THE EDGE Blood Lactate Test Strips are to be used with THE EDGE Blood Lactate Meter.

If the result continues to fall outside of the printed range; contact the authorized

representative found at the end of this insert.

Interference studies were performed with 2 levels of lactate concentrations (15 and 24 mg/dL). Each of these samples was divided into a test pool and a control pool and each potential endogenous and exogenous interfering substance was added to the test pool. Each substance was tested at least 2 concentrations. The following interferents may affect test results. If you are taking the drugs listed in the table below, you must NOT use THE EDGE Blood Lactate Monitoring System to test your blood lactate levels.

If your readings are above or below your prescribed range of expected blood lactate

values, repeat the test. If you have symptoms that do not match your results or if your results continue to fall outside the expected blood lactate values, please do not alter your treatment on the basis of test results without previously consulting your doctor or healthcare professional

3 lots of THE EDGE Blood Lactate Test Strips were used for within-run repeatability study. Venous blood in heparin-tubes with 5 levels of lactate was used for testing.

Blood lactate readings were recorded for 1 day resulting in 300 data points for each

concentration; as shown in the following tables:

3 lots of THE EDGE Blood Lactate Test Strip were used for intermediate precision study. 3 levels of control materials were prepared for lactate test and measured once per day for 10 days with multiple users. The operators are different every other day. 300 data points were obtained for each level, as shown in the following table:

Traceability

The system is calibrated using reference plasma values determined with a AU480 chemistry analyzer. The AU480 chemistry analyzer is calibrated using a series of standards traceable to Gravimetric Standard.

|  |
| --- |
| Bilirubin, conjugated |
| Dopamine |
| Hemoglobin |
| Cholesterol |
| Triglyceride |

The lactate concentration was calibrated by AU480 chemistry analyzer and is traceable to Gravimetric Standard.