RESULTS

Sorbitol Dehydrogenase activity is reported as U/L.

REPORTABLE RANGE

The linearity of the procedure described is 50.0 U/L. The limit of quantitation for the procedure described is 1.0 U/L. This data results in a reportable range of 1.0 – 50.0 U/L.

PRECISION STUDIES

Precision data was collected on two concentrations of control sera in duplicate in each of forty runs.

Concentration U/L	Total SD U/L	Total CV%	Concentration U/L	Within Run SD (U/L)	Within Run CV%
10.9	0.36	3.3	10.9	0.14	1.3
34.6	0.85	2.5	34.6	0.39	1.1

ACCURACY

The performance of this method (y) was compared with the performance of another commercially available method (x) on a Roche/Hitachi® 717 automated analyzer. One hundred veterinary patient serum samples ranging from 1.0 U/L to 36 U/L gave a correlation coefficient of 0.9993. Linear regression analysis gave the following equation:

This method = 1.23 (reference method) - 0.3 U/L.

The information presented above is based on results from SEKISUI Diagnostics studies and is current at the date of publication.

REFERENCES

1. Dooley, J.F., Turnquist, L.J., and Racich, L., Kinetic Determination of Serum Sorbitol Dehydrogenase Activity with a Centrifugal Analyzer. Clin. Chem. 25/12, 2026-2029 (1979).
2. Horney, B.S., Honor, D.J., MacKenzie, A., Burton, S., Stability of Sorbitol Dehydrogenase Activity in Bovine and Equine Sera. Vet. Clin. Pathol. 22(1), 5-9 (1993).
3. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, A.A.C.C. Press, 3rd ed., Washington (1990).
4. Merck Veterinary Manual Serum Biochemical Reference Ranges, Merck & Co. Inc. (2008).

TRADEMARKS

SYMBOLS		
LOT Batch Code	Manufacturer	Use by date
REF Catalog number	Consult instructions for use	Temperature limit
Environment hazard	Health hazard	Toxic

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SEKURE® CHEMISTRY

SORBITOL DEHYDROGENASE ASSAY

CATALOGUE NUMBER: 740-10 **SIZE**: 10 x 1.18 mg + 125 mL + 20 mL

NOTE: Changes are highlighted.

INTENDED USE

For the *in vitro* quantitative measurement of sorbitol dehydrogenase activity in animal serum.
For veterinary use only.

TEST SUMMARY

This enzyme, L-iditol dehydrogenase or sorbitol dehydrogenase (SDH; EC 1.1.1.14) catalyzes the reversible oxidation-reduction reaction between sorbitol and fructose.

Sorbitol dehydrogenase has been identified in several human and animal tissues. It is located primarily in the cytoplasm and mitochondria of the liver, kidney and seminal vesicles. SDH activity in serum is usually low but increases during acute episodes of liver damage.(1) Measurement of SDH is a specific indicator of liver cell damage and parenchymal hepatic diseases. SDH activity rises rapidly in liver damage and decreases very shortly after peaking.

This method of SDH activity measurement is modelled on the oxidation-reduction reaction between sorbitol and fructose. The method has been optimized for use on a variety of automated clinical chemistry analyzers.

TEST PRINCIPLE

$$\text{D-Fructose} + \text{NADH} \underset{}{\overset{\text{SDH}}{\rightleftharpoons}} \text{D-Sorbitol} + \text{NAD}$$

The rate of oxidation of NADH is directly proportional to the rate of conversion of D-Fructose to D-Sorbitol. The rate of decrease in absorbance at 340 nm allows measurement of SDH activity.

REAGENTS

NADH Reagent (R1): Nicotinamide adenine dinucleotide, reduced form, disodium salt, (740-10: 1.18 mg/vial).

NADH Reagent Buffer (R1a): A solution containing buffer (pH 7.5) and a preservative.

Fructose Reagent (R2): A solution containing 72% β-D(-) Fructose.

WARNINGS & PRECAUTIONS FOR USE

NADH Reagent

Danger

Contains: sodium azide (CAS No) 26628-22-8

Hazard statements
H301+H311 - Toxic if swallowed or in contact with skin
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - If swallowed: Immediately call a poison center or doctor.
P302+P352 - If on skin: Wash with plenty of water.
P312 - Call a poison center or doctor if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P322 - Specific treatment (see supplemental first aid instruction on this label)
P330 - Rinse mouth.
P361+P364 - Take off immediately all contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

NADH Reagent Buffer (R1a)

Warning

Contains: trichloromethane, chloroform (CAS No) 67-66-3, Hydrochloric acid (CAS No) 7647-01-0

Hazard statement
H351 - Suspected of causing cancer
H361 - Suspected of damaging fertility or the unborn child

Precautionary statement
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

See Material Safety Data Sheet for additional information.

REAGENT PREPARATION, STORAGE & STABILITY

Working NADH Reagent (R1): Add the required volume of NADH Reagent (R1a) buffer as specified on the instrument application. Mix gently, wait two minutes, re-mix.

Fructose Reagent (R2): Reagent is ready for use; however, consult instrument specific applications for required preparations.

Supplied reagents stable at 2-8°C until expiry date when stored unreconstituted in the dark.

Prepared NADH reagent stable at 2-8°C for 24 hours when stored closed.

Prepared Fructose reagent is stable in the absence of microbial growth.

Stability claims are based on real time studies.

REAGENT DETERIORATION

The reagent solutions should be clear. Turbidity would indicate deterioration.

DISPOSAL

Reagents must be disposed of in accordance with all Federal, Provincial, State and local regulations. Avoid release to the environment. Refer to Material Safety Data Sheet.

SPECIMEN

Fresh, clear, unhemolysed serum. Serum should be separated from cells and analyzed as soon as possible.

SAMPLE STORAGE

Temperature	Bovine	Equine
Room Temperature (21°C)	5 hours	5 hours
Refrigerated (0-5°C)	24 hours	5 hours
Frozen (-30°C)	72 hours	48 hours

Frozen equine and bovine serum lose as much as 25% of their SDH activity in a week.[2]

ANALYTICAL SPECIFICITY

Cross contamination studies have not been performed on automated instruments. Certain reagent/ instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Interferences from icterus, lipemia and hemolysis were evaluated for this sorbitol dehydrogenase method on a Roche/Hitachi® 717 analyzer using a significance criterion of >10% variance from control.

Hemoglobin produces significant interference with this method[1]; hemolysed samples are to be avoided.

Substance Tested	Concentration of Analyte	Concentration of Interferent Where Interference is Insignificant	
Unconjugated Bilirubin	8.4 U/L	24 mg/dL	410 µmol/L
	22.3 U/L	36 mg/dL	616 µmol/L
Conjugated Bilirubin	8.7 U/L	3 mg/dL	36 µmol/L
	22.8 U/L	12 mg/dL	142 µmol/L
Intralipid	8.3 U/L	200 mg/dL	600 mg/dL (6.8 mmol/L) Simulated Triglycerides
	22.5 U/L	400 mg/dL	1200 mg/dL (13.5 mmol/L) Simulated Triglycerides

Samples containing the following should not be used: Sulfasalazine, and Temozolomide.
The information presented above is based on results from SEKISUI Diagnostics studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory test may be found by consulting Young, D.S.[3]

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

SEKISUI Diagnostics' Sorbitol Dehydrogenase reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED

1) Automated analyzer capable of accurately measuring absorbance at appropriate wavelengths as per instrument application.
2) Quality Control materials.
3) Calibration Material (if required).

TEST CONDITION

For data presented in this insert, studies using this reagent were performed on an automated analyzer using a rate test mode, with a sample to reagent ratio of 1:11.5 and wavelength readings of (primary/secondary) 340/415. For assistance with applications on automated analyzers within Canada and the U.S., please contact SEKISUI Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used. Consult the SEKISUI Diagnostic's application for the calibration factor, if applicable, of your specific analyzer.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required in accordance with local, state and federal guidelines. The results should fall within the acceptable range as established by the laboratory.

CALCULATIONS

The analyzer automatically calculates the sorbitol dehydrogenase concentration of each sample.

TEST LIMITATIONS

A sample with a sorbitol dehydrogenase value exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS[4]

6.1 - 18 U/L (cow)	3.1 - 7.6 U/L (dog)	9.3 - 21 U/L (goat)
1.2 - 8.5 U/L (horse)	2.4 - 6.1 U/L (cat)	
0.5 - 4.9 U/L (pig)	3.5 - 21 U/L (sheep)	

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

PERFORMANCE CHARACTERISTICS

Data presented was collected on a Roche/Hitachi® 717 analyzer unless otherwise stated.