

## Taking **Quality** A Step Further

At Spectra, we go above and beyond to deliver quality results that promote quality patient care. Our **Quality Management System** is designed to help us exceed industry standards.

### Testing Systems Undergo Rigorous Evaluation, Validation & Maintenance

- Our laboratory equipment must meet several performance criteria to fulfill our manufacturer and regulatory requirements prior to use. This includes, but is not limited to:

- Method correlation
- Precision
- Accuracy
- Linearity
- Sensitivity
- Reference range

- We strictly adhere to routine calibration and preventative maintenance schedules to ensure that all equipment performs according to specifications
- We work closely with suppliers to minimize reagent lot changes and variation
- Parallel testing and validation is performed on new reagent lots before they are accepted and put into production

### Stringent QC Analysis for High-Volume Testing Ensures Reliable Results

Quality Control surveillance is conducted at a higher frequency than required by regulations to accommodate high-volume testing.

- Our advanced computer-based statistical analysis programs automatically evaluate and validate acceptable performance before test results are reported. Repeat criteria and abnormality flags are programmed to hold questionable test results for review and verification
- Current result values may be compared to previous values (delta check) and held for verification if the difference exceeds a pre-defined limit
- For instances where there are multiples of the same analyzer, we perform validations of acceptable analyzer-to-analyzer correlation

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### **Standardization Across Both Laboratories Is Our Focus**

You can expect consistent results from Spectra - whether your specimens are tested at our Rockleigh, NJ or Milpitas, CA facility.

- Identical equipment and maintenance
- Identical reagents, calibrators, and reagent lots
- Identical testing procedures
- Identical quality control documentation
- Cross-laboratory QC checks conducted on a routine basis

### **Accreditations & Certifications**

As part of our deep commitment to quality and continuous improvement, we adhere to rigorous regulatory standards. Spectra is the first medical testing laboratory in the United States to be accredited to ISO 15189 by the American Association for Laboratory Accreditation (A2LA).

- The Joint Commission
- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- American Association for Laboratory Accreditation (A2LA) ISO 15189
- California Clinical Laboratory License
- New York State Environmental Laboratory Approval Program (ELAP)

*\*Complete listing of accreditations and licenses is available at [www.spectra-labs.com](http://www.spectra-labs.com)*