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Laboratory Quality Control and Quality Assurance and the Role of Process Behavior Charting

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Diagnostic laboratories provide services that may significantly impact the decisions of a production operation. It is imperative that the diagnostic services provide accurate, consistent results in a timely, cost effective fashion. Accuracy is important to producers due to the impact of the results on health management decisions. As a result, laboratories strive to utilize assays with high specificity. Consistency tracking allows the laboratory manager to understand the normal variation for the assay and what values are outside that normal variation. Consistency measures are tracked within lab as well as used to compare with other laboratories. Response time is critical to a production operation. With acute disease outbreaks, results are needed quickly to make effective decisions. Shorter turn-around times increase the need for an established QA/QC program to be "real-time", with validity controls in place prior to results being reported.

The QA/QC program at the Boehringer Ingelheim Vetmedica, Inc, Health Management Center (BIVI HMC) employs statistical process behavior charting as a tool to monitor various parameters of all assays conducted. Validity measures include tracking the serum control values on all plates as well as plate validity values and inter-well variation of duplicate samples. For several assays there is a bank of internal serum standards that are routinely run each day. The QA process behavior charts are updated daily to track variation and to detect unusual variation and/or any differences between assay lots and reagents. Results from samples sent to outside laboratories for comparison purposes are also charted for the same reasons to ensure consistency and accuracy of the data that is reported to the diagnostic customer. The process behavior charts allow unpredictable results to be easily noticed and alert technicians of potential assay problems. The computer system in place at BIVI HMC automatically produces new charts daily so that unpredictable results can be detected and acted upon before any results are reported.

The following are two examples of how the statistical process behavior charting resulted in early action to process changes. *Example 1:* Signals were detected in the process behavior charts of the PRRS ELISA NHC (normal host cell background wells) values. The values in the NHC wells were producing unusually high S/P ratios for the ELISA. High NHC values can potentially lead to producing false positive results. Based on technician observation and process behavior charting, further investigation into these signals was conducted. It was discovered in the testing process, loose particulate matter from the usage of recycled paper towel product was sticking to the wells during the blotting phase of the assay, which intensified the color reaction. This assignable cause lead to abnormally high NHC values that were being tracked. Although, because this was a random process, the antigen wells could also have been affected. As a result, the paper towels were changed to a non-recycled product, and the problem has resolved. *Example 2:* For the IDEXX PRRS ELISA, there is a validity measure provided by the manufacturer to serve as a check that the test performed correctly. The validity calculation utilizes the positive and negative antigen wells. The NHC wells are not part of the calculation. However, the S/P ratio calculation, which is the reported format for results, considers both the sample antigen and NHC wells, and the positive antigen and NHC wells. Given this, a plate that has an unusually high value in the positive control NHC well that is not readily visible, and that generates a validity measure that is acceptable, will generate artificially high S/P ratios resulting in some false positive results. This phenomenon has occurred approximately five times in a 27 month period in our lab. The assignable cause has not yet been clearly identified, however, it is clearly noticeable in the process behavior charts, and its impact on reported results is easily avoided.

In summary, through continuous monitoring of QA/QC data using process behavior charting, many potential problems are immediately detected. Assignable causes are then investigated by the lab manager and technicians to correct the situation and initiate improvements in the system.