TRAINING UPDATE

Lab Location:	SGAH & WAH	**Date Distributed:**	7/1/2013
Department:	Core	**Due Date:**	7/31/2013
		Implementation:	**8/1/2013**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Human Chorionic Gonadotropin, Quantitative by Dimension Vista® System SGAH.C107, WAH.C103 v001

Dimension Vista Limits Chart AG.F200.002

Description of change(s):

Section	Reason
10.5	Revise manual dilution to refer to addenda
19	Add addendum A (Simple Steps for Manual Dilution)

Revise Vista Limits chart to show revised dilution factor for HCG

This revised SOP will be implemented on August 1, 2013

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

Approved draft for training all sites (version 001)

Technical SOP

Title	**Human Chorionic Gonadotropin, Quantitative by Dimension Vista® System**
Prepared by	Ashkan Chini Date: 6/25/2012
Owner	Robert SanLuis Date: 6/25/2012

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

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

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Human Chorionic Gonadotropin, Quantitative	Dimension Vista® System	HCGQ

Synonyms/Abbreviations
Pregnancy test, Quant/ Quant hCG/ Beta HCG, BHCG

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The BHCG method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCIR technology. The LOCIR reagents include two synthetic bead reagents and a biotinylated anti–shCG 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–shCG monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a bead–shCG–biotinylated antibody sandwich. 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 to the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional to the free and intact, nicked and non–nicked s human chorionic gonadotropin 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:	24 hours
	Refrigerated:	7 days
	Frozen:	2 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.	

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

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
Beta Human Chorionic Gonadotropin	Siemens, Flex® reagent cartridge, Cat. No. K6430

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
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	**Beta Human Chorionic Gonadotropin**
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 5 days.
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
BHCG CAL	Siemens Dimension Vista®, Cat. No. KC632

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) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	BHCG CAL
Preparation	BHCG CAL is ready for use. No preparation is required.
Storage/Stability	• Store at 2-8° C • **Unopened calibrator** is stable until expiration date stamped on the box. • **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	BHCG CAL
Assay Range	1 – 1000 mIU/mL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mIU/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™ Immunoassay Plus Control Levels 1, 2 and 3	Bio-Rad Laboratories Cat # 361, 362 and 363

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.

Control	Liquichek Immunoassay Plus Controls, Level 1, 2 and 3
Preparation	Before sampling, allow the control to reach room temperature (18-25°C) and swirl gently to ensure homogeneity. Promptly replace the stopper and return to 2-8°C storage after each use.

Storage/Stability	• This product will be stable until the expiration date when stored unopened at -20 to -70° C. • **Thawed and unopened:** all analytes will be stable for 30 days. • **Thawed and opened:** all analytes will be stable for 14 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 -20 to -70°C.
- Centrifuge

7.3 Supplies

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

8. PROCEDURE

BHCG Flex® reagent cartridge Cat. No. K6430 is required to perform this test.

Beta Human Chorionic Gonadotropin 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
Reagent 1 Volume:	25 µL
Reagent 2 Volume:	25 µL
Reagent 3 Volume:	100 µL
Reaction Time:	10 minutes
Test Temperature:	37° C
Wavelength:	612 & 680 nm
Type of measurement:	Chemiluminescence

9. CALCULATIONS

The instrument automatically calculates the concentration of BHCG in mIU/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

mIU/mL

10.4 Clinically Reportable Range (CRR)

1 – 1,000,000 mIU/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 mIU/mL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 1 mIU/mL
≥ 1000 mIU/mL	**On Board Automated Dilution:** Results ≥ 1000 mIU/mL will automatically have repeat testing performed into the instrument using dilution factor of 200. No multiplication is necessary.

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> 200,000 mIU/mL	**Manual Dilution**: Using the primary tube, make a 1:1000 dilution (refer to addendum A for step by step dilution instructions). On the Vista, set the "**Manual Dilution Factor**" to 1000. No multiplication is necessary. **Diluent**: Reagent Grade Water Enter dilution factor as a whole number. Re-assay. Readout is corrected for dilution.
> 1,000,000 mIU/mL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 1,000,000 mIU/mL-REP"

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

11. EXPECTED VALUES

11.1 Reference Ranges

Age	Non- Pregnant Female	Male
All	0-6 mIU/mL	0-2 mIU/mL

HCG levels with Gestational Age

Gestational Age	hCG mIU/mL
0.2-1 week	5-50
1-2 weeks	50-500
2-3 weeks	100-5,000
3-4 weeks	500-10,000
4-5 weeks	1,000-50,000
5-6 weeks	10,000-100,000
6-8 weeks	15,000-200,000
2-3 months	10,000-100,000

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Human chorionic gonadotropin (hCG) is a heterodimeric (α plus s) sialoglycoprotein hormone produced by the placenta soon after a fertilized ovum implants into the uterine wall. Presence of hCG in serum shortly after conception, followed by a rapid rise in concentration, makes it an excellent marker to confirm and monitor a pregnancy. Physiologically, hCG appears to maintain the corpus luteum and support the endometrium. Serum and plasma hCG concentrations peak during the first trimester, then

decrease and plateau during the remainder of pregnancy, circulating as the intact heterodimer in the blood of healthy women who have an uncomplicated pregnancy.

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 Beta Human Chorionic Gonadotropin concentrations are:

BHCG Concentration	Acceptable S.D. Maximum
26 mIU/mL	2.5 mIU/mL
550 mIU/mL	27.2 mIU/mL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1 – 1,000 mIU/mL

14.2 Precision

Material	Mean mIU/mL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Liquichek Immuno. Control			
Level 1	5	0.2 (3.2)	0.2 (3.6)
Serum Pool 1	25	0.6 (2.6)	0.7 (2.8)
Serum Pool 2	417	5.9 (1.4)	8.5 (2.0)

14.3 Interfering Substances

HIL Interference:

The BHCG 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	BHCG mIU/mL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	25	<10
Bilirubin (unconjugated)	60 mg/dL	25	<10
Bilirubin (conjugated)	60 mg/dL	25	<10
Lipemia Intralipid®	3000 mg/dL	25	<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. Siemens Dimension Vista® Limits Chart
11. Quest Diagnostics Records Management Procedure
12. Dimension Vista® System Error Messages Chart
13. Centrifuge Use, Maintenance and Functions 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 BHCG Flex® Reagent Cartridge K6430

17. REFERENCES

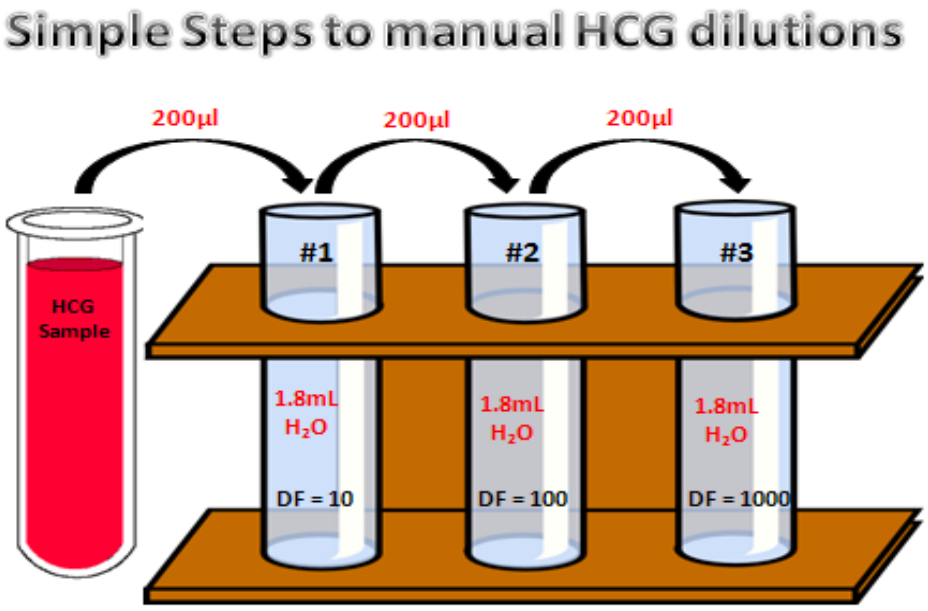
1. Package Insert, BHCG Flex® Reagent Cartridge K6430, Siemens Healthcare Diagnostics Inc., 03/19/2008.
2. Package Insert, BHCG CAL, Siemens Healthcare Diagnostics Inc., 07/2012.
3. Package Insert, Liquichek Immunoassay Plus Control, Bio-Rad Laboratories, 02/2012.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	6/3/13	10.5	Revise manual dilution to refer to addenda	A Chini	R SanLuis
000	6/3/13	19	Add addendum A	L Barrett	R SanLuis

19. ADDENDA

A. Simple Steps for Manual Dilution



Materials required for HCG serial dilution

- Transfer plastic pipettes
- Three 10mL glass test tubes
- Three automatic pipettes (200µL micropipette, 1mL pipette and 2mL pipette) with their appropriate pipette tips.
- 10mL NERL water

Procedure

1. Set up three glass test tubes each labeled 1, 2 and 3 and transfer 2mL of NERL water in each glass tube.
2. Remove 200µL of water from each test tube and discard.
3. Transfer 200µL of patient plasma/serum to tube #1 (Creating a 1:10 sample dilution)
4. Use a transfer plastic pipette and mix thoroughly (at least five to six times) to create a homogenous mixture.
5. Pipette 200µL of the mixture from tube #1 and transfer to Tube #2 and repeat step 4.
6. Pipette 200µL of the mixture from tube #2 and transfer to Tube #3 and repeat step 4.
7. Transfer the mixture from test tube #3 to a limited sample cup labeled with patient name and accession number. Proceed with the manual dilution testing procedures using 1000 dilution factor.

NOTE

- You can perform the same serial dilutions with the same dilution factor by decreasing the volume size in each step when there is a limited patient sample.
- DO NOT forget to discard the pipette tips after each transfer to avoid a sample carryover from the previous dilution.

DIMENSION VISTA® LIMITS CHART

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☐ Washington Adventist Hospital

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SPECIAL DILUTION ON VISTA	SGAH	WAH
ACTM	µg/mL	2	2.0 - 600.0	3	2.0 - 900.0	Drug 2 Cal Level 1, or Drug Free Serum	N/A	x	x
ALB	g/dL	4	0.0 - 32.0	Not Available	0.0 - 32.0	Do NOT Dilute	N/A	x	x
ALC	mg/dL	4	3 - 1,200	Not Available	3 - 1,200	Do NOT Dilute	N/A	x	x
ALP	U/L	2.33	4 - 2,330	10	4 - 10,000	Enzyme Diluent	N/A	x	x
ALTI	U/L	3.5	6 - 3,500	Not Available	6 - 10,000	Do NOT Dilute	10	x	x
AMON	µmol/L	2	25 - 2,000	3	25 - 3,000	Water	N/A	x	x
AMY	U/L	2	2 - 1,300	10	2 - 6,500	Enzyme Diluent	N/A	x	x
AST	U/L	2	3 - 2,000	Not Available	3 - 10,000	Do NOT Dilute	10	x	x
BUN	mg/dL	4	1 - 600	Not Available	1 - 600	Do NOT Dilute	N/A	x	x
CA	mg/dL	2	5.0 - 30.0	3	5.0 - 45.0	Water	N/A	x	x
CHOL	mg/dL	4	50 - 2,400	5	50 - 3,000	Water	N/A	x	x
CKI	U/L	7	7 - 7000	40	7 - 40,000	Water	N/A	x	x
CL	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	N/A	x	x
CRBM	µg/mL	4	0.5 - 80.0	Not Available	0.5 - 80.0	Do NOT Dilute	N/A	x	x
CREA	mg/dL	2	0.1 - 40.0	3	0.1 - 60.0	Water	N/A	x	x
CRP	mg/dL	20	0.3 - 380.0	Not Available	0.3 - 380.0	Do NOT Dilute	N/A	x	x
CTNI	ng/mL	5	0.02 - 200.00	Not Available	0.02 - 200.00	Do NOT Dilute	N/A	x	x
DBIL	mg/dL	4	0.1 - 64.0	5	0.1 - 80.0	Water	N/A	x	x
DGNA	ng/mL	Not Available	0.06 - 5.00	10	0.06 - 50.00	Drug 4 Cal. Level 1 or Digoxin-Free Serum	N/A	x	x
ECO2	mmol/L	Not Available	1 - 45	2	1 - 90	Water	N/A	x	x
FT4	ng/dL	Not Available	0.10 - 8.00	Not Available	0.10 - 8.00	Do NOT Dilute	N/A	x	x
GENT	µg/mL	4	0.2 - 48.0	Not Available	0.2 - 48.0	Do NOT Dilute	N/A	x	x
GGT	U/L	2	3 - 1,600	20	3 - 16,000	Enzyme Diluent	N/A	x	x
GLUC	mg/dL	4	1 - 2,000	5	1 - 2,500	Water	N/A	x	x
HCG	mIU/mL	200	1 - 200,000	**1000**	1 - 1,000,000	Water	N/A	x	x
HDLC	mg/dL	4	3 - 600	Not Available	3 - 600	Do NOT Dilute	N/A	x	x
K	mmol/L	Not Available	1.0 - 10.0	Not Available	1.0 - 10.0	Do NOT Dilute	N/A	x	x
LA	mmol/L	4	0.1 - 60.0	Not Available	0.1 - 60.0	Do NOT Dilute	N/A	x	x
LDI	U/L	4	6 - 4,000	20	6 - 20,000	Enzyme Diluent	N/A	x	x
LI	mmol/L	Not Available	0.20 - 5.00	3	0.20 - 15.00	Lithium Free Serum	N/A	x	x
LIPL	U/L	20	10 – 30,000	Not Available	10 – 30,000	Do NOT Dilute	N/A	x	x
MG	mg/dL	2	0.2 - 40.0	3	0.2 - 60.0	Water	N/A	x	x
MMB	ng/mL	20	0.5 - 6,000.0	Not Available	0.5 - 6,000.0	Do NOT Dilute	N/A	x	x
MYO	ng/mL	20	1 - 20,000	Not Available	1 - 20,000	Do NOT Dilute	N/A	x	x

DIMENSION VISTA® LIMITS CHART

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ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SPECIAL DILUTION ON VISTA	SGAH	WAH
NA	mmol/L	Not Available	50 - 200	Not Available	50 - 200	Do NOT Dilute	N/A	x	x
PHNO	µg/mL	4	2.1 - 320.0	Not Available	2.1 - 320.0	Do NOT Dilute	N/A	x	x
PHOS	mg/dL	2	0.1 - 18.0	5	0.1 - 45.0	Water	N/A	x	x
PTN	µg/mL	4	0.4 - 160.0	Not Available	0.4 - 160.0	Do NOT Dilute	N/A	x	x
SAL	mg/dL	3	1.7 - 300.0	Not Available	1.7 - 300.0	Do NOT Dilute	N/A	x	x
TBIL	mg/dL	4	0.1 - 100.0	5	0.1 - 125.0	Water	N/A	x	x
TGL	mg/dL	4	2 - 4,000	5	2- 5,000	Water	N/A	x	x
THEO	µg/mL	4	2.0 - 160.0	Not Available	2.0 - 160.0	Do NOT Dilute	N/A	x	x
TOBR	µg/mL	4	0.3 - 48.0	Not Available	0.3 – 48.0	Do NOT Dilute	N/A	x	x
TP	g/dL	2	0.0 - 24.0	3	0.0 - 36.0	Water	N/A	x	x
TSH	µIU/mL	5	0.01 - 500.00	Not Available	0.01 - 500.00	Do NOT Dilute	N/A	x	x
UCFP (CSF)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	N/A	x	x
URCA	mg/dL	4	0.2 - 60.0	5	0.2 - 75.0	Water	N/A	x	x
VALP	µg/mL	2	3.0 - 300.0	3	3.0- 450.0	Drug 2 Cal Level 1, Drug Free serum, or Water	N/A	x	x
VANC	µg/mL	Not Available	0.8 - 50.0	3	0.8 - 150.0	Drug Cal 2 Level 1, Drug Free Serum, or Water	N/A	x	x

ANALYTE	UNITS	INSTRUMENT DILUTION FACTOR	MAXIMUM RANGE AFTER ON BOARD DILUTION	MAXIMUM OFF BOARD DILUTION	CLINICALLY REPORTABLE RANGE (CRR)	DILUENT	SGAH	WAH
Urine CREA	mg/dL	Not Available	0.1 - 200.0	3	0.1 - 600.0	Enzyme Diluent	x	x
Urine K	mmol/L	Not Available	1.0 - 300.0	Do Not Dilute	1.0 - 300.0	Do Not Dilute	x	x
Urine SOD	mmol/L	Not Available	5 - 300	Do Not Dilute	5 - 300	Do Not Dilute	x	x
UCFP (urine only)	mg/dL	1.84	5 - 460	10	5 - 2500	Water	x	x