

	BIO-PM 4.16 Verification of 3500-3500xL Genetic Analyzers	
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4.16 Verification of 3500/3500xL Genetic Analyzers

4.16.1 Purpose

Evaluate the performance of the instruments following repair, service, or calibration conducted by an authorized service technician.

4.16.2 Procedure

Each 3500/3500xL Genetic Analyzer must be calibrated by an authorized service technician annually (Planned Maintenance). The PM certificate will be maintained with each instrument.

A Field Service Report shall be provided by an authorized service technician and maintained with the instrument for periodic service calls resulting from instrument malfunction.

All Planned Maintenance and field service calls must be followed by a Performance Check of the instrument.

All Performance Checks must include allelic ladder and a 2800M positive control for each amplification kit being utilized on the particular instrument. The electropherograms and base pair size data shall be maintained. If the Planned Maintenance or field service call altered the optics of the instrument, a spectral calibration shall be performed.

Prior to the instrument re-activation for casework samples, the base pair sizes, allele calls, and relative peak heights of the 2800M positive control shall be compared to the recorded positive control evaluated prior to the repair service, or calibration. If a spectral was generated as part of the Performance Verification, the effectiveness of the spectral shall be evaluated according to 4.3.3. Supervisor (or their designee) approval shall be noted.