



MiraVista Diagnostics/MiraBella Technologies

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Director
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Quality Systems

Quality control and assurance are essential in the development of diagnostic tests for use in patient management. Similarly, performance of high-complexity tests requires careful oversight of test performance. Our quality systems policies and procedures have been approved by CLIA, CAP, several state departments of health, the Select Agents Program of the Centers for Disease Control, and cGMP standards. The key components of our quality system include the following:

- Commitment of our management and staff to quality services
- Written quality control manual that defines our quality systems
- Senior-level quality systems supervisor with > 20 years experience in the development and implementation of quality control and quality assurance
- Compliance with cGMP in test development
- Education of new employees about our quality systems
- Regular review of quality surveillance results with all employees
 - The laboratory runs tests on patient specimens concurrently with the controls of graded reactivity plus a negative control. Control values must fall within acceptable ranges and not vary from those seen in previous assays before the assay is considered valid and results are released. A general or technical supervisor releases all assays before results are reported.
 - Any problems or trends seen are immediately discussed with a supervisor. Any assay problems are documented.
 - All control values are evaluated as part of the monthly and semi-annual QC reports. Any unusual shifts or trends are investigated.
- National programs are not available for proficiency testing for the unique tests we offer. For this reason we perform in-house created blinded proficiency and competency testing twice per year. Anyone that does not pass must undergo supervised re-training.

Personnel

L. Joseph Wheat, M.D. founded MiraVista Diagnostics and MiraBella Technologies in 2002. Both organizations focus on developing improved fungal diagnostic testing. For over two decades, Dr. Wheat served as a Professor of Medicine and Pathology at Indiana University School of Medicine, Indianapolis.

Laboratory technicians and supervisors have over 65 years combined experience.

If you have any questions regarding our Quality System please contact me.

Ann LeMonte

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