TRAINING UPDATE

Lab Location:	FWMC	**Date Distributed:**	8/223/2022
Department:	Core Lab	**Due Date:**	9/9/2022

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Title: FWMC-LAB-HEM-0024 D-Dimer (FEU) Innovance D-Dimer Assay Sysmex CA-600 Instrument
Description of change(s):
In response to a CAP failure for DDimer, please review the attached SOP and take the brief quiz.

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

FWMC-LAB-HEM-0024 D-Dimer (FEU) Innovance D-Dimer Assay Sysmex CA-600 Instrument

Copy of version 2.0 (approved and current)

Last Approval or Periodic Review Completed	9/30/2021
Next Periodic Review Needed On or Before	9/30/2023
Effective Date	9/30/2021

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Organization Fort Washington Medical Center

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	9/30/2021	2.0	Senda Beltaifa	
Approval	Lab Service director	9/30/2021	2.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	9/29/2021	2.0	Leslie Barrett	
Approval	Lab Director	7/30/2021	1.0	Senda Beltaifa	
Approval	Lab Service director	7/29/2021	1.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	7/27/2021	1.0	Leslie Barrett	

Prior History

Existing FWMC SOP placed on Lab EDCS

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	9/29/2021	9/30/2021	Indefinite
1.0	Retired	Initial version	7/27/2021	7/30/2021	9/30/2021

Current Status: *Active* **PolicyStat ID:** *6182772*

FWMC
FORT WASHINGTON MEDICAL CENTER
A Nexus Health Company

Origination: *04/2013*
Approved: *04/2019*
Last Revised: *04/2019*
Expiration: *04/2021*
Owner: *Sharon Kennedy-Dews: Director Laboratory Services*
Policy Area: *Laboratory*
References:

FWMC-LAB-HEM-0024 D-DIMER (FEU)-INNOVANCE® D-Dimer Assay-Sysmex® CA-600 Instrument

Procedure:

D-DIMER (FEU)- INNOVANCE® D-Dimer Assay- Sysmex® CA-600 Instrument

PRINCIPLE

Coagulation activation results in the cleavage of fibrinogen to fibrin. The fibrin monomers spontaneously aggregate to fibrin and are cross-linked by Factor XIII; this produces a fibrin clot. In response to the coagulation process the fibrinolytic system is activated resulting in the conversion of plasminogen into plasmin, which cleaves fibrin (and fibrinogen) into the fragments D and E. Due to the cross-linkages between the D-domains in the fibrin clot, the action of plasmin releases fibrin degradation products with cross-linked D-domains. The smallest unit is the D-Dimer. Detection of D-Dimers, which specifies cross-linked fibrin degradation products generated by reactive fibrinolysis, is an indicator of coagulation activity.

Elevated D-dimer levels are observed in all diseases and conditions with increased coagulation activation, e.g. thromboembolic disease, disseminated intravascular coagulopathy (DIC), acute aortic dissection, myocardial infarction, malignant diseases, obstetrical complications, third trimester of pregnancy, surgery or polytrauma.[1-6]

The INNOVANCE® D-Dimer assay is intended for use in conjunction with a non-high clinical pre-test probability (PTP) assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE). Elevated concentrations of D-Dimer are indicative of the presence of a clot and have been reported in deep vein thrombosis, pulmonary embolism and disseminated intravascular coagulation.

Polystyrene particles covalently coated with monoclonal antibody (8D3)[8] are aggregated when mixed with samples containing D-Dimer. D-Dimer cross-linkage region has a stereosymmetrical structure, i.e. the epitope for the monoclonal occurs twice. Consequently, one antibody suffices in order to trigger and aggregation reaction, which is then detected turbidimetrically via the increase in turbidity.

SPECIMEN

Type:

Mix nine parts of freshly collected blood with one part of 0.11 mol/L (3.2%) sodium citrate anticoagulant, avoiding the formation of foam. Invert the tube gently three or four times immediately after venipuncture to ensure proper mixing of blood and anticoagulant. A syringe or evacuated tubes (blue top) may be used with caution for collection. If multiple specimens are collected, the coagulation sample should be the first or second tube collected. If blood is drawn from an indwelling catheter, the line should be flushed with 5.0 mL saline and the first 5.0 mL of blood or six dead space volumes of the catheter discarded or used for other laboratory tests. The citrate concentration must be adjusted in patients who have hematocrit values above 55%. Specimens that are clotted, collected in the wrong tube, have visible hemolysis or have less than the expected fill should be rejected.

Handling Conditions:

The specimen should be transported at room temperature. The whole blood specimen is checked for clot formation by gentle inversion. Centrifuge the blood specimen for a minimum of 15 minutes at 1500 x g within 4 hours after collection. Patient plasma should be tested within 4 hours if stored at room temperature. If immediate testing is to be done, the plasma may remain on the packed cells or separated. To separate plasma, use a plastic transfer pipette; remove the plasma to a plastic tube. If testing is not completed within 4 hours or if shipment is required, the plasma may be stored frozen at ≤-18 °C or below for up to four weeks if frozen

within 4 hours of blood collection. Frozen plasma samples must be rapidly thawed at 37 °C while gently mixing and tested within 2 hours. ***Do not refreeze***

EQUIPMENT, MATERIALS and PREPARATION

Equipment:

Sysmex® CA-600 System
4.0 mL Sample Cups
Reaction Tubes
Waste and Rinse Bottles

Materials:

INNOVANCE D-Dimer Kit containing:
INNOVANCE D-Dimer Reagent
INNOVANCE D-Dimer Buffer
INNOVANCE D-Dimer Supplement
INNOVANCE D-Dimer Diluent
INNOVANCE D-Dimer Calibrator
INNOVANCE D-Dimer Control 1
INNOVANCE D-Dimer Control 2

CA System Buffer or Dade® Owrens Veronal Buffer (OVB)
CA Clean™ I
CA Clean™ II (CA-600 only)
Preservative-free distilled or deionized water

Preparation:

All components of a kit are lot-specific. The combination of lots other than those specified for the particular kit lot may lead to incorrect results.

Follow the preparation instructions prior to use according to Table 1. Storage instructions are detailed in section "Storage and Stability".

Table 1: Instructions for the preparation of the kit components

Instructions	INNOVANCE D-Dimer Reagent	INNOVANCE D-Dimer Buffer/Supplement/Diluent	INNOVANCE D-Dimer Calibrator
Reconstitution	1. Dissolve with 4.0 mL distilled water 2. Invert 3 times 3. Leave the vial for at least 15 minutes at 15 -25 ° C	Ready to use	1. Dissolve with 1.0 mL distilled water 2. Mix carefully without foam formation 3. Leave the vial for at least 15 minutes at 15 -25 ° C
Prior to placing on the system	1. Mix well (again) by inverting 3 times 2. Avoid foam formation 3. Remove bubbles	1. Mix carefully 2. Avoid foam formation 3. Buffer only: resuspend potential precipitates by gently swirling. Any residual precipitates after resuspension do not impact test results 4. Remove bubbles	1. Mix (again) carefully 2. Do not use if vial contains visible clot

Aliquoting	1. Mix well (again) by inverting 3 times 2. Aliquot into an empty vial provided with the same kit 3. Discard empty vials if unused until complete consumption of the kit.	1. Aliquot into an empty vial provided with the same kit. 2. Discard empty vials if unused until complete consumption of the kit.	N/A
Freeze and thaw	1. Use the original container or the empty vial provided with the same kit 2. Follow storage instructions in the section "Storage and Stability: 3. Thaw at 37 °C within 10 minutes. Thereafter the vial may no longer be stored at 2 – 8 °C. 4. Do not freeze again after thawing.		Refer to section "Storage and Stability" Mix carefully after thaw
Placing on the system	Place INNOVANCE D-Dimer Reagent in Reagent Holder position 6.	1. Place INNOVANCE D-Dimer Buffer in Reagent Holder position 4. 2. Place INNOVANCE D-Dimer Supplement in Reagent Holder position 8. 3. Place INNOVANCE D-Dimer Diluent in Reagent Holder position 10.	Place INNOVANCE D-Dimer Calibrator in Sample Rack position 1.
Note	The reconstitution, opening, or freezing date may be noted on the vial label using the framed free space.		

Storage and Stability:

The kit may be used up to the expiry date indicated on the label if stored unopened at 2 – 8 °C.

Table 2: Stability after reconstitution or first opening (closed vial)

Temp	INNOVANCE DDi Reagent-original vial	INNOVANCE DDi Reagent-cup	INNOVANCE DDi Diluent-original vial	INNOVANCE DDi Diluent-cup	INNOVANCE DDi Buffer-original vial	INNOVANCE DDi Buffer-cup	INNOVANCE D-Dimer Supplement-original vial	INNOVANCE D-Dimer Supplement-cup	INNOVANCE D-Dimer Diluent
2 -8° C	4 weeks		4 weeks		4 weeks		4 weeks		4 weeks
≤-18 C	4 weeks		4 weeks		4 weeks		4 weeks		4 weeks
15–25 °C	-	-	-	-	-	-	-	-	-
Onboard stability	16 hours	4 hours	16 hours	4 hours	16 hours	4 hours	16 hours	4 hours	16 hours

Do not refreeze and thaw. Follow freeze and thaw instructions in section "Preparation of the Reagents".

Information about on board stability is specified in the Reference Guides (Application Sheets) for the different analyzers.

Temp	INNOVANCE D-Dimer Calibrator
2 -8° C	-
≤-18 C	-
15–25 °C	4 hours
On board stability	-

INNOVANCE D-Dimer Control 1:

INNOVANCE D-Dimer Control 2:

Lyophilized human plasma based products containing D-Dimer containing

5-chloro-2-methyl-4-isothiazole-3-one
2- methyl-4-isothiazole-3-one (< 1 mg/L)
Sodium azide (< 1 g/L)

Assayed controls used for the assessment of precision and analytical bias in the normal and pathological range for the determination of D-Dimer in the INNOVANCE D-Dimer Kit.

- Reconstitute the INNOVANCE D-Dimer Control 1and 2 with 1.0 mL of deionized water
- Mix carefully (without foam formation).
- Allow to stand for at least 15 minutes at +15 to +25 °C.
- Mix carefully once more before using.

Storage and Stability

If stored unopened at +2 to +8 °C, INNOVANCE® D-Dimer

- Re-stopper vial and invert gently to dissolve (without foam formation)
- Let stand at +15 to +25 °C for at least 15 minutes before inverting
- Mix carefully once more before using

Stability after reconstitution:

≤-18 °C: 4 weeks (do not refreeze)**
2-8 °C: 7 days (closed vial)
15-25 °C: 8 hours (closed vial)

**Must be frozen in the original containers. Do not refreeze after thawing.

INNOVANCE D-Dimer Controls 1 and 2 may be frozen in the original container and thawed once after reconstitution. The previous storage time at 15-25 ?C must not have exceeded 4 hours. The plasma must be well sealed and frozen as quickly as possible. Thawing must be completed at 37 ?C and within a maximum of 10 minutes. INNOVANCE D-Dimer Control 1 and INNOVANCE D-Dimer Control 2 should not stand for more than 4 hours at 15-25 °C after thawing. INNOVANCE D-Dimer Control 1 and INNOVANCE D-Dimer Control 2 should not be used if they contain visible clots.

CA System Buffer or Dade® Owrens Veronal Buffer (OVB) is liquid and ready to use

Store at 2-8 °C. Do Not Freeze.
Stable unopened at 2-8 °C until expiration date on bottle.

Owren's Buffer ---Opened bottle stable for 8 weeks at 2-8 °C.

Dade System Buffer ----Open bottle stable for 30 days a 15-25°C (room temperature).

Place fresh CA System Buffer (OVB) on the instrument in Position 12 at the start of each eight hour shift.

CA Clean I is liquid and ready to use. Store at 2-8 °C. Do not freeze. Stable unopened at 2-8 °C until expiration date on bottle. Opened bottle is stable for 30 days at 2-8 °C.

CA Clean II is liquid and ready to use. Stable unopened at 5-35 °C until expiration date. Opened or bottle is stable for 60 days.

These products are for in vitro diagnostic use only.

WARNING: Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests found to be in conformance with the In Vitro Diagnostic Directive in the EU or FDA approved tests. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

WARNING: Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into a sink, flush with a large volume of water to prevent azide build up.

Reagent Integrity:

Indication of deterioration: No evidence of vacuum in vial upon opening, difficulty in reconstituting reagent, control values outside of determined range

QUALITY CONTROL

INNOVANCE D-Dimer Control 1
INNOVANCE D-Dimer Control 2

1. INNOVANCE D-Dimer Controls must be tested at least every eight hours of testing and for each vial of reagent for the respective measurement range to ensure that the system is functioning correctly. Control of the lower measurement range is performed with INNOVANCE D-Dimer Control 1, and for the upper range with INNOVANCE D- Dimer Control.2.
2. The measured values obtained must be within the acceptance ranges given in the respective Table of Assigned Values.
3. If values are obtained outside the acceptance ranges, the measurement must be repeated. If the deviations are confirmed, a new calibration must be performed.
4. Do not report patient results unless the cause of the deviating control results has been identified and corrected.

PROCEDURES FOR SETUP

Loading Reagents

(when the instrument is not operating)

1. Press the [Set Reagents] key from the 'Main Menu'.
2. Press the reagent position for D-Dimer Reagent. Enter the reagent volume using the drop down screen.
3. Using the arrow keys toggle to the D Dimer Buffer. Enter the reagent volume.
4. Using the arrow keys toggle to the D Dimer Supplement. Enter the reagent volume.
5. Press the [Enter], [Quit], [Main menu], [Fix] keys.
6. Open Light Shield.
7. Place D-Dimer Reagent in Reagent holder position 6.
8. Place D-Dimer Buffer in Reagent holder position 4.
9. Place D-Dimer Supplement in Reagent holder position 8.
10. Place D-Dimer Diluent in Reagent holder position 10.
11. Place CA Clean I in Holder position 11.
12. Place CA Clean II in rinse Holder position I3. (CA-600 only)
13. Place Buffer in buffer position 12.

Loading Consumables and Discarding Waste Material

(do the following as necessary)

1. **Replenish Reaction tubes.**
   - Reaction tubes should be replenished as needed. The instrument will keep track of the last reaction tube position used.
2. **Replenish Rinse Solution.**
   - Confirm that the instrument is not operating **or** has been interrupted due to insufficient rinse (error message "Replenish Rinse fluid").
   - Remove the cap with the float switch from the Rinse solution container by turning the cap counter-clockwise.
3. ***Caution*:** Do not touch the float switch. Rinse the float switch thoroughly with deionized or distilled water if contact is made.
   - Replace the Rinse solution with distilled or deionized water.
   - Replace the float switch by tightening the cap clockwise to close.
   - Verify that the tubing is securely connected and is not kinked.
   - If the analysis was interrupted due to insufficient rinse, press [Resume] key.
4. **Dispose of Liquid Waste.**
   - Confirm that the instrument is not operating or has been interrupted due to waste is full.
   - Remove the cap with the float switch from the Waste container by turning the cap counter-clockwise.

- ***Caution:*** **Biohazard**
- Dispose of the Biohazardous liquid waste.
- Replace the float switch by tight the cap clockwise to close.
- Verify that the tubing is securely connected and is not kinked.

5. **Dispose of Used Reaction Tubes from the Trash Box.**
   - Confirm that the instrument is not operating.
   - On the right side of the instrument, remove the reaction tube trash box.
   - Discard the used reaction tubes. Caution: Biohazard.
   - Clean the reaction tube trash box with tap water, and thoroughly wipe off moisture from the reaction tube trash box.
   - Restore the reaction tube trash box.

CALIBRATION

The reference curve is valid for the respective lot of the reagent employed. A new curve should be prepared with a new lot of INNOVANCE D-Dimer using INNOVANCE D-Dimer Calibrator provided in the same kit and if indicated by any change in analytical conditions. The calibration curve can be used as long as the assay-dependent assigned values (i.e. INNOVANCE D-Dimer Control 1 and INNOVANCE D-Dimer Control 2) are within the corresponding acceptance ranges.

In Order to calibrate the INNOVANCE D-Dimer assay, the INNOVANCE D- Dimer Calibrator must be placed in position 1 of the sample rack.

1. From the [Main menu] press [Standard Curve].
2. Press [Select Test].
3. Press [DDi] to display 'Standard Curve' Screen.
4. Select [Lot No. Entry].
5. Select Reagent 1 and Reagent 2.
6. Enter lot number. Press [Enter], [Quit].
7. Select [Standard Analysis].
8. Enter the assay value of the calibrator from the INNOVANCE D-Dimer Calibrator lot number package insert.
9. Press [Enter]
10. Verify that the dilution set is correct. Press [SELECT Dil. Set] until dilution set number 1 appears in the upper left corner.
11. Select 2 replicates for each dilution.
12. Press [START] key to start analysis for the Standard. The message "**Analyzing**" will be displayed. When the samples have been aspirated the "**Replace Rack? Yes**" message will appear.
13. Check that the standard curve is acceptable. If acceptable, press [Fix] to store the new standard curve.

SAMPLE PROCESSING

Select test group to be used. Go to [Main Menu], [Settings], [Analysis Settings]. [Test group]. Arrow to appropriate group Select [Return], [Fix] Return to Main Menu.

Samples can be programmed and loaded on the instrument using one of four different options depending whether the sample is bar-coded and/or the host is connected:

I. Manually enter sample ID (non-barcoded) /
No automatic inquiry of tests (no host connection or the host is down)

II. Manually enter sample ID (non-barcoded) /
Automatic inquiry of tests (host is connected or the host connection is operational)

III. Sample ID number (barcoded sample) read by barcode reader /
No automatic inquiry of tests (no host connection or the host is down)

IV. Sample ID number (barcoded sample) read by barcode reader /

Automatic inquiry of tests (host is connected or the host connection is operational)

I. **Manually enter sample ID (non-barcoded)/**
No automatic inquiry of tests (no host connection or the host is down)

1. From the 'Main Menu', press [ID NO. Entry]. If "**ID No. Entry"** does not appear, press [Next] for next available rack/position.
2. Use the up and down arrow keys to select the desired sample position.
3. The numeric keypad is displayed. Enter the sample ID number. Press the D Dimer [DDi] key.
4. Continue to select test to be performed on the sample if necessary.
5. Press [Enter]. Each test selected should show the symbol "?".
6. Load the sample in the respective sample rack position.
7. Repeat until all sample ID numbers and tests are entered for the respective sample rack positions.
8. When all samples are programmed and loaded in the respective sample rack position, press [Quit] on the numeric keypad
9. With all reagents and consumables on board, place the sample rack into position. The bar code labels will face the user.
10. Press [Start].
11. Select [First Tube] or [Continue]
[Continue] will pick up cuvettes from the last position of cuvettes used.
[First] will begin picking up cuvettes from the top, right hand position of reaction tube tray.
12. The message "Analyzing" will be displayed. When all samples have been aspirated, the "Replace Rack?Yes" message will appear.

II. **Manually enter sample ID (non-barcoded) /**
Automatic inquiry of tests (host is connected or the host connection is operational)

1. From the Main Menu, press [ID NO. Entry]. If ID No. Entry does not appear, press [Next] for next available rack/position.
2. Use the up and down arrow keys to select the desired sample position.
3. The numeric keypad is displayed. Enter the sample ID number.
4. Press [Enter].
5. Load samples in the respective rack position.
6. Repeat until all sample ID numbers are entered for the respective sample rack positions.
7. When all samples are programmed and loaded in the respective sample rack positions,
press [Quit] on the numeric keypad.
8. With all reagents and consumables on board, place the sample rack into position. The bar code labels will face the user.
9. Press [Start].
10. Select [First Tube] or [Continue]
[Continue] will pick up cuvettes from the last position of cuvettes used.
[First] will begin picking up cuvettes from the top, right hand position of reaction tube tray.
11. The message "Analyzing" will be displayed. When all samples have been aspirated, the "Replace Rack?Yes" message will appear

III. **Sample ID number (barcoded sample) read by bar-code reader /**
No automatic inquiry of tests (no host connection or the host is down)

1. From the Main Menu, press [ID NO. Entry]. If ID No. Entry does not appear, press [Next] for the next available rack/position.
2. Use the up and down arrow keys to select each tube position on the rack. Press the D Dimer key [DDi].
3. Continue to select test to be performed on the sample if necessary.
4. Press [Enter]. Each test selected should show the symbol "?".
5. Load the sample in the respective sample rack position.
6. With all reagents and consumables on board, place the sample rack into position. The bar code labels will face the user.
7. Press [Start].
8. Select [First Tube] or [Continue]

[Continue] will pick up cuvettes from the last position of cuvettes used.
[First] will begin picking up cuvettes from the top, right hand position of reaction tube tray.

9. The message "Analyzing" will be displayed. When all samples have been aspirated, the "Replace Rack?Yes" message will appear.

IV. **Sample ID number (barcoded sample) read by barcode reader / Automatic inquiry of tests (host is operational)**

1. When the host computer is connected using bi-directional communication, host inquiry takes place when the sample ID is read and the analysis parameters are automatically registered.
2. Load the sample in the respective sample rack position.
3. Press [Start] to begin processing.
4. Select [First Tube] or [Continue]
[Continue] will pick up cuvettes from the last position of cuvettes used.
[First] will begin picking up cuvettes from the top, right hand position of reaction tube tray.
5. The message "Analyzing" will be displayed. When all samples have been aspirated, the "Replace Rack?Yes" message will appear.

NOTE: *The cause of any printed error code must be investigated and the appropriate corrective action taken prior to reporting results.*

QUALITY CONTROL PROCESSING

Controls are run from the sample rack.

1. From the Main Menu, press [ID NO. ENTRY].
2. Press the [QC] key on the numeric keypad and the quality control file number e.g. for QC file five, press [QC] and [05].
3. Press the [DDi] key.
4. Press [ENTER]. The Worklist will display the ID as a quality control file number. e.g. "QC05"
5. Place the control material in a sample rack.
6. If necessary, continue to program routine patient or other levels of quality control material. When completed, press [Start].

REPORTING RESULTS:

The D-Dimer concentration in mg/L is calculated automatically by the analyzer based on the reference curve. The D-Dimer level is expressed as initial fibrinogen equivalent unit (FEU). An FEU is the quantity of fibrinogen initially present that leads to the observed D-Dimer level. Increases in D-Dimer concentration observed with thromboembolic events can be variable due to localization, extension and age of the thrombus. Therefore, a thromboembolic event cannot be excluded with certainty solely on the basis of a D-Dimer concentration being within the reference range of ostensibly healthy persons.

Record and report patient and quality control values according to laboratory procedure.

Hemolyzed, lipemic, or icteric samples must be noted with the result.

Reference Interval:

Reference interval values determined for D-Dimer are 0.19 mg/L - 0.49 mg/L.

Cut-off value for D-Dimer is ≥ 0.50 mg/L.

The INNOVANCE D-Dimer assay is intended for use as an aid in the diagnosis of venous thromboembolism(VTE) deep vein thrombosis (DVT) or pulmonary embolism PE).

Critical Value: None

PROCEDURE NOTES

Overall performance of D-Dimer testing is dependent on reagent and instrument performance. Acceptable variability (imprecision) should be such, that the total coefficient of variation (CV) of the analytic system is less than 20% on the same lot of control plasma.

A new reference curve should be established with each change of reagent lot and change of instrument or with any deviation from

control or proficiency testing limits and when required by government regulations (every 6 months).

The INNOVANCE D-Dimer total measuring range on the Sysmex CA-500/CA-600 Series Systems extends from 0.19 to 35.20 mg/L FEU. This total measuring range is achieved by a manually requested redilution of the sample if the redilution limits of 0.19 to 4.40 mg/L FEU are exceeded.

All components of the INNOVANCE D-Dimer Kit are lot dependent. The combination of lots other than those specified may lead to incorrect results.

LIMITATIONS OF THE PROCEDURE

Turbidity and particles in plasma may interfere with the determination. Therefore plasmas containing particles must be centrifuged for 10 minutes at approximately 15,000 x g again prior to testing.

Lipemic samples or samples containing particles that cannot be clarified by centrifuging must be excluded from testing.

Higher levels of lipids or turbid samples can lead to falsely elevated or decreased values.

Patient samples may contain heterophilic antibodies (e.g. human anti-mouse antibodies (HAMA) and rheumatoid factors) that could react with immunoassays to give a falsely elevated or depressed result. This assay has been designed to minimize interference from heterophilic antibodies. Nevertheless, complete elimination from this interference cannot be guaranteed.

INTERFERING SUBSTANCES

Levels of the following do not interfere with the INNOVANCE D-Dimer assay:

Analyte	Interference Up to
Bilirubin	12 mg/dL
Hemoglobin	200 mg/dL
Triglycerides	400 mg/dL

General Reagent Specificity

There is no significant effect on the determination of D-Dimer due to levels of the following

Analyte	Interference Up to
Creatinine	**30 mg/dL**
Heparin, sodium	**3.0 U/mL**
Rheumatoid Factors	**1330 IU/mL**
Albumin	**6 g/L**
Fibrinogen	**1000 mg/dL**
Urea	**500 mg/dL**
Uric Acid	**20 mg/dL**
Immunoglobulin G (IgG)	5 g/dL

REFERENCES:

1. INNOVANCE D-Dimer Kit package insert. Dade Behring. Marburg, Germany, December, 2010.
2. INNOVANCE D-Dimer Control package insert. Dade Behring. Marburg, Germany, April 2010
3. Dade® CA System Buffer package insert. Dade Behring. Marburg, Germany, May 2008
4. Dade® Owrens Veronal Buffer package insert. Dade Behring. Marburg, Germany, May, 2012
5. Clinical Laboratory Standards Institute. Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays: Approved Guideline-Fourth Edition.
   CLSI Publication H21-A5. Wayne, PA, January, 2008
6. Application Sheet for INNOVANCE D-Dimer on CA 500/CA-600 System
7. Sysmex® CA-500/CA-600 Operator's Manual

All revision dates: 04/2019, 06/2014

9/29/21 Reference Interval: Removed critical value. R SanLuis

Attachments

No Attachments

Approval Signatures

Approver	Date
Dr. Senda Beltaifa: Medical Director Lab	See electronic signature