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.

<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>10.9</td>
<td>0.36</td>
<td>3.3</td>
<td>10.9</td>
<td>0.14</td>
<td>1.3</td>
</tr>
<tr>
<td>34.6</td>
<td>0.85</td>
<td>2.5</td>
<td>34.6</td>
<td>0.39</td>
<td>1.1</td>
</tr>
</tbody>
</table>

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

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.

Definitions for Symbols

<table>
<thead>
<tr>
<th>LOT</th>
<th>Batch code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Catalog number</td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>IVD</td>
<td>in vitro diagnostic medical device</td>
</tr>
</tbody>
</table>

IN74025-14
August 9, 2018
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 (-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.

### 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.

### 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

<table>
<thead>
<tr>
<th>Animal</th>
<th>Reference Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cow</td>
<td>6.1 - 18 U/L</td>
</tr>
<tr>
<td>Dog</td>
<td>3.1 - 7.6 U/L</td>
</tr>
<tr>
<td>Horse</td>
<td>1.2 - 8.5 U/L</td>
</tr>
<tr>
<td>Cat</td>
<td>2.4 - 6.1 U/L</td>
</tr>
<tr>
<td>Pig</td>
<td>0.5 - 4.9 U/L</td>
</tr>
<tr>
<td>Sheep</td>
<td>3.5 - 21 U/L</td>
</tr>
</tbody>
</table>

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.