

XIFIN LIS for Molecular Diagnostics

# Keeping Your Lab Prepared for the Next Generation of Diagnostic Testing

Growth in molecular diagnostics is being fueled by the continued discovery of genetic markers with proven clinical utility and the increasing adoption and reimbursement of genetic-based diagnostic tests and programs. To cost-effectively meet these growing demands, molecular diagnostic labs need a laboratory information system (LIS) designed to meet their unique automation and data requirements.

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To meet growing demands, molecular diagnostic labs need a flexible, scalable laboratory information system

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XIFIN LIS for molecular diagnostics provides a flexible and intuitive cloud-based workflow management system to support the operations of anatomic pathology and molecular laboratories. Architected for interoperability, the integrated molecular workflow module can be used as an end-to-end solution or integrated with other systems.

#### **Flexible Image and Data Management**

- Enables tailored input screens to capture unique data elements for case-specific reporting requirements
- Lets lab technologists and other administrators define required data elements from pre-configured components
- Facilitates single sign-on integration with BioView and other FISH imaging platforms
- Integrates artificial intelligence (AI) analytics platforms for seamless importing into configured LIS data elements
- Includes supporting clinical documentation integration to aid reimbursement appeals

#### **Configurable Workflow Management**

- Includes configurable modality-specific workflows with automated test reflexing
- Provides real-time workflow visibility including concurrent cases and color-coding for turnaround time monitoring
- Delivers flexible batch workflow with technical workflow steps and quality control
- Incorporates wet lab support, including configurable lab procedures, reagent and control management, plate-mapping, and audit trails
- Enables project setup and management for clinical trials

#### **TCPC Partnerships**

- Drives new revenue opportunities leveraging existing lab resources
- Cloud-based deployment enables streamlined TCPC workflow
- Delivers rapid client and report setup for physician partners



# Configurable Modality-Specific Workflows with Automated Test Reflexing

## Molecular Diagnostics

- > Chromosomal Microarray
- > FISH
- > PCR

## Anatomic Pathology

- > Bone Marrow
- > Cytogenetics
- > Flow Cytometry
- > Gastrointestinal
- > Gynecological Cytology
- > Immunohistochemistry (IHC) / Special Stains
- > Morphology
- > Non-Gynecological Cytology
- > Prostate
- > Surgical

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### Multiple Myeloma Gene Expression Profile Report

**PATIENT INFORMATION**

PATIENT	
Case Number: CL 12-001427	Subject ID: Doe, John
DOB: 11/05/1939	Sex: Male
Specimen ID/IRN: 1548655	

**PHYSICIAN**

Physician Name: Smith, Chris	Company/Practice: Seaside Cancer Center	Phone Number:
Address: 123 Main Street	City: San Diego	State: CA
		Zip: 92130

**SPECIMEN**

Specimen Type: Bone Marrow Aspirate	Specimen Collected: 01/14/2019
Specimen Received: 01/15/2019	Date Reported: 01/18/2019
	Accession/Case No: 105319

**Diagnosis/Reason for Referral:**

**SUMMARY REPORT**

**GENE EXPRESSION SCORE**

<b>All Patients</b>	<b>Your Patient</b>
LOW RISK (0-45.2)   HIGH RISK (45.2-100)	SCORE: 33.8
	CLASSIFICATION: LOW RISK
	PROGNOSIS: Favorable

A score of less than 45.2 indicates that a newly diagnosed patient has a 73% probability of being recurrence-free at 5 years. Additionally, the patient has a high probability of having a favorable prognosis. A score of 45.2 or above indicates that a newly diagnosed patient has a 26% probability of being recurrence-free at 5 years, and a high probability of having an unfavorable prognosis.

- Risk Score is an independent predictor of outcome endpoints such as event free survival (EFS) and overall survival (OS) in multivariate analysis that involved comparisons to the International Staging System (ISS) and high-risk translocations.
- Favorable prognosis indicates that the patient has a superior 5-year actuarial probability of overall survival of 80% versus 30% for patients with a high risk unfavorable prognosis.

**Scoring Explanation**

The score and the probability of favorable clinical outcome in terms of Event-Free Survival (EFS) and Overall Survival (OS) are derived from mathematical models using microarray technology and multivariate analysis of several large cohorts of patients with over an 8-year continuous follow-up and complete clinical and pathological outcomes analysis at the University of Arkansas for Medical Sciences [1, 2, 3]. Using sophisticated mathematical modeling, a cut-point of 45.2 discriminates high risk versus low risk patients with high risk patients showing inferior 5-year actuarial probabilities of EFS (18% vs 60%, P, <.001) and OS (28% vs 79%, P, <.001). The cut-point of 45.2 for discriminating low and high risk patients is represented by a vertical red line in the linear risk chart.

The signature score can also distinguish between high and low risk myeloma patients treated in other medical centers and validated in clinical trials using differing clinical treatment protocols as shown by the Phase II CREST and SUMMIT trials [4] and the Phase III APEX trials using bortezomib in a relapsed/refractory setting [3]. In addition, the signature score has been further validated in a cohort of high-risk patients with specific chromosomal translocations. [5].

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Body Site: Urine, Voided  
Specimen ID:  
Clinical Info:  
Fixative: Nucleic  
Other Specimen ID:  
Nuclei Score: 25

Electronically Signed By:  
*Chris Smith, MD*  
Chris Smith, MD  
1/15/2019 2:46:54 PM

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## Dynamic Reporting

- Automates uploading of results directly from devices and from analysis software
- Provides dynamic, logic-driven reports with images, graphs and tables
- Delivers comprehensive summary reporting
- Includes batch resulting

## Connectivity and Interoperability

- Interfaces via open API with instruments and analytics platforms
- Streamlines image uploading and selection for inclusion in patient reporting
- Efficiently provides results to EHRs by interfacing with middleware solutions such as LKTransfer as well as custom-built analytics and software solutions
- Streamlines integration with XIFIN RPM and other billing platforms

Customizable reports are branded for your laboratory and synthesize and display a host of information, including multi-modal tests, graphical charts, and calculated probable outcome scores.



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