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Cornell University Animal Health Diagnostic Center

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To: Clients of the Animal Health Diagnostic Center (AHDC)
Subject: Testing Service Update

Please share this information with your practice manager and professional staff

Sample Requirements for Equine Infectious Anemia (EIA) Testing

All test kits that are used for testing of horses for infection by equine infectious anemia (EIA) virus must be approved by the USDA's Center for Veterinary Biologics (CVB). In the licensing process, a manufacturer must submit test performance data to CVB as part of the approval process. Data that is submitted includes the type of samples that were used to achieve the level of test performance reported. This information defines how the test can be used. For example, the test kit information will specify whether for a serological test one can use serum or plasma. If the test kit specifies "serum", then under QA standards, the test is not valid if plasma is used. The definition of what is an "acceptable" sample is a key component of the test kit as approved.

For EIA testing, both AGID and ELISA, acceptable specimen is defined by the kit. For EIA ELISA testing the kit states: **"Specimens may be stored at 2-7C for up to twenty one days. If longer storage is desired, store at -20C (-4F)".** The simple interpretation of this statement is that the specimen must be tested within 21 days of sampling if it is maintained at 2-7C (refrigerated) during this period. This does not mean that samples can be shipped on day 21 and meet the kit requirements. For EIA AGID testing the kit states: **"Specimens may be stored at 2-7C for up to twenty eight days. If longer storage is desired, store at -20C (-4F)".** In the past, many labs have ignored this type of restriction on the acceptability of the specimens. However, all laboratories certified by the USDA to perform EIA testing, public and private, are required to follow kit manufacturer's instructions and the issue of the age of the specimen for EIA testing can no longer be ignored. Laboratories are responsible for enforcing the sample requirements and the failure to adhere to the kit instructions can be the basis for losing their USDA license for performing EIA tests.

"Acceptable" sample requirements have not been strictly defined in the past, but failure to adhere to the specimen requirements in the future may result in test delays as "expired" samples will not be tested. **To insure that testing is not delayed, the best procedure is to remove the serum from the clot tube and freeze the serum.** There is no time limit on testing of frozen serum. Frozen serum should be shipped on ice packs overnight so that the sample arrives frozen. A statement attesting to the proper handling of the samples signed by the submitting veterinarian would also be advisable should the sample thaw during transit. Otherwise the laboratory has no way of knowing if the sample was handled properly when the sampling date exceeds the day limit.

If there are questions as to the acceptability of a specimen, please contact the AHDC **before** submitting the specimen. Unacceptable specimens can not be returned to the submitter. In addition, EIA test paperwork for all New York State horses tested at any laboratory may be reviewed by Ag & Markets staff to determine the time elapsed between when the sample was taken and when it was tested.