



## Clinical Pathology Module

Pristima XD Core is a fully integrated, end-to-end enterprise solution for tracking and managing veterinary facilities and research subjects throughout the preclinical research process.

Xybion software drives data collection workflows while ensuring quality, efficiency, and compliance in global pharma companies and CROs.

### Need flexible deployment?

Xybion offers on-premise or hosted solutions.

### Are You SEND Ready?

Pristima XD Core's Savante module provides the most automated solution to produce SEND datasets.

## Integrate And Harmonize Your Laboratories

Pristima XD Core's clinical pathology module includes a sample-driven architecture and delivers advanced capabilities for the online collection, identification, labeling, analysis and approval of the individual sample. Each sample in the system is uniquely identified with a tracking number that references the animal, unique study, dote, sample type, and panel of tests to perform.

Pristima XD Core includes a library of over 100 clinical pathology instrument interfaces including hematology, serum chemistry and urine analyzers. With the ability to communicate directly to instruments using bidirectional mode or a less interactive host-query mode, the system's flexibility can accommodate the varying practices of our client community

### Advanced Quality Control Database

The clinical pathology module includes a QC database of quality control samples and results for each instrument providing for quick capture of QC sample data, tracking linearity and user alerts when results exceed expected ranges. Optionally, clinical pathologists have the ability to perform online cell counting and morphology. The system allows user-assigned keys to increment or decrement counts of user-defined cell types and save them in the database.

As a fully integrated component of the Pristima XD Core sample collection schedules and analysis are managed by the study protocol and subject 21 CFR Part 11 electronic signatures and audit trail.

### Software Validation

Preclinical research must comply with GLP guidelines which require validation of all laboratory information management systems. Our experts deliver timely services in compliance with current guidelines and best practices to ensure a successful, timely, and cost-effective validation project.

- Project Management
- Requirements Documentation
- IQ/OQ/PQ test protocols
- Custom User Guides
- Validation Trace Matrices
- Validation Report