

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k120014

**B. Purpose for Submission:**

Clearance of a new device

**C. Measurand:**

PT, APTT, Fibrinogen, TT, and AT

**D. Type of Test:**

Quality Control Material, Assayed

**E. Applicant:**

Diagnostica Stago, Inc.

**F. Proprietary and Established Names:**

STA<sup>®</sup> - Coag Control (N + ABN) PLUS

**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 STA<sup>®</sup> - Coag Control (N +ABN) PLUS is a kit containing assayed normal and abnormal plasmas intended for the quality control of the following quantitative tests on STA-R<sup>®</sup> and STA Compact<sup>®</sup> analyzers: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, thrombin time (TT), and antithrombin (AT).

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

STA-R<sup>®</sup> and STA Compact<sup>®</sup> analyzers

## **I. Device Description:**

The STA<sup>®</sup> - Coag Control (N + ABN) PLUS kit is a set of two control levels. Each kit provides:

- 12 x 2-mL vials of Reagent 1 (STA<sup>®</sup> - Coag Control N PLUS), citrated normal human plasma, lyophilized.
- 12 x 2-mL vials of Reagent 2 (STA<sup>®</sup> - Coag Control ABN PLUS), citrated abnormal human plasma, lyophilized.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

STA<sup>®</sup> - System Control N + P

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

k943518

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device: STA<sup>®</sup> - Coag Control (N + ABN) PLUS</b>	<b>Predicate: STA<sup>®</sup> - System Control N + P</b>
Intended Use	For the quality control of the following coagulation assays: prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, thrombin time (TT) and antithrombin (AT) in the normal and abnormal ranges.	Same, except: - additional analytes claimed for the intended use in the normal and abnormal ranges - thrombin time determined in the normal range only.
Number of levels per set	2 (one normal and one abnormal)	Same
Matrix	Citrated Human plasma	Same
Form	Lyophilized	Same
Reagent preparation	Reconstitution with distilled water	Same
Analyzers	STA-R <sup>®</sup> and STA Compact <sup>®</sup>	Same in addition to STA Satellite <sup>®</sup>
Shelf-life	24 months at 2-8°C in intact vials	Same

<b>Differences</b>		
<b>Item</b>	<b>Device: STA<sup>®</sup> - Coag Control (N + ABN) PLUS</b>	<b>Predicate: STA<sup>®</sup> - System Control N + P</b>
Reconstituted reagent stability	24 hours on-board analyzers	8 hours on-board analyzers

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

CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline-First Edition

**L. Test Principle:**

STA<sup>®</sup> - Coag Control (N + ABN) PLUS are used as controls for clotting assays (PT, APTT, fibrinogen, and TT) and chromogenic assays (AT) performed on STA-R<sup>®</sup> and STA Compact<sup>®</sup> analyzers. These analyzers utilize the chronometric principle (viscosity based detection system) for clotting assays while the chromogenic assays are based on the photometric method (measurement of absorbance of monochromatic light).

## M. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

Precision studies were carried out according to the CLSI document EP5-A2. Three lots of STA<sup>®</sup> - Coag Control (N + ABN) PLUS and one lot of assay reagents were analyzed in duplicate, two runs per day for 20 operating days at an internal site and two external sites. Each control level was tested as an unknown sample and assayed on a STA-R<sup>®</sup> analyzer for: PT (STA<sup>®</sup> - Neoplastine<sup>®</sup> CI and STA<sup>®</sup> - Neoplastine<sup>®</sup> CI Plus), APTT (STA<sup>®</sup> - PTT A, STA<sup>®</sup> - C.K. Prest<sup>®</sup> and STA<sup>®</sup> - Cephascreen<sup>®</sup>), fibrinogen (STA<sup>®</sup> - Fibrinogen), TT (STA<sup>®</sup> -Thrombin), and AT (STA<sup>®</sup> - Stachrom<sup>®</sup> AT III).

In addition, each control level was tested as an unknown sample and assayed on a STA Compact<sup>®</sup> analyzer at the internal site using the same assay reagents as above.

For each site, the coefficient of variation (CV) and standard deviation (SD) for within-run, between-run, within-day, between-day, within-laboratory, between-lot, between-site (laboratory) and total precision for each lot and control level were estimated.

For pooled data on the STA-R<sup>®</sup> analyzer from the three sites, the CV and SD for within-run, between-run, between-lot, between-site and total precision were estimated by using a mixed model fitted to the pooled data (i.e., a fully nested ANOVA model).

All results met the acceptance criteria.

#### b. *Linearity/assay reportable range:*

Not applicable

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

##### Value assignment:

Prothrombin time (PT): For each control level, the target clotting time corresponds to the mean of at least three determinations, each using at least 3 different lots of STA<sup>®</sup> - Neoplastine<sup>®</sup> CI or STA<sup>®</sup> - Neoplastine<sup>®</sup> CI Plus. The determinations are carried out on a minimum of 2 analyzers (STA-R<sup>®</sup> and STA Compact<sup>®</sup>) and performed by a minimum of 2 laboratory technicians. The control ranges for PT (values in sec and %) are then assigned by calculating the lower and upper limits.

Activated Partial Thromboplastin Time (APTT): For each control level, the target clotting time corresponds to the mean of at least three determinations, each using at least 3 different lots of STA<sup>®</sup> - PTT A, STA<sup>®</sup> - C.K. Prest<sup>®</sup> and 5 different lots of

STA<sup>®</sup> - Cephascreen<sup>®</sup>. The determinations are carried out on a minimum of 2 analyzers (STA-R<sup>®</sup> and STA Compact<sup>®</sup>) and by a minimum of 2 laboratory technicians. The control ranges for APTT (sec) are then assigned by calculating the lower and upper limits.

Fibrinogen Assay: For each control level, the target fibrinogen level corresponds to the mean of at least four determinations using a total of at least 2 different lots of STA<sup>®</sup> - Fibrinogen and STA<sup>®</sup> - Fib. The determinations are carried out on a minimum of 2 analyzers (STA-R<sup>®</sup> and STA Compact<sup>®</sup>) and by a minimum of 2 laboratory technicians. The control ranges for fibrinogen (g/L) are then assigned by calculating the lower and upper limits.

Thrombin Time (TT): For each control level, the target clotting time corresponds to the mean of at least three determinations, each using at least 3 different lots of STA<sup>®</sup> - Thrombin. The determinations are carried out on a minimum of 2 analyzers (STA-R<sup>®</sup> and STA Compact<sup>®</sup>) and by a minimum of 2 laboratory technicians. The control ranges for TT (sec) are then assigned by calculating the lower and upper limits.

Antithrombin Assay (AT): For each control level, the target antithrombin level corresponds to the mean of at least three determinations, each made on two vials. The determinations are carried out using a total of at least 3 different lots of STA<sup>®</sup> - Stachrom<sup>®</sup> AT III, on a minimum of 2 analyzers (STA-R<sup>®</sup> and STA Compact<sup>®</sup>) and by a minimum of 2 laboratory technicians. The control ranges for AT (%) are then assigned by calculating the lower and upper limits.

Open vial stability: The 24-hour open vial stability claim was verified using one lot of STA<sup>®</sup> - Coag Control (N + ABN) PLUS Reagents. Three vials of each control level were reconstituted, prepared and stored onboard the STA Compact<sup>®</sup> and STA-R<sup>®</sup> analyzers in their original vials and tested at 4, 8, 17, 24 and 25 hour time points in parallel with freshly reconstituted reagents from the same lot that were used immediately. At each time interval, each vial was tested in triplicate for PT (with STA<sup>®</sup> - Neoplastine<sup>®</sup> CI and STA<sup>®</sup> Neoplastine<sup>®</sup> CI Plus), APTT (with STA<sup>®</sup> - PTT A, STA<sup>®</sup> - C.K. Prest<sup>®</sup> and STA<sup>®</sup> - Cephascreen<sup>®</sup>), fibrinogen (with STA<sup>®</sup> - Fibrinogen), TT (with STA<sup>®</sup> - Thrombin), and AT (with STA<sup>®</sup> - Stachrom<sup>®</sup> AT III). The median values were compared to their established baseline range (using the median value at zero hour as a baseline).

Results obtained were analyzed using linear regression (median results (y-axis) versus test hour (x-axis)) with the stated allowable drift acceptance criteria. In addition, the 95% confidence interval limits were computed and plotted.

In each case, the upper or lower limit of the 95% confidence interval of the regression line did not intersect with the acceptance criteria. The stability duration was taken as the maximum time point tested minus one hour time.

All results met the acceptance criteria supporting an on-board stability claim of 24 hours.

Closed vial stability: A 24-month closed vial stability (shelf-life) claim was verified using three lots of STA<sup>®</sup> - Coag Control N PLUS and STA<sup>®</sup> - Coag Control ABN PLUS reagents as patient samples. Each control reagent was tested on the STA-R<sup>®</sup> analyzer to perform PT (with STA<sup>®</sup> - Neoplastine<sup>®</sup> CI and STA<sup>®</sup> - Neoplastine<sup>®</sup> CI Plus), APTT (with STA<sup>®</sup> - PTT A, STA<sup>®</sup> - C.K. Prest<sup>®</sup> and STA<sup>®</sup> - Cephascreen<sup>®</sup>), fibrinogen (with STA<sup>®</sup> - Fibrinogen), TT (with STA<sup>®</sup> - Thrombin), and AT (with STA<sup>®</sup> - Stachrom<sup>®</sup> AT III) assays.

Control reagents stored at 2-8°C in their original vials were tested in 10 replicates at the following time points: T0, T0 + 6 months, T0 + 12 months, T0 + 18 months, T0 + 24 months and T0 + 25 months. All test results obtained were compared to the median value at T0 as a baseline.

The results met pre-determined acceptance criteria (i.e. deviation in absolute value from the median value at T0) and support the 24-month shelf-life claim.

*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:

The end-user is instructed to refer to the product assay sheet accompanying the product information sheet.

**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.