TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/6/2018
Department:	Core Lab	**Due Date:**	7/31/2018
		Implementation:	**7/31/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Cardiac Troponin I by Dimension Vista® System SGAH.C112 v5

Cardiac Troponin-I by Dimension® Xpand Chemistry Analyzer GEC.C20 v6

Description of change(s):

***Note**: significant changes to critical value process in both SOPs, other changes are format updates*

Vista SOP

Section	Reason
10.6	Remove repeat value below AMR/CRR
11.2	Add delta criteria for subsequent values
14.3	Add biotin interference
16	Update SOP title
17	Update package insert date

Xpand SOP

Section	Reason
7.2	Change freezer range to meet QC & calibrator requirements (match practice)
11.2	Add delta criteria for subsequent values
16	Update SOP title
17	Update package insert dates

DI Screen shots are included after the 2 SOPs. The examples show the different scenarios and what action to take (*DI SOP revision is in process*)

These revised SOPs will be implemented on July 31, 2018

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

Technical SOP

Title	**Cardiac Troponin I by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/25/2012

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**

Form revised 2/02/2007

TABLE OF CONTENTS

1. Test Information 2
2. Analytical Principle 3
3. Specimen Requirements 3
4. Reagents 4
5. Calibrators/Standards 4
6. Quality Control 6
7. Equipment And Supplies 8
8. Procedure 9
9. Calculations 10
10. Reporting Results And Repeat Criteria 10
11. Expected Values 11
12. Clinical Significance 12
13. Procedure Notes 13
14. Limitations Of Method 13
15. Safety 14
16. Related Documents 14
17. References 14
18. Revision History 15
19. Addenda 15

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Troponin I	Dimension Vista® System	TROPI1

Synonyms/Abbreviations
Troponin, Tropi, CTNI, Included in Batteries/Packages: CIEP4

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The CTNI method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI technology. The LOCI reagents include two synthetic bead reagents and a biotinylated anti-cardiac troponin I monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-cardiac troponin I monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form bead-cardiac troponin I-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the cardiac troponin I concentration in the 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 and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Plasma (Lithium Heparin) Serum
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 8 hours
	Refrigerated: 2 days
	Frozen: 8 weeks
Timing Considerations	Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.

Form revised 2/02/2007

Criteria	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.

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. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

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
Cardiac Troponin I	Siemens, Flex® reagent cartridge, Cat. No. K6421
CTNI Sample Diluent	Siemens Healthcare Diagnostics, Cat. No. KD692

4.2 Reagent Preparation and Storage

Reagent	**Cardiac Troponin I**
Container	Reagent cartridge
Storage	Store at 2-8°C
Stability	• Stable until expiration date stamped on reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Open wells: 7 days for wells 1 - 12
Preparation	All reagents are liquid and ready to use.

Reagent	**CTNI Sample Diluent**
Container	Reagent plastic bottle
Storage	Store at 2-8°C

Form revised 2/02/2007

Stability	• **Unopened:** stable until expiration date stamped on bottle • **Opened:** o Stable for 30 days when recapped and stored at 2-8°C. **Do not use this vial on board the instrument.** o Once the stopper is punctured, stable for 30 days on board the instrument.
Preparation	CTNI SDIL is ready for use. No preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CTNI CAL	Siemens Dimension Vista®, Cat. No. KC678

5.2 Calibrator Preparation and Storage

Calibrator	CTNI CAL
Preparation	Before use, thaw at room temperature (22 – 28°C), swirl and invert gently to mix. **Do not use glass pipettes when transferring calibrators to sample cups.**
Storage/Stability	• Store at -15°C to -25°C • **Unopened Frozen:** stable until expiration date on the box. • **Unopened Thawed:** stable for 7 days when stored at 2-8°C • **Opened Calibrator:** o Once the stopper is punctured, stable for 7 days when stored on board Dimension Vista System. o Once cap is removed, stable for 7 days when recapped immediately after use and stored at 2-8°C. **Do not use this vial on board the instrument.**

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CTNI CAL
Assay Range	0.02 – 40.00 ng/mL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in ng/mL
Frequency	• Every new reagent cartridge lot. • Every 30 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	6 levels, n = 3

5.4 Calibration Procedure

Auto Calibration:

1. Place the required calibrator vials in a carrier. Make sure the barcode labels are entirely visible through the slots.
2. Place the carrier in the loading area.
3. Position the carrier with the labels facing away from the user.
4. Press the **Load** button.
5. Automatic calibration requires that calibrators be on the instrument. As the time for processing approaches, the instrument reviews onboard inventory for the appropriate calibrators.

Manual Calibration:

1. Verify that calibrators and reagents are in inventory on the instrument.
2. Press **System > Method Summary > Calibration**.
3. Select a method from the sidebar menu. Press the **Order Calibration** button on the screen.
4. Verify that the information on the screen is correct. Verify that the calibrator lot is correct using the drop-down menu.
   a. When calibrating using Vials press **OK**.
   b. When calibrating using Cups, check the Use Cups box. This displays the rack and cup position fields. For additional cups use the positions in ascending order. Be sure to use the number of calibration levels and cups as specified in the method IFU. Scan the rack barcode and place calibrator cups in an adapter in position 1 on a rack. Press **OK** and load the rack on the instrument.
5. The status field in the calibration screen changes sequentially to Awaiting Scheduling, Preparing Calibrators and Processing.

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Cardiac Markers Plus Control LT Levels 1C, 2 and 3	Bio-Rad Laboratories Cat # 297, 298 and 299

6.2 Control Preparation and Storage

Control	Liquichek Cardiac Markers Plus Control LT, Level 1C, 2 and 3
Preparation	Allow the frozen control to thaw at room temperature (18-25°C) for approximately 30 minutes or until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer). Immediately load the vial on the analyzer. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	**Frozen**: stable until the expiration date at -20 to -50° C. **Thawed and Unopened**: When stored unopened at 2-8°C and the stopper is not punctured, stable for 10 days. **Thawed and Opened**: Once the stopper is punctured, stable for 10 days when stored at 2-8°C. Once thawed, do not re-freeze

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing (notated on the QC frequency sheets posted on the instruments).

Refer to the Dimension Vista® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension Vista® Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

Form revised 2/02/2007

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.
- 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.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Vista® System

Form revised 2/02/2007

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C
- Freezer capable of sustaining range not to exceed -15 to -25°C for calibrator
- Freezer capable of sustaining range not to exceed -20 to -50°C for QC product
- Centrifuge

7.3 Supplies

- Aliquot Plates
- System Fluids
- Assorted calibrated pipettes (MLA or equivalent) and disposable tips

8. PROCEDURE

CTNI Flex® reagent cartridge Cat. No. K6421 is required to perform this test.

Cardiac Troponin I is performed on the Dimension Vista® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

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	Sample Processing
1.	A sample rack holding tubes or cups is placed on the rack input lane.
2.	The sample shuttle moves the rack to the barcode reader which identifies the rack and samples to the system.
3.	The rack moves into the sample server and to the rack positioner.
4.	At the same time, aliquot plates move from the aliquot loader into position.
5.	The aliquot probe aspirates the sample from the tubes or cups and dispenses it into the wells of the aliquot plates.
6.	After each aspirate-dispense action, the probe is thoroughly rinsed inside and out to prevent sample carryover.
7.	When sample aspiration is completed, the sample server moves the rack back to the sample shuttle, where it is placed on the output lane and can be removed by the operator.

8.2	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension Vista® QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension Vista® Operator's Manual

8.2	Specimen Testing
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension Vista® system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

Test Conditions	
Sample Volume:	20 µL
Chemibead Reagent Volume:	20 µL
Biotinylated Antibody Volume:	20 µL
Sensibead Reagent Volume:	13 µL
Assay Buffer Volume:	100 µL
Reaction Time:	10 minutes
Test Temperature:	37° C
Wavelength:	680 and 612 nm
Type of measurement:	Chemiluminescence

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

The instrument automatically calculates the concentration of Cardiac Troponin I in ng/mL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

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

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

0.02 – 200.00 ng/mL

10.5 Review Patient Data

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

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall below or within the AMR or CRR may be reported without repeat. Values that exceed the upper ranges must be repeated.

IF the result is …	THEN…
< 0.02 ng/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 0.02 ng/mL
≥ 40.00 ng/mL	**On Board Automated Dilution:** Results ≥ 40.00 ng/mL will automatically have repeat testing performed into the instrument using dilution factor of 5. No multiplication is necessary.
> 200.00 ng/mL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 200.00 ng/mL-REP" Bring to the attention of your supervisor prior to releasing result.

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

11. EXPECTED VALUES

11.1 Reference Ranges

0.00 – 0.05 ng/mL

11.2 Critical Values

Initial (first) critical value: > 0.09 ng/mL

Treatment of **subsequent critical values** is based on delta criteria:

Prior Critical Value	Delta Threshold	Example
0.10 - 1.00 ng/mL	10 times prior value	Prior value of 0.30, next value must be 3.00 or greater
1.01 - 20.00 ng/mL	5.00 ng/mL	Prior value of 4.10, next value must be 9.10 or more
20.01 ng/mL or more	25.00 ng/mL	Prior value of 22.00, next value must be 47.00 or more

If the subsequent critical value does NOT qualify to be called, document this by appending the code **TROPC** to the result. This code translates to "Laboratory value indicates a critical value previously reported."

Notes:

- Data Innovations (DI) will flag results that meet delta criteria to be called (Error code contains 'CALL' and the Error name contains 'CALL TROP').
- When DI is down, ALL critical troponin values must be called.

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Troponin is the contractile regulatory protein complex of striated muscle. It is found periodically along the thin filament of the myofibrils, in conjunction with the protein tropomyosin. The troponin complex consists of three distinct polypeptide components: troponin-C (the calcium binding element), troponin-I (the actinomyosin ATPase inhibitory element), and troponin-T (the tropomyosin binding element). The complex serves to regulate the calcium dependent interaction of myosin and actin and thus plays an integral role in muscle contraction. Troponin-I exists in three distinct molecular forms which correspond to specific isotypes found in fast-twitch skeletal muscle, slow-twitch skeletal muscle, and heart, respectively.

Several reports in the literature have indicated that cardiac troponin-I is released into blood within hours of the onset of symptoms of myocardial infarction and that it remains elevated for several days post-infarction. The cumulative data from these reports indicate that troponin-I levels become abnormal 4–8 hours following onset of chest pain, peak at 12–16 hours, and remain elevated for 5–9 days following an infarction.

Measurement of cardiac troponin-I levels provide sensitive and specific determination of myocardial injury over a wide diagnostic window. Elevations in cardiac troponin-I levels have been observed across a spectrum of acute coronary syndromes including Q-wave MI, non-Q-wave MI and unstable angina. A significantly higher incidence of mortality has been

observed in patients with non-Q-wave MI and unstable angina who have detectable levels of cardiac troponin-I. This suggests that cardiac troponin-I provides a means for risk stratification of these individuals.

13. PROCEDURE NOTES

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

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Vista Operator's Guide.

The expected maximum observed standard deviations for repeatability using n = 5 replicates at the following Cardiac Troponin I concentrations are:

CTNI Concentration	Acceptable S.D. Maximum
0.5 ng/mL	0.063 ng/mL
8.0 ng/mL	0.939 ng/mL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.02 – 40.00 ng/mL

14.2 Precision

Material	Mean ng/mL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Serum Pool	0.123	0.005 (4.2)	0.007 (5.8)
Serum Pool	0.55	0.012 (2.3)	0.016 (2.9)
Serum Pool	31.4	0.95 (3.0)	1.18 (3.8)

14.3 Interfering Substances

Specimens that contain biotin at a concentration of 100 ng/mL demonstrate a less than or equal to 10% change in results. Biotin concentrations greater than this may lead to falsely depressed results for patient samples. Results from patients taking biotin supplements or receiving high-dose biotin therapy should be interpreted with caution due to possible interference with this test.

HIL Interference:
The CTNI method was evaluated for interference according to CLSI/NCCLS EP7-A2. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Substance Concentration	CTNI ng/mL	Bias %
Hemoglobin (hemolysate)	500 mg/dL	0.945	<10
Bilirubin (unconjugated)	40 mg/dL	0.907	<10
Bilirubin (conjugated)	40 mg/dL	0.879	<10
Lipemia Cholesterol	500 mg/dL	0.941	<10
Lipemia Intralipid®	3000 mg/dL	0.970	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

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.

CTNI Flex® Reagent Cartridge may cause an allergic skin reaction.
Contains: 5-chloro-2-methyl-3(2h)-isothiazolone mixture with 2-methyl-3(2h)-isothiazolone.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

16. RELATED DOCUMENTS

1. Dimension Vista® Clinical Chemistry System Operator's Manual
2. Dimension Vista® Calibration/Verification Procedure
3. Dimension Vista® Cal Accept Guidelines
4. Dimension Vista® Calibration summary
5. Dimension Vista® Sample Processing, Startup and Maintenance procedure
6. Laboratory Quality Control Program
7. QC Schedule for Siemens Dimension Vista®
8. Laboratory Safety Manual
9. Safety Data Sheets (SDS)
10. Dimension Vista® Limits Chart (AG.F200)
11. Quest Diagnostics Records Management Procedure
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Function Checks (Lab policy)
14. Specimen Acceptability Requirements (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Critical Values (Lab policy)
17. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
18. Current package insert CTNI Flex® Reagent Cartridge K6421

17. REFERENCES

1. Package Insert, CTNI Flex® Reagent Cartridge K6421, Siemens Healthcare Diagnostics Inc., 10/17/2017.

2. Package Insert, CTNI CAL, Siemens Healthcare Diagnostics Inc., 3/2015.
3. Package Insert, Liquichek Cardiac Markers Plus Control LT, Bio-Rad Laboratories, 12/2015.
4. Package Insert, CTNI Sample Diluent, Siemens Healthcare Diagnostics Inc., 07/2017.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	3/8/2013	4.2	Added CTNI Diluent onboard stability	A Chini	R SanLuis
000	3/8/2013	10.5	Removed manual dilution, added on board manual dilution	A Chini	R SanLuis
001	2/4/15	5.2	Change in frozen storage temperature	L Barrett	R SanLuis
001	2/4/15	7.2	Change freezer requirements	L Barrett	R SanLuis
001	2/4/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
2	7/6/15	3.2	Specify anticoagulant	L Barrett	R SanLuis
2	7/6/15	4.2	Add hazard warning	L Barrett	R SanLuis
2	7/6/15	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
2	7/6/15	11.1	Change upper value from 0.10 to 0.05	L Barrett	R SanLuis
2	7/6/15	11.2	Change critical from ≥0.60 to >0.09	L Barrett	R SanLuis
3	1/19/17	Header	Add WAH	L Barrett	R SanLuis
3	1/19/17	3.2	Remove specimen onboard stability	L Barrett	R SanLuis
3	1/19/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
3	1/19/17	6.1, 6.2	Update QC material and storage	L Barrett	R SanLuis
3	1/19/17	7.2	Specify freezer requirements by product	L Barrett	R SanLuis
3	1/19/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
3	1/19/17	15	Update to new standard wording, add reagent warning from section 4	L Barrett	R SanLuis
3	1/19/17	17	Update QC product	L Barrett	R SanLuis
4	6/1/18	10.6	Remove repeat value below AMR/CRR	L Barrett	R SanLuis
4	6/1/18	11.2	Add delta criteria for subsequent values	L Barrett	R SanLuis
4	6/1/18	14.3	Add biotin interference	L Barrett	R SanLuis
4	6/1/18	16	Update SOP title	L Barrett	R SanLuis
4	6/1/18	17	Update package insert dates	L Barrett	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Cardiac Troponin-I by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 3/24/2011
Owner	Robert SanLuis Date: 4/2/2015

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**

Quest Diagnostics
Site: Germantown Emergency Center
Title: **Cardiac Troponin-I by Dimension® Xpand Chemistry Analyzer**

TABLE OF CONTENTS

1. Test Information 2
2. Analytical Principle 3
3. Specimen Requirements 4
4. Reagents 5
5. Calibrators/Standards 5
6. Quality Control 6
7. Equipment And Supplies 8
8. Procedure 9
9. Calculations 10
10. Reporting Results And Repeat Criteria 10
11. Expected Values 11
12. Clinical Significance 12
13. Procedure Notes 13
14. Limitations Of Method 13
15. Safety 14
16. Related Documents 14
17. References 14
18. Revision History 15
19. Addenda 16

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Troponin-I	Dimension® Xpand Chemistry Analyzer	TROPI1

Synonyms/Abbreviations
Cardiac Troponin-I / TROP, TROPI, CTNI Troponin is part of battery/package CIEP4

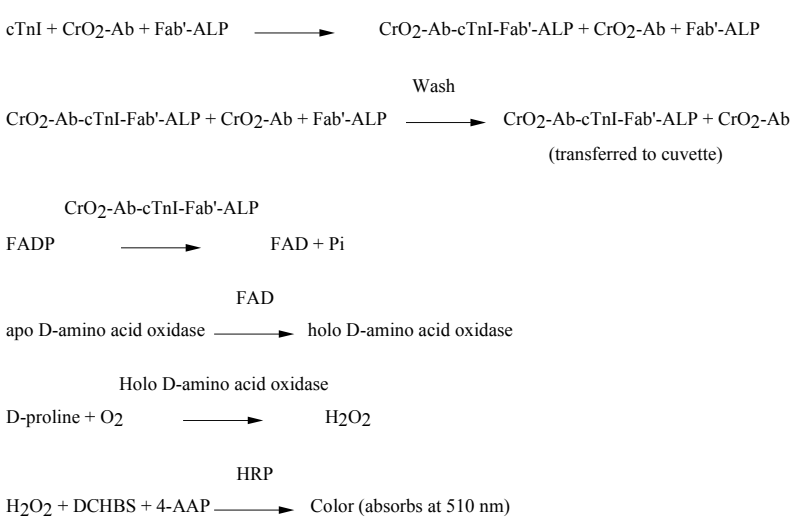
Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The CTNI method is a one step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles coated with a monoclonal antibody specific for the cardiac troponin-I molecule, and a conjugate reagent [alkaline phosphatase (ALP)] labeled monoclonal antibody specific for cardiac troponin-I, to form a particle/cardiac troponin-I/conjugate sandwich. Unbound conjugate is removed by magnetic separation and washing. After separation and washing, the particle/cardiac troponin-I/conjugate sandwich is transferred to the cuvette where the sandwich bound ALP triggers an amplification cascade.* ALP dephosphorylates synthetic flavin adenine dinucleotide phosphate (FADP) to produce FAD. FAD binds to apo D-amino acid oxidase and converts it to active holo D-amino acid oxidase. Each molecule of holo D-amino acid oxidase then produces multiple molecules of hydrogen peroxide (H_2O_2) which, in the presence of horseradish peroxidase (HRP), convert 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4-AAP) to a colored product that absorbs at 510 nm. The color change measured is directly proportional to the concentration of cardiac troponin-I present in the patient sample.

* Technology licensed from London Biotechnology, Ltd., London, U.K.



cTnI = cardiac troponin-I

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3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Use normal procedures for blood collection. Collect anytime requested by physician. Serial samples are generally taken at 6-8 hour intervals over the first 48 hours after the onset of chest pain in patients suspected of suffering myocardial infarction.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	Plasma (Lithium Heparin)	
-Other Acceptable	Serum	
Collection Container	Plasma: Mint green top tube (PST) Serum: Red top tube, Serum separator tube (SST)	
Volume - Optimum	1.0 mL	
- Minimum	0.5 mL	
Transport Container and Temperature	Collection container or Plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	(20-25°C) 8 hours
	Refrigerated:	(2-8°C) 2 days
	Frozen:	(-20°C or colder) 1 month
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request redraw. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)	
Other Considerations	Allow to clot completely prior to centrifugation.	

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.

Form revised 2/02/2007

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
Cardiac Troponin-I	Siemens, Flex® reagent cartridge, Cat. No. RF421C

4.2 Reagent Preparation and Storage

Reagent	Cardiac Troponin-I
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Stable until expiration date stamped on reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Open wells: 3 days for wells 1 – 8
Preparation	Hydrating, dilution and mixing are automatically performed by the instrument.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Cardiac Troponin I Calibrator	Siemens Dimension®, Cat. No. RC421C

5.2 Calibrator Preparation and Storage

Calibrator	Cardiac Troponin I Calibrator
Preparation	Before use, thaw and equilibrate at room temperature for one hour (not to exceed two hours). Mix the contents of the vial by inverting gently ten (10) times. Do not use glass pipettes when transferring calibrators to sample cups.
Storage/Stability	• Store frozen at -25 to -15°C • **Unopened frozen vials:** stable until expiration date on label • **Unopened thawed vials:** stable for 5 days at 2-8°C. • **Opened thawed vials:** stable for 24 hours when thawed, recapped and stored at 2-8°C.

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	Cardiac Troponin-I Calibrator
Assay Range	0.04 – 40.0 ng/mL
Suggested calibration level	See reagent package insert for lot specific assigned values in ng/mL
Frequency	• Every new reagent cartridge lot. • Every 60 days for any one lot. • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Levels 1, 2 n = 4 Level 3 n = 3 Level 4, 5 n = 2
Assigned Coefficients	C_0 - 989.0 C_1 8439.0 C_2 - 2.9 C_3 101.0 C_4 0.5
Procedure	Refer to Calibration / Verification Siemens Dimension® Xpand procedure for specific instructions.

5.4 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek Cardiac Markers Plus Control, Levels 1, 2 and 3	Bio-Rad Laboratories Ca. No. 181, 182 and 183

6.2 Control Preparation and Storage

Control	Liquichek Cardiac Markers Plus Control, Levels 1, 2 and 3
Preparation	Allow the frozen control to thaw at room temperature (18-25°C) until completely thawed. Swirl the contents gently to ensure homogeneity. (Do not use a mechanical mixer)

	Use immediately. After each use, promptly replace the stopper and return to 2-8°C storage.
Storage/Stability	**Thawed and opened**: Troponin I stable for 10 days at 2-8°C. **Unopened**: stable until the expiration date at -20 to -70°C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension X-pand® Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

Form revised 2/02/2007

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.
- 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.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -25°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- Purified water (Millipore® or equivalent)
- Calibrated pipettes and disposable tips
- Reaction Vessels, Cat. No. RXV1A
- Chemistry Wash, Cat. No. RD701

Form revised 2/02/2007

- Reagent Probe Cleaner, Cat. No. RD702
- Sample Probe Cleaner, Cat. No. RD703

8. PROCEDURE

CTNI Flex® reagent cartridge Cat. No. RF421C is required to perform this test.

Troponin-I is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

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.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension® Xpand system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Repeat critical values and document according to Critical Values procedure. Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

Test Conditions		
Sample Size:	50 µL	
Antibody-CrO_2:	25 µL	
Antibody-ALP:	40 µL	
Incubating Temp.:	42°C	
Incubation Period:	4.0 minutes	
Cuvette	**Reaction**	**Blanking**
Transfer Volume:	65 µL	0 µL
FADP Reagent Volume:	24 µL	24 µL
APO Reagent Volume:	24 µL	24 µL
Diluent Volume:	267 µL	332 µL
Temperature:	37.0°C	N/A
Reaction Time:	5.4 minutes	N/A
Wavelength:	510 and 700 nm	N/A
Type of Measurement:	Bichromatic rate	N/A

9. CALCULATIONS

The instrument automatically calculates and prints the concentration of Troponin-I in ng/mL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results to two decimal points.

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

0.04 - 200.00 ng/mL

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high

percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

Values that fall below or within the AMR or CRR may be reported without repeat.

Values that exceed the upper ranges must be repeated.
Any samples immediately following a sample that reached upper AMR and are above the upper normal limit will be repeated along with a low level control to ensure no carryover occurred.

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values requiring **manual dilution** must be repeated.

IF the result is …	THEN…
≤ 0.04 ng/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: <0.04 ng/mL
≥ 40.00 ng/mL	**On Board Automated Dilution:** Results ≥ 40.00 ng/mL will automatically have repeat testing performed into the instrument using dilution factor of 2.5. No multiplication is necessary.
> 100.00 ng/mL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 5 **Diluent:** Purified water. Enter dilution factor as a whole number on the "Enter Sample Data" screen. For values requiring manual dilution, report the assay with code of –REP
>200.00 ng/mL	If the recommended dilution does not give results within the clinically reportable range, report as: ">200.00 ng/mL-REP" Bring to the attention of your supervisor prior to releasing result.

.

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

11. EXPECTED VALUES

11.1 Reference Ranges

0.00 – 0.07 ng/mL

11.2 Critical Values

Initial (first) critical value: > 0.09 ng/mL

Treatment of **subsequent critical values** is based on delta criteria:

Prior Critical Value	Delta Threshold	Example
0.10 - 1.00 ng/mL	10 times prior value	Prior value of 0.30, next value must be 3.00 or greater
1.01 - 20.00 ng/mL	5.00 ng/mL	Prior value of 4.10, next value must be 9.10 or more
20.01 ng/mL or more	25.00 ng/mL	Prior value of 22.00, next value must be 47.00 or more

If the subsequent critical value does NOT qualify to be called, document this by appending the code **TROPC** to the result. This code translates to "Laboratory value indicates a critical value previously reported."

Notes:

- Data Innovations (DI) will flag results that meet delta criteria to be called (Error code contains 'CALL' and the Error name contains 'CALL TROP').
- When DI is down, ALL critical troponin values must be called.

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Troponin-I is the contractile regulatory protein complex of striated muscle. It is found periodically along the thin filament of the myofibrils, in conjunction with the protein tropomyosin. The troponin complex consists of three distinct polypeptide components: troponin-C (the calcium binding element), troponin-I (the actinomyosin ATPase inhibitory element), and troponin-T (the tropomyosin binding element). The complex serves to regulate the calcium-dependent interaction of myosin and actin and thus plays an integral role in muscle contraction.

Troponin-I exists in three distinct molecular forms which correspond to specific isotypes found in fast-twitch skeletal muscle, slow-twitch skeletal muscle, and heart, respectively.

Several reports in the literature have indicated that cardiac troponin-I is released into blood within hours of the onset of symptoms of myocardial infarction and that it remains elevated for several days post-infarction. The cumulative data from these reports indicate that troponin-I levels become abnormal 4-8 hours following onset of chest pain, peak at 12-16 hours, and remain elevated for 5-9 days following an infarction.

Measurement of cardiac troponin-I levels provide sensitive and specific determination of myocardial injury over a wide diagnostic window. Elevations in cardiac troponin-I levels have been observed across a spectrum of acute coronary syndromes including Q-wave MI, non-Q-wave MI and unstable angina. A significantly higher incidence of mortality has been

observed in patients with non-Q-wave MI and unstable angina who have detectable levels of cardiac troponin-I. This suggests that cardiac troponin-I provides a means for risk stratification of these individuals.

13. PROCEDURE NOTES

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

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Xpand Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

Concentration	S.D.
2.0 ng/mL	> 0.20 ng/mL
25.0 ng/mL	> 1.50 ng/mL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.04 – 40.00 ng/mL

14.2 Precision

Material	Mean ng/mL	Standard Deviation (%CV)	
		Within-run	Total
MAS Tru-Liquid Control			
Level 1	0.35	0.01 (2.7)	0.03 (7.7)
Level 2	5.28	0.05 (1.0)	0.22 (4.2)
Level 3	14.52	0.14 (1.0)	0.71 (4.9)
Serum Pool			
Level 1	0.08	0.01 (7.3)	0.01 (15.1)
Level 2	0.16	0.01 (4.0)	0.01 (9.2)
Level 3	0.47	0.01 (2.9)	0.03 (6.2)
Level 4	1.44	0.04 (2.6)	0.07 (5.2)
Level 5	27.71	0.53 (1.9)	0.99 (3.6)
Level 6	40.05	0.75 (1.9)	1.81 (4.5)

14.3 Interfering Substances

Patient samples may contain heterophile antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay has been designed to minimize interference from heterophile antibodies. Complete elimination of the

interference cannot be guaranteed. A test result that is inconsistent with the clinical picture and patient history should be interpreted with caution.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available.

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.

Cardiac Troponin-I Flex® Reagent Cartridge and CTNI CAL may cause an allergic skin reaction. Flex contains 2-Chloracetamide. CAL contains 5-chloro-2-methyl-3(2h)-isothiazolone mixture with 2-methyl-3(2h)-isothiazolone. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Siemens Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Specimen Acceptability Requirements (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Critical Values (Lab policy)
18. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert CTNI Flex® Reagent Cartridge RF421C

17. REFERENCES

1. Package Insert, CTNI Flex® Reagent Cartridge RF421C, Siemens Healthcare Diagnostics Inc., 8/4/2017.
2. Package insert, Cardiac Troponin-I Calibrator RC421C, Siemens Healthcare Diagnostics Inc., 3/2015.
3. Package insert, Liquichek Cardiac Markers Plus Control Levels 1, 2 & 3. Bio-Rad Laboratories, 6/2017.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C072.001		
000	7/15/11	6.7	Add use of published TEA for acceptability criteria	L Barrett	N Cacciabeve
000	7/15/11	10.5	Change repeat criteria to manual dilutions only	R SanLuis	N Cacciabeve
000	7/15/11	11.2	Requirement for subsequent critical values and interpretation of code revised	L Barrett	N Cacciabeve
000	7/15/11	15	Update to approved format	L Barrett	N Cacciabeve
001	2/8/12	5.3	Changed calibration level statement	A. Chini	J Buss
001	2/8/12	6.1 & 6.2	Updated QC information	A. Chini	J Buss
001	2/8/12	10.2	Correct rounding to 2 decimals	A. Chini	J Buss
001	2/8/12	10.5	Remove QNSR code	L Barrett	J Buss
001	2/8/12	10.5	Add repeat criteria for possible carryover	J Buss	J Buss
001	2/8/12	17	Updated References	A. Chini	J Buss
002	4/2/15		Update owner	L Barrett	R SanLuis
002	4/2/15	1, 7.1	Add analyzer name	L Barrett	R SanLuis
002	4/2/15	5.2	Change in frozen storage temperature	L Barrett	R SanLuis
002	4/2/15	6.2	Update stability to 10 days	L Barrett	R SanLuis
002	4/2/15	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
002	4/2/15	7.2	Change freezer requirements	L Barrett	R SanLuis
002	4/2/15	8.2	Remove Lynx, specify Xpand process	L Barrett	R SanLuis
002	4/2/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
3	7/6/15	3.2	Specify anticoagulant	L Barrett	R SanLuis
3	7/6/15	11.1	Change upper value from 0.10 to 0.07	L Barrett	R SanLuis
3	7/6/15	11.2	Change critical from ≥0.60 to >0.09	L Barrett	R SanLuis
4	7/26/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
4	7/26/17	5.3	Remove specific calibration steps and reference separate SOP	L Barrett	R SanLuis
4	7/26/17	10.5	Move patient review from section 6	L Barrett	R SanLuis
4	7/26/17	10.6	Remove repeat value below AMR/CRR	L Barrett	R SanLuis
4	7/26/17	15	Update to new standard wording, move reagent hazard warning from 4.2	L Barrett	R SanLuis
4	7/26/17	17	Update package insert dates	L Barrett	R SanLuis

Version	Date	Section	Reason	Reviser	Approval
5	6/1/18	7.2	Change freezer range to meet QC & calibrator requirements (match practice)	L Barrett	R SanLuis
5	6/1/18	11.2	Add delta criteria for subsequent values	L Barrett	R SanLuis
5	6/1/18	16	Update SOP title	L Barrett	R SanLuis
5	6/1/18	17	Update package insert dates	L Barrett	R SanLuis

19. ADDENDA

None

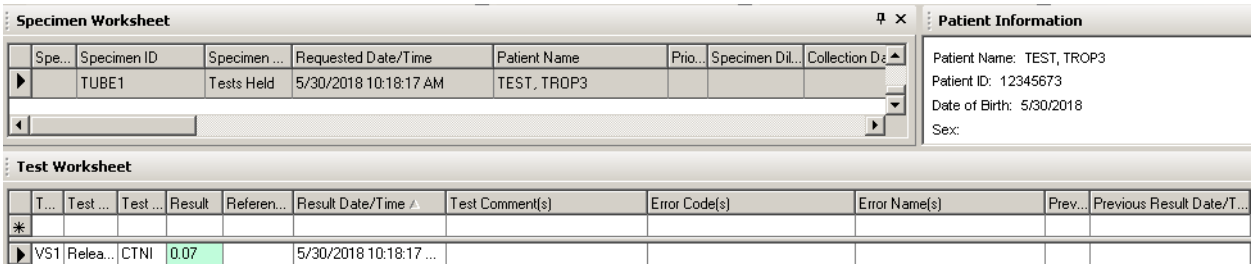
Addendum 4

Troponin Critical Value Actions

Example 1

Normal troponin

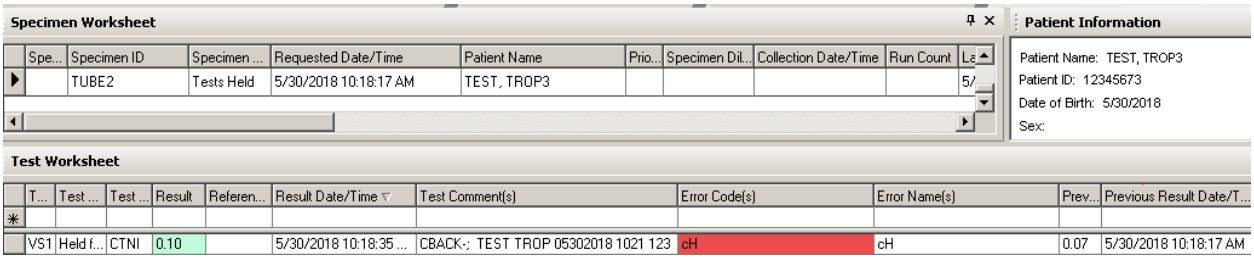
Action: Auto-released by DI



Example 2

First (initial) critical troponin for this patient

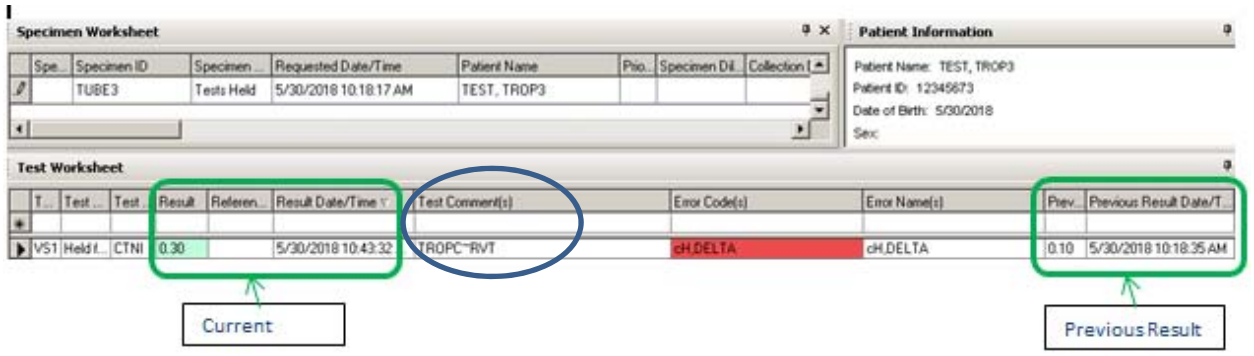
Action: Call critical troponin to provider and document per policy in Test Comment field



Example 3

The previous critical troponin value is between 0.1 - 1.0 ng/mL.
The current troponin value is NOT ≥ 10 times the previous value.

Action: Change the Test Comment field to TROPC and result



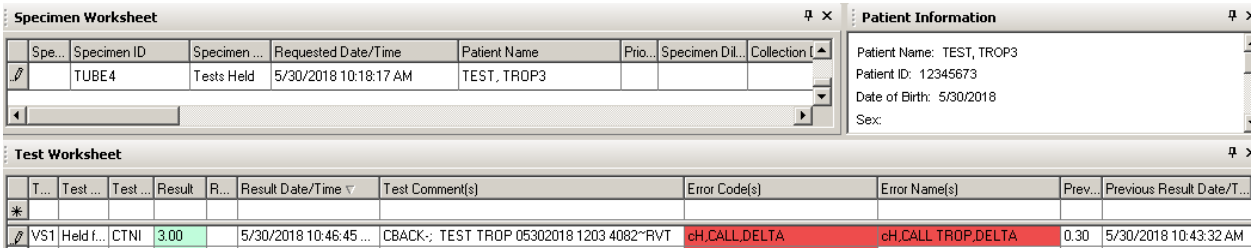
Form revised 3/31/00

Addendum 4 continued

Example 4

The previous critical troponin value is between 0.1 - 1.0 ng/mL.
The current troponin value is ≥ 10 times the previous value.
The Error Code has "CALL" and the Error Name has "CALL TROP"

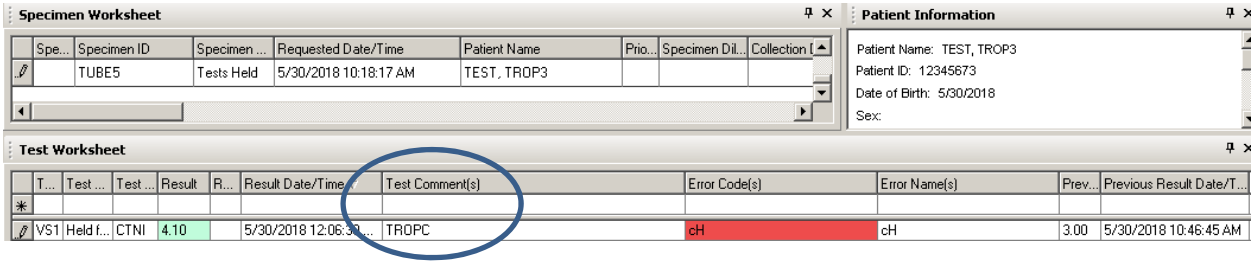
Action: Call critical troponin to provider and document per policy in Test Comment field



Example 5

The previous critical troponin value is between 1.01 – 20.00 ng/dL.
The current troponin value is NOT ≥ 5 ng/dL more than the previous value.

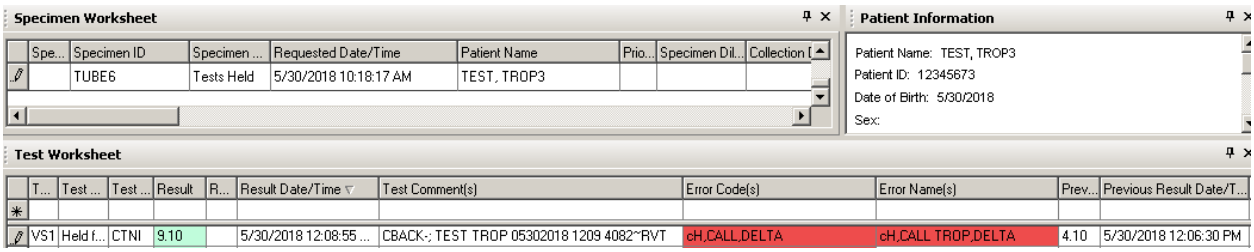
Action: Change the Test Comment field to TROPC and result



Example 6

The previous critical troponin value is between 1.01 -20.00 ng/dL.
The current troponin value is ≥ 5 ng/dL more than the previous value.
The Error Code has "CALL" and the Error Name has "CALL TROP"

Action: Call critical troponin to provider and document per policy in Test Comment field

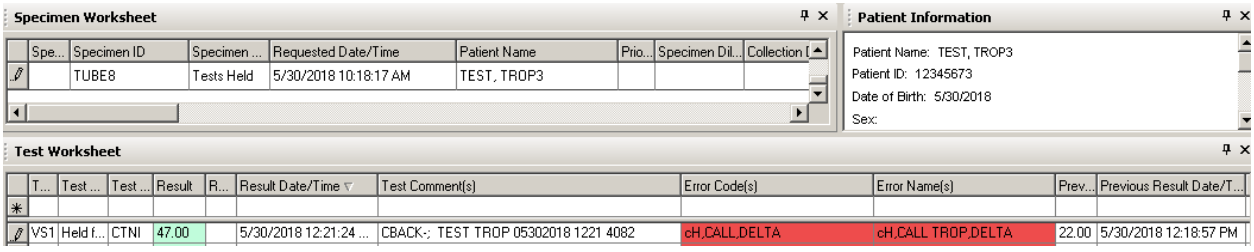


Addendum 4 continued

Example 7

The previous critical troponin value is 20.01 ng/mL or more.
The current troponin value is ≥ 25 ng/mL more than the previous value.
The Error Code has "CALL" and the Error Name has "CALL TROP"

Action: Call critical troponin to provider and document per policy in Test Comment field



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