



i-STAT ACT Celite vs. i-STAT ACT Kaolin (2392)

This Performance Verification report is an example of one institution's results. As a part of the implementation process, your facility will participate in its own performance verification, and the results from your institution may differ from what is reported in this document. This report was chosen from a pool of hundreds of performance verification reports on file at Abbott Point of Care from sites that followed Abbott Point of Care's recommended protocol.

Intended Use

The i-STAT Celite Activated Clotting time (*Celite*ACT) test is useful for monitoring patients receiving heparin for treatment of pulmonary embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures such as catheterization, cardiac surgery, surgery, organ transplant, and dialysis.

Intended Use

The i-STAT Kaolin Activated Clotting time (*Kaolin*ACT) test is an *in vitro* diagnostic test that uses fresh whole blood to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

PROCEDURAL NOTES

A. **Protocol**

The analytical performance verification protocol recommended in the i-STAT® System Manual was essentially followed.

1. **Comparative Methods**

The i-STAT Kaolin served as the comparative method for all analytes.

B. **Data Analysis**

1. **Method Comparison**

- a. Duplicate analyses were performed on the i-STAT and comparative systems for most method comparison specimens. Note, however, that only the first of the duplicates was used in the method comparison calculations.
- b. For Deming regression analysis, imprecisions of the i-STAT (S_{yy}) and the comparative (S_{xx}) systems were estimated from duplicate analyses performed on patient specimens.
- c. Based on criteria recommended by NCCLS¹, the range of data collected for some analytes should be considered insufficient to produce reliable regression coefficients. In these instances, partitioned system difference analysis is recommended for the evaluation of methodological differences.

C. **i-STAT Lot Numbers**

Celite ACT cartridges: R05032
Kaolin ACT cartridges: R05032

Controls: Level 1 - B03357
Level 2 – B04021

Software version: JAMS/CLEW A98

¹ National Committee for Clinical Laboratory standards. User comparison of quantitative clinical laboratory methods using patient samples; Proposed Guideline. NCCLS publication EP9-P. Villanova, PA: NCCLS; 1986; pp 6-7, 16-17, 20-21.

METHOD COMPARISON SUMMARIES

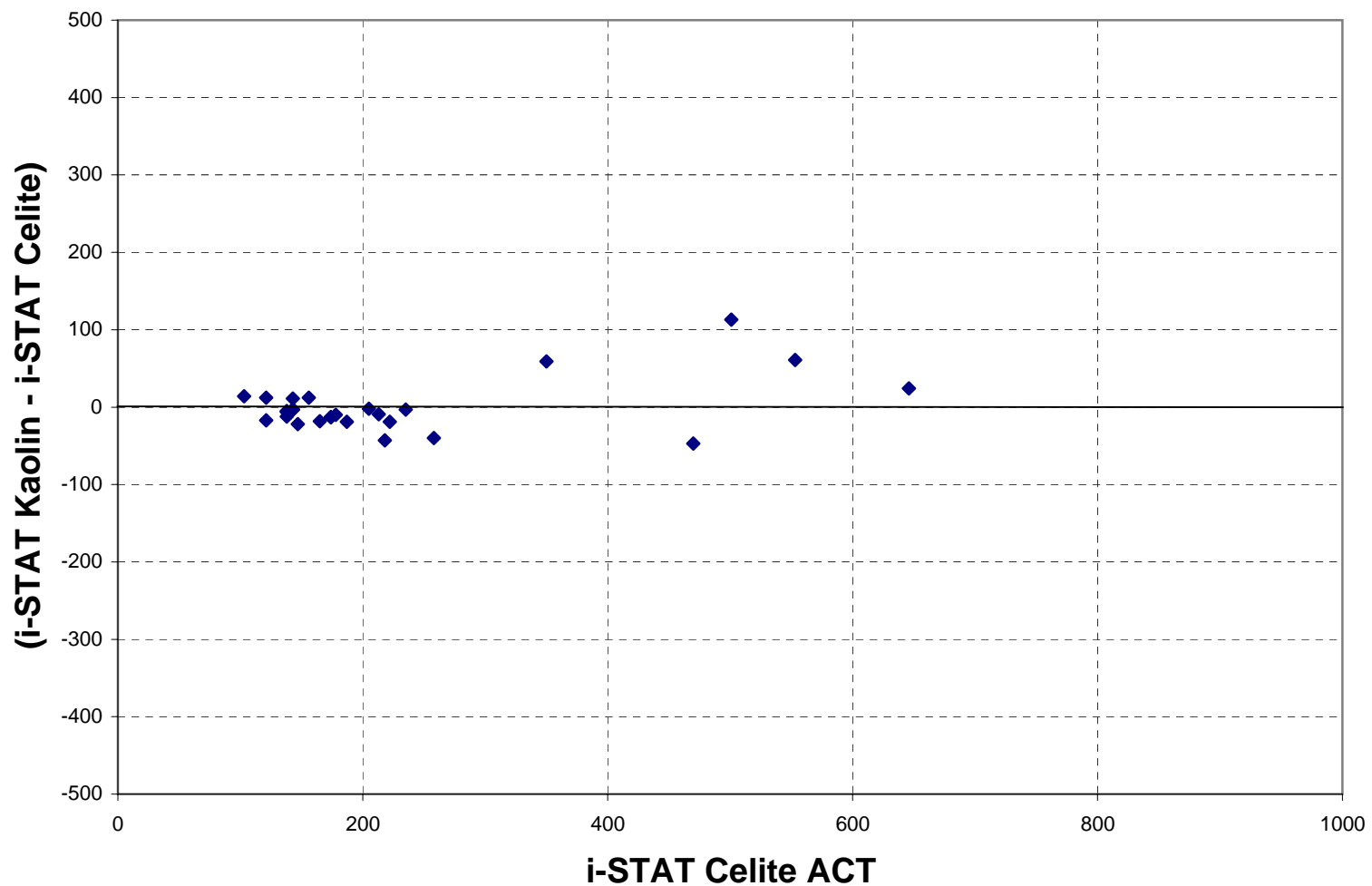
SYSTEM DIFFERENCE ANALYSIS

DIFFERENCE = (i-STAT Kaolin – i-STAT Celite)

ANALYTE	CONCENTRATION RANGE	N	AVERAGE DIFFERENCE	S_D[*]
ACT	50-150	11	-3.091	11.66
	150-500	14	-11.79	26.19
	500-1000	3	66.00	44.71

* S_D is the standard deviation of the differences.

ACT Difference Plot i-STAT Kaolin - i-STAT Celite



METHOD COMPARISON SUMMARIES

DEMING REGRESSION ANALYSIS

x = i-STAT Celite (whole blood)

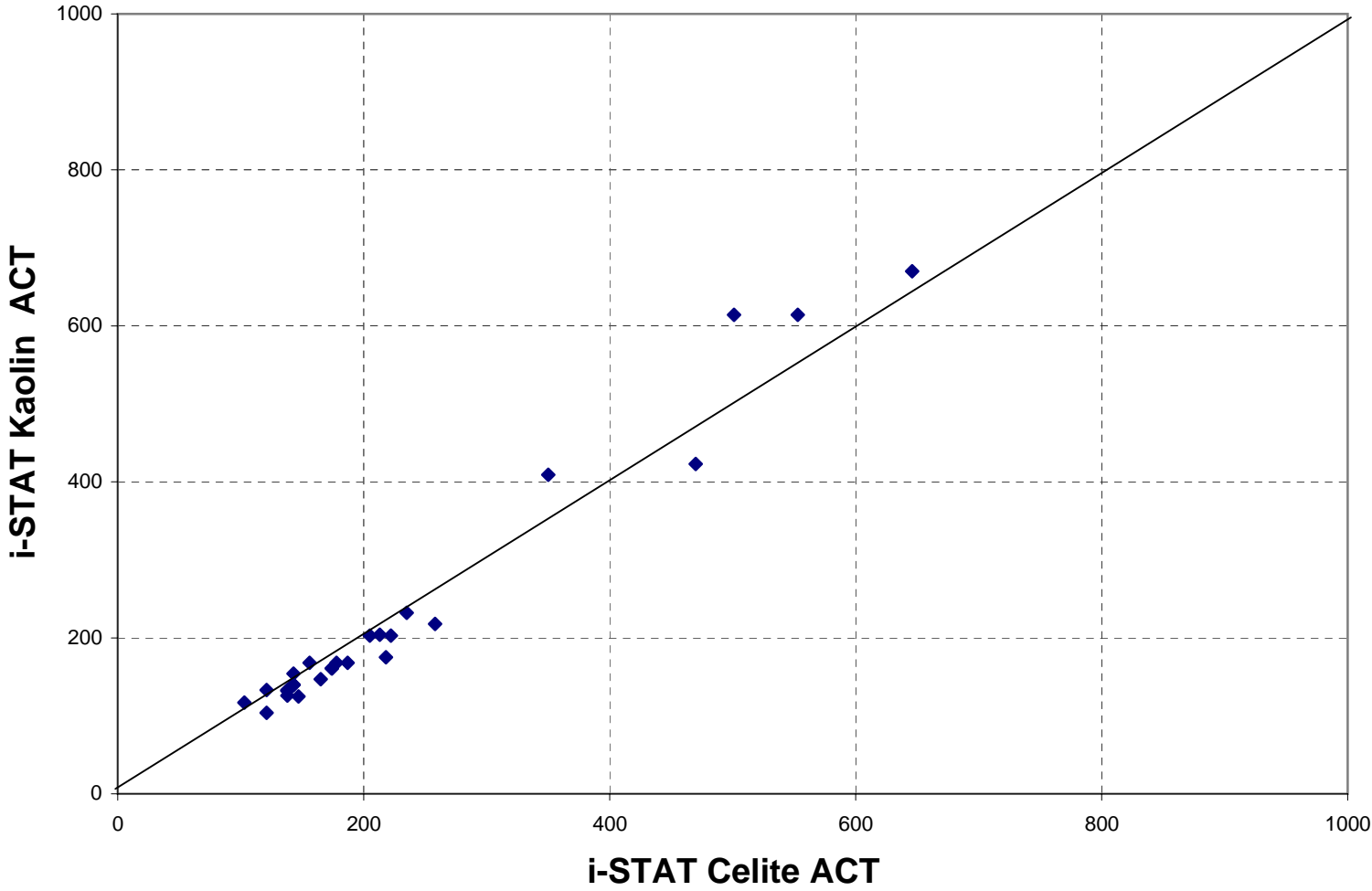
y = i-STAT Kaolin (whole blood)

[-----DEMING-----]

Analyte	n	Sxx	Syy	Slope	Int't.	Sy.x	r
ACT	28	9.050	10.71	1.1297	-29.599	21.356	0.9838

ACT Regression Plot

i-STAT Kaolin vs i-STAT Celite



ACT - Cath Lab

Sample	i-STAT 1 (Kaolin)	i-STAT 2 (Kaolin)	i-STAT 1 (Celite)	i-STAT 2 (Celite)	Heparin/plt inhib
1	125	134	147	151	
2	104	code 80	121	121	
3	423	409	470	478	5000 hep
4	232	232	235	240	
5	168	175	178	178	
6	154	140	143	147	pulled sheath
7	117	126	103	109	baseline
8	204		213		5000 hep
9	203	189	205	205	
10	168		156		pulled sheath
11	133		138		baseline
12	409	458	350	377	5000 hep
13	614		501		
14	161	161	174	178	
15	126		138		pulled sheath
16	140		143		baseline
17	670		646		10000 hep & reapro
18	168	168	187		
19	140	133	143		pulled sheath
20	133		121		baseline
21	614	621	553	523	10000 hep
22	218		258		
23	175	187	218		
24	147	147	165		
25	140		143		
26	203		222		
27	161		174		
28	132	132	138		