

Ghidorah 3: Achieving Efficiency in A Laboratory Information Management System (LIMS)

Jesse E. Lynch, Brendan Karlstrand, Jonathan Chavez, Lisa Read, Kenneth Holloway, Bernadette Choi, Keven Welch, Scott King, Kevin Archambeault, Kathy Boggess
Gaithersburg, MD



Introduction

In 1964, Ishiro Honda introduced Ghidorah, the three-headed monster, via 'Earth's Greatest Battle'.

In 2021, MRIGlobal reincarnates Ghidorah - LIMS, via science's greatest battle – Data Management.

Since its inception, MRIGlobal has strived to maintain state-of-the-art scientific technologies and facilities in order to provide our clients with the best science possible. The development of this LIMS Release Candidate, funded through an MRIGlobal Capital Expenditure, culminated in 3,330 labor hours by Fluent Consultants, Inc. in collaboration with MRIGlobal staff over the course of 10 months.

ISO/IEC-17025 Program Compliance

Production data is protected and secured in multiple ways. Physical server access is limited to personnel with appropriate badge access. Remote access to Production servers and databases is controlled by Active Directory. The application limits access by utilizing an active directory log-in through a web browser. Finally, each user is assigned a User Role which granularizes access to pages and data within the application. A complete software validation was conducted. Standard Operating Procedures (SOPs) are written and available.

The screenshot shows a 'User Role Security Matrix' with columns for various application pages and roles (No Role, Analyst, Scientist, QA, Manager, Admin). Below it is a 'Users' list with columns for ID, Name, Login, Active, and Role.

System Design

Critical Design – Ability to deploy on existing MRIGlobal and external infrastructure and product flexibility intended for various work uses and programs

- Backend –**
- SQL database with 3 table types – Reference Values/Code Set, Transaction, and Audit
 - Utilizes various stored procedures for complex data retrieval from the database
 - SQL Server Reporting Services to generate system reports

- Frontend –**
- Compatible with multiple web browsers.
 - Based on .NET Core (ASP.net 5.0) framework.
 - Download/Upload interface for sample transmittal and instrument eData files
 - QA/QC/PT/Daily Client reporting tools
 - Equipment tracing and Reagent Lot/Qualified Reagent Lot tracing/inventory
 - Lot status dashboard:
 - Setup
 - Received
 - Additional Testing
 - Awaiting Analysis
 - Analysis Complete
 - Cancelled

Features – “The One Who is Many”

In-Processing

- Transmittal uploading
- QA shipment uploading
- Site code assignment
- Sample batching
- Sample batch component assignment
- In-depth Issues log

Lot List

- Action icons
- Lot details
- Sample check-in
- Ordinal editing
- Sample label printing
- Receipt report printing
- Lot status display
- Site code display
- Sample count tracking

Prep Batches

- Method assignment
- Summary Report printing
- Track lot ID assignment
- Track analysis batch

Extraction Batches

- Extraction control (+/-) tracking
- Reagent set pre-population
- Reagent lot association
- Equipment ID tracking
- Summary Report printing
- QC sample type tracking
- QC lot ID tracking

Analysis Batches

- Replicate assignment
- Qualified reagent lot assignment
- Single or Multiplex assay layout
- Export instrument file for Quant Studio qPCR
- Import/reconcile analysis results
- Interpreted result assignment
- Failed run log

Reporting – Daily Results and Quality Assurance (QC Charts not pictured)

Results Reporting - Daily

Select One or More Lots

Filter Lots By:

From Date: 01/30/2022

To Date: 02/01/2022

Site Code:

Select Parameters:

Results Page One Only

Sample Inventory

Run Report

Lot#	Date	Time	Customer	Sample Count	Tier 1 PCR	Tier 1 LMX	Tier 1 Micro	Tier 2 Testing	Tier 2 Pending Sample ID	Tier 2 Pending Location ID	Comments
1	1/30/2022	7:58 PM	SITE 1	2	C	C	NT	NT	NA	NA	
2	1/31/2022	12:57 PM	SITE 2	1	C	C	C	NT	NA	NA	
3	1/31/2022	12:57 PM	SITE 2	1	C	C	C	NT	NA	NA	
4	1/31/2022	12:57 PM	SITE 2	1	C	C	C	NT	NA	NA	

Summary Key For Tier 1 Results

'C' = If a 'C' is present for Tier 1 PCR, Tier 1 LMX, and Tier 1 Micro the samples are deemed 'Not Detected'

'NT' = Unless a 'P' is present in the 'Tier 2 Testing' column

'P' = Testing is still in progress for the method indicated (Tier 1 PCR, Tier 1 LMX, and Tier 2 Testing). If a 'P' is listed in the 'Tier 2 Testing' column, Tier 2 testing is required and is still in progress. Samples requiring Tier 2 testing will be listed in the 'Tier 2 Pending Sample ID' column

'ND' = Tier 2 testing complete and all Tier 2 pending samples listed in the 'Tier 2 Pending Sample ID' column are deemed 'Not Detected'

'CN' = Client Notified of Tier 2 testing results.

'NT' = Not tested for

False Negatives/Positives Report

From Date: 12/20/2021

To Date: 12/21/2022

Group By: By Agent - Target By Sample - Target

Include QA Automated

Include QA Manual

Run Report

False Negatives/Positives by Sample for 12/20/2021 to 12/21/2022

Agent	Conc.	Target	Dil.	Meth. Res.	Test Res.	Result Qual.	Raw Result	Cutoff (ECL)	Filter Lot	Buffer Lot	Stock Id	Analysis Batch Id
A		Target-2		+		=(0/1)	Undeterm ned	0.1	21607	CNP112921	WV/LE1214 21A/JH/LE1 00521B	387
A		Target-1				+(1/1)	38.1900	0.1				283

The screenshot shows a 'Lot List' table with columns for Actions, Id, Site Code, and Created. Below it is an 'Analysis Batch' details view for lot 384, showing Technique (Q55), Plate Type (PCR-96-Q55), Test Set (Q55 Tier 1-96-(C1,D4)), and Status (Awaiting Analysis).

The screenshot shows the 'Administration' page with sections for Method Test Setup, Reagent Setup, and Other.

Qualified Reagent Lot Tracing

The screenshots show 'Reagent Lot Detail' for LMX-Pac-CH-EF and 'Analysis Batch' for 379. Both views include a 'Qualified Reagent Lots' table with columns for Master Mix / Bead Lot #, Pos Control Lot #, Ancillary Reagent Lot #, and Prep Date.

Thank you

We would like to extend a special thank you to our laboratory team as well as our IT infrastructure team - Sean Burkett, Barney Frazier, & Dave Bliss - without whom this implementation would not be possible.

Contact Information

Jesse E. Lynch

T: 240.361.4074 65 West Watkins Mill Rd
E: jlynch@mriglobal.org Gaithersburg, MD 21702

The science you expect. The people you know.