Throughout its 25-year history Spectrum Labs has been, and remains so, dedicated to providing the highest quality testing and treatment for our clients. Below is an overview of quality assurance and control measures for all laboratory operations:

- Spectrum Labs, Inc. holds licensure with both USDA and CLIA (a governing board for human diagnostic and reference laboratories). Both agencies mandate on-site inspections every 2 years and Spectrum is current with regard to this. Inspectors not only audit processes employed but also all records.

- Spectrum also sends out patient samples and control sera annually to an independent laboratory for confirmatory testing with our method/results. The test method utilized differs from our ELISA-based methodology, but quantitates the IgE levels as our test does and to antigens we test for. This validates assay specificity, sensitivity and robustness. All documentation is reviewed by laboratory and company managers and maintained for reference.

- Additionally, included in every testing scenario are both inter- and intra-assay controls. Positive/immunoreactive, pooled sera (species specific) are freshly prepared on a monthly basis and maintained at –20 degrees C.

- All Certificates of Analysis on purchased reagents are maintained and performance of said reagents is validated following receipt of material. This
method of quarantine prior to implementation helps to insure our high standards of quality. Detecting antibodies are benchmarked against the current lot in use. Service agreements and Preventative Maintenance schedules are in place for all instrumentation/robotics.

- All SOP’s (Standard Operating Procedures) are periodically reviewed and updated to reflect any changes deemed necessary by vendor or technological advancements. All employees read and sign-off on these documents.

- All laboratory personnel are reviewed for competency and cross-training annually. In the first year of employment they are reviewed at 90- and 180-days.

- Spectrum Continues to maintain GLP standards, as it has always done, via the above measures in addition to continued employee training, enrichment and Research and Development efforts.