Scope

This document outlines the level of compliance of the PR2A Luminometer and Athena software to the following:

- 21 CFR Part 11 Electronic Records; Electronic Signatures, US FDA, March 20 1997 (revised as of April 1, 2013)

System Overview

The PR2A reader is a Bioluminescence measurement device controlled by "Athena (V1.0.0.0)" PC based software. The Athena software is a standard solution software package. The PR2A is a measurement device and therefore does not generate any electronic records itself. All actions and records are generated by the Athena software when connected to and controlling the PR2A. Therefore, all further information in the document will refer solely to the Athena software.

Compliance

FDA CFR Part 11	Compliant	Protak Strategy
11.10(a) – Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	YES	Athena raw data files (.prg) are protected by a file check system. Any alteration or modification will result in a file corruption warning.
Controls for Closed Systems		
11.10(c) – Protection of records to enable their accurate and ready retrieval throughout the records retention period.	YES	Athena raw data files (.prg) are stored in a location chosen by the end user. These files can be read at any time by opening within Athena
11.10(d) – Limiting system access to authorized individuals.	N/A	There is no access control within the Athena software itself. Access is controlled by the Windows Login of the PC used.
11.10(b) – The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.	YES	Athena allows the options to print paper records or to export to PDF, Excel, Word and HTML formats for viewing of data.

11.10(e) – Use of secure, computer-generated, timestamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	YES	Athena records the User, Date and time of each assay read and the sample type in the .prg file. All actions of Athena during the assay is recorded in a .txt log file.
11.10(f) – Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	YES	The Athena software controls all steps in the use of the PR2A for assays. These cannot be changed by the user.
11.10(g) – Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	N/A	There is no access control within the Athena software itself. Access is controlled by the Windows Login of the PC used.
11.10(h) – Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	YES	The Athena software checks that it is communicating with a Protak Scientific PR2A reader. The system will not communicate with any other sources
11.10(i) – Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	YES	Full user training for the use of the PR2A and Athena is available.

Controls for Open Systems		
11.10(j) – The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	N/A	Athena does not use electronic Signatures. The control of the User is managed solely by the Windows Login of the PC used. Customer SOP's should ensure control of the PC to authorised users only.

Signature Manifestations		
11.50(a) – Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: (1) the printed name of the signer; (2) the date and time when the signature was executed; (3) the meaning (such as review, approval, responsibility, or authorship) associated with the signature; and (4) the items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	N/A	Athena does not use electronic Signatures. Athena records the User, Date and time of each assay read and the sample type. The control of the User is managed solely by the Windows Login of the PC used. Customer SOP's should ensure control of the PC to authorised users only.

Signature/Record Linking		
11.70 – Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means	N/A	Athena does not use electronic Signatures. The control of the User is managed solely by the Windows Login of the PC used. Customer SOP's should ensure control of the PC to authorised users only.

Document History:

Version	Date	Description of changes
A	15/11/2019	Initial Version