

YOKOGAWA

Co-innovating tomorrow™

OpreX™ Production Management

OpreX LIMS

Laboratory Information Management System

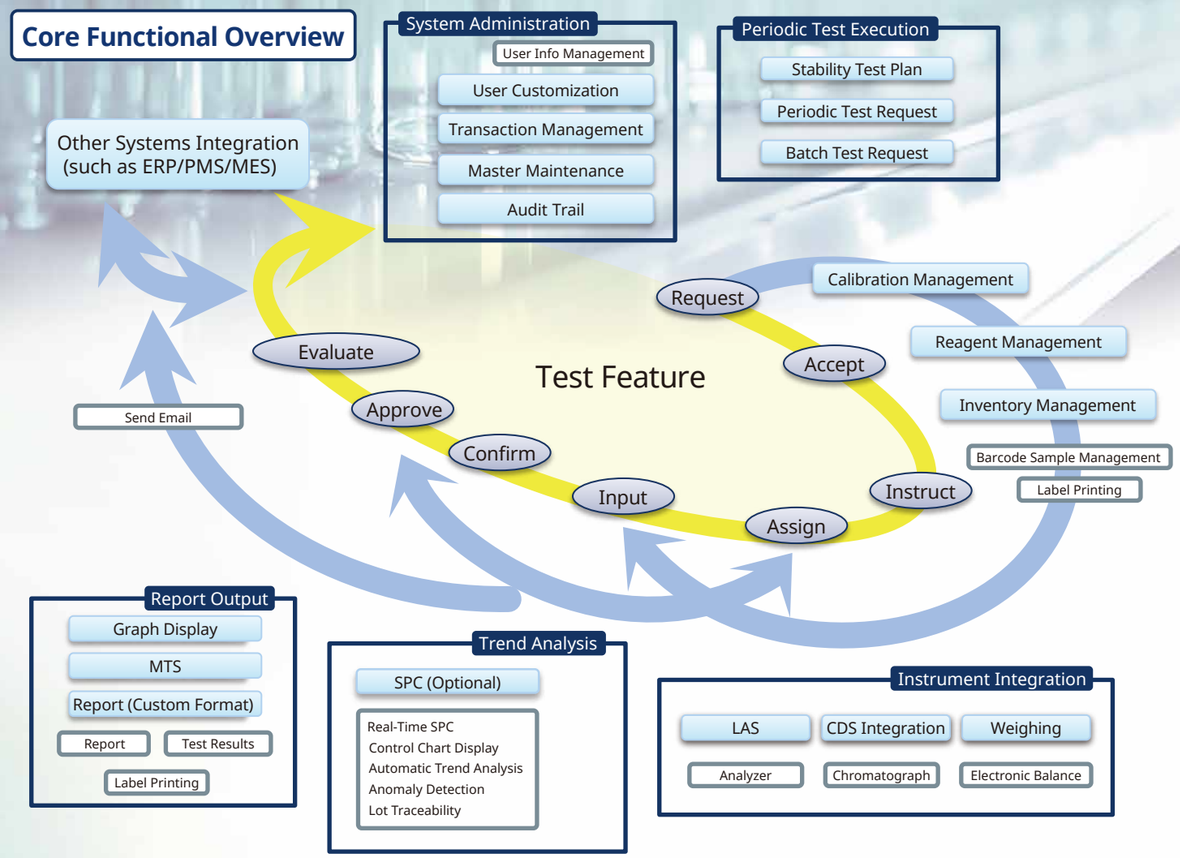
Quality Information Management Support Package

Bulletin 54A30C11-01EN

Accelerate Your Workflow with Intuitive Operations!

Navigate Testing Tasks with Greater Accuracy

A Multilingual LIMS Package to Improve Usability and Simplify Data Management



Driving Quality Excellence

As manufacturing becomes increasingly globalized, quality management is becoming increasingly complex—spanning diverse raw material sourcing, overseas production, and compliance with various regulations.
In this increasingly complex business environment, maintaining and improving quality-related customer satisfaction requires a company-wide approach—one that establishes a system for managing quality throughout the entire product lifecycle.

Comprehensive Support for Quality Management

For years, we have supported Japanese manufacturers and analytical centers in addressing challenges and improving efficiency in testing operations.
Built on this experience, OpreX LIMS continues to evolve—improving and strengthening quality management functions and usability, always from the perspective of frontline users.
This enables faster and more accurate data collection, analysis, reporting, and approval, while promoting seamless information sharing.

Value Delivered by OpreX LIMS

- Enable flexible workflows to meet diverse testing requirements.
- Standardize operations and ensure compliance with ISO, 21 CFR Part 11, and PIC/S—enhancing quality assurance.
- Designed for global use with multilingual support—currently available in Japanese, English, Chinese, Korean, and Portuguese—with time zone compatibility.
- Integrate with ERP and manufacturing systems to utilize quality data company-wide.
- Manage access rights for instruments and items, enforce password expiration policies, and lock unattended terminals.

Proven Track Record

- Trusted by 230+ sites globally across petrochemical, chemical, food, pharma, and analytical centers
  See how OpreX LIMS is used across industries:
  https://www.yokogawa.co.jp/solutions/solutions/information-solutions/lims-solution/

Key Features and Functions

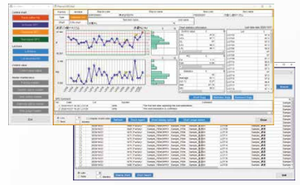
Intuitive Interface with Single-Click Operation

- The layout is designed for clarity and can be easily customized for each user and task.
- Quickly find the information you need with a single click, and switch between screens effortlessly using tabs.
- By making it easy to check test progress and results online, the system also enhances information sharing and management.



SPC Function

Key Features
1. Real-time SPC
2. Control Chart Display
3. Automatic Trend Analysis
4. Anomaly Detection
5. Lot Traceability



- OpreX LIMS monitors test results in real time and automatically detects trend anomalies. (*1) When an issue is identified, an email alert is sent to the responsible person.

  *1: Follows the eight anomaly detection rules defined in ISO 8258:1991 Shewhart Control Charts (JIS Z 9021).

- With the lot traceability function, operators can track lot information and identify which process experienced an anomaly.

System Reliability, Security, and Traceability

- Secure System Configuration
- User ID / Password Management
- Password Expiration and Reuse Control
- Granular Access Control (by Function and Sample)
- Automatic Tracking of Test Data Changes (who, when, and why)
- Automatic Tracking of Master Data Changes

Seamless Integration with Analyzers

- Low-cost network integration by making full use of existing analyzers
- Universal interface for any analyzer model or brand
- Built-in support for diverse data formats
- Broad integration with major Chromatography Data Systems
- Barcode-based assignment for analyzer scheduling
- Accelerate workflows with automated analytical data collection

Implementation Benefits

Standardize and Streamline Analysis & QC

- Standardize operations through workflows
- Accelerate business cycles with smart automation
- Smooth handovers and transfer of know-how among testers

Regulatory & Standards Compliance

- Strengthen quality assurance by complying with GMP, ISO, and other relevant regulations
- Continuous updates to meet changing regulations and standards

ERP & Manufacturing System Integration

- Shorten lead times by streamlining batch release processes
- Real-time updates to material and product inventory data based on pass/fail decisions

Analyzer Connectivity
– LAS (Laboratory Automation System)

- Minimize human error and reduce manual workload
- Improve data reliability
- Enable low-cost network integration
- Ensure easy system replacement after implementation

Features & Configuration

Core Features



From test planning to final reporting, manage every step seamlessly. Includes sample acceptance, test instruction issuance, result entry, pass/fail evaluation, approvals, and report generation.

1. Test Request: Enter test plans manually, register via external interfaces, or auto-generate scheduled test plans. Test items and pass/fail criteria are populated from master data linked to each sample (item).
2. Sample Acceptance: Validate sample receipt via list selection or barcode scanning.
3. Test Instruction: Issue instructions for accepted samples (specimens) and assign testers for each test item. Pre-registration simplifies the workflow.
4. Result Entry (Analysis Work): After reviewing the assigned test items, testers perform the analysis and enter raw data and pass/fail results. Automatic data import from analyzers assigned to each sample is also supported.
5. Confirmation, Approval, and Shipment Decision (Evaluate): Confirm each test item, approve the entire sample, and perform final pass/fail evaluation. All actions are recorded with electronic signatures.

Reagent Management



Manage expiration dates, usage history, and disposal records and approvals for reagents used in analysis.

Calibration Management



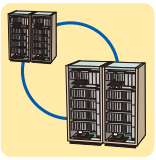
Manage calibration expiration, track calibration records & approvals, and automatically issue calibration instructions.

Report (Custom Format)



Import data into user-created Excel forms to generate documents such as test instructions, result reports, and monthly summaries.

Integration with Other Systems



Integrates with upper-level systems such as ERP, production management, MES, and logistics systems. Enables synchronized test planning, inventory updates triggered by release decisions, and transmission of test report data.

Stability Test Plan



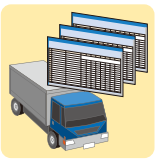
Manages stability testing to evaluate time-dependent changes in samples. Automatically generates test instructions based on sampling intervals and manages test items by interval.

Quality Management



Automatically calculates and displays control limits (2σ, 3σ) based on standard deviation.

Customer-Specific Report Creation



Generate test certificates per shipping destination or customer. Supports customer-specific specifications, including item name substitution and unit conversion.

Implementation and Support Services

- Consulting for shipment package analysis and adaptation
- Hardware and software support
- Training and post-implementation maintenance services

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