TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	4/12/2017
Department:	Core	**Due Date:**	5/9/2017
		Implementation:	**5/9/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Salicylate by Dimension® Xpand Chemistry Analyzer GEC.C26 v4

Description of change(s):

Most changes are updates to the format

Section	Reason
3.2	Add SST
4,5,6	Remove individual section labeling instructions and add general one
6.4, 6.6	Replace LIS with Unity Real Time
10.5	Move patient review from section 6
14.1	Add note to explain lower limit
14.3	Add salicyluric acid and ceftriaxone
15	Update to new standard wording, update reagent warning & move from section 4
17	Update package insert dates

This revised SOP will be implemented on May 9, 2017

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

Technical SOP

Title	**Salicylate by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 4/12/2011
Owner	Robert SanLuis Date: 11/9/2012

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
Salicylate	Dimension® Xpand Chemistry Analyzer	SALIC

Synonyms/Abbreviations
ASA, Aspirin, SALIC

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The salicylate method is a modification of the Trinder colorimetric technique. Under acidic conditions, ferric nitrate forms a complex with salicylate. The amount of salicylate-ferric complex formed is proportional to the salicylate concentration and is measured using a two filter (510, 700 nm) endpoint with sample-reagent blanking technique.

Salicylate + $Fe(NO_3)_3$ ----------> Salicylate-Fe^{3+} complex
(non-absorbing at 510 nm) (absorbs at 510 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 may be used for samples to be analyzed by this method.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Serum None	
Collection Container	Serum: Red top tube, Serum separator tube (SST)	
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL	
Transport Container and Temperature	Collection tube or plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	(20-25°C) 7 days
	Refrigerated:	(2-8°C) 2 weeks
	Frozen:	(-20°C or colder) 6 months
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.	

Criteria	
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code.
Other Considerations	Allow to clot completely prior to centrifugation. Specimens should be free of particulate matter.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Salicylate	Siemens, Flex® reagent cartridge, Cat. No. DF20

4.2 Reagent Preparation and Storage

Reagent	Salicylate
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed or unhydrated cartridge 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.
Preparation	Reagents are supplied ready for use. No additional preparation is required.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
Salicylate Calibrator	Siemens Dimension®, Cat. No. DC38

5.2 Calibrator Preparation and Storage

Calibrator	Salicylate Calibrator
Preparation	• Allow to equilibrate at room temperature and mix thoroughly before use.
Storage/Stability	• Store at 2-8° C • Unopened calibrator is stable until expiration date stamped on the box. • Open calibrator is stable for 3 months when vials are stored securely capped at 2-8°C.

5.3 Calibration Parameter

Criteria	**Special Notations**
Reference Material	Salicylate Calibrator
Assay Range	0.2 – 100 mg/dL (per manufacture)
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 3 months for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate
Assigned Coefficients	C_0 –1.330 C_1 0.666

5.4 Calibration Procedure

1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated - if lot number is incorrect Press F1: Other Lot
3. Enter all information on screen
4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.

6. Press F7: Load/run
7. Load cups into assigned position
8. Press F4: RUN

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

Control	Liquichek Immunoassay Plus Control Levels 1, 2 and 3
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	**Thawed and opened**: stable for 14 days at 2-8°C. **Thawed and unopened**: stable for 30 days at 2-8°C. Unopened 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.

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

6.4 Tolerance Limits and Criteria for Acceptable QC

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

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

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

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups

8. PROCEDURE

SAL Flex® reagent cartridge Cat. No. DF20 is required to perform this test.
Salicylate is performed on the Dimension Xpand® System after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension® Xpand procedure.
2.	Check reagent inventory

8.1	Instruction Set-Up Protocol
3.	Sampling, reagent delivery, mixing, processing, and printing of results are automatically performed by the Dimension® Xpand system. For details of the automated parameters, see below under "Test conditions."

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

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

Test Conditions	
Sample Size:	15 µL
Reagent 1 Volume:	50 µL
Reagent 2 Volume:	50 µL
Reagent 3 Volume:	50 µL
Test Temperature:	37° C
Wavelength:	510 and 700 nm
Type of measurement:	Bichromatic endpoint

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of Salicylate in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results to one decimal point.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

1.7 - 300.0 mg/dL

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

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 are reported as follows:

IF the result is …	THEN…
< 1.7 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 1.7 mg/dL
≥ 100.0 mg/dL	**On Board Automated Dilution**: Results ≥ 100.0 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 3. No multiplication is necessary.

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IF the result is …	THEN…
> 300.0 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 300.0 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

2.8 – 20.0 mg/dL

11.2 Critical Values

> 30.0 mg/dL

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The SAL method used on the Dimension® Xpand clinical chemistry system is an *in vitro* diagnostic test intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs (including aspirin) in human serum. Salicylate test results may be used in the diagnosis and treatment of salicylate overdose and for monitoring salicylate levels during therapy.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Reference range and therapeutic range are equivalent.

13. PROCEDURE NOTES

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

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

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

Concentration	S.D.
20 mg/dL	>1.0 mg/dL
100 mg/dL	>2.0 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

1.7 – 100.0 mg/dL

Note: manufacture's low limit for AMR is 0.2 but GEC utilizes a value of 1.7 to maintain consistency with SGMC and WAH.

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Within-run	Between-day
Serum Pool			
Level 1	25.9	0.22	0.26
Level 2	46.6	0.22	0.37
Level 3	88.6	0.33	0.76

14.3 Interfering Substances

Sodium azide at a concentration of 0.05% increases salicylate results by 20 mg/dL.
Bilirubin (unconjugated) of 20 mg/dL at a SAL concentration of 33 mg/dL decreased SAL results by 20%.
Lipemia (Intralipid®) of 600 mg/dL and above at a SAL concentration of 33 mg/dL tripped a test report message; therefore the magnitude of the interference could not be determined.
At salicylates concentration of 20 and 40 mg/dL [1.45 and 2.90 mmol/L], salicyluric acid at 100 mg/dL increases the SAL result by 55%.
Therapeutic doses of ceftriaxone (Rocephin®) may produce falsely elevated results with this assay. A falsely elevated result should be interpreted with caution and confirmed by another method.

HIL Interference:
The SAL method was evaluated for interference from hemolysis, icterus and lipemia according to CLSI EP7-P. 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	Test Concentration SI Units	SAL concentration mg/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	32.9	<10
Bilirubin (unconjugated)	5 mg/dL	33.0	<10
Lipemia Intralipid®	200 mg/dL	32.6	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

SAL Flex® Reagent Cartridge causes serious eye irritation. May cause an allergic skin reaction.
Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing should not be allowed out of the workplace. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Salicylate Calibrator may cause an allergic skin reaction. IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Critical Values (Lab policy)

18. Current Allowable Total Error Specifications
    at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert SAL Flex® Reagent Cartridge DF20

17. REFERENCES

1. Package Insert, SAL Flex® Reagent Cartridge DF20, Siemens Healthcare Diagnostics Inc., 01/30/2015.
2. Package Insert, Salicylate Calibrator DC38, Siemens Healthcare Diagnostics Inc., 3/2015.
3. Package Insert, Liquichek Immunoassay Plus Controls, Bio-Rad Laboratories, 4/2015.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP C077.001		
000	04/25/12	6.7	Add use of TEA for lot to lot runs	L Barrett	J Buss
000	04/25/12	10.4	CRR edited to correct range.	J Buss	Dr Cacciabeve
000	04/25/12	10.5	Remove code QNSR	L Barrett	J Buss
000	04/25/12	15	Update to standard wording	L Barrett	J Buss
001	11/9/12		Update owner	L Barrett	R SanLuis
001	11/9/12	1, 7.1	Add analyzer name	L Barrett	R SanLuis
001	11/9/12	5.3	Refer to PI for calibration levels	A Chini	R SanLuis
001	11/9/12	8, 16	Update SOP titles	L Barrett	R SanLuis
001	11/9/12	8.2	Remove Lynx, specify Xpand process	A Chini	R SanLuis
001	11/9/12	10.4	Revise CRR lower limit	A Chini	R SanLuis
001	11/9/12	10.5	Revise Repeat Criteria, remove manual dilution	A Chini	R SanLuis
001	11/9/12	14.1	Revise AMR lower limit	A Chini	R SanLuis
002	01/26/15	3.2	Remove spun barrier tube	L Barrett	R SanLuis
002	01/26/15	5.4	Remove outdated steps, reference calibration SOP	H Genser	R SanLuis
002	01/26/15	10.5	Remove erroneous instruction	H Genser	R SanLuis
002	01/26/15	12	Add interpret with patient history	H Genser	R SanLuis
002	01/26/15	Footer	version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
3	3/24/17	3.2	Add SST	L Barrett	R SanLuis
3	3/24/17	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
3	3/24/17	6.4, 6.6	Replace LIS with Unity Real Time	L Barrett	R SanLuis
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3	3/24/17	15	Update to new standard wording, update reagent warning & move from section 4	L Barrett	R SanLuis
3	3/24/17	17	Update package insert dates	L Barrett	R SanLuis

19. ADDENDA

None