DXC (SALY) SALICYLATE

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PURPOSE

To provide instructions for the quantitative determination of salicylate on the DXC 600/800.

PRINCIPLE

SALY reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Salicylate Calibrator, is intended for quantitative determination of Salicylate concentration in human serum or plasma.

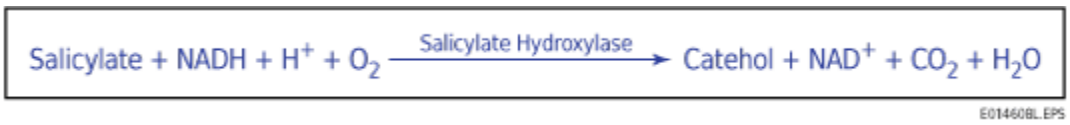
BACKGROUND

Clinical Significance

Salicylates are a class of analgesic, antipyretic, and anti-inflammatory drugs that includes aspirin. Salicylate overdose results in disturbances of the central nervous system and the gastrointestinal tract as well as encephalopathy and renal failure.

Methodology

SALY reagent is used to measure SALY concentration by a timed-endpoint method. In the reaction, salicylate hydroxylase catalyzes the conversion of salicylate and NADH to catechol and NAD in the presence of oxygen. The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 56 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of SALY in the sample and is used by the System to calculate and express the SALY concentration.



RELATED DOCUMENTS

R-PO-CH-0810	Quality Control Program General Laboratory
R-PO-CH-0809	Quality Control Westgard Rules Statistics
R-PR-AD-0540	Specimen Rejection/Cancellation Protocol
J-F-CH-0820	DXC 800 Controls
M-F-CH-0820	Chemistry Controls
J-F-CH-0826	DXC 800 Calibrators
M-F-CH-0826	Chemistry Calibrators
M-F-CH-1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH-1940	DXC 800 (AMR) Analytical Measurement Range

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SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma is the specimen of choice. Acceptable anticoagulants are listed in PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma/Serum (Lithium heparin is preferred. Serum, sodium heparin and EDTA are acceptable)	0.5mL	• Separate serum from cells within 2 hours • Room Temp 8 hours • Refrigerated 48 hours • After 48 hours, separate and freeze at -15 to -20**°C**

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two SALY Reagent Cartridges (2 x 45 tests)
One bottle Salicylate Calibrator (liquid), 5 mL

Volume per Test	
Sample Volume	4 µL
Total Reagent Volume	225 µL
Cartridge Volumes	A – – B 150 µL C 75 µL

Reactive Ingredients	
Salicylate NADH Reagent: NADH (1.2 mmol/L)	9.3 mL
Salicylate Enzyme Reagent: Salicylate Hydroxylase (> 770 U/L)	4.6 mL
Calibrator Constituent: Sodium Salicylate [20.7 mg/dL (1.5 mmol/L)]	5 mL

Also non-reactive chemicals necessary for optimal system performance.

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Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

SALY reagent, when stored unopened at +2°C to +8°C, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 60 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Salicylate Calibrator (included in reagent kit)
Saline (low calibrator)

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems Salicylate Calibrator is stable until the expiration date printed on the label if stored capped in the original container at +2°C to +8°C. DO NOT FREEZE.

Calibration Information

1. The system must have a valid calibration curve in memory before control or patient samples can be run.

2. Under typical operating conditions the SALY reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.
4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Calibrator Assigned Values

The assigned value for Salicylate Calibrator was achieved based upon the addition of sodium salicylate to achieve a target concentration of 20.7 mg/dL (1.5 mmol/L). The calibrator values are specific to the assay methodologies of the SYNCHRON Systems. Values by other methodologies may be different.

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Calibrator Summary

SYNCHRON® Systems Salicylate Calibrator is prepared in an aqueous solution by weighing the appropriate amount of sodium salicylate to achieve 20.7 mg/dL (1.5 mmol/L). The calibrator is designed for generation of a two-point calibration curve using saline as a low-level calibrator.

Calibrator Limitations

The SYNCHRON® Systems Salicylate Calibrator should be used only in conjunction with SYNCHRON Systems and SYNCHRON SALY reagents.

Traceability

Salicylate measurand (analyte) in this calibrator is traceable to the manual Trinder method. The traceability process is based on prEN ISO 17511.
The values were verified using representative samples from this lot of calibrator and are specific to the assay methodologies of the SYNCHRON® System(s). Values determined by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.
2. After reagent load is completed, calibration may be required.
3. Program controls for analysis.
4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with a minimum of 47 paired serum and plasma samples. Values of serum (X) ranging from 5 mg/dL to 95 mg/dL were compared with the values of plasma (Y) yielding the following results.

Anticoagulant	Level of Anticoagulant Tested
Lithium Heparin	14 Units/mL
Sodium Heparin	14 Units/mL
EDTA	1.5 mg/mL

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PERFORMANCE CHARACTERISTICS

Reference Range

Reference Range (Therapeutic)	Critical (Toxic)
2 -29 mg/dL	>30 mg/dL

For Critical Value reporting protocol, refer to FHS Critical Policy

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical range:

Sample Type	Conventional Units
Serum or Plasma	4 – 100 mg/dL

Samples with concentrations outside of the analytical range will be reported as "<4.0 mg/dL" ("<0.3 mmol/L"). Samples reported out as greater than the analytical range may be confirmed by diluting with saline and reanalyzing. The appropriate dilution factor should be applied to the reported result.

Reporting results outside of analytical range

Lower limit of detection	4 mg/dL	Results below 4; report as <4 mg/dL
Upper limit of linearity	100 mg/dL	Result >100 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >200 are reported as >200 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for SALY determination is 4 mg/dL (0.3 mmol/L).

LIMITATIONS

None identified.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC hemolysate	300 mg/dL INDEX OF 8	NSI
Bilirubin	Porcine	12 mg/dL INDEX OF 8	NSI
Lipemia	Human	200 mg/dL INDEX of 5 Airfuge recommended	No Significant Interference within ±3.0 mg/dL or 10%

2. Refer to References (8,9,10) for other interferences caused by drugs, disease and preanalytical variables.

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ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
4/30/15-Updated critical value to >30.			
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