

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K071319

B. Purpose for Submission:

To seek clearance for the i-STAT Activated Clotting Time (ACT) Control Set

C. Measurand:

Activated Clotting Time (ACT)

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

- i-STAT Activated Clotting Time (ACT) Control Set Level 1, Model Number 07G82-01

- i-STAT Activated Clotting Time (ACT) Control Set Level 2, Model Number 07G82-02

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5425

2. Classification:

II

3. Product code:

GGN

4. Panel:

Hematology

H. Intended Use:

1. Intended use(s):

i-STAT Activated Clotting Time (ACT) Control Set is used to verify the integrity of newly received i-STAT Activated Clotting Time cartridges.

2. Indication(s) for use:

i-STAT Activated Clotting Time (ACT) Control Set is used to verify the integrity of newly received i-STAT Activated Clotting Time cartridges.

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The control set consists of bi-level human plasma, with added purified biochemicals and preservatives. It is provided in lyophilized form for increased stability. CaCl_2 is the reconstituting solution.

The controls are used to verify the integrity of newly received i-STAT ACT cartridges: Kaolin ACT test (K023582) and Celite ACT test (K992571) for the instruments: i-STAT 200 Portable Clinical Analyzer (K940918) and i-STAT Model 200 Portable Clinical Analyzer (K001154).

J. Substantial Equivalence Information:

1. Predicate device name(s):

i-STAT Coagulation Control Set

2. Predicate 510(k) number(s):

K981752

3. Comparison with predicate:

Similarities		
Item	Device: Bio-Rad i-STAT Activated Clotting Time (ACT) Control Set	Predicate: Biopool Intl., Inc. i-STAT Coagulation Control Set
Intended Use	i-STAT Activated Clotting Time (ACT) Control Set is used to verify the integrity of newly received i-STAT Activated Clotting Time cartridges	Same
Matrix	Human plasma	Same
Form	Lyophilized	Same
Open vial stability	Use immediately	Same

Differences		
Item	Device: Bio-Rad i-STAT Activated Clotting Time (ACT) Control Set	Predicate: Biopool Intl., Inc. i-STAT Coagulation Control Set
Storage	Refrigerated (2-8° C)	Refrigerated (2-10° C)

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle:

The use of ACT Control Set, levels 1 and 2, is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices.

M. Performance Characteristics (if/when applicable):

1. Analytical performance: N/A

a. Precision/Reproducibility:

b. Linearity/assay reportable range:

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

- Shelf life stability: stability studies were performed to determine shelf life for these controls. Product claim for shelf life is 18 months at 2-8°C.

Real Time Stability Testing: The Activated Clotting Time (ACT) Control Set stability was determined by storing the product under the recommended storage conditions (2-8°C) for the life of the product. These studies were conducted for three experimental lots (E-lots). Several vials of each level were tested at each time point and the results of the real time stabilities samples were compared to the results of reference vials stored at -70°C (Pseudo-T₀). Failure was assumed to have taken place when the product's analyte results had changed by greater than or equal to the established acceptance criteria, $\pm 10\%$ deviation of the reference values.

Real Time Stability Studies - Activated Clotting Time (ACT) Control Set				
		E – lot 1	E – lot 2	E – lot 3
		Day 549	Day 531	Day 510
Level 1	Real time sample	221 sec.	239 sec.	251 sec.
	Pseudo-T ₀ samples	220 sec.	233 sec.	251 sec.
	Deviation of the reference value	0.46%	2.43%	0.00%
Level 2	Real time sample	719 sec.	544 sec.	648 sec.
	Pseudo-T ₀ samples	701 sec.	543 sec.	636 sec.
	Deviation of the reference value	2.52%	0.18%	1.89%
Acceptance Criteria		$\pm 10\%$ deviation of the reference values		

- Open vial stability: there is no open vial claim for this product. The package insert provides the instruction to indicate that the “control solution must be used immediately (less than 30 seconds) after completing the reconstitution and mixing steps.”

d. Detection limit:

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies: N/A

a. Method comparison with predicate device:

b. Matrix comparison:

3. Clinical studies: N/A

a. Clinical Sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off: N/A
5. Expected values/Reference range:

The i-STAT Activated Clotting Time (ACT) Control Set recovery results for three experimental lots show that the products met targeted activated clotting time.

Results for Activated Clotting Time (ACT) Control Set			
		Level 1	Level 2
Target Range		150-250 ACT (seconds)	450-650 (seconds)
E - lot 1	N	12	12
	Mean	205	626
	SD	7.3	35.1
	CV	3.58%	5.62%
E - lot 2	N	12	12
	Mean	224	491
	SD	11.7	15.1
	CV	5.23%	3.08%
E - lot 3	N	12	12
	Mean	234	564
	SD	3.3	10.5
	CV	1.42%	1.87%

Accompanying value assignment sheet displays target values and ranges.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.