TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2017
Department:	Core Lab	**Due Date:**	7/27/2017
		Implementation:	**7/25/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
D - Dimer SGAH.G04 v8
Description of change(s):
The following info was added to help answer CAP checklist question HEM.37935. There is no change that affects test performance process Section 14.4: add clinical sensitivity and specificity values Section 17: add reference for clinical specificity This revised SOP will be implemented July 25, 2017

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**D-Dimer**
Prepared by	Ashkan Chini Date: 4/7/2011
Owner	Robert SanLuis Date: 6/3/2014

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
D - Dimer Quantitative	Immunoturbidometric / STA® Compact	DDIMER

Synonyms/Abbreviations
D - Dimer

Department
Coagulation

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2. ANALYTICAL PRINCIPLE

This assay is based on the change in turbidity of a microparticle suspension that is measured by photometry. A suspension of latex microparticles, coated by covalent bonding with monoclonal antibodies specific for D-dimer, is mixed with the test plasma whose D-dimer level is to be assayed. An antigen-antibody reaction takes place, leading to an agglutination of the latex microparticles which induces an increase in turbidity of the reaction medium. This increase in turbidity is reflected by an increase in absorbance, the latter being measured photometrically. The increase in absorbance is a function of the D-dimer level present in the test sample.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting plasma may be used for samples to be analyzed by this method. Vacutainer tube must be filled to the line to ensure the proper ratio of blood to anticoagulant.
Special Collection Procedures	If hematocrit >55%, refer to appendices A and B for collection instructions.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	PLT Poor Plasma (sodium citrate) None	
Collection Container	Light blue top tube (3.2% sodium citrate) Citrated blood 9:1 (blood to anticoagulant)	
Volume - Optimum **- Minimum** **- Optimum** **- Minimum**	2.7 mL (9:1 blood to anticoagulant) in a 2.7 ml tube 2.4 mL (9:1 blood to anticoagulant) in a 2.7 ml tube 1.8 mL (9:1 blood to anticoagulant) in a 1.8 mL tube 1.8 mL (9:1 blood to anticoagulant) in a 1.8 mL tube	
Transport Container and Temperature	Light blue vacutainer (as above) or a clean plastic screw capped vial at room temperature.	
Stability & Storage Requirements	Room Temperature (20 ± 5°C):	8 hours
	Refrigerated:	Not recommended
	Frozen plasma:	1 month at -20°C

Criteria	
Specimen preparation	Centrifuge whole blood for specified time /speed documented on each centrifuge for preparing platelet-poor plasma.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Clotted or under-filled tubes are not accepted. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message.
Compromising Physical Characteristics	Moderate to gross hemolysis. Reject sample and request a recollection. Credit the test with appropriate LIS English text code HMM (Specimen moderately hemolyzed) or HMT (Specimen markedly hemolyzed) Lipemia: Acceptable Icterus: Acceptable
Other Considerations	None

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
STA - LIATEST® D – DI: Buffer & Latex	Diagnostic Stago (REF 00515)
STA – Owren-Koller Buffer	Diagnostic Stago (REF 00360)

4.2 Reagent Preparations and Storage

Reagent 1 & 2	**STA - LIATEST® D – DI: Buffer and Latex**
Container	Manufacturer supplied vial
Storage	2-8°C
Stability	Unopened reagents are stable until expiration date indicated on the box label. With the STA-mini Reducer and perforated cap in place the stability of Reagents 1 and 2 after opening and in their original vials is 15 days on the Stago.

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Preparation	Allow Reagent 1 and 2 to stand at room temperature (18-25°C) for 15 minutes before use. Mix the reagents by gentle swirling of the vials without creating any bubbles. Then place the perforated cap on each vial.

Reagent 3	**STA – Owren-Koller Buffer**
Container	Manufacturer supplied vial
Storage	2-8°C
Stability	The buffer solution in intact bottles is stable until the expiration date indicated on the box label. After opening it remains stable for 3 days.
Preparation	Allow it to stand at room temperature (18-25°C) for 30 minutes before use.

5. CALIBRATORS/STANDARDS

5.1 Calibration Procedure

The pre-calibrated D-dimer values are identical for all the vials of each lot. To enter the calibration data on the analyzer, scan the barcode printed on the assay value insert across the instrument barcode reader.
The calibration data will be validated for the lot being used once the Stago D-dimer controls are run and tested.

The calibration curve is considered verified for the new reagent lot when both the STA®-LIATEST Control N + P are within acceptable range. The acceptable STA®-LIATEST Control N + P range is supplied by Stago. QC ranges must fall within the acceptable range which is established utilizing the peer group data in combination with our current/historic analytic performance.

To examine calibration curve on screen:
- Through the MAIN MENU under CALIB/CONTROL select CALIBRATION.
- Move the cursor to D-Dimer and press **Enter** ↵. Curve will appear on STA® Compact screen.

To print calibration curve:
- While examining the curve on the STA® Compact screen, press ESC key for options.
- Select print Option **Enter**↵. Select Execute **Enter**↵.
- The curve will print along with the information on all reagents and control lot numbers. Also included are control results and ranges.

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6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalogue Number
STA - LIATEST Control N + P	Stago Diagnostic, Cat. No. 00526

6.2 Control Preparations and Storage

Control	STA - LIATEST Control N + P
Preparation	Reconstitute each vial of Reagent 1 or 2 with exactly 1 mL of Reagent Grade water. Allow the reconstituted material to stand at room temperature (18-25°C) for 30 minutes. Then, swirl the vial gently before use.
Storage	2-8°C
Stability	The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8°C. Once reconstituted, Reagents 1 and 2 remain stable for 8 hours.

1. QC can be run automatically at pre-set intervals (in Test Set-up) or by ordering manually from the Quality Control Menu.
2. All control ranges are monitored automatically by the STA® Compact. If any controls are outside the ± 2 SD 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 QC file. All results for a 24-hour period are converted to a "mean" value at midnight. This mean is used in the statistical data and is plotted on the Levy-Jennings chart as a daily mean.
3. To print all the QC data points for the D-Dimer test, perform the following procedure prior to midnight. From the MAIN MENU under CAL. /CONTROL select QUALITY CONTROL press **Enter** ↵. Cursor to the D-Dimer test and press **Enter** ↵to view the Levy-Jennings chart. Press **F1** to view the results in tabular form. Press **F6, select Execute then** press **Enter** ↵to print the individual values under current controls. Press ESC key to exit (back to graph). Press **F2** or **F3** to view other levels and continue with **F1** to view the result list.

6.3 Frequency

Controls are run every 4 hours of patient testing and with the change of any reagent used in test performance.

Controls are run after any maintenance is performed on the analyzer.

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6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	The established QC ranges are in the QC file of the STA Compact. The quality control results from the instrument are transmitted to Unity Real Time and can be viewed in that program. Any out-of-range QC results will be flagged.
2	If all controls are within QC parameters all sample results can be reported.
3	Rejected runs must be effectively addressed by corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed. Supervisor may override rejection of partial or complete runs only with detailed documentation that follows criteria that is approved by the Medical Director.
4	Corrective action documentation must include the following: QC rule(s) violated, the root cause of the problem, steps taken to correct the problem, how patient samples were handled, and the date and initials of the person recording the information. See the QC/QA SOP "QC Responsibilities" for more detail.
5	If the assay is down and results will not be reported in the scheduled turnaround time, clients will be notified of the situation.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Linearity must be verified with each new lot and at least every six months.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.

- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

STA® Compact – Analyzer

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge calibrated for preparing platelet-poor plasma

7.3 Supplies

- Cuvette Roll – Diagnostic Stago
- STA – brass adapters
- Plastic micro cups
- STA Mini-Reducer
- Plastic transfer pipettes
- Micro adapter
- Glass micro cups

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-up Protocol
1	At the start of each shift, verify instrument temperatures and availability of cuvettes and cleaner solution by accessing the System Status screen from the main bar.
2	Record the temperatures on the maintenance sheet. If the reagent arm 2, measuring block, or reagent drawer temperatures are out of range, corrective action must be taken prior to patients being run.
3	Make sure that there is an adequate supply of reagents in the analyzer, and they are in date.
4	Load cuvettes and cleaner/wash solution on the analyzer if needed.

8.2	Analytical Procedure
1	Refer to START-UP procedure for STA® Compact before running patient specimens on the STA® Compact at the start of each shift.
2	Request quality control. Through MAIN MENU under CALIB. /CONTROL select QUALITY CONTROL and press **Enter** ↵. Cursor to the D-Dimer test. Select D-Dimer by pressing **F1** and then **F10.** Type in your Access Code to run the QC.
3	Load patients' samples: Access the sample drawer(s) through the MAIN MENU, under LOADING, Select Sample, press **Enter** ↵. After the drawer opens, identify the type of specimen, such as micro sample (press **F8**), or stat (press **F12**). Identify the sample by bar coding or manually entering on the keyboard the patient identification number and then placing the specimen into the drawer.
4	In MANUAL MODE, the operator must order the test(s) from the Selection menu or from the Recorded Profile/s Cursor to the test and press **Enter** ↵to select. When all tests are ordered, press F10 to save.
5	In AUTO MODE, the STA®/STA® Compact will automatically order the test(s) selected in the AUTO MODE profile.
6	If TELELOADING is selected as the AUTO MODE profile, the STA®/STA® Compact will query the host computer and download the test(s) as well as assign the status (i.e. stat).
7	As soon as the sample drawer closes, the TEST STATUS screen will appear. If there is not enough reagent(s) to run the test(s), the suspect reagent(s) will appear in red with the amount of depletion. This depletion of reagent will BLOCK the SAMPLE PIPETTING. 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)
8	If the patients' results fall outside the assay reportable range **4.0 µg/mL** the instrument will automatically do a 1:5 dilution on the samples in question. This auto dilution will let the instrument report results up to **20.0 µg/mL**.
9	All patient results are displayed on the TEST PANEL screen and automatically print out and transmit if selected on the system status menu.
10	For results in question that need operator intervention, cursor to the identification number in the TEST PANEL screen and press enter. This will display the FILE PROCESSING screen. Follow the options on the left-hand side of the screen (i.e. **F3** - rerun test).

8.3	Reagent and QC Loading Instructions
1	When Reagent/QC material is reconstituted and ready for use proceed to step 2
2	From Home Page select **Loading** – **Products**
3	Scan the Reagent/QC

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8.3	Reagent and QC Loading Instructions
4	The Instrument will ask whether the volume is correct, or it needs to be modified.
5	Accept or modify the volume then press **Enter**
6	Load the Reagent/QC which was just scanned. **Note:** Neoplastine CI Plus reagent vial requires to be sitting in the position which is systematically stirred by a lateral movement.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

1. The STA® Compact automatically plots the results in delta OD off of a standard curve and converts the results to µg/ml FEU.

2. The assay uses the sample undiluted. If the result is greater than the reportable range, 4.0, a dependent test with a 1:5 dilution will be ordered to take the reportable range to 20.0. The STA® Compact automatically corrects the result for the dilution change.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

N/A

10.2 Rounding

No rounding is necessary. The instrument reports results up to two decimal points.

10.3 Units of Measure

µg/mL FEU

10.4 Clinically Reportable Range (CRR)

0.27 – 20.00 µg/mL FEU

10.5 Review Patient Data

Each result is reviewed for error messages. Refer to the STA® Compact system manual "Error messages" section for troubleshooting. Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

The printout from the STA Compact is reviewed for repeat criteria and samples are repeated if needed. Results will be transmitted to the LIS and released using the OEM function.

IF the result is …	THEN…
< Mmin	Repeat, check for clots. If result is still <Mmin, report as <0.27 µg/mL FEU-REP
> Mmax	Check for clots, repeat using the D-Di 1:5 test
If D-Di 1:5 is quantifiable	Report the result with comment REP
If D-Di 1:5 is > Mmax	Repeat. Report the result as > 20.0 µg/mL FEU-REP
For any of the above situations, be sure the specimen is not under-filled or over-filled, then check the Hematocrit (HCT) result. If the HCT is greater than 55%, refer to appendices A and B for special tube preparation.	

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

≤ 0.50 µg/mL FEU

11.2 Critical Values

None established

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS if the value is greater than 0.50 µg/mL FEU:

Less than or equal to 0.50 µg/mL FEU = Negative
Greater than 0.50 µg/mL FEU = Positive
Positive results are non-specific and are seen in a variety of conditions including DVT, pulmonary embolism, recent surgery, cancer, trauma and pregnancy.
Values greater than 0.50 µg/mL FEU may also be seen in otherwise healthy patients >70 years of age.

Reference:
van der Graaf F, et. al.

Exclusion of Deep Venous Thrombosis with D-Dimer Testing
Thromb Haemost. 2000;83:191-198

For patients greater than 49 years of age with a result >0.50, the following **additional** comment is also automatically added to the report by the LIS:

The application of age adjusted cut-off values for D-dimer increases specificity without modifying sensitivity, thereby improving the clinical utility of D-dimer testing in patients aged 50 or more.

Age (Y)	Age Adjusted Cut-off
<= 50	N/A
51-60	0.55 mcg/mL FEU (0.51-0.60)
61-70	0.65 mcg/mL FEU (0.61-0.70)
71-80	0.75 mcg/mL FEU (0.71-0.80)
> 80	0.80 mcg/mL FEU

Ref: Diagnostic Accuracy of Conventional or Age Adjusted D-Dimer cut-off values in Older Patients with suspected venous thromboembolism: Systematic Review and Meta-Analysis British Medical Journal 2013; 346:2492

12. CLINICAL SIGNIFICANCE

D-Dimer quantitative assay detects the presence of Disseminated Intravascular Coagulation (DIC). In DIC, the fibrinolytic system is activated and therefore the D-Dimer level increases. D-Dimer assays can help in the diagnosis of DIC in these cases. It is established that a normal D-Dimer level is an important factor to rule out the diagnosis of deep venous thromboses (DVT) or pulmonary embolisms (PE). The decrease of D-Dimer levels during heparin therapy for a DVT allows the monitoring of evolution and prognosis of the thrombosis. This decrease reflects the quality of the endogenic thrombolysis. The D-Dimer level increases during the activation states of coagulation because they induce the production of thrombin which is followed by the formation of fibrin and leads to fibrinolysis, the latter being most frequently reactive. The D-Dimer level thus increases following coagulation activation.

Increased levels of D-Dimer have been reported in post-operative period, cancers, cirrhosis, and hemorrhages.

13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

1. The detection threshold of the STA® Liatest® D-Dimer on the STA® Compact is 0.27 µg/mL FEU. The printout limits are pre-set at 0.27 – 4.00 µg/mL FEU. When a dependent test is

set-up to extend the reportable range of the main test, the printout limit should be extended to 20.00 µg/mL FEU.

2. The STA® Liatest® D-Dimer results are expressed in FEU, Fibrinogen Equivalent Units. By definition, an FEU is the quantity of fibrinogen initially present that leads to the observed level of D-Dimer. In general, the actual quantity of D-Dimer is approximately half of an FEU.
3. A >Mmax result on the primary assay dilution (1:1 dilution) indicates a result that is greater than 4.00 µg/mL FEU. In this case the analyzer will automatically do a 1:5 dilution to obtain the result.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.27 – 4.00 µg/mL FEU

14.2 Precision

Different plasmas were used for the intra assay and inter assay reproducibility studies on the STA® Compact.

	Repeatability		Within-laboratory Precision	
Sample	**Sample 1**	**Sample 2**	**Sample 1**	**Sample 2**
Mean (µg/mL)	0.67	2.20	0.67	2.20
SD (µg/mL)	0.042	0.049	0.049	0.085

14.3 Interfering Substances

1. Cloudy plasmas may lead to an under-estimation of the D-Dimer level. Ensure that the absorbance value at 540 nm of the plasma diluted 1:6 with STA® -Owren-Koller buffer is < 0.35.
2. Concentration of Fibrinogen Degradation Products greater than 15 µg/ml may lead to an over-estimation of the D-Dimer level.
3. The presence of rheumatoid factor at a level greater than 50 IU/ml may lead to an over-estimation of the D-Dimer level.
4. The STA® Liatest® D-Dimer is insensitive to fibrinogen and the E fragment. A low cross-reactivity is observed with the D fragment.
5. The STA® Liatest® D-Dimer is insensitive to the following substances: hemoglobin (up to 2 g/l); conjugated bilirubin (up to 290 mg/L); unconjugated bilirubin (up to 200 mg/L); unfractionated heparin (up to 2 IU/mL; LMWH (up to 2 anti-Xa IU/ml)

14.4 Clinical Sensitivity/Specificity/Predictive Values

This test is appropriately sensitive for the exclusion of DVT and PE:

- negative predictive value (NPV), sensitivity and specificity of 100%, 100% and 55.2% for DVT exclusion, respectively

- NPV, sensitivity and specificity of 99.7%, 97.0% and 75.5% for PE exclusion, respectively

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Hemolysis, Icteria and Lipemia Interference (Lab policy)
5. Repeat Testing Requirements (Lab policy)
6. STA Compact Operating Instructions, Coagulation procedure
7. Verification of Platelet Poor Plasma, Coagulation procedure
8. Current package insert for STA® LIATEST D-DIMER

17. REFERENCES

1. van der Graaf F, et. al., Exclusion of Deep Venous Thrombosis with D-Dimer Testing, Thromb Haemost. 2000;83:191-198
2. Diagnostic Stago STA® LIATEST D-DIMER package insert: Revised August 2015.
3. STA - LIATEST Control N + P (REF 00526): citrated control plasmas normal and abnormal levels; Control Plasmas for Assays of Coagulation Parameters on STA®, Revised 03/2015.
4. STA® Compact Operators Manual. STA® DSI-TSD-SM August 2004, STA® DSI-TSD-US April 2003, and V1.3 revised February 2003.
5. Diagnostic Stago STA® Owren-Koller Buffer Solution for Coagulation Tests. Revised: May 2014.
6. Diagnostic Accuracy of Conventional or Age Adjusted D-Dimer cut-off values in Older Patients with suspected venous thromboembolism: Systematic Review and Meta-Analysis British Medical Journal 2013; 346:2492
7. D-Dimer for the Exclusion of Thromboembolism (DiET) Study Completed, STAGO Website article, http://www.stago-us.com/news-events

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes G003.006		
000	6/11/12	2.0	Update to match package insert	J.Buss	J. Buss, RSL
000	6/11/12	3.2	Add frozen temperature	J.Buss	J. Buss, RSL
000	6/11/12	4.1	Remove Millipore water	J. Buss	J. Buss, RSL

Version	Date	Section	Reason	Reviser	Approval
000	6/11/12	4.2	D-DI reagent open stability edited	J.Buss	J. Buss, RSL
000	6/11/12	6.3	Add QC performed after maintenance	J.Buss	J. Buss, RSL
000	6/11/12	15	Update to standard wording	L. Barrett	J. Buss, RSL
001	6/3/14		Update owner	L Barrett	R SanLuis
001	6/3/14	3.1	Add reference to Appendices	A Chini	R SanLuis
001	6/3/14	3.2	Update tube volumes	A Chini	R SanLuis
001	6/3/14	4.2	Change storage temp and prep for buffer	A Chini	R SanLuis
001	6/3/14	6.2	Add step to print QC	A Chini	R SanLuis
001	6/3/14	10.4	Change CRR lower value	A Chini	R SanLuis
001	6/3/14	10.5	Add instruction for Hct >55	A Chini	R SanLuis
001	6/3/14	13, 14.1	Change lower value of analytical range	A Chini	R SanLuis
001	6/3/14	14.3	Update to match package insert	A Chini	R SanLuis
001	6/3/14	16	Update titles	L Barrett	R SanLuis
001	6/3/14	19	Add Appendix A and B	A Chini	R SanLuis
001	6/3/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
2	4/7/15	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
2	4/7/15	10.5	Correct <Mmin reporting value	L Barrett	R SanLuis
3	1/12/16	3.2	Change whole blood to plasma	A Chini	R SanLuis
3	1/12/16	4	Delete reagent grade water	A Chini	R SanLuis
3	1/12/16	5	Add explanation for Liatest D-dimer and Bio-Rad QC. Add Liatest QC info.	A Chini	R SanLuis
3	1/12/16	6.1, 6.2	Update to Bio-Rad QC	A Chini	R SanLuis
3	1/12/16	6.2	Add instruction for loading onboard	A Chini	R SanLuis
3	1/12/16	6.5	Update to match auto verification system	A Chini	R SanLuis
3	1/12/16	6.7	Add TEa criteria, linearity check with log change, QC sent to Bio-Rad monthly	A Chini	R SanLuis
3	1/12/16	7.3	Add micro adapter and glass micro cups	A Chini	R SanLuis
3	1/12/16	14.2	Update precision data	A Chini	R SanLuis
3	1/12/16	17	Add Bio-Rad QC	A Chini	R SanLuis
4	7/25/16	Header	Add other sites	L Barrett	R SanLuis
4	7/25/16	5.1	Removed Bio-Rad QC information	A Chini	R SanLuis
4	7/25/16	6.1, 6.2	Replace Bio-Rad QC with STA Coag Controls	A Chini	R SanLuis
4	7/25/16	6.7	Remove QC submission to Bio-Rad	A Chini	R SanLuis
4	7/25/16	8.3	Add QC/Reagent Loading Instructions	A Chini	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
4	7/25/16	11.3	Move report comment from 10.5	L Barrett	R SanLuis
4	7/25/16	17	Remove Bio-Rad insert	A Chini	R SanLuis
5	1/23/17	4, 6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
5	1/23/17	10.5	Review data moved from section 6	L Barrett	R SanLuis
5	1/23/17	11.3	Specify interpretation comment is included if result >0.50, add second report comment for >49 years old	L Barrett	R SanLuis
5	1/23/17	15	Update to new standard wording	L Barrett	R SanLuis
5	1/23/17	17	Add reference for age adjusted value	L Barrett	R SanLuis
6	5/1/17	6.3	Remove run QC at beginning of shift	L Barrett	R SanLuis
7	6/16/17	14.4	Add values	L Barrett	R SanLuis
7	6/16/17	17	Add reference for clinical specificity	L Barrett	R SanLuis

19. ADDENDA

A. Instructions for Preparing Collection Tube for Hematocrit >55%
B. Phlebotomist Instructions for Blood Collection

Appendix A

Instructions for Preparing Collection Tube for Hematocrit >55%

Explanation:

Polycythemia is a disease state in which the proportion of blood volume that is occupied by red blood cells increases - basically when Hematocrit (HCT) is greater than 55%. It can cause prolonged coagulation results.
When a prolonged coagulation result is obtained, check the specimen for a clot first.
If the specimen is not clotted, be sure the specimen is not under-filled or over-filled, then check the HCT result.
If a HCT result of greater than 55% is obtained, immediately notify the doctor or attending nurse and ask for a redraw using a special tube prepared by the lab.

To prepare a special tube in the lab use the following instructions and formula:

The anticoagulant volume in the collection tube must be adjusted to obtain a 9:1 ratio of blood to Sodium Citrate. Under or over-filling of the specially prepared collection tube is not acceptable.
The vacuum in the collection tube will be broken to adjust the volume of collection anticoagulant. Because of this special collection technique, the stability for these whole blood specimens is reduced to four (4) hours after collection.

Formula to calculate the anticoagulant volume is:
Anticoagulant in mL = [(100 – HCT) / (595 – HCT)] x Volume of blood

Example 1: Specimen with a 70% HCT in a 2.7 mL tube:

Patient with HCT of 70%
Using a 2.7 mL tube
Anticoagulant in mL = [(100 – 70) / (595 – 70)] x 2.7 = 0.15 mL or 150 uL
Pipette a 2.7 mL tube in a way to leave only 150 uL of anticoagulant in there.
A 2.7 mL tube contains 0.3mL anticoagulant; therefore remove 0.15mL

Example 2: Specimen with a 70% HCT in a 1.8 mL tube:

Patient with HCT of 70%
Using a 1.8 mL tube
Anticoagulant in mL = [(100 – 70) / (595 – 70)] x 1.8 = 0.1 mL or 100 uL
Pipette a 1.8 mL tube in a way to leave only 100 uL of anticoagulant in there.
A 1.8 mL tube contains 0.2mL anticoagulant; therefore remove 0.1mL

Example 3: Specimen with a 60% HCT in a 2.7 mL tube:

Patient with HCT of 60%
Using a 2.7 mL tube
Anticoagulant in mL = [(100 – 60) / (595 – 60)] x 2.7 = 0.2 mL or 200 uL
Pipette a 2.7 mL tube in a way to leave only 200 uL of anticoagulant in there.
A 2.7 mL tube contains 0.3mL anticoagulant; therefore remove 0.1mL

Example 4: Specimen with a 60% HCT in a 1.8 mL tube:

Patient with HCT of 60%
Using a 1.8 mL tube
Anticoagulant in mL = [(100 – 60) / (595 – 60)] x 1.8 = 0.13 mL or 130 uL
Pipette a 1.8 mL tube in a way to leave only 130 uL of anticoagulant in there.
A 1.8 mL tube contains 0.2mL anticoagulant; therefore remove 0.07mL

Appendix B

Phlebotomist Instructions for Blood Collection

The technologist will prepare a special tube in which the anticoagulant has been adjusted, therefore the tube is not vacuumed. The technologist will inform the phlebotomist of the exact amount of blood needed to fill the tube.

<u>Equipment and Supplies</u>

Latex free gloves
Latex free tourniquet
Latex free Band Aid or Tape
Alcohol Prep (70% alcohol)
2x2 sterile gauze
Collection tube
Blood Collection Set 21 or 23 gauge winged set
Blood Transfer Device
3mL syringe
Biohazard bag
Biohazard sharps container
LIS collection list and label/Lab requisition

<u>Collection Steps</u>

1. Introduce yourself to the patient by stating your first and last name.
2. Positively identify the patient according to the SOP 'Patient Identification', Phlebotomy procedure manual.
3. Wash hands. Apply gloves.
4. Explain the procedure to the patient and obtain patient's consent to draw blood.
5. Collect equipment and correct technologist-provided collection tube.
6. Assemble equipment and break needle and syringe seals in the presence of the patient.
7. Apply tourniquet about midway between the elbow and the shoulder 3-4 inches above the venipuncture site). Place patient's arm in a downward position to prevent reflux of 'backflow' of blood from the tube into the venous system. Ask the patient to close hand gently.
8. Palpate/feel for vein locating a vein that will flow fast (reducing the possibility of the blood clotting).
9. Clean the area for venipuncture with a 70% alcohol pad decontaminating the collection site.
10. Allow the area to air-dry completely.
11. Assemble the 21 or 23 gauge winged set to the 3mL syringe. Pull back the plunger to dispel all the air out of the syringe.
12. With the bevel up, align the needle with the vein while holding the skin taut. Insert the needle at a 15-30 degree angle with the skin. Remove your hand from drawing the skin taut. Grasp the syringe and draw back bringing the plunger tip to the exact amount of blood requested by the technologist.
13. Release the tourniquet. Ask the patient to open hand.

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14. Place gauze above the puncture site and remove the needle while simultaneously applying pressure on the puncture sit. Firmly activate needle safety shield, a click must be heard to ensure that the safety shield is secure.
15. Remove 21 or 23 gauge winged set from syringe.
16. Attach the blood-filled syringe to the Blood Transfer Device.
17. Connect the Blood Transfer Device to the un-vacuumed tube, provided by the technologist, and slow and gently fill the collection tube. DO NOT FORCE blood into tube. Pressure can lead to tube explosion and blood exposure.
18. Place the cap on the tube and invert a few times to make sure the anticoagulant is mixed with blood.
19. Dispose of all blood collection equipment into the nearest sharps container. DO NOT disassemble the syringe from the Blood Transfer Device.
20. Dispose of all other used materials in appropriate container and wash hands.
21. Label the sample with the LIS collection label and write the time, date, and your tech code.
22. Transport specimen to the Lab.