TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	2/13/2015
Department:	Chemistry	**Due Date:**	3/16/2015
		Implementation:	**3/17/2015**

DESCRIPTION OF REVISION

Name of procedure:

Dimension Vista Calibrator Guide AG.F205.2
Dimension Vista® System SOPs:
Cardiac Troponin I SGAH.C112, WAH.C108 v2

Myoglobin SGAH.C115, WAH.C111 v2

Creatine Kinase SGAH.C105, WAH.C101 v2

Cholesterol, High Density Lipoprotein (HDLC) SGAH.C104, WAH.C100 v1

Description of change(s):

This practice has already been implemented, document revisions have been made to match

Vista Calibrator Guide has updated storage temperature for CTNI CAL, MMB CAL and ENZ 6 CAL (*LIPID CAL had previously been changed*)

SOPs -

Section	Reason
5.2	Change in frozen storage temperature
7.2	Change freezer requirements

These revised SOPs and FORM will be implemented on March 17, 2015

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

Dimension Vista Calibrator Guide

Calibrator	Reagent	Storage Temp.	Calibrator Stability when in use
ALPI CAL	ALPI	2 – 8º C	Stable for 7 days on board Vista
BHCG CAL	BHCG	2 – 8º C	Stable for 7 days on board Vista
BILI CAL	TBIL, DBIL	2 – 8º C	Stable for 14 days on board Vista
CTNI CAL	CTNI	-25 to -15º C	Stable for 7 days on board Vista
MMB CAL	MMB	2 – 8º C	Stable for 7 days on board Vista
MYO CAL	MYO	-25 to -15º C	Stable for 7 days on board Vista
CHEM 1 CAL	BUN, CA, CHOL, CREA, GLU, LA, MG, UA	-25 to -15º C	Stable for 7 days on board Vista
CHEM 2 CAL	PHOS, SAL, TRIG	2 – 8º C	Stable for 1 day on board Vista
CHEM 3 CAL	CO2, ETOH, AMM	2 – 8º C	Stable for 1 day on board Vista
CHEM 4 CAL	ALB, TP	2 – 8º C	Stable for 7 days on board Vista
PROT 2 CAL	CRP	2 – 8º C	Stable for 12 days on board Vista
DRUG 1 CAL	PHNO, PTN, THEO	2 – 8º C	Stable for 15 days on board Vista
DRUG 2 CAL	ACTM, CRBM, GENT, TOBR, VALP, VANC	2 – 8º C	Stable for 15 days on board Vista
DRUG 4 CAL	DIG, LITH	2 – 8º C	Stable for 14 days on board Vista
ENZ 1 CAL	AMY, GGT, LIP	2 – 8º C	Stable for 7 days on board Vista
ENZ 2 CAL	ALTI, AST	2 – 8º C	Stable for 7 days on board Vista
ENZ 5 CAL	LDI	2 – 8º C	Stable for 7 days on board Vista
ENZ 6 CAL	CKI	-25 to -15º C	Stable for 7 days on board Vista
LIPID CAL	HDLC	-25 to -15° C	Stable for 7 days on board Vista
LOCI CAL	FT4, TSH	-25 to -15° C	Stable for 7 days on board Vista
UCFP CAL	UCFP	2 – 8º C	Stable for 7 days on board Vista
UDAT CAL	AMPH, BARB, BENZ, COC, OPI, PCP, THC	2 – 8º C	Stable for 15 days on board Vista

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**

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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

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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 (Heparin) Serum	
Collection Container	Plasma: Green top tube 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
	Instrument on board aliquot stability	2 hours

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Criteria	
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.
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.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

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

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	Cardiac Troponin I
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days.

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	• Once wells 1 - 12 have been entered by the instrument, they are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

Reagent	**CTNI Sample Diluent**
Container	Reagent plastic bottle
Storage	Store at 2-8° C
Stability	• Unopened diluent is stable until expiration date stamped on the reagent bottle. • Once opened, diluent is stable for 30 days when recapped and stored at 2-8° C. **Do not use this vial on board the instrument.** • Once the stopper of the vial is punctured, diluent is 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

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

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 calibrator (frozen)** is stable until expiration date stamped on the box. • **Unopened calibrator (thawed)** is stable for 7 days when stored at 2-8°C • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values

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	are 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.

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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 Levels 1, 2 and 3	Bio-Rad Laboratories Cat # 181, 182 and 183

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation. A barcode label is produced and placed on the vial.

Control	Liquichek Cardiac Markers Plus Controls, Level 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	Unthawed controls are stable until the expiration date at -20 to -70° C. Once the control is thawed and opened, Troponin I will be stable for 10 days when stored tightly capped at 2-8 °C.

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

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Vista® 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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.

6.7 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

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -15 to -25°C.
- 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.

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.

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
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

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 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 within the AMR or CRR may be reported without repeat. Values that fall outside these 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 – 0.10 ng/mL

11.2 Critical Values

≥ 0.60 ng/mL

Treatment of **Subsequent critical values** for Troponin-I:
Only the first critical value for each hospital encounter must be called. Subsequent critical values for troponin must be documented by appending the code **TROPC** to the result. This code translates to "Laboratory value indicates a critical value previously reported."

11.3 Priority 3 Limit(s)

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.1 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)

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14.3 Interfering Substances

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 Intralipid®	500 mg/dL 3000 mg/dL	0.941 0.970	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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

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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. Material Safety Data Sheets (MSDS)
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. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
17. Current package insert CTNI Flex® Reagent Cartridge K6421

17. REFERENCES

1. Package Insert, CTNI Flex® Reagent Cartridge K6421, Siemens Healthcare Diagnostics Inc., 11/06/2012.
2. Package Insert, CTNI CAL, Siemens Healthcare Diagnostics Inc., 11/2014.
3. Package Insert, Liquichek Cardiac Markers PlusControl, Bio-Rad Laboratories, 11/2011.
4. Package Insert, CTNI Sample Diluent, Siemens Healthcare Diagnostics Inc., 04/2012.

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

19. ADDENDA

None

Technical SOP

Title	**Myoglobin by Dimension Vista® System**	
Prepared by	Ashkan Chini	Date: 6/25/2012
Owner	Robert SanLuis~~, Jean Buss~~	Date: 2/4/2015

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: Shady Grove Adventist Hospital
Title: **Myoglobin by Dimension Vista® System**

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Myoglobin	Dimension Vista® System	MYOGL

Synonyms/Abbreviations
Myoglobin Quant, MYO

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The MYO method is a homogeneous sandwich chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and a biotinylated anti-myoglobin monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with an anti-myoglobin monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a bead-myoglobin-biotinylated antibody sandwich. Sensibeads are added and bind to form bead-pair immunocomplexes. Illumination of the complex by light 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 myoglobin 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 (Heparin) Serum
Collection Container	Plasma: Green top tube 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: 7 days
	Frozen: 28 days
	Instrument on board aliquot stability 2 hours

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Criteria	
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.
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.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Myoglobin	Siemens, Flex® reagent cartridge, Cat. No. K6422

4.2 Reagent Preparation and Storage

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	**Myoglobin**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 12 have been entered by the instrument, they

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	are stable for 7 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
MYO CAL	Siemens Dimension Vista®, Cat. No. KC624

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

Calibrator	MYO CAL
Preparation	Before use, thaw at room temperature (22 – 28° C), swirl and invert gently to mix.
Storage/Stability	• Store at -15°C to -25°C • **Unopened (frozen) calibrator** is stable until expiration date stamped on the box. • **Unopened thawed calibrator** is stable for 30 days when stored at 2-8° C. Do not re-freeze. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 30 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	MYO CAL
Assay Range	1 – 1000 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 Levels 1, 2 and 3	Bio-Rad Laboratories Cat # 181, 182 and 183

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation. A barcode label is produced and placed on the vial.

Control	Liquichek Cardiac Markers Plus Controls, Level 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	Unthawed controls are stable until the expiration date at -20 to -70° C. Once the control is thawed and opened, MYO will be stable for 20 days when stored tightly capped at 2-8° C.

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

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Vista® 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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.

6.7 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.

Quest Diagnostics
Site: Shady Grove Adventist Hospital Title: **Myoglobin by Dimension Vista® System**

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- 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

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -15 to -25°C.
- Centrifuge

7.3 Supplies

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

8. PROCEDURE

MYO Flex® reagent cartridge Cat. No. K6422 is required to perform this test.

Myoglobin 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.

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.

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
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:	2 µL
Chemibead Reagent Volume:	30 µL
Biotinylated Antibody Volume:	30 µL
Sensibead Volume:	20 µL
Assay Buffer Volume:	70 µL
Reaction Time:	10 minutes
Test Temperature:	37° C
Wavelength:	680 and 612 nm
Type of measurement:	Chemiluminescence

9. CALCULATIONS

The instrument automatically calculates the concentration of Myoglobin 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 as a whole number.

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

1 – 20,000 ng/mL

10.5 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 within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
< 1 ng/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 1 ng/mL
≥ 1000 ng/mL	**On Board Automated Dilution:** Results ≥ 1000 ng/mL will automatically have repeat testing performed into the instrument using dilution factor of 20. No multiplication is necessary.
> 20,000 ng/mL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 20,000 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

10 – 92 ng/mL

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Myoglobin is a heme protein found in both cardiac and skeletal muscle cells and is released in the serum when damage occurs to these cells. In the absence of skeletal muscle trauma or other factors associated with non-cardiac related increase in circulating myoglobin, myoglobin levels have been used as an early marker for detection of myocardial infarction (MI). Following myocardial necrosis associated with MI, myoglobin is one of the first markers to rise above normal levels, increasing measurably above baseline within 1–3 hours post infarct, peaking at 6–12 hours and returning to baseline within 24–36 hours. Reports suggest the measurement of myoglobin as an aid in risk stratification of chest pain patients and as an aid in the diagnosis of myocardial infarction. Negative predictive values for myocardial infarction of up to 100% have been reported at certain periods after the onset of symptoms.

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 you Dimension Vista Operator's Guide.

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

MYO Concentration	Acceptable S.D. Maximum
110 ng/mL	24 ng/mL
367 ng/mL	75 ng/mL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1 – 1000 ng/mL

14.2 Precision

Material	Mean ng/mL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Liquichek Cardiac Control			
Level 1	113	2.7 (2.4)	4.0 (3.6)
Serum Pool Level 1	110	5.4 (4.9)	5.5 (5.0)
Serum Pool Level 2	502	17.3 (3.4)	18.7 (3.7)
Serum Pool Level 3	831	23.1 (2.8)	27.6 (3.3)

14.3 Interfering Substances

HIL Interference:
The MYO 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	MYO ng/mL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	120	<10
Bilirubin (unconjugated)	60 mg/dL	100	<10
Bilirubin (conjugated)	60 mg/dL	98	<10
Lipemia Intralipid®	3000 mg/dL	94	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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. Material Safety Data Sheets (MSDS)
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. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
17. Current package insert MYO Flex® Reagent Cartridge K6422

17. REFERENCES

1. Package Insert, MYO Flex® Reagent Cartridge K6422, Siemens Healthcare Diagnostics Inc., 10/29/2012.
2. Package Insert, MYO CAL, Siemens Healthcare Diagnostics Inc., 01/2015.
3. Package Insert, Liquichek Cardiac Markers Plus Control, Bio-Rad Laboratories, 11/2011.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	2/4/15		Update owner	L Barrett	R SanLuis
000	2/4/15	5.2	Change in frozen storage temperature	L Barrett	R SanLuis
000	2/4/15	7.2	Change freezer requirements	L Barrett	R SanLuis
000	2/4/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Creatine Kinase by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/11/2014

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
Creatine Kinase	Dimension Vista® System	CPK

Synonyms/Abbreviations
CK, CPK, CKI

Department
Chemistry

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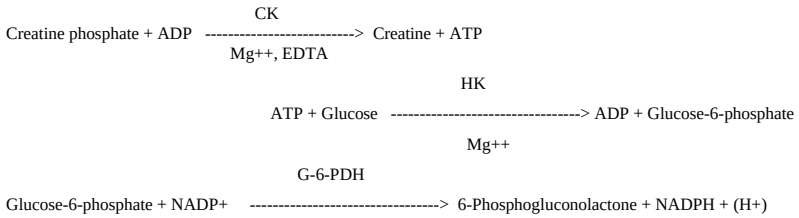
2. ANALYTICAL PRINCIPLE

In a coupled enzyme reaction, the creatine kinase in patient samples catalyzes the transphosphorylation of phosphate from creatine phosphate to adenosine diphosphate (ADP) producing adenosine triphosphate (ATP). Hexokinase (HK) phosphorylates glucose from the ATP. The resulting glucose-6-phosphate is oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) with the simultaneous reduction of nicotinamide adenine dinucleotide phosphate (NADP).

The rate of formation of NADPH is directly proportional to the CK activity in the sample and is measured bichromatically at 340 and 540 nm.



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	Plasma (Heparin)
-Other Acceptable	Serum
Collection Container	Plasma: Green top tube Serum: Red top tube, Serum separator tube (SST)
Volume - Optimum	1.0 mL
- Minimum	0.5 mL

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Criteria	
Transport Container and Temperature	Collection container or Plastic vial at room temperature
Stability & Storage Requirements	Room Temperature: 2 hours
	Refrigerated: 7 days
	Frozen: 29 days
	Instrument on board aliquot stability 2 hours
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.
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.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Creatine Kinase	Siemens, Flex® reagent cartridge, Cat. No. K2038

4.2 Reagent Preparation and Storage

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration. Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

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Reagent	**Creatine Kinase**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 8 have been entered by the instrument, they are stable for 5 days. • Once wells 9 - 12 have been entered by the instrument, they are stable for 10 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
ENZ 6 CAL	Siemens Dimension Vista®, Cat. No. KC360

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

Calibrator	ENZ 6 CAL
Preparation	Thaw at room temperature to 30 – 45 minutes. Do not thaw in a water bath or water about 25° C. Before use, gently invert the calibrator vials at least ten times to ensure that the contents are thoroughly mixed. **Do not vortex.**
Storage/Stability	• Store at -15°C to -25°C • **Unopened frozen calibrator** is stable until expiration date stamped on the box. • **Unopened thawed calibrator** is stable for 7 days at 2-8° C. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are 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	ENZ 6 CAL
Assay Range	7 – 1000 U/L
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in U/L
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

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™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation. A barcode label is produced and placed on the vial.

Control	Liquichek Unassayed Chemistry Controls, Level 1 and 2
Preparation	Allow the frozen control to stand 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	Once the control is thawed, all analytes will be stable for 15 days at 2-8°C. Unthawed controls are 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 (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

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Vista® 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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.

6.7 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

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range to not exceed -15 to -25°C.
- Centrifuge

7.3 Supplies

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

8. PROCEDURE

CKI Flex® reagent cartridge Cat. No. K2038 is required to perform this test.

Creatine Kinase 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.

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.

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
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:	5.9 µL
Reagent 1 Volume:	47.1 µL
Reagent 2 Volume:	23.1 µL
Reaction Time:	9.5 minutes
Test Temperature:	37° C
Wavelength:	340 and 540 nm
Type of measurement:	Bichromatic rate

9. CALCULATIONS

The instrument automatically calculates the concentration of Creatine Kinase in U/L.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

U/L

10.4 Clinically Reportable Range (CRR)

7 – 100,000 U/L

Notes: Extended CRR

1) For pediatric samples (patient <18 years), dilute the specimen until a result is obtained.
2) Upon physician special request, specimens can be diluted until a result is obtained.

10.5 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 within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
< 7 U/L	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 7 U/L
≥ 1,000 U/L	**On Board Automated Dilution:** Results ≥ 1,000 U/L will automatically have repeat testing performed into the instrument using dilution factor of 7. No multiplication is necessary.
> 7,000 U/L	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 100 **Notes: Extended CRR** 1) For pediatric samples (patient <18 years), dilute the specimen until a result is obtained. 2) Upon physician special request, specimens can be diluted until a result is obtained. **DILUENT**: Water Enter dilution factor as a whole number. Re-assay. Readout is corrected for dilution.
> 100,000 U/L	If the recommended dilution does not give results within the clinically reportable range, report as: "> 100,000 U/L-REP" Bring to the attention of your supervisor prior to releasing result. *(See notes above for Extended CRR).*

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

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Female	Male
Adult (>18 years):	21 – 215 U/L	32 – 232 U/L
Pediatric:		
0– 90 days	43-474	29-303
3 – 12 months	27-242	25-172
13 months – 23 months	25-177	28-162
2 – 10 years	25-177	31-152
11 – 14 years	31-172	31-152
15 – 18 years	28-142	34-147

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Measurements of creatine kinase are used in the diagnosis and treatment of myocardial infarction and muscle diseases. Creatine kinase (CK) may also be elevated following muscle injury or strenuous exercise.

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 creatine kinase concentrations are:

CKI Concentration	Acceptable S.D. Maximum
107 U/L	>5.9 U/L
810 U/L	>39.4 U/L

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

7 – 1000 U/L

14.2 Precision

Material	Mean U/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	112	1.42 (1.3)	2.70 (2.4)
Level 3	878	9.40 (1.1)	10.25 (1.2)

14.3 Interfering Substances

Hemolysis at 300 mg/dL of hemoglobin increases CKI results by 22% at creatine kinase activities of 192 U/L.

HIL Interference:
The CKI 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	CKI U/L	Bias %
Hemoglobin (hemolysate)	300 mg/dL	192	22
	100 mg/dL	491	<10
Bilirubin (unconjugated)	80 mg/dL	186, 506	<10
Bilirubin (conjugated)	80 mg/dL	186, 516	<10
Lipemia Intralipid®	3000 mg/dL	188, 492	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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. Material Safety Data Sheets (MSDS)
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. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
17. Current package insert CKI Flex® Reagent Cartridge K2038

17. REFERENCES

1. Goshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144
2. Package Insert, CKI Flex® Reagent Cartridge K2038, Siemens Healthcare Diagnostics Inc., 7/16/2013.
3. Package Insert, ENZ 6 CAL, Siemens Healthcare Diagnostics Inc., 01/2015.
4. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 01/2013.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/11/14		Update owner	L Barrett	R SanLuis
000	6/11/14	10.4, 10.5	Change upper limit of CRR, add instruction for extending for pediatric specimens and special requests	R SanLuis	R SanLuis
000	6/11/14	16	Update titles	L Barrett	R SanLuis
000	6/11/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	R SanLuis
1	2/4/15	5.2	Change in frozen storage temperature	L Barrett	R SanLuis
1	2/4/15	7.2	Change freezer requirements	L Barrett	R SanLuis

19. ADDENDA

None

Technical SOP

Title	**Cholesterol, High Density Lipoprotein (HDLC) by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis, ~~Jean Buss~~ Date: 2/4/2015

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**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
High Density Lipoprotein Cholesterol	Dimension Vista® System	HDL

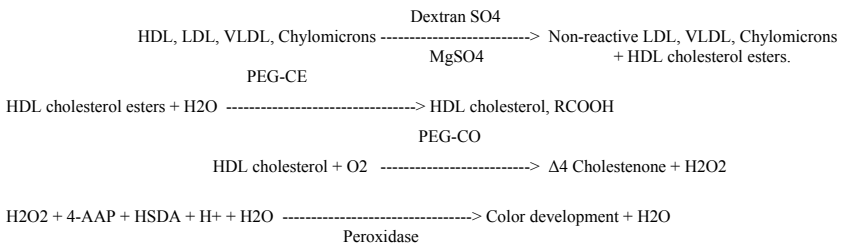
Synonyms/Abbreviations
HDL, HDLC; Included in Batteries/Packages: LIPD

Department
Chemistry

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

The HDLC assay measures serum HDL cholesterol levels directly without the need for sample pretreatment or specialized centrifugation steps, using a two reagent format. In the first reaction, chylomicrons, VLDL and LDL form water soluble complexes with dextran sulfate in the presence of magnesium sulfate. These complexes are resistant to the polyethylene glycol (PEG)-modified cholesterol esterase (CE) and cholesterol oxidase (CO) that react with HDL cholesterol. In the second reaction, in the presence of oxygen, the HDL cholesterol is oxidized to Δ-4-cholestenone and hydrogen peroxide. The generated hydrogen peroxide then reacts with 4-aminoantipyrine (4-AAP) and N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (HSDA) in the presence of peroxidase to form a colored dye that is measured using a bichromatic (600/700 nm) technique. The color intensity of the dye is directly proportional to the serum HDL-C concentration.



3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	Blood should be collected after a 12 hour period of fasting by normal procedures.
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	Plasma (Heparin)
-Other Acceptable	Serum

Criteria	
Collection Container	Plasma: Green top tube 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: 7 days
	Frozen: 3 months
	Instrument on board aliquot stability 2 hours
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.
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.

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
HDLC	Siemens, Flex® reagent cartridge, Cat. No. K3048A

4.2 Reagent Preparation and Storage

NOTES: Each container must be labeled with (1) substance name, (2) lot number, (3) expiration date, (4) any special storage instructions; check for visible signs of degradation. When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Reagent	**High Density Lipoprotein Cholesterol**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed wells on the instrument are stable for 30 days. • Once wells 1 - 12 have been entered by the instrument, they are stable for 3 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
LIPID CAL	Siemens Dimension Vista®, Cat. No. KC220A

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) any special storage instructions; check for visible signs of degradation. **When placed onboard the analyzer, the instrument captures the date / time loaded and calculates and tracks the opened expiration.**

Calibrator	LIPID CAL
Preparation	Allow LIPID calibrator to thaw and equilibrate to room temperature (22 – 28° C) for 1 hour. Before use, **gently** invert the calibrator vials at least 10 times to ensure that the contents are thoroughly mixed. **Do not vortex.**
Storage/Stability	• Store at -15°C to -25°C • **Unopened frozen calibrator** is stable until expiration date stamped on the box. • **Unopened thawed calibrator** is stable for 30 days when stored at 2-8° C. • **Opened Calibrator:** once the stopper of the vial is punctured, assigned values are stable for 7 days when stored on board the Dimension Vista System. • **Opened Calibrator:** once cap is removed, assigned values are stable for 30 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	LIPID CAL
Assay Range	3 – 150 mg/dL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	2 levels, n = 5

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™ Unassayed Chemistry Control Levels 1 and 2	Bio-Rad Laboratories Cat. No. 691 and 692

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation. A barcode label is produced and placed on the vial.

Control	Liquichek Unassayed Chemistry Controls, Level 1 and 2
Preparation	Allow the frozen control to stand 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	Once the control is thawed, all analytes will be stable for 15 days at 2-8°C. Unthawed controls are 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 (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

Step	Action
1	Acceptable ranges for QC are programmed into the Laboratory Information System (LIS), 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.

6.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Vista® 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.

6.6 Documentation

- QC tolerance limits are programmed into the instrument and the LIS. The LIS 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.

6.7 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

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -15 to -25°C.
- Centrifuge

7.3 Supplies

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

8. PROCEDURE

HDLC Flex® reagent cartridge Cat. No. K3048A is required to perform this test.

High Density Lipoprotein Cholesterol 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.

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.

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
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:	1.3 µL
Reagent 1 Volume:	135 µL
Reagent 2 Volume:	44.4 µL
Reaction Time:	8.9 minutes
Test Temperature:	37° C
Wavelength:	600 & 700 nm
Type of measurement:	Bichromatic endpoint

9. CALCULATIONS

Total Cholesterol (TC) = High density lipoprotein (HDL) + Low density lipoprotein (LDL) + Very low density lipoprotein (VLDL) or TC = HDL + LDL + VLDL

The following calculations are performed by the LIS when a Lipid Panel is performed:

Calculated LDL = TC – HDL – VLDL

VLDL = Triglycerides (Trig) ÷ 5

Total Cholesterol/HDL Ratio = TC ÷ HDL

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

3 – 600 mg/dL

10.5 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 within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
< 3 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 3 mg/dL
≥ 150 mg/dL	**On Board Automated Dilution:** Results ≥ 150 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 4. No multiplication is necessary.
> 600 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 600 mg/dL-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

Age	Female	Male
Adult (>19 years):	>39 mg/dL	>39 mg/dL
Pediatric:		
5 – 14 years	37-75	38-76
15 – 19 years	36-76	31-65

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases, and in the assessment of risk for atherosclerosis and cardiovascular disease.
Plasma lipoproteins are spherical particles of varying composition. The outer surface of

these particles is made up of phospholipids, free cholesterol and protein; the inner core contains mostly esterified cholesterol and triglyceride. Lipoproteins function to solubilize and transport cholesterol and triglycerides in the bloodstream.
Four types of lipoproteins are recognized clinically based on the relative proportions of their lipid and protein content: chylomicrons, very low-density lipoproteins (VLDL), low-density lipoproteins (LDL) and high-density lipoproteins (HDL). The primary function of HDL is to transport cholesterol from peripheral tissues to the liver where it is metabolized. This process, known as reverse cholesterol transport, has been proposed to be a cardiovascular protective mechanism. Patients with low levels of HDL cholesterol are generally considered to be at increased risk for coronary artery disease.

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 HDLC concentrations are:

HDLC Concentration	Acceptable S.D. Maximum
35 mg/dL	1.5 mg/dL
70 mg/dL	2.2 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

3 – 150 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Multiqual Unassayed Control			
Level 1	26	0.6 (2.3)	0.7 (2.7)
Level 2	47	0.8 (1.6)	1.1 (2.3)
Level 3	67	1.3 (1.9)	1.4 (2.1)
Serum Pool	41	0.7 (1.8)	0.9 (2.3)

14.3 Interfering Substances

HIL Interference:
The HDLC 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	HDLC mg/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/gL	40	<10
Bilirubin (unconjugated)	80 mg/dL	40	<10
Bilirubin (conjugated)	60 mg/dL	40	<10
Lipemia Intralipid®	1000 mg/dL	40	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

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®
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11. Quest Diagnostics Records Management Procedure
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14. Hemolysis, Icteria and Lipemia Interference (Lab policy)
15. Repeat Testing Requirement (Lab policy)
16. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
17. Current package insert HDLC Flex® Reagent Cartridge K3048

17. REFERENCES

1. Ghoshal, Amit K. and Soldin, Steven J., Evaluation of the Dade Behring Dimension® RxL: Integrated chemistry system-pediatric reference ranges. Clinica Chimica Acta 2003; 331:144.
2. Package Insert, HDLC Flex® Reagent Cartridge K3048A, Siemens Healthcare Diagnostics Inc., 09/4/2013.
3. Package Insert, LIPID CAL, Siemens Healthcare Diagnostics Inc., 12/2014.
4. Package Insert, Unassayed Liquichek Chemistry Controls, Bio-Rad Laboratories, 01/2013.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	2/4/15		Update owner	L Barrett	R SanLuis
000	2/4/15	5.2	Change in frozen storage temperature	L Barrett	R SanLuis
000	2/4/15	7.2	Change freezer requirements	L Barrett	R SanLuis
000	2/4/15	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None