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Re: tCO₂ Testing Program - Maine Harness Racing Commission

Background

In May of 2010, the Maine Harness Racing Commission (MHRC) adopted a new instrument to conduct the testing for total carbon dioxide in blood samples from horses. The older equipment a Beckman-Coulter instrument was replaced with a Nova-4 device. The Nova-4 was set up at the MHRC facility and the testing is conducted by an assigned staff member. A number of rule violations (Maine Rules 01-017 Ch. 17) have been challenged and the reliability of some test results is at issue. Testing data from May to December of 2010 has been reviewed with the focus on reliability of the test results and the use of those results to support the violation of the rules.

Summary

The Nova-4 system was put into service at the MHRC facility by a member of the staff with the help of a company representative from the Nova Biomedical Company. The MHRC did not establish a Standard Operating Procedure (SOP) for the tCO₂ testing procedure prior to

embarking on a testing program for horses. Since testing of this nature addresses the enforcement of State rules and can result in penalties under the law the procedure is considered a forensic procedure. The guidelines for forensic determinations have been published by the Society of Forensic Toxicology (SOFT) and are available on line. Linearity was determined one time on May 19, 2010 but the procedure was not done properly. A linearity check should be done out to two decimal places (ie. 28.26) in order to average the five readings and develop a proper value for each point. A zero should also be included which was not done. Linear response samples from more than one vendor should also be run. After repair or change of equipment (ie. new membrane) a linear response protocol must be done.

The daily calibration check using two levels at 12 mmol/L and 23 mmol/L falls outside the critical range of maximum acceptable test levels of 37.0 mmol/L and 39.0 mmol/L. The two calibrators must bracket the levels of interest if the results are to be relied upon. If an expected average level is in the 37 mmol/L range than a 30 mmol/l and 40 mmol/L calibrator must be employed. The 30 and 40 mmol/L calibrators must also have an assayed target value. Calibrators run in triplicate at the beginning and end of the batch analysis would then be averaged to determine what adjustment should be made to the raw data for the unknown samples. The adjusted values for each unknown sample would then be reported. This is not the case in the tests done by the MHRC from May to December of 2010.

Testing data for November 8, 2010 has been summarized in Figure 1 to demonstrate what adjustments must be made for test results.

Opinion

The tests for tCO₂ conducted by the MHRC from May 2010 to December 2010 are not scientifically reliable. The assayed value of the calibrators has not been published. The results have not been adjusted to daily variations in equipment response as shown by variations in detector response. Linear response determinations have not been done after equipment maintenance and changes. Calibrators used were not in the proper range for the measurements being made. As a result of the above the testing results should not be used as evidence in the enforcement of Harness Racing Rules.

Sincerely,

Patrick M. Demers

Forensic Chemist

Figure 1.

The raw data, for November 8, 2010, shows that sample #25738 (bold) would have been in violation of the rule. That same data adjusted for a 10% over reading would show no violation.

Calibrator		mmol/L	mmol/L	time	sample	raw data	adj. data
Target		23.0	12.0	1606	25730	33.2	29.9
Date	Time	Results		1607	25731	34.0	30.6
8-Nov-2010	1538	25.4	13.5	1608	25732	35.2	31.7
8-Nov-2010	1603	25.7	13.5	1609	25733	34.5	31.1
8-Nov-2010	1629	25.3	13.2	1611	25679	34.2	30.8
8-Nov-2010	1651	26.0	13.5	1612	25612	33.1	29.8
				1613	25681	36.8	33.1
				1614	25680	35.0	31.5
Total		102.4	53.7	1615	25738	40.6	36.5
Mean		25.6	13.4	1617	25738	40.3	36.3
Adj Factor		0.90	0.89	1620	25736	35.7	32.1
				1621	25735	34.7	31.2
				1622	25734	31.9	28.7
				1623	25622	38.9	35.0
				1625	25721	38.4	34.6
				1626	25738	40.5	36.5
				1628	25738	40.2	36.2