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.

PRECISION STUDIES
Total precision data was collected on two concentrations of control sera in duplicate in each of forty runs.

<table>
<thead>
<tr>
<th>Concentration U/L</th>
<th>Total SD U/L</th>
<th>Total CV%</th>
<th>Concentration U/L</th>
<th>Within Run SD (U/L)</th>
<th>Within Run CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.3</td>
<td>0.34</td>
<td>3.3</td>
<td>10.4</td>
<td>0.12</td>
<td>1.2</td>
</tr>
<tr>
<td>32.7</td>
<td>1.03</td>
<td>3.2</td>
<td>33.1</td>
<td>0.32</td>
<td>1.0</td>
</tr>
</tbody>
</table>

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:

This method = 1.43 (reference method) - 0.9 U/L.

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

REFERENCES

TRADEMARKS
The word SEKURE and the Sekure logo are trademarks of Sekisui Diagnostics, LLC.

All trademarks, brands, product names and trade names are the property of their respective companies.
NADH Reagent Buffer (R1a)

**Warning**

**Hazard statement** Suspected of damaging fertility or the unborn child.

**Precautionary statement**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Call a poison centre/doctor.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

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**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Bovine</th>
<th>Equine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temperature (21°C)</td>
<td>5 hours</td>
<td>5 hours</td>
</tr>
<tr>
<td>Refrigerated (0-5°C)</td>
<td>24 hours</td>
<td>5 hours</td>
</tr>
<tr>
<td>Frozen (-30°C)</td>
<td>72 hours</td>
<td>48 hours</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Concentration of Analyte</th>
<th>Substance Tested</th>
<th>Concentration of Interferent Where Interference is Insignificant</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.3 U/L</td>
<td>Unconjugated Bilirubin</td>
<td>16 mg/dL</td>
</tr>
<tr>
<td>8.3 U/L</td>
<td>Conjugated Bilirubin</td>
<td>16 mg/dL</td>
</tr>
<tr>
<td>8.2 U/L</td>
<td>Intralipid</td>
<td>100 mg/dL</td>
</tr>
</tbody>
</table>

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

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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.