510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION

A. 510(k) Number:

k120900

B. Purpose for Submission:

To obtain clearance for control material for the PT and ACT assays run on the Abbott i-STAT handheld and wireless Clinical Analyzers.

C. Measurand:

Prothrombin Time (PT)

Activated Clotting Time (ACT)

D. Type of Test:

Quantitative clotting assay

E. Applicant:

Cliniqa Corporation

F. Proprietary and Established Names:

Cliniqa Coagulation Control Set

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5425, Multipurpose system for in vitro coagulation studies

2. Classification:

   Class II

3. Product code:

   GGN, Plasma, Coagulation Control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   The i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used for quality control of i-STAT PT cartridges on i-STAT handheld and wireless systems.

   The i-STAT ACT Control Level 1 (normal) and ACT Control Level 2 (abnormal) are used for quality control of i-STAT ACT cartridges on i-STAT handheld and wireless systems.

2. Indication(s) for use:

   Same as Intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   For use with Abbott i-STAT® handheld and wireless systems

I. Device Description:

Cliniqa i-STAT® PT Control Level 1 - The PT Control Level 1 is produced from a pool of normal human plasma. After addition of buffer, the pool is aliquotted into 1mL portions. The aliquots are lyophilized, stoppered and capped. The lyophilized plasma is reconstituted with the supplied $CaCl_2$ solution prior to use.

Cliniqa i-STAT® PT Control Level 2 - The PT Control Level 2 is made from mixing pools of normal human plasma with factor depleted human plasma to yield a target INR between 2-3. The mixture is dispensed into vials in 1mL portions, lyophilized, stoppered and capped. The lyophilized plasma is reconstituted with the supplied $CaCl_2$ solution prior to use.

Cliniqa i-STAT® ACT Control Level 1 - The ACT Control Level 1 is produced from a pool of normal human plasma. After addition of buffer, the pool is aliquotted into 1mL portions. The aliquots are lyophilized, stoppered and capped. The lyophilized plasma is reconstituted with the supplied $CaCl_2$ solution prior to use.

Cliniqa i-STAT® ACT Control Level 2 - The ACT Control Level 2 is made from mixing pools of normal human plasma with factor depleted human plasma to yield a target clotting time between 400-800 seconds. The mixture is dispensed into vials in 1mL portions, lyophilized, stoppered and capped. The lyophilized plasma is

reconstituted with the supplied $CaCl_2$ solution prior to use.

Calcium Chloride Solution - The solution contains 10 mM ± 2 mM $CaCl_2$, which is aliquotted into vials and capped.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Biopool International, Inc. i-STAT® coagulation control set

2. Predicate 510(k) number(s):
   k981752

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used for quality control of i-STAT PT cartridges on i-STAT handheld and wireless systems. The i-STAT ACT Control Level 1 (normal) and ACT Control Level 2 (abnormal) are used for quality control of i-STAT ACT cartridges on i-STAT handheld and wireless systems.	The i-STAT Activated Partial Thromboplastin (aPTT), Prothrombin Time (PT) and Activated Clotting Time (ACT) Controls are intended to be used with the i-STAT portable Clinical Analyzer and i-STAT aPTT, PT, and ACT test cartridges to provide a method for verifying the integrity of newly received cartridges.
Matrix	Human Plasma	Same
Physical Form	Lyophilized	Same
Shelf Storage	2-8ºC	Same
Reconstituted Stability	Immediate use	Same

Differences		
Item	Device	Predicate
Reagents and Systems	Abbott i-STAT® handheld and wireless systems PT and ACT reagents	Abbot i-STAT® handheld system PT, ACT and aPTT reagents
Analytes	PT (seconds, INR) Clotting time (seconds)	PT (seconds); Clotting time (seconds); aPTT (seconds)
Target Values	PT Level 1: 1.2-1.5 INR PT Level 2: 2.0-3.0 INR ACT Level 1: 80-200 sec ACT Level 2: 400-800 sec	PT Normal: 10.3-12.9 sec. PT Abnormal: 17.2-36.4 sec. ACT Normal: 94-152 sec. ACT Abnormal: 198-531 sec. aPTT Normal: 24.1-33.7 sec. aPTT Abnormal: 48.2-147.9 sec.

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

Not applicable

L. Test Principle:

The controls are used for verification of the newly received i-STAT® PT and ACT cartridges. The controls are meant to test performance of the test strips by comparing the measurements the controls produced with the i-STAT® cartridges with a target values and ranges previously assigned to the controls. Instructions are outlined in the i-STAT system manual for the user to follow if results fall outside the range.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-site repeatability was determined for 3 lots of each control level. Testing was performed twice a day, in duplicate, using two instruments over a period of 20 non-consecutive testing days. The %CV for each lot combined for both instruments met the pre-specified acceptance criteria of CV<7.5%. The acceptance criteria of %CV<7.5% for the ACT was also met. A further analysis for variability introduced by the two instruments used in the repeatability study, determined that the instrument-to-instrument variability observed in this study also met the acceptance criteria of %CV<7.5%.

Please see the table below for a summary of results.

		Precision	Seconds	INR
PT Control Level 1	**Lot 1**	**Instrument to Instrument**	Mean 14.95s SD 0.07 0.4%CV	Mean 1.26 SD 0.014 1.1 %CV
		Total	Mean 14.92s SD 0.47 3.2%CV	Mean 1.3 SD 0.055 4.3 %CV
	Lot 2	**Instrument to Instrument**	Mean 13.96s SD 0.007 0.05%CV	Mean 1.17 SD 0 0%CV
		Total	Mean 14.0s SD 0.47 3.4%CV	Mean 1.3 SD 0.058 4.6 %CV
	Lot 3	**Instrument to Instrument**	Mean 14.35s SD 0.07 0.5%CV	Mean 1.21 SD 0.014 1.1 %CV
		Total	Mean 14.4s SD 0.50 3.5%CV	Mean 1.21 SD 0.051 4.3 %CV
PT Control Level 2	**Lot 1**	**Instrument to Instrument**	Mean 23.75s SD 0.14 0.06%CV	Mean 2.07 SD 0.05 2.4 %CV
		Total	Mean 23.7s SD 0.96 4.0%CV	Mean 2.0 SD 0.09 4.6 %CV
	Lot 2	**Instrument to Instrument**	Mean 23.1s SD 0.28 1.2%CV	Mean 2 SD 0.08 0%CV
		Total	Mean 23.1s SD 0.83 3.6%CV	Mean 2.0 SD 0.08 4.0 %CV
	Lot 3	**Instrument to Instrument**	Mean 30.95s SD 0.35 1.1%CV	Mean 2.7 SD 0 0 %CV
		Total	Mean 31.0s SD 1.08 3.5%CV	Mean 2.7 SD 0.10 3.7 %CV

		Precision	Celite	Kaolin
ACT Control Level 1	**Lot 1**	**Instrument to Instrument**	Mean 188s SD 0.14 0.1%CV	Mean 171 SD 1.4 0.8 %CV
		Total	Mean 188s SD 6.1 3.3%CV	Mean 171 SD 4.7 2.7 %CV
	Lot 2	**Instrument to Instrument**	Mean 154s SD 0.14 0.1%CV	Mean 146 SD 1.4 1%CV
		Total	Mean 154s SD 5.3 3.5%CV	Mean 146 SD 4.1 2.8 %CV
	Lot 3	**Instrument to Instrument**	Mean 146s SD 0.07 0.05%CV	Mean 128 SD 2.1 0.02 %CV
		Total	Mean 146s SD 5.2 3.6%CV	Mean 128 SD 4.6 3.6 %CV
ACT Control Level 2	**Lot 1**	**Instrument to Instrument**	Mean 550s SD 2.8 1.00%CV	Mean 452 SD 4.2 0.9 %CV
		Total	Mean 550s SD 28.9 5.3%CV	Mean 452 SD 23.4 5.2 %CV
	Lot 2	**Instrument to Instrument**	Mean 577s SD 4.9 0.9%CV	Mean 471 SD 4.2 0.9%CV
		Total	Mean 577s SD 23 4.0%CV	Mean 471 SD 14.7 3.1 %CV
	Lot 3	**Instrument to Instrument**	Mean 546s SD 0.71 0.1%CV	Mean 453 SD 6.4 1.0 %CV
		Total	Mean 545s SD 25.4 4.7%CV	Mean 451 SD 25.2 5.6 %CV

Reproducibility was assessed by daily testing at 3 sites over a period of five non-consecutive days. Each vial of control material was tested with two different instruments. Sites 1 and 2 included one operator and two instruments each, whereas site 3 included 3 operators and 10 instruments. Within-site and between-site variability met the pre-determined acceptance criteria of %CV <7.5, as summarized in the tables below:

	Seconds			INR		
PT Control Level 1	**Mean 15.1 sec, 0.72 SD , 4.8%CV**			**Mean 1.28 INR, 0.08 SD , 6.0%CV**		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
	Mean 14.9s	Mean 14.7s	Mean 15.7s	Mean 1.3	Mean 1.2	Mean 1.3
	0.14 SD	0.29 SD	0.75 SD	0.02 SD	0.04 SD	0.07 SD
	0.9 %CV	2.0 %CV	4.8 %CV	1.5 %CV	3.3 %CV	5.4 %CV
PT Control Level 2	**Mean 23.9 sec, 0.75 SD , 3.0%CV**			**Mean 2.1 INR, 0.07 SD , 3.50%CV**		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
	Mean 24.2s	Mean 23.7s	Mean 23.9s	Mean 2.1	Mean 2.1	Mean 2.1
	0.38 SD	0.34 SD	2.1 SD	0.07 SD	0.05 SD	0.05 SD
	1.6 %CV	1.4 %CV	0.34%CV	3.3 %CV	2.4 %CV	2.4 %CV

	Celite			Kaolin		
ACT Control Level 1	**Mean 156, 5.3 SD , 3.5%CV**			**Mean 148, 3.9 SD , 2.6%CV**		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
	Mean 152s	Mean 158s	Mean 158s	Mean 146s	Mean 151s	Mean 148s
	3.79 SD	3.68 SD	3.85 SD	1.96 SD	2.68 SD	3.03 SD
	2.5 %CV	2.3 %CV	2.4 %CV	1.3 %CV	1.8 %CV	2.00 %CV
ACT Control Level 2	**Mean, 550, 29 SD , 5.3%CV**			**Mean 457, 17 SD , 3.7%CV**		
	Site 1	Site 2	Site 3	Site 1	Site 2	Site 3
	Mean 558s	Mean 564s	Mean 529s	Mean 455s	Mean 458s	Mean 458s
	15 SD	29 SD	17 SD	11 SD	14 SD	17 SD
	2.7 %CV	5.2 %CV	3.1 %CV	2.4 %CV	3.0 %CV	3.7 %CV

b. Linearity/assay reportable range:

Not applicable

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

Value assignment:

The value assignment testing is performed by Abbot Pont of Care (APOC). The target values of control materials are based on 48 repeat measurements with the i-STAT PT or ACT assays with at minimum of 10 instruments for each control level. In addition to the value assignment testing, APOC further calculates the target and value ranges, and publishes the allowable value ranges on its website. Control fluid assignment ranges are set at fixed ranges around the acceptable CV of 7.5% and 10% for the PT and ACT, respectively.

Stability:

Real time stability studies are currently still ongoing. The stability claim is based on preliminary real time stability data available at time of clearance. One lot of control material each was tested at time zero and at multiple intermediate time points. These preliminary results met the predetermined acceptance criteria and therefore support the following shelf lives at refrigerated storage between 2°C and 8°C:

Control Material	Shelf-life data at time of clearance
PT Control Level 1	375 days
PT Control Level 2	300 days
ACT Control Level 1	375 days
ACT Control Level 2	375 days

To further support the stability claim, accelerated stability studies were performed on 3 lots of control material at 45ºC and 56°C to project a shelf life of 2 years at 4°C. In short, samples were stored at either 45°C or 56°C. Two vials of controls were tested each on day 0, 4, 8, 12, and 16 when stored at 45°C and day 0, 2, 4, 6, and 8 when stored at 56°C. Testing consisted of analysis with the Abbot i-STAT PT assay or both the Abbot i-STAT ACT Celite and Kaolin reagents. The Arrhenius equation was utilized to assess the rate of degradation. Days to failure were determined based on a limit of 10% degradation. Taken together, the accelerated stability data project a shelf life of 2 years at refrigerated storage for the PT control levels 1 and 2 as well as the ACT control levels 1 and 2.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

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

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Target values and ranges will be available on the Abbott Point of Care website (www.abbottpointofcare.com)

N. Proposed Labeling:

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

O. Conclusion:

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