT 1 Analyzer.



- For i-STAT 1 Analyzers used in conjunction with CDS Version 5 or i-STAT/DE, the ACT customization options are located on the RESULTS tab of the Preferences section of the individual customization profile (see highlight below). Users should select the desired calibration mode for each i-STAT ACT cartridge type (Celite and/or Kaolin).

The screenshot shows the 'Preferences' window with the 'Results' tab selected. The window contains a table of analyte ranges and several configuration options.

Analyte	Reference Ranges		Action Ranges		Custom Reportable Ranges	
	Low	High	Low	High	Low	High
Na	138	146	-99999.9	99999.9	-99999.9	99999.9
K	3.5	4.9	-99999.9	99999.9	-99999.9	99999.9
Cl	98	109	-99999.9	99999.9	-99999.9	99999.9
BUN	8	26	-99999.9	99999.9	-99999.9	99999.9
Creat	0.6	1.3	-99999.9	99999.9	-99999.9	99999.9
Glu	70	105	-99999.9	99999.9	-99999.9	99999.9
Lac	0.36	1.25	-99999.9	99999.9	-99999.9	99999.9
AnGap	10	20	-99999.9	99999.9	-99999.9	99999.9
Hct	38	51	-99999.9	99999.9	-99999.9	99999.9

Below the table, there are several configuration options:

- Print Reference Ranges
- Operator Test Selection
- ACT Options (i-STAT 1 Analyzer Only)**
 - ACT-C**: NONWRM PREWRM
 - ACT-K**: NONWRM PREWRM
- Hematocrit Options**: Reference Anticoagulant: K3EDTA K2EDTA/Heparin/None
- Hct, CPB Adjustment**: Prompt Never Always
- Decimal Separator**: Period (.) Comma (,)
- Base Excess Calculation**: Extracellular Fluid Blood
- i-STAT Reserved**: 1: [0] 2: [0] 3: [0] 4: [0] 5: [0] 6: [0] 7: [0] 8: [0]

Buttons on the right side include 'Selection' (with a 'DEFAULT0' dropdown), 'Description' (with an empty text box), 'Default Values', 'OK', and 'Cancel'.

LIMITATIONS AND WARNINGS

- The NONWRM calibration mode applies to the Patient Path only, and will not be applied to the Control or Proficiency Testing pathway. Control or Proficiency samples run in the Patient Pathway may produce erroneous results.
- Different locations within a given hospital may utilize different calibration modes/customization profiles. Prior to testing patient samples, ensure the appropriate calibration mode is employed.

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