TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	9/24/2014
Department:	Core	**Due Date:**	10/21/2014
		Implementation:	**10/22/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Startup and Maintenance, Siemens Dimension® Xpand GEC.C07 v6
Description of change(s):
Section 5: Item B.6 - changed to automatic process and add option for manual process. Item C.3 - specified frequency This revised SOP will be implemented on October 22, 2014

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

Approved draft for training all sites (version 6)

Non-Technical SOP

Title	**Startup and Maintenance, Siemens Dimension® Xpand**	
Prepared by	Leslie Barrett	Date: 8/10/2009
Owner	Robert SanLuis	Date: 6/8/2011

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

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

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

To outline the daily startup procedure for the Siemens Dimension Xpand instruments and describe all other maintenance that must be performed as scheduled.

2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension Xpand instruments.

3. RESPONSIBILITY

Core Laboratory personnel are responsible for performing and complying with this procedure.
The Technical Supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

None

5. PROCEDURE

A. General Information and Schedule

1. The daily startup, weekly and monthly maintenance will be performed by the night shift.

2. The daily monitoring of the instrument waste will be performed on all three shifts.

3. The Core Laboratory Group Leads are responsible for the weekly review of maintenance logs.

4. The Core Laboratory Supervisor, Operational Director or designee is responsible for the monthly review of maintenance.

5. A check off log is provided on each instrument for the technologist to sign. The required checkpoints must be completed as scheduled. A technologist on each shift must initial that they have completed the required checkpoints.

6. Documentation - After **any** maintenance is completed the following must be performed.
   a. Run System Check. Document results on the forms provided for each instrument.
   b. Run QC.
   c. Do not release any patient result until the System check and QC successfully passes.
   d. Document function check on the maintenance Log Sheet.

B. Daily Startup

1. Delete all segments positions
   a. Press Alt/S
   b. Press F3 Delete
   c. Respond to prompts.

2. Access the Daily Maintenance Program. From the Operating Menu:
   a. Press F4: System Prep
   b. Press F8: Daily Maint

3. Record the cuvette and reagent temperatures in the Maintenance Log.

4. Clean the sample area and empty cuvette waste
   a. With the instrument in Standby, press Pause to stop the sampler systems from moving.
   b. Raise the sample and reagent lids and remove all segments from the sample area.
   c. Clean the inside of the sample with a damp cloth.
   d. Close the sample and reagent lids.
   e. Press Pause to restart the sampler system.
   f. Open the right cabinet door and cut the cuvette string about 12 inches down from the instrument. Be sure to cut the between two cuvettes to prevent spilling fluids from a sealed cuvette.
   g. Empty the accumulated cuvette waste.

5. Check for other maintenance when F2: Check Counts or F3: HM Counts appears in the function key area. Sample, R1 and R2 probes are to be changed before or at 30,000 cycles.

6. Run System Check:
   The instrument is preprogrammed at a specific time interval to run a system check automatically on a daily basis.
   - Ensure there is a CHK Flex on the instrument prior to the system Check running.
   - The instrument will flag if there is not enough CHK Flex reagent in the inventory.

   At any time the operator has the ability to run the system check manually to verify instrument performance.

7. Record System Check results in the Maintenance Log.
   Note: Unacceptable System Check results appear on the print out in white letters on a black background. An asterisk on the report indicates that the cuvette had a processing problem. If the System Check Printout indicates that your results are not acceptable refer to System Check Trouble shooting in the Operators Guide.

8. Check/replenish reagent, IMT and HM inventory:
   a. For reagent inventory, press Alt/I
   b. For IMT, from the Operating Menu, press:
      1) F4: System Prep
      2) F3: IMT
      3) F1: Change Consumables
   c. For HM, from the Operating Menu, press
      1) F4: System Prep
      2) F6: System Counters
      3) F6: HM Counters

9. Process Quality Control according to Laboratory procedures.

C. Weekly Maintenance

1. Clean HM Wash Probes and the R2 reagents Probe
   a. With the system in Stand by, go to the HM Pump Prime screen
   b. Raise the sample and regent lids.
   c. Dip a clean cotton swab in water and, beginning at the top of the probe, wipe down the outside of both wash station probes.
   d. Turn the splined shaft on the R2 reagent arm until the R2 probe comes up out of the R2 reagent drain. Then move the arm until you can easily access the R2 probe.
   e. Dip a clean cotton swab in 0.1N sodium hydroxide and scrub the nut at the top of the probe tube. Then, beginning at the top, wipe down the outside of the R2 reagent probe.
   f. Press F1: HM Wash Pump to prime the HM wash pump.
   g. Document the cleaning on the Weekly Log Sheet.

2. Replace IMT Sensor, Run Dilution Check & Condition Sensor.
   (This is done every 5 days and the instrument will give a reminder) For step by step procedure see the IMT Info section in the Dimension Quick Reference Guide or the Operator's Guide 2-59.

3. Clean Windows according to the Dimension Xpand Maintenance Log.
   All the windows are cleaned the first week.
   Only the dirty windows are cleaned the rest of the month

D. Monthly Maintenance

1. Siemens Dimension
   a. Replace IMT Pump Tubing
   b. Replace / Clean Air Filters
   c. Replace HM Pump Heads
      For step by step procedure see the Operator's Guide 3-15.
   d. Stylette the HM Wash Probes
   e. IMT System Clean (The instrument will give a reminder)
      For step by step procedure see the IMT Info section in the Dimension Quick Reference Guide or the Operator's Guide.

2. Millipore
   a. Culture Millipore Water. Clean tip with alcohol pads first. Then pour a 1:10 bleach/water solution over the tip and let sit for a minimum of 15 minutes. Let water flow into the basin until half full and then culture the water.
   b. Replace Chlorine Tablet as needed by the indicator light on the Millipore. Refer to Millipore (AFS – Analyzer Feed System) procedure for step-by-step instructions.

E. Non-scheduled or 'As Needed' Maintenance

Note: not limited to those listed below

1. Sample probe change before or at 30,000 cycles.
2. Reagent probes (R1 and R2) change before or at 30,000 cycles.
3. Source lamp changed
4. IMT probe change
5. IMT tubing change
6. Any scheduled maintenance that is performed off-cycle

6. RELATED DOCUMENTS

Millipore (AFS – Analyzer Feed System), Chemistry procedure
The Dimension Quick Reference Guide
Dimension Xpand Maintenance Log (AG.F179)
Dimension Xpand Daily System Check (AG.F290)
Dimension Xpand QuikLYTE Results (AG.F291)

7. REFERENCES

Dimension Xpand Clinical Chemistry Operators' Guide, 09/2008

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP C041.002		
000	2/11/11	Update owner and title page Section 5: item A.8 relocated from end of section, item F added	W. McMillan	Dr Cacciabeve
001	6/8/11	Update owner Section 5: change Stylette HM wash probes and clean windows to weekly maintenance, remove monthly monopump maintenance Section 9: add maintenance form	L Barrett	Dr Cacciabeve
002	1/29/12	Section 5: Items B.5 and F.1&2 - add frequency for change before or at 30,000 cycles. Section 9: edit log sheets to reflect cycle count for probe changes.	J Buss	Dr Cacciabeve
003	8/14/12	Sections 1 & 2: add analyzer name Section 5: remove instructions specific to SGAH and/or WAH; change IMT System clean, Stylette HM wash probe & Millipore to monthly frequency, add HM pump heads Section 9: remove RXL log, add Xpand log	L Barrett, A Chini	R SanLuis
004	7/15/14	Section 5: Item B.6 changed to automatic process Section 6: Update logs Section 9: Log moved to section 6 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett, A Chini	R SanLuis
5	9/16/14	Section 5: Item B.6 clarified, add option for manual process. Item C.3specified frequency	H Genser	R SanLuis

9. ADDENDA AND APPENDICES

None