

PRECISION STUDIES

Total 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%
10.3	0.34	3.3	10.4	0.12	1.2
32.7	1.03	3.2	33.1	0.32	1.0

Within run precision data was collected on two concentrations of control sera each run 20 times in a single assay.

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. Twenty-five veterinary patient serum samples ranging from 1.3 U/L to 10.2 U/L gave a correlation coefficient of 0.9874. Linear regression analysis gave the following equation:

$$\text{This method} = 1.43 (\text{reference method}) - 0.9 \text{ U/L.}$$









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., Clin. Chem. 25/12, 2026-2029 (1979).
2. Secchi, G.C., Ghidoni, A., Enzymol Biol. Clin., 2:99, 1962.
3. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, A.A.C.C. Press, 3rd ed., Washington (1990).
4. Merck Veterinary Manual, 8th ed., 1998.

TRADEMARKS

All trademarks, brands, product names and trade names are the property of their respective companies.

Definitions for Symbols	
 Batch code	 Use by YYYY-MM-DD or YYYY-MM
 Manufacturer	 Catalog number
 Consult instructions for use	 Temperature limitation
 In vitro diagnostic medical device	 Dangerous for the Environment

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SORBITOL DEHYDROGENASE ASSAY

CATALOGUE NUMBER: 740-25
740-10 **SIZE:** 20 x 0.2 mg + 50 mL + 10 mL
10 x 1.18 mg + 125 mL + 20 mL

INTENDED USE

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

TEST SUMMARY

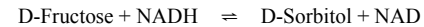
This enzyme, L-idoitol dehydrogenase or sorbitol dehydrogenase (SDH; EC 1.1.1.14) catalyzes the reversible oxidation-reduction reaction between sorbitol and fructose.

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

SDH



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, (740-25: 0.2 mg/vial; 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

Product contains sodium azide.

R51/53: Toxic to aquatic organisms; may cause long term adverse effects in aquatic environment.

S35: This material and its container must be disposed of in a safe way.

S61: Avoid release to the environment. Refer to special instructions/safety data sheets.

S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible)

R25: Toxic if swallowed

R22: Contact with acids liberate toxic gas.

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 unconstituted 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

Serum SDH is reported to be very labile and activity drops approximately 1% per hour at room temperature and approximately 0.5% per hour when frozen.⁽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; hemolysed samples are to be avoided.

Concentration of Analyte	Substance Tested	Concentration of Interferent Where Interference is Insignificant	
8.3 U/L	Unconjugated Bilirubin	16 mg/dL	274 µmol/L
8.3 U/L	Conjugated Bilirubin	16 mg/dL	274 µmol/L
8.2 U/L	Intralipid	100 mg/dL	300 mg/dL (3.4 mmol/L) Simulated Triglycerides

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 - 18.4 U/L (cow)	3.1 - 7.6 U/L (dog)	9.3 - 20.7 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 - 20.6 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.

RESULTS

Sorbitol Dehydrogenase activity is reported as U/L.

REPORTABLE RANGE

The linearity of the procedure described is 50 U/L. The lower limit of detection of the procedure described is 0.5 U/L. This data results in a reportable range of 0.5-50 U/L.