I. PRINCIPLE

A. Fibrinogen is a plasma protein that is converted from a soluble protein to an insoluble polymer by the action of thrombin, resulting in the formation of a fibrin clot. The STA® fibrinogen kit is intended for the quantitative determination of fibrinogen in plasma by the Clauss principle.
B. In the presence of an excess of thrombin, the clotting time of diluted plasma becomes a function of the fibrinogen concentration. The clotting time of diluted plasma is inversely proportional to the level of plasma fibrinogen.
C. The clot is detected by the STA-Compact MAX®. The STA-Compact Max® is a fully automated coagulation instrument that uses an electromagnetic mechanical clot detection system.
D. The oscillation of a steel ball within the cuvette with the thrombin and diluted plasma is monitored by the STA-Compact Max®. Movement of the steel ball is mediated by 2 activating coils, working alternately to induce and maintain a natural oscillation. The amplitude of the oscillation is constantly monitored. A chronometer keeps track of elapsed time. Typically, the oscillation of the steel ball is stopped by clot formation and a sensor registers the time. But based on different algorithms the chronometer is stopped even if the clot is weak, and even if the ball does not stop. The time is compared with a standard curve stored curve on the STA-Compact Max®.
E. An increase of the fibrinogen level is observed in cases of diabetes, inflammatory syndromes and obesity.
F. A decrease of the fibrinogen level is observed in DIC, fibrinolysis, thrombolytic therapy and hereditary diseases.

II. SPECIMEN

A. Citrated blood 9:1 (blood to anticoagulant) 3.2% sodium citrate. Follow NCCLS guidelines H3-A3 and H21-A4. No other anticoagulant is acceptable.
1. **Collection of blood through intravenous lines** that have been previously flushed with heparin should be avoided, if possible.
   a. If the blood must be drawn from an indwelling catheter, the line should be flushed with 5.0 ml saline and the first 5 mL of blood or six times the line volume (dead space volume of the catheter) discarded before the coagulation tube is filled.
   b. For those samples collected from a normal saline lock, twice the dead space volume of the catheter and extension set should be discarded.
   c. When using a winged blood collection set for venipuncture and a coagulation tube is the first tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection tubing dead space and to assure maintenance of the proper anticoagulant/blood ratio. The discard tube should be a non-additive or a coagulation tube.
   d. If only a citrated tube is drawn for coagulation testing, no discard tube is necessary.
   e. The optimal amount of sample is 2.7 ml whole blood; the minimum acceptable amount of whole blood sample is 1.8 ml of whole blood.

2. The citrate concentration must be adjusted in patients who have **hematocrit values above 55%**. Citrate additive volume adjustments made to citrate tubes should be prepared for providers of patients with HCT>55% for coagulation testing. Communication must be made with provider/RN so that they can retrieve the citrate volume adjusted tube for collection.
   a. The corrected ratio of blood to anticoagulant is calculated by the following formula:
   C = 1.85 x 0.001 (100 - Hct) x volume of blood for a 2.7 ml draw
   C = 1.85 (0.001) (2.7) (100 - Hct)
   C = 0.004995 (100 - Hct)
   Example: HCT = 65% in a 2.7 ml draw
   C = 0.004995 (100 - 65)
   C = 0.004995 (35) = 0.175 ml of 3.2% sodium citrate needed
   b. A total of 0.30 ml or 300 ul of 3.2% sodium citrate is present in a 2.7 ml vacuum tube. For example, using a calibrated pipet, 0.125 ml (0.30 - 0.175) or 125 ul NaCitrate need to be removed from a 2.7 ml tube prior to specimen collection of the patient with 65% HCT. See Table below:

Corrected Ratio of Blood to Anticoagulant (3.2% NaCitrate)

% HCT	100 - HCT	3.2 % NaCitrate needed	Amount of NaCitrate to be removed from 2.7 ml tube
56	44	0.2198	0.0802 ml or 80.2 ul
57	43	0.2148	0.0852 ml or 85.2 ul
58	42	0.2098	0.0902 ml or 90.2 ul
59	41	0.2048	0.0952 ml or 95.2 ul
60	40	0.1998	0.1002 ml or 100.2 ul
61	39	0.1948	0.1052 ml or 105.2 ul
62	38	0.1898	0.1102 ml or 110.2 ul
63	37	0.1848	0.1152 ml or 115.2 ul
64	36	0.1798	0.1202 ml or 120.2 ul
65	35	0.1748	0.1252 ml or 125.2 ul
66	34	0.1698	0.1302 ml or 130.2 ul
67	33	0.1648	0.1352 ml or 135.2 ul
68	32	0.1598	0.1402 ml or 140.2 ul

B. Rejection Criteria: Specimens that are clotted, collected in the wrong tube, over draws, have grossly visible hemolysis or have less than the expected fill (less than 90% of maximum fill), and samples drawn above an IV, may yield incorrect results and should be rejected.
notes:///882572110060866C/393A3D15FDCFCF01852565D10057A0C9/13D563623CB5EAE0882577920062D7B2

C. Centrifugation: Routine: 10 minutes at 4,500 RPM in Hettich, Stat/ME: 2 minutes (at 7200 RPM) in STATSpin. Specimens must be centrifuged as soon as possible after collection at a speed and time required to produce platelet-poor plasma (platelet count <10x109/L).

D. Plasma Storage:
1. FIB specimens that are uncentrifuged with plasma remaining in the capped tube above the packed cells should be kept at 18-24 degrees C and tested no longer than

4 hours after the time of specimen collection.

2. FIB specimens that are centrifuged and plasma separated from cells can be kept for 4 hours at 2-4 degrees C or 18-24 degrees C.
3. If agitation of the specimen is likely after centrifugation, the plasma should be removed within one hour of collection and tested within four hours from the time of specimen collection.
4. If testing is not complete within 4 hours, the plasma must be removed and frozen.
   - Platelet poor plasma should be removed from the cells and frozen at -20 degrees C for up to 2 weeks or at -70 degrees C for up to 12 months
   - A frost-free freezer should not be used.
   - Frozen plasma samples must be rapidly thawed at 37 degrees C while gently mixing and tested immediately after thawing.
   - If testing is delayed, the sample may be held for 2 hours at 4 degrees C until tested.
5. For additional information regarding specimen collection, refer to Coagulation Procedure “Specimen Handling for Coagulation” in the Coagulation Procedure Binder.

III. REAGENTS AND EQUIPMENT

Centrifuge
Reagent Grade Water
Pipettes
STA-Desorb U (REF 00975)
Pipette tips
Cuvette roll (contains 1000 cuvettes) (REF 38669)
STA® - Cleaner Solution (REF 00973)
Owren-Koller buffer (Cat. No. 00360)
STA®-Fibrinogen (Cat. No. 0674)
STA Compact Max®

A. Reagent 1: STA®- Fibrinogen: Freeze-dried titrated human calcium thrombin (approx. 80 NIH unit/ml) containing a specific heparin inhibitor.

1. Reconstitute each vial with 5.0 ml of reagent grade water. Replace the perforated plastic cap on the vial.

2. Let sit 30 minutes at room temperature. Swirl gently.

3. The reagent is now ready to load/barcode onto the instrument. Click **Products,** then **Loading Products** or click the  icon to open the product drawer. Scan the barcode on the reagent bottle. Press **Enter**, and then place the reagent into an open well in the product drawer on the STA Compact Max®. Select  and click **Confirm** to close the drawer.

4. Stability after reconstitution:

5 days on board analyzer with perforated cap in place
14 days at 2-8°C in original capped vial.

5. If reconstituted and stored at 2-8°C, allow the reagent to stand at room temperature (18-25°C) for 30 minutes before use.
6. Reagent bottles may be pooled and stored in the refrigerator at 2-8°C. Once QC has been run on an aliquot from a reagent pool, additional QC within an 8 hour period does not need to be performed unless a new bottle of reagent is added to the pool. instrument for testing and QC. The on-board stability time of the first aliquot applies to additional reagent added to the first aliquot.

B. Reagent 2: STA® - Owren-Koller buffer: Ready to use buffer.

1. Used by the STA-Compact Max® to perform dilutions of controls and patients' plasmas.
2. Click **Patient Analyses** then **Loading Samples** or click the  icon to open the sample drawer. After the drawer opens, scan the bar code on the diluent vial. Select **Diluent** and click **Confirm**. Press **Enter** and then place the diluent vial into position #8 in the sample drawer on the STA Compact Max®. Select  to close the drawer
3. Onboard stability is 72 hours.

C. STA® Coag Control Normal Plus and Abnormal Plus: Citrated control plasmas, both are freeze dried.

1. Reconstitute each vial with 2.0 ml reagent grade water.
2. Let sit for 30 minutes at room temperature. Swirl gently.
3. Stable on board for 24 hours.

D. STA® – DESORB U: is a decontaminating solution (contains KOH < 1%) for use with the STA® line of instruments. Install a new STA® - maxi reducer (REF 00801) and the perforated cap on a freshly opened bottle before loading in the reagent drawer. The analyzer will display the **Pipetting Blocked** icon  at the bottom of the screen when there is not sufficient STA – DESORB U to run requested testing. Stability is 5 days on STA Compact Max®.

E. STA® - Cleaner Solution: is a washing aqueous solution used on the STA® line of instruments. Sufficient STA® - Cleaner Solution must be loaded to operate the analyzer.

IV. CALIBRATION

A. STA® -Fibrinogen5 is a pre-calibrated reagent, with identical values for every vial within a lot number. The following procedure for loading a new FBG curve should be preceded by parallel testing of the old reagent lot with new reagent lot. Refer to Associated Documents, "How to Build a User Defined Test on the STA Compact, Fibrinogen/D-Dimer for Parallel Testing of Lot Numbers". The kit reagents are pre-calibrated: this calibration is identical for all reagents of each lot.

B. Entering the data for the calibration curve: The database of the STA-Compact® monitors all reagent lot numbers. When the operator scans a new lot of fibrinogen reagent, the STA-Compact Max® will request the operator to scan the bar code printed on the bar code insert across the STA-Compact Max® bar code reader.

C. The calibration curve will be validated for the lot being used when the two fibrinogen control levels have been run. If the validation controls are outside the assayed range, the STA-Compact Max® will not run patient samples.

D. View calibration curve on STA Compact Max® on the screen: In the **TEST PANEL** screen select **CALIBRATION** or click the  icon. Calibration is either "valid" (green triangle), "to be validated" (purple triangle), "in process" (yellow triangle), or "not done" (red triangle). In the CALIBRATION screen double click **FIB**. The curve will appear on STA Compact Max ® screen. After clicking FIB, click  to order the calibration. Click  to return to the TEST PANEL.

E. Print calibration curve: While viewing the curve on the **CALIBRATION** screen, click the  icon. The STA Compact Max® cannot print a calibration curve while the analyzer is running.

V. LINEARITY/CALIBRATION VERIFICATION

A. Fibrinogen linearity is required every 6 months and with a lot conversion. AMR for Fibrinogen is 150 - 900 mg/dL. This is at the normal dilution (1:20) the instrument uses to assay samples. Auto re-dilution at 1:8 for values below 150 mg/dL and at 1:40 for values above 900 mg/dL extends the range to 60 - 1800 mg/dL. Verification of the extended low range covers values from 35 - 250 mg/dL.

AMR 150 - 900 mg/dL

1. Find a patient with a fibrinogen between 700-800 mg/dl. Either a labor/delivery patient or post-partum patient may satisfy this requirement.
2. Run the fibrinogen test. The result should be between 700 and 800 mg/dL.
   a. In **PATIENT ANALYSIS** - **Loading Samples**, verify that Manual Mode is active. If not, click "Manual Mode" at the bottom of the screen.
   b. At the prompt enter the sample ID and press Enter.
   c. Load the sample onto any position of the Sample drawer.
   d. In the **Select Methodologies** screen under "Methodologies", double click on **FIB** and click "Confirm".
   e. Click  to begin testing.
3. When the result is displayed in the Test Panel Screen, double click **FIB** and click **Add** to add dependent tests from the "Add Analysis" menu.
   a. Select each of the following tests:

1	**FLIN 1/15** (dilution factor 0.75)
2	**FLIN 1/40** (dilution factor 2.0)
3	**FLIN 1/80** (dilution factor 4.0)
4	**FLIN 1/100** (dilution factor 5.0)

b. Click "Confirm".

c. Click  to begin testing.

4. Print the test results. Target Recovery: +/- 20% (CAP guidelines)

EXTENDED LOW RANGE 35 - 150 mg/dL

5. Find a patient with a fibrinogen value between 500-600.

6. Perform serial dilutions of the 500-600 sample: 1:2, 1:4, 1:8, and 1:16 using O.K. Buffer.
   a. Run the 1:2 dilution as a standard **FIB** test (see sec. A., 2., a., above).
   b. Run the 1:4 and 1:8 dilutions as dependent tests, using **FIB 1:8** as the test (see sec. A., 3., above).
   c. Run the 1:16 dilution as a dependent test, using **FIB 1:4** as the test (see sec. A., 3., above).

7. Print the results. Target Recovery: +/- 20% (CAP guidelines).

B. Calculate recover percentages independently using EP Evaluator or fax to Stago Technical Support Specialist for processing. Stago TSS: Chris Arce, Fax # 973-775-8027or email to chris.arce@us.stago.com. Note: EP Evaluator will not work for analyses where the units are not already converted to mg/dl.

C. NORMAL PATIENT STUDY - A normal patient study must be performed on all new reagent lots for Fibrinogen if the standard validation procedure (correlation) for new lots is not within acceptable limits.
NOTE: Refer to **SFOFCD-0373, Fibrinogen and D Dimer for Parallel Testing of Lot Numbers**, for more detailed instructions.

1. Collect patient blood samples from the outpatient clinic for 5 days. Criteria for "normal patient" samples:

   a. 3 females and 3 males
   b. Ages: 20 – 70 years old
   c. No coagulation tests requested by patient's physician
   d. Not pregnant

2. Perform parallel normal patient study on the new lot of reagent with the existing lot.

3. Send the results to the Regional Lab. All the Northern California Kaiser Labs will also submit their individual normal patient study and Regional Lab will

calculate the Patient Reference Mean from this data reflecting the entire region's population.

VI. QUALITY CONTROL

A. Preparation of Controls - Reconstitute each vial of Reagent 1 or 2 with exactly **2 ml** of distilled water. Allow the reconstituted material to stand at room temperature 18-25°C for 30 minutes. Mix by turning the vial upside down, 3-4 times, to obtain a homogeneous solution. Swirl the vial gently before use, and at the beginning of each shift.
Location - Stock supply is stored in the CHEM REF#2, or the left-side store room refrigerators. A limited supply is kept in the under counter refrigerator in the Coagulation area, 2425 COAG UC Ref.

B. STA®-Coag Control N Plus+ABN Plus: After the reconstitution period, click **Products,** then **Loading Products** or click the  icon to request the product drawer (STA Compact Max®) to open. Scan the barcode on the bottle. Press **Enter**, and then place the controls in the drawer. Select  and click Confirm to close the drawer.

C. QC can be run automatically at pre-set intervals (in Test Set-up) or by ordering manually from the Quality Control Menu. Two levels of controls are run every 8 hours of patient testing (approximately 9AM, 5PM, & 1AM) and each time there is a change in reagents.

D. If QC is out of range, the instrument will audibly and visually alarm the operator. Otherwise, the results can be found in the individual QC files. Control results are automatically filed in the STA Compact Max ® QC file and load to RILIS.

E. All results for a 24-hour period will be converted to a "mean" value on the first run after midnight. This mean is used in the statistical data and is plotted on the Levy-Jennings chart as a daily mean.

F. Individual QC results need to be verified in RILIS (ARE) once completed. Scan the appropriate barcode for each QC level. The barcodes are different for each analyzer and are posted next to each instrument. Enter the QC results on the STA® Compact Max Quality Control Log.notes:///882572110060866C/393A3D15FDCFCF01852565D10057A0C9/2E2EF1E2683FB62A88257670007C7D7F

G. Controls will automatically transmit to RILIS. Transmitted QC results have to be verified using the following accession numbers.

STA® Compact Max-A
Level 1 (Norm) Control (PT, APTT and FIB) - 31-QC-250016
Level 2 (Abnorm) Control (PT, APTT and FIB) - 31-QC-250015

STA® Compact MAX-B
Level 1 (Norm) Control (PT, APTT and FIB) - 31-QC-251016
Level 2 (Abnorm) Control (PT, APTT and FIB) - 31-QC-251015

H. In the event that the QC is out of range, a comment box will appear to document corrective action to be performed.

I. If RILIS is down and you are unable to verify the QC results, you may print all the QC data points for the PT+ test. Perform the following procedure before running 1 AM controls:

1. Click the  icon or click **Quality Controls** and the windows **Methodologies List** appears.
2. Double click the **FIB** test.
3. Click the QC Tables  icon and then click the  icon.
4. In the dialog box **Printout** select **Print** then click **Confirm.**
5. **Click the**  icon to return to the QC Graph.
6. Click **Next Level** and repeat process for other levels.

J. Corrective Action for out of range QC Results:

1. If the control is out of range, re-run the control fluid.
2. If still out of limit, check STA Fibrinogen and OK Buffer reagent stability. Reconstitute fresh reagents if necessary.
3. If still out of range, check instrument performance. Call Stago Hotline (800-725-0607) for troubleshooting. Inform the Supervisor for further investigation. Unresolved issues must be referred to Biomed (Clin. Tech. x33479). Use the back up instrument for testing.
4. Document actions taken to identify and correct the problem. All out of range QC runs must be documented in RILIS when prompted in ARE. Document instrument problems in the “Supplemental Maintenance” and Q.C. problems in the RILIS control result comment and on the “Out-of-Control” section of the “Q.C. and Maintenance” binder for the instrument.
5. All "in-range" repeated controls (controls run for reasons other than failed QC; for example, "new reagent vial") must be documented in the RILIS control file comment.
6. Record QC results on the appropriate QC forms and RILIS control file, and verify QC data using the RILIS control file.

VII. PROCEDURE

A. Refer to Sta-Compact Max® START UP Procedure with Maintenance, SFOWI-1318notes:///882572110060866C/7CD4CC966DB8ED5E852568A70054661E/41D9B52C7930905F8825803C007B353D before running patient specimens on the instrument at the start of each shift.

B. Request quality control:

1. Click the  icon or click **Quality Controls** and the windows **Methodologies List** appears.
2. Select the check box for the **FIB** test and click the  icon.
3. Type the access code "CQ" and then click **Confirm**. A yellow triangle  is displayed to the right of the methodology showing the selected Quality Control is running.

C. **Load patient samples**: Click **Patient Analysis** then **Loading Samples** or click the  icon to open the sample drawer. After the drawer opens, identify the type of specimen, such as micro-sample and/or stat (urgent) by clicking the box. Identify the sample by scanning the bar-code or manually entering the ID using the keyboard, place the specimen into the drawer. Select the **Methodologies**, click **Confirm** and then click the  icon.

1. In MANUAL MODE, the operator must order the test(s) from the Selection menu, or from the Recorded Profile(s). Double click each methodology or Profile, click **Confirm**.
2. In AUTO MODE, the STA Compact Max® will automatically order the test(s) selected in the AUTO MODE profile.
3. If DOWNLOADING is selected as the AUTO MODE profile, the STA Compact Max® will query the host computer and download the test(s) as well as assign the status (i.e. stat).

D. As soon as the sample drawer closes, the ANALYSIS STATUS screen will appear. If there is not enough reagent(s) to run the test(s), the deficient reagent(s) and the amount of reagent necessary to complete the testing will appear in red. This deficiency will BLOCK the SAMPLE PIPETTING and the  icon will appear on the bottom of the screen. When this occurs, add the necessary reagent(s) to run the samples by responding N (NO) to the warning message "NEW TESTS ARE DELAYED - REACTIVATE?" Reagents can then be loaded in the drawer. By responding Y (YES) to the warning message "NEW TESTS ARE DELAYED - REACTIVATE?", the instrument will continue to perform all tests for which there is sufficient reagent (i.e. while waiting for reagents to stabilize after reconstitution).

E. All patient results are displayed on the **TEST PANEL** screen and automatically print out and transmit if selected on the **SYSTEM** menu.

For results in question that need operator intervention, cursor to the identification number in the **TEST PANEL** screen and double click. This will display the **PATIENT REPORT FORM** screen for the specific sample. Follow the options on the bottom of the screen (i.e. Confirm, Re-run, Delete, Add test). Click the  icon to save the changes and then click the  icon to return to the **TEST PANEL.**

VIII. CALCULATIONS

A. The STA-Compact Max® automatically converts the results in seconds from a standard curve (log-log) to mg/dL. The assay uses a dilution of 1:20 sample plasma to buffer. If the auto redilute feature is necessary the results are displayed on the Screen in Blue numerals, instead of the normal Black numerals.

1. Samples with a concentration of <150 mg/dL are automatically diluted 1:8 and rerun.
2. Samples with a concentration of >900 mg/dL are automatically diluted 1:40 and

rerun.

B. Also see the Notes section below and the D. Special Notes Related to Fibrinogen Results in the Reporting Results section, below.

IX. REFERENCE RANGE

Fibrinogen Reference Range: 209 - 504 mg/dL.

X. REPORTING RESULTS

A. The results for a fibrinogen are reported out to the nearest whole number in mg/dL (Example: 130 mg/dl), and the result printout may also display the clotting time in seconds.

B. Report results in RILIS Millennium using Accession Result Entry **(ARE)**. Enter Accession number and press **RETRIEVE**. Compare instrument result from the RILIS result. Press **VERIFY** after results are confirmed.

C. REPORTABLE RANGEnotes:///882572110060866C/393A3D15FDCFCF01852565D10057A0C9/DDD47D00242CE61E8825761200616E4B**: 60 - 1800 mg/dl**.

FBG (1:8)	FBG (1:20)	FBG (1:40)
60-149 mg/dl	150-900 mg/dL	901-1800 mg/dL

The STA-Compact Max® is programmed to automatically perform a dilution on those Fibrinogen results that exceed the upper or lower reportable limits. Results outside the reportable range should be reported as less than or greater than the range. The analyzer linear limit is 0 - 1800 mg/dl.

D. Special Notes Related to Fibrinogen Results:

1. **>Mmax** STA-Compact Max® result for fibrinogen means the fibrinogen value is **extremely low**. Report as **<60 mg/dl.**
2. **<Mmin** STA-Compact Max® result for fibrinogen means the fibrinogen value is **extremely high**. Report as **>1800 mg/dl.**

Note: The fibrinogen curve is **inverse**.

a. When results indicate "less than", the measurement time in seconds is short, but the actual fibrinogen concentration is very high.

b. When results indicate "greater than", the measurement time in seconds is long, but the actual fibrinogen concentration is very low.

Value **below 150** mg/dL will be diluted **1:8** If result of 1:8 dilution is <60 mg/dL:	Value **above 900** mg/dL will be diluted **1:40** If result of 1:40 dilution is >1800 mg/dL:
>Mmax displayed in red on the Test Panel screen	**<Mmin** displayed in red on the Test Panel screen
Time>time displayed in red on the File Processing Screen	**Time<time** displayed in red on the File Processing Screen
Time>time on the printout	**Time<time** on the printout
Report as <60	Report as >1800

Results outside the reportable range should be reported as less than or greater than the range. **If the result is >MMax on the instrument, type in "59" in RILIS and the result will automatically convert to <60. If the result is <MMin on the instrument, type in "1801" in RILIS and the result will automatically convert to >1800. Do not use the convert to alpha option in RILIS**, this option will not flag the result as high. The analyzer is programmed to automatically repeat those results that exceed the upper or lower reportable limits.

E. The cause of any error code must be investigated and appropriate action taken prior to reporting results. All specimens that produce critical values or suspect values (very high or very low results) should be checked for clots prior to reporting results. **Note**: Patient results with analyzer indication "to be confirmed" (in blue letters on the Test Panel screen) must be investigated for specimen problem or instrument error and **test repeated** on the backup analyzer **prior to** releasing result. If discrepancy remains unresolved for specimen, request recollection and do not report result. **Results >Mmax or <Mmin must be repeated to confirm.**

F. **STAT and ME orders:** Such FIB orders are usually from the Post-Operative department and must be performed immediately by centrifuging in the STATSpin and processing STAT on the analyzer. At least one analyzer must be available at all times to perform the test, as results are required by the physician ASAP in order to make the Cryoprecipitate transfusion decision.

G. If a specimen is clotted, results are invalid. Notify the MD/RN. In ARE, use Alpha response "TND" and document with a Result Comment using template "TND" and enter CLOTTED as the description. Template reads:

Test not done. Specimen _. Provider notified on _ at _ by _.

XI. NOTES

A. When the STA-Compact Max® redilutes a patient sample at a more appropriate dilution 1:8 if <150 mg/dl and 1:40 if > 900 mg/dL (as pre-determined in Test Set-up) the results in the TEST PANEL screen which appear in Blue numerals have already been corrected by the STA-Compact® for the dilutional difference.

B. Patients receiving thrombolytic therapy will have a rapid drop in the plasma fibrinogen level. fibrinogen result will be inaccurate if patient is drawn during thrombolytic therapy.

XII. LIMITATIONS

A. In patients receiving drugs that affect the fibrinolytic system, the plasma levels of fibrinogen degradation products (FDP) may be extremely high. FDPs may inhibit both thrombin action of fibrinogen and fibrin polymerization. At normal fibrinogen concentrations, FDPs have a minimal effect on the fibrinogen assay. At fibrinogen concentrations below 150 mg/dL, FDPs greater than 130 g/mL increasingly inhibit the thrombin clotting rate assay. High levels of paraproteins may interfere with the polymerization of fibrin monomers.

B. The clinical use of topical bovine thrombin has led to the generation of antibodies in some patients. These antibodies may lead to artifactual prolongation of the thrombin clotting rate assay of fibrinogen.

C. Heparin may interfere with this assay. However, the STA®-Fibrinogen reagent contains a specific inhibitor of heparin. Any prolongation of the assay is therefore, related to a real coagulation factor deficiency of fibrinogen.

D. The STA® - Fibrinogen procedure is insensitive to the following substances: Fibrin degradation products (up to 130 µg/mL), Hirudin (up to 3 µg/mL), Heparin (up to 2 IU/mL).

E. The STA Compact's mechanical clot detection method is insensitive to the presence of hemolysis, lipemia, and icterus in plasmas, and the Fibrinogen result is therefore unaffected by these specimen characteristics.

XIII. REFERENCES

A. STA®- Fibrinogen, Quantitative Determination of fibrinogen by STA® Analyzers. Package insert English 2 – Revised March 2015.

B. STA® - Coag Control N Plus+ABN Plus (Cat. No. 00677), Revised September 2014.

C. STA Compact Max® Operator's Manual. Version 0931946C, revised September 2015

D. STA® - Desorb U (Cat. No. 0975) Decontamination solution for STA® analyzer systems. Package insert #26265 – revised July 2015.

E. STA®- Owren-Koller buffer (Cat. No. 00360). Revised June 2015