Sample Indices - Serum, Plasma
Beckman UniCel DxC Systems

Technical Procedure 3035

Prepared By	Date Adopted	Supersedes Procedure #
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For *In Vitro* Diagnostic Use Only

Principle

Intended Use

The serum index function, in conjunction with Synchron Systems DIL1, is intended for the semi-quantitative determination of sample condition in terms of icterus (bilirubin), hemolysis (hemoglobin), and lipemia in serum or plasma on Synchron Systems. Serum index is not intended to be used to diagnose a patient, but to indicate the condition of a test sample.

Clinical Significance

Bilirubin, hemoglobin, and/or lipemia may act as an interferent depending upon an analyte being measured. Refer to individual chemistry procedures for more information on interferences affecting specific analytes.

Methodology

DIL1 buffer is used to measure the serum indices by a spectrophotometric method.

A precise volume of sample (14 microliters) is injected in a cuvette containing 200 microliters of buffer. The ratio used is one part sample to 14.3 parts reagent. The system monitors the absorbance at 340, 410, 470, 600, and 670 nanometers and solves a set of equations to determine the response for each index. The response is directly proportional to the sample condition in terms of icterus (bilirubin), hemolysis (hemoglobin), and lipemia.

Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens.

Tubes of blood should be kept closed at all times in a vertical, stopper-up position. Serum or plasma should be physically separated from contact with cells as soon as possible. A maximum limit of two hours from the time of collection is recommended.

Separated serum or plasma should not remain at +15°C to +30°C 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.

Refer to individual chemistry procedures for information on specimen requirements affecting specific analytes.

Treated samples (e.g., after reagent treatment and centrifugation or column preparation) do not represent the original specimen condition for serum index.

Reagents

Reagent Required

Synchron Systems DIL1 (Diluent 1), 2 x 500 Test Cartridge **Kit Reorder #467826**

Contents

Each kit contains two cartridges of DIL 1

Note: The number of tests available varies depending on the number of urine samples, serum index and immunoprotein assays in proportion to the total samples processed.

Volumes per Test

Sample Volume	14 µL
Reagent Volume	200 µL

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Reagent Preparation

No preparation is required. **Do not mix.**

Date and initial cartridge, and document in reagent log before loading each new cartridge.

Acceptable Reagent Performance

The acceptability of this reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria, as defined in the *Quality Control* section of this procedure.

Reagent Storage and Stability

DIL1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL1 is stable for 60 days on instrument or until the expiration date, if sooner.

Equipment

This test is performed on the Beckman UniCel DxC 800 Systems; Beckman-Coulter, Brea, California. For technical assistance, call the Beckman-Coulter hotline: 1-800-854-3633.

Refer to the Beckman *UniCel DxC 800 systems Reference Manual* for detailed instructions.

System Information

Calibration

Calibration is not required

Testing Procedure

1. If necessary, load the reagent onto the system.
2. The serum index function will be disabled on the DxC800. Sample programming will be performed by Remisol.
3. After loading samples onto the system, follow the protocols for system operation.

Reporting Results

Validated index results:

Slight and moderate hemolysis comments will be sent to the LIS for the listed tests except grossly hemolyzed samples:

Comment	Index & Approximate HGB Range (mg/dL)	Affected Tests
Slight Hemolysis	2 to 3 (~50-150 mg/dL HGB)	ALT, AMM, AMY7, AST, CK, FE, K, LD, TBIL
Moderate Hemolysis	4 to 6 (~150-300 mg/dL HGB)	ALT, AMM, AMY7, AST, CK, FE, K, LD, TBIL, DBIL, GGT, MG, PHOS, URIC, LACT
Gross Hemolysis	7 to 10, DH (>300 mg/dL HGB)	Reject all

Slight, moderate and grossly icteric comments will be sent to the LIS for the listed tests:

Comment	Index & Approximate Bilirubin Range (mg/dL)	Affected Tests
Slightly Icteric	≥ 3 to ≤ 7 (~3-10.5 mg/dL Bilirubin)	LACT, TRIG
Moderately Icteric	≥ 8 to ≤ 18 (~10.5-27.0 mg/dL Bilirubin)	CREA, LACT, TRIG, SALY, URIC
Grossly Icteric	≥ 19 (~>27.0 mg/dL Bilirubin)	CREA, LACT, TRIG, SALY, URIC

The lipemia index was not able to accurately correlate with visual turbidity of samples. All grossly lipemic samples will require ultracentrifugation except for cholesterol and triglyceride testing. QNS samples for ultracentrifugation should be canceled and request for redraw for more sample.is recommended. The absolute minimum volume required for ultracentrifugation is 175 µL of serum or plasma. Depending on the test(s) ordered, more sample may be required. Slight and moderate lipemia may affect the following tests: ALT, AMM, C3, C4, CAR, HPT, IGM, LIP, MG, LD, PAB, SALY, THE, TOB and VPA.

These tests may flag for dilutions when results are suppressed or above AMR. Lipemia comments can then be manually entered into the LIS.

A typical lipemia index chart will have index readings from 0 to 10, visual turbidity level (Beckman Coulter scale) from 0 to 4+ with an Intralipid range from 0 to 400 mg/dL.

Limitations

1. Sulfasalazine interferes with this methodology. Samples containing sulfasalazine should not be used.
2. The integrity of all indices should be verified if any of the indices are suppressed OIR HI.
3. Results for samples containing rare Ig-M immunocomplexes may be suppressed with RX RATE HI and INIT RATE HI messages.
4. Fluorescein interferes with this methodology. Samples containing fluorescein should not be used.

Interferences

Bilirubin Index Interferences

Substance	Source	Level Tested	Observed Effect
Hemoglobin	RBC Hemolysate	500 mg/dL	NSI[a]
Lipemia	Intralipid	400 mg/dL	NSI

[a] NSI = No Significant Interference (within ± 1 unit).

Hemoglobin Index Interferences

Substance	Source	Level Tested	Observed Effect
Bilirubin	Bovine	30 mg/dL	≤ - 2 units
Lipemia	Intralipid	400 mg/dL	NSI[a]

[a] NSI = No Significant Interference (within ± 1 unit).

Lipemia Index Interferences

Substance	Source	Level Tested	Observed Effect
Bilirubin	Human	30 mg/dL	NSI[a]
Hemoglobin	RBC Hemolysate	500 mg/dL	NSI

[a] NSI = No Significant Interference (within ± 1 unit).

Samples at a Lipemia Index Level of 9 and above should be ultracentrifuged and the analysis performed on the infranate. The high percentage of inert lipid particles may cause inaccurate volumetric aspiration and delivery.

Additional Information

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

Further Reading

1. Tietz, N. W., "Specimen Collection and Processing; Sources of Biological Variation," Textbook of Clinical Chemistry, 2nd Edition, W. B. Saunders, Philadelphia, PA (1994).
2. National Committee for Clinical Laboratory Standards, Procedures for the Handling and Processing of Blood Specimens, Approved Guideline, NCCLS publication H18-A, Villanova, PA (1990).
3. Tietz, N. W., "Clinical Guide to Laboratory Tests," 3rd Edition, W. B. Saunders, Philadelphia, PA (1995).
4. Henry, J. B., "Clinical Diagnosis and Management by Laboratory Methods," 21st Edition, W. B. Saunders, Philadelphia, PA (2007).
5. Friedman, R. B. and Young, D. S., Effects of Disease on Clinical Laboratory Tests, 4th Edition, AACC Press, Washington, D.C. (2001).
6. Young, D. S., Effects of Preanalytical Variables on Clinical Laboratory Tests, 2nd Edition, AACC Press, Washington, D.C. (1997).
7. Serum Index, Chemistry Reference Manual, Synchron Systems A45586 AH, (April 2013), pp 47-53.