Salicylate using Abbott Architect ci4100

SOP Number:	HSL-0300.01	**Creation Date:**	8/24/18
Department:	STAT Lab	**Effective Date:**	8/24/18
Policy, Procedure, or Both:	Procedure	**Revision Date(s):**	
Author:	Kim Clark, MT (ASCP)	**Version:**	1

Applicable Standards	
Standard	Organization
COM.10000	CAP
Related Documents	

Version History		
Version	Effective Date	Retired Date
1	08/24/2018	

Review History (Up to the Last 15 Occurrences)			
Date	Version	Revision Type	Review By
8/22/18	1	**New Policy/Procedure**	System Laboratory Medical Director, Joe A. Lewis. M.D.. F.C.A.P.

Distribution
Christus Spohn Shoreline STAT Lab

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Salicylate Using Abbott Architect ci4100
Proc. #: HSL0300.01

Intended Use
The MULTIGENT Salicylate assay is intended for the quantitative determination of salicylate in human serum or plasma on the ARCHITECT *c* Systems.

Clinical Significance
Salicylate is a common drug used for its analgesic and anti-inflammatory properties. Its accessibility leads to its implication in a large number of accidental ingestions by children and it is a common choice among adults and adolescents for attempted suicidal poisoning.
Salicylate overdose results in disturbances of the central nervous system and the gastrointestinal tract, as well as encephalopathy and renal failure. Salicylate intoxication represents an acute medical emergency. Rapid quantitation of the drug is necessary for effective patient management.
This enzymatic Salicylate assay provides a rapid, specific, and simplified method for salicylate determination. It is based on the action of salicylate hydroxylase on salicylate and NADH which results in a decrease in absorbance proportional to the amount of salicylate present.

Principle

Salicylate hydroxylase catalyzes the conversion of salicylate and NADH to catechol and NAD+ in the presence of oxygen. The resulting decrease in absorbance at 340 nm, due to the conversion of NADH to NAD+, is directly proportional to the concentration of salicylate in the sample.

Methodology: Enzymatic/Colorimetric

Specimen Collection and Handling

Serum: Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation.
Centrifuge according to tube manufacturer's instructions to ensure proper separation of serum from blood cells.
• **Plasma:** Use plasma collected by standard venipuncture techniques into glass or plastic tubes. Acceptable anticoagulants are lithium heparin (with or without gel barrier), EDTA, and sodium heparin.
Ensure centrifugation is adequate to remove platelets. Centrifuge according to tube manufacturer's instructions to ensure proper separation of plasma from blood cells.
Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.

Specimen Storage
Separated samples may be stored for up to 14 days at 4 to 8°C prior to being tested. If testing will be delayed more than 14 days, separated samples may be stored frozen at -20°C for up to 6 months.

NOTE: Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

Materials and Equipment Required

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Salicylate Using Abbott Architect ci4100
Proc. #: HSL0300.01

TEST INSTRUMENT: Abbott ARCHITECT System

MATERIALS PROVIDED

3K01-20 MULTIGENT Salicylate

MATERIALS REQUIRED BUT NOT PROVIDED

- 3K01-01 MULTIGENT Salicylate Calibrator
- Saline (0.85% to 0.90% NaCl) for specimens that require dilution

Reagent Handling and Storage:

***CAUTION*:**

1. For in vitro diagnostic use.
2. Do not use components beyond the expiration date.
3. Do not mix materials from different kit lot numbers.

• Do not mix fresh reagents with in-use reagents.
CAUTION: This product requires the handling of human specimens.
It is recommended that all human sourced materials be considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
• The following warning and precaution apply to R2: Contains sodium azide. EUH032 Contact with acids liberates very toxic gas.
These materials and their containers must be disposed of in a safe way.

Reagent Handling
- R1 Ready for use. Before use invert several times, avoiding the formation of bubbles.
- R2 Ready for use. Before use invert several times, avoiding the formation of bubbles.
- Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate.

To minimize volume depletion, do not use a transfer pipette to remove the bubbles.
CAUTION: Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration that could impact results.
- Do not mix materials from different kit lot numbers.
- When either the R1 or R2 reagent cartridge becomes empty, replace both cartridges.

Reagent Storage
- Reagent stability is 43 days if the reagent is uncapped and onboard.
- Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent Preparation:

3K01-20 MULTIGENT Salicylate is supplied as a liquid, ready-to-use, two-reagent kit which contains: **R1 & R2**

Reactive Ingredients		Concentration
R1	NADH	1.2 mmol/L
R2	Salicylate hydroxylase	≥ 770 U/L

Inactive Ingredients: R1 contains a buffer. R2 contains sodium azide 0.1%, bovine serum albumin, a buffer, and a stabilizer.

Calibrator: 3K01-01 MULTIGENT Salicylate Calibrator

Calibration

Frequency:
Calibration is stable for 43 days (1032 hours) for any one lot. Calibration is required with each change in reagent lot number.

A new calibration is required:

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Calibrator Required: 3K01-01 MULTIGENT Salicylate Calibrator

Reagents:
3K01-01 MULTIGENT Salicylate Calibrator, 2 x 5 mL MULTIGENT Salicylate Calibrator consists of:
- Salicylate 20.7 mg/dL (1.50 mmol/L)
- Preservative

Calibrator Preparation:
The calibrator is supplied in liquid form and is ready to use. Invert bottle several times before use, avoiding the formation of foam.

Calibration Procedure:
Before performing the assay, refer to the ASSAY PARAMETERS, which are included in the MULTIGENT Salicylate reagent package insert. For further instructions, refer to the CALIBRATION and QUALITY CONTROL sections of the MULTIGENT Salicylate reagent package insert.

1. Verify that the CAL values are correct in the instrument parameter files.
2. Mix bottles several times by gentle inversion.
3. Open the bottle, place an appropriate amount of the calibrator in a separate sample cup, and place in the assigned position.
4. Calibrate as outlined in *Section 6* of the **ARCHITECT System Operations Manual**.
5. Follow the established quality control procedures for your laboratory and the instructions found in *Section 5* of the **ARCHITECT System Operations Manual**.
6. Cap bottle tightly and return to refrigerated storage after use.
7. Verify control results are within acceptable limits before reporting patient results.

Troubleshooting and Overall Acceptance Criteria Failure

See ARCHITECT Operations Manual for further calibration troubleshooting.

Quality Control:

Controls are tested according to each location/site Quality Control Procedure.

- If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Procedure

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

Calculations

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

Reporting Results

The result unit for the MULTIGENT Salicylate assay can be reported as mg/dL or mmol/L..

Specific Performance Characteristics

Reference Ranges

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Serum/Plasma (Abbott Package Insert)

Salicylate blood levels do not correlate well with degree of toxicity in chronic salicylism. Other drugs may displace protein-bound salicylate leading to increased toxicity. Salicylate doses in patients on chronic therapy may approach toxic levels. Salicylate levels in such patients are best performed just prior to the next dose.

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Salicylate Using Abbott Architect ci4100
Proc. #: HSL0300.01

Reference Interval

	Conventional Units (mg/dL)	SI Units (mmol/L)
Therapeutic	15 to 30	1.09 to 2.17
Toxic Levels	> 30	> 2.17
Lethal	> 70	> 5.07

Serum/Plasma (this facility)

Critical Values : Refer to Critical Value Policy

Performance Characteristics

Reportable Range
The reportable range of the assay is 5.0 to 100.0 mg/dL (0.36 to 7.24 mmol/L).

Limit of Quantitation (LOQ)
The LOQ for the MULTIGENT Salicylate assay was calculated to be 5.0 mg/dL (0.36 mmol/L).

Dilution:
Specimens with salicylate values exceeding 100.0 mg/dL (7.24 mmol/L) are flagged and may be diluted by following the Automated Dilution Protocol.

Automated Dilution Protocol
If using the Automated Dilution Protocol, **the system performs a 1:5 dilution** of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

Precision:
Acceptance criteria:
≤ 5.0% total CV at ≥ 15.0 mg/dL or ≤ 1.5 SD from ≥ 3.0 mg/dL to < 15.0 mg/dL

Sample		Level 1	Level 2	Level 3
N		80	80	80
Mean (mg/dL)		9.2	18.8	45.5
Within Run	SD	0.536	0.363	0.456
	%CV	5.8	1.9	1.0
Between Run	SD	0.000	0.000	0.113
	%CV	0.0	0.0	0.2
Between Day	SD	0.216	0.292	0.298
	%CV	2.3	1.6	0.7
Total	SD	0.578	0.466	0.556
	%CV	6.3	2.5	1.2

TECHNICAL PROCEDURE MANUAL
CHRISTUS Spohn Hospital Corpus Christi Shoreline STAT Lab
Salicylate Using Abbott Architect ci4100
Proc. #: HSL0300.01

Limitations of Procedure

Configure Salicylate SmartWash parameters in the following assay files on the ARCHITECT *c* System.

Configure	REF	COMPONENT	REAGENT / ASSAY	WASH	VOL	REP
Amik	6L35	R1 and R2	SALIM	AcidW	345	1

Interfering Substances

The following compounds, when tested with the MULTIGENT Salicylate assay at the concentrations indicated, resulted in less than 7.5% or 1.5 mg/dL error in detecting salicylate. Interference effects were assessed by Dose Response method. Representative results are shown below.

Interfering Substance	Interferent Concentration	Salicylate (mg/dL)	Recovery %
Bilirubin	24 mg/dL	29.5	93.4
Hemoglobin	600 mg/dL	29.3	93.3
Triglyceride	872 mg/dL	33.8	96.5

Specificity

Cross-Reactivity

You and Bittikofer tested 61 commonly administered drugs for potential interference in an evaluation of another assay using the same enzymatic methodology. None of the evaluated drugs interfered with the measurement of salicylate.

References:

1. ABBOTT ARCHITECT Salicylate package insert
   Abbott Laboratories
   Diagnostics Division
   Abbott Park, IL 60064
   Aug 2015 306748/R08
2. ABBOTT ARCHITECT Salicylate Calibrator package insert
   Abbott Laboratories
   Diagnostics Division
   Abbott Park, IL 60064
3. Abbott ARCHITECT Operator's Guide

Effective Date for this procedure:

Revised by: Rebecca Olog, MT (ASCP)
Revised by: Kimberlee J. Clark, MT(ASP)