



Preventive maintenance of Genetic Analyzers Applied Biosystems®

Instrument models covered:

ABI310, ABI100-Avant™, ABI3100, ABI3130, ABI3130xl, ABI3500, ABI3500xl, ABI3500 Dx, ABI3500xl Dx, SeqStudio

We recommend to carry out the preventive maintenance of genetic analyzers by Applied Biosystems® according to the needs of the laboratory, at least once a year.

Preventive maintenance consists of:

- Instrument inspection (required) – carried out by a certified service engineer to ensure trouble-free instrument operation. Note: Some tasks can be made for some models only.
- Instrument performance verification (required) – reliability check of the genetic analyzer using installation standards, carried out by a certified service engineer or application specialist in accordance with the recommendations of the "Best Practice Guidelines CMGS (Clinical Molecular Genetics Society) for sequencing and/or fragment analysis. The IPV procedure also serves as a proof that the instrument is in order after the inspection, as demonstrated by analysis of installation standards (included in the quote).
- Instrument operator training (optional but highly recommended) – professional training for instrument operators to secure their qualification and efficient use of instruments, carried out by a certified application specialist

Instrument inspection:

- System verification – Identifies and records the system hardware on site
 - Instrument version, Computer and operating system version, Operating system settings
- Software verification – Records the software and firmware versions installed
 - Operating system and service pack, Firmware and data collection software, Data analysis software
- Mobile subsystems – functionality check
 - Polymer-handling system, Autosampler
- Other subsystems – functionality check
 - High-voltage power supply, Oven, Low voltage internal power supply, Laser
 - Optical path – settings and finetuning, CCD – functional check and settings
- Cleaning / Wash
 - Interior cleaning, Autosampler cleaning,
 - Polymer-delivery pump wash, Lower-polymer block wash
 - Optical system cleaning (without the need of additional spectral calibrations)
- Service Protocol – The service protocol is issued including listing of all exceptions and possible defects

Instrument performance verification:

- Instrument performance verification for DNA sequencing – Using the sequencing standard of the manufacturer and the instrument protocol applicable for a local instrument configuration a functional test is performed in order to obtain the Contiguous Read Length – CRL – the longest uninterrupted sequence with mean Quality Value; $QV \geq 20$ and check its correctness. Data are compared to published specifications.
- Instrument performance verification for fragment analysis – Using the installation standard of the manufacturer (dye set DS-33) and the instrument protocol applicable for a local instrument configuration a functional test is performed in order to obtain i.) Standard deviation of the mean of the size of detected allelic peaks of the installation standard (ST DEV SIZE) in all capillaries of the instrument and ii.) Height of detected allelic peaks (AVERAGE HEIGHT) in all capillaries of the instrument. Data are compared to published specifications.
- Validation Protocol - the validation protocol is issued after performing IPV.
 - Please note: The test can be modified based on the needs of the laboratory, i.e. either both tests are performed at the same time or independently of each other. Instrument performance verification is performed in accordance with manufacturer's recommendations.

Instrument operator training:

- Working principle of the instrument, instrument handling – the DataCollection software
- Maintenance and operational demands of the instrument, instrument calibrations performed by the user, reagents and accessories needed
- Data analysis software package – Sequencing Analysis, SeqScape/VariantReporter, GeneMapper
- Basic troubleshooting of instrument malfunctions, questions and answers session – using their own data instrument operators are taught how to uncover sources of problems observed during instrument operation
- Instrument operator training certificate – the certificate is issued for every instrument operator after participating at the training