



Combining LIMS and ELN in a complete end to end flow

Unicorn or Reality?

Anthonie de Groot

**Infectious Diseases
and Vaccines**

Melinda, *Goddess of Healing*
Melinda's artwork reflects her journey living with HIV.

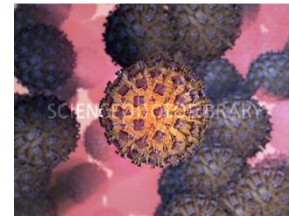
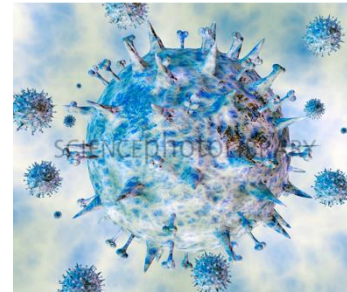
Janssen  | PHARMACEUTICAL COMPANIES
OF *Johnson & Johnson*

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DI 5 APRIL >>> 2016



Janssen Clinical Immunology department

- Klinische sample analyse
- GCLP kwaliteits systeem
- Bescherming tegen infectie ziekten



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Insane documentation

- Sample opslag
 - 10 vriezers
 - 132 Lades
 - 4 boxen
 - 5.280 excel files
 - version controlled 50.000+
 - 81 positions
 - 427.680 samples
 - 15 fields
 - 6.415.200 velden
 - version controlled 60.000.000 velden
 - 30 medewerkers
 - 15 personen op het lab



Insane documentation

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 - 10 vriezers
 - 132 Lades
 - 4 boxen

100% DATACHECK

- 427.680 samples
- 15 fields
- 6.415.200 velden
 - version controlled 60.000.000 velden
- 30 people
 - 15 people in the lab



Insane documentation

- Lab notebooks (papier)
 - ± 400 velden per LNB
 - ± 50 LNB's per studie
 - ± 20.000 velden
 - Studies binnen een maand

3. Test information – Neutralization, Day 1

Raw materials	Supplier	Mat./Cat.#	Batch#	Expiry date
MDCK cells	Crucell	H296-015		
PBS pH7.4	Gibco	10010		
Triple Select	Gibco	12563		
MDCK cell culture medium	Crucell	4000340		
MDCK cell diluent	Crucell	4000706		
Sample diluent	Crucell	4000725		
Virus diluent	Crucell	4000707		

Critical Equipment	ENS#	Calibration due date
Pipetman P20		
Pipetman P200		
Pipetman P1000		
Multichannel		
Class II biosafety cabinet cells		
37°C 10% CO ₂ incubator cells		
Incubator probe		
37°C 10% CO ₂ incubator assay		
Incubator probe		
Class II biosafety cabinet assay		
Freezer for serum samples		
Freezer for GCs		
Freezer for virus		
TECAN EVO □ 150 □ 200	□ 6037 □ 7641	
Biopest	□ 6036 □ 7906	

Other Equipment	ENS#
Centrifuge	
Pipetboy	
Fridge	
Scepter	

Quality Controls	Supplier	Batch#	Expiry date
HQC	Crucell		
LQC	Crucell		



Insane documentation

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Critical Equipment	ENS#	Calibration due date
Roetman P20		

Freezer for serum samples		
Freezer for QCs		
Freezer for virus		
TECAN EVO □ 150 □ 200	□ 6037 □ 7641	
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Centrifuge		HQC	Crucell		
Rigetbox		LQC	Crucell		
Fridge					
Scepter					

Page 2 of 10



Insane documentation

- Resultaten

- 200 Subjects
 - 3 Visits
 - 3 Strains
 - 2 Assays
 - 3600 Resultaten
- 200 Vriezer files
- 50 Pipeteer files
- 50 Import files
- 50 Resultaat files
- 1 Gecombineerde resultaat file
 - 351

3. Test information – Neutralization, Day 1

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Pipetboy		LQC	Crucell		
Fridge					
Scepter					



Insane documentation

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100% DATACHECK

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Centrifuge		HQC	Crucell		
Pipetboy		LQC	Crucell		
Fridge					
Scepter					



Documentatie

- 60% van alle tijd is documentatie
- Deviatie maken bij het vinden van een fout
- Fouten ontstonden door teveel documentatie



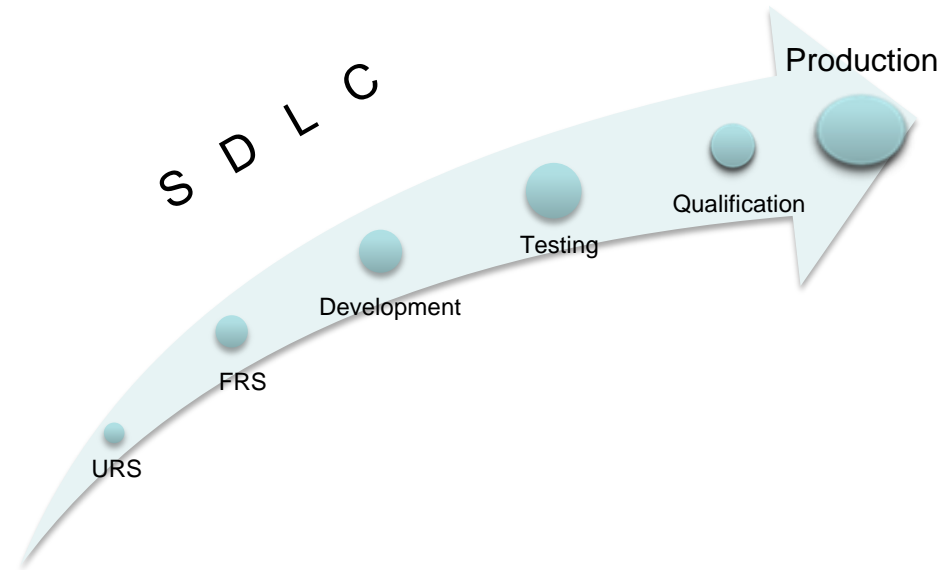
Labware LIMS & ELN

- LIMS & ELN voor alles
 - Studie informatie
 - Reagentia
 - Instrumenten
 - Sample opslag
 - Assays
 - Resultaten van SDMS via interface
 - Scientific review
 - Archivering
 - EHS rondjes
 - Site selection
 - Cleaning cycle
 - Bestellen
 - Deviaties
 - Custom lab werk
 - etc...



Implementatie

- 3 Fases
- 1.5 jaar
- 2 admins
- 5 Developers
- SDLC
- Fase 1 & 2 klaar
 - Binnen budget
 - Binnen timelines
 - Meer dan verwacht
 - Geen major issues



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 **LABWARE**
Results Count

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End to End flow – ondersteunende functies

<<<Sample Analysis>>

Project ID:

<<<>>

Study Status:

Responsible scientist:

Trial Number:

Disease Type:

Experimental Start Date:

Experimental End Date:

Comment:

Research Facility:

Fields on Sample Login:

<<<Approval Allowed>>

Ready For Approval: True False

Summary Samples Results Items						
External File Link Visits Parameter Set Schedule						
	Visit	Service Method	Parameter Set	Mandatory	Priority	
1	1	ELISA_PRE_F_MAN	Elisamanual	✓	0	
2	2	ELISA_PRE_F_MAN	Elisamanual	✓	0	
3	3	ELISA_PRE_F_MAN	Elisamanual	✓	0	
4	1	ELISPOT_1_RSV	Elispot	✓	0	
5	2	ELISPOT_1_RSV	Elispot	✓	0	
6	3	ELISPOT_1_RSV	Elispot	✓	0	
7	1	MAGPIX_MANUAL	Magpix	✓	0	
8	2	MAGPIX_MANUAL	Magpix	✓	0	
9	3	MAGPIX_MANUAL	Magpix	✓	0	



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End to End flow – ondersteunende functies

The screenshot displays a software interface for instrument management. The top part shows a table with columns for Name, Last Calib., Next Calib., Last PM, and Next PM. Below this, a detailed view for an instrument named 'Stepper' is shown, including fields for Description, Software Version, Vendor, Serial No, Location, and Validated?. The interface also includes tabs for Instrument, Calibration, Preventive, and Service, and a section for State (In Service/Out of Service) and Event (Calibration, Preventive Maintenance, Service) with dates and times.

Standards & Reagents

Project Setup | Sample Reception | Lab Workflow | Review | Standards & Reagents | Admin

Stock	Type	Name	Supplier Lot N°	Arrival Date	Expiry Date	First End of Use Date
1x PBS 500mL Bottle (Gibco)	MATERIALS	PBS-0004	3a	02/04/2015	01/02/2017	02/04/2016
DMEM Culture medium with Penn/Strep 555mL Bottle (LSS)	PREPARED	DME-0045	DME-0045	23/02/2016	05/04/2016	05/04/2016
1x PBS 500mL Bottle (Gibco)	MATERIALS	PBS-0010	1155478.0	07/04/2015	07/04/2016	07/04/2016
1x PBS 500mL Bottle (Gibco)	MATERIALS	PBS-0014	123456.0	14/04/2015	08/04/2016	08/04/2016
ANTIBODY	ANTIBODY	AB1-0006	96321	29/03/2016	08/04/2016	08/04/2016
DMEM Culture medium with Penn/Strep 555mL Bottle (LSS)	PREPARED	DME-0046	DME-0046	26/02/2016	08/04/2016	08/04/2016
1x PBS 500mL Bottle (Gibco)	MATERIALS	PBS-0019	123445.0	23/04/2015	14/04/2016	14/04/2016
DMEM Culture medium with Penn/Strep 555mL Bottle (LSS)	PREPARED	DME-0048	DME-0048	23/03/2016	04/05/2016	04/05/2016
Prepared primers with no incoming QC	ID_PREPARED	PRI-0011	PRI-0011	07/12/2015	06/06/2016	06/06/2016
Prepared primers with no incoming QC	ID_PREPARED	PRI-0016	PRI-0016	07/12/2015	06/06/2016	06/06/2016
1x PBS aliquot (Gibco)	MATERIALS	PBS-0021	78677678	24/06/2015	01/06/2019	24/06/2016
Magnix Kit 6, Cutakine	MATERIALS	MAG-	MAG123456	18/12/2015	21/07/2016	21/07/2016

There are no standards/reagents waiting for approval
 There are 8 ranges waiting for approval
 There are no LSS sheets waiting for review

Infectious Diseases and Vaccines

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End to End flow – ondersteunende functies

EIA_PREF_M-16-00025
EIA_PREF_M-16-00026
EIA_PREF_M-16-00027

Well	Type	ID	Label	Raw Result	Result
A1	QC	42816	INT-0004-00047		
A2	Dilution	42816	INT-0004-00047		
A3	Dilution	42816	INT-0004-00047		
A4	Dilution	42816	INT-0004-00047		
A5	Dilution	42816	INT-0004-00047		
A6	Dilution	42816	INT-0004-00047		
A7	Dilution	42816	INT-0004-00047		
A8	Dilution	42816	INT-0004-00047		
A9	Dilution	42816	INT-0004-00047		
A10	Dilution	42816	INT-0004-00047		
A11	Dilution	42816	INT-0004-00047		
A12	Empty				
B1	QC				
B2	Dilution				
B3	Dilution				
B4	Dilution				
B5	Dilution				
B6	Dilution				
B7	Dilution				
B8	Dilution				
B9	Dilution				
B10	Dilution				
B11	Dilution				
B12	Empty				
C1	QC				
C2	Dilution				
C3	Dilution				
C4	Dilution				

Name: EIA_PREF_M-16-000
Template Name: ELISA_PRE_F_MAN_
Created By: AALHOMMA
Created On: 29/MAR/2016 09:1
Changed By: AALHOMMA
Changed On: 29/MAR/2016 09:1
Assays:
Parent Plate:
Status: I
Plate Type:
Locked: false

Position Id: A1
Label: INT-0004-00047
Analysis:
Result:
Raw Result:
Sample Number: 42816
Substance Name: QC
Dilution Factor: 10.0

	1	2	3	4	5	6	7	8	9	10	11	12
A	QC	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
B	QC	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
C	QC	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
D	QC	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
E	Standard	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
F	Standard	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
G	Unknown	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty
H	Unknown	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Dilution	Empty



End to End flow – ondersteunende functies

DG23			
Project #	P102252	Link to SOP	Docspace Link
Assay #	EIA_PREF_M-16-00016	Resp. Scientist	
Materials			
Scan/Browse	Component	Lot #	Expiry Date
#	Tween-20	TWE-0001-00001	01-Oct-2016 0:00
#	Round Bottom Plates	NUN-0003-00001	01-Oct-2016 0:00
#	10L PBS (washing)	PBS-0004-00001	02-Apr-2016 0:00
#	0,5L PBS (sample buffer)	PBS-0004-00001	02-Apr-2016 0:00
#	FBS		
#	αHu.IgG(Fc)-HRP	HI-0001-00001	26-Oct-2017 0:00
#	LumiGlo Component A	LUM-0002-00001	01-Oct-2018 0:00
#	LumiGlo Component B		
#	Streptavidin coated plate		
#	RSV Pre-F Protein Biotinylated	RSV-0002-00001	22-Oct-2019 0:00
Calculation Variables			
Stock RSV Protein Conc.	2070	µg/ml	
Secondary Ab dilution factor	3750		
Solution and Buffer Preparation			
Solution	Recipe		
Coating buffer	RSV Pre-F Protein	PBS	
	2.66 µl	22	ml
Wash buffer	PBS	Tween-20	
	2200 ml	1.1	ml
Sample buffer	PBS	Tween-20	FBS
	100 ml	0.2 ml	1 ml
2nd Antibody solution	2nd Ab Stock	Sample Buffer	
	5.87 µl	22	ml
LumiGlo	LumiGlo A	LumiGlo B	
	5.2 ml	5.2	ml
Incubation times			
Action	Start	End	
Coating F-Protein (1hr RT)	29-Mar-16 9:13	29-Mar-16 10:14	OK Start Coating End Coating
Blocking (1hr RT)	29-Mar-16 9:14	29-Mar-16 10:14	OK Start Block End Block
Sample Incubation (2hrs RT)	29-Mar-16 9:14	29-Mar-16 11:14	OK Start Incubation End Incubation
2nd Ab. Incubation (1hr RT)	29-Mar-16 9:14	29-Mar-16 10:14	OK Start 2nd Ab Inc. End 2nd Ab Inc.



End to End flow – ondersteunende functies

Flags Dialog - EXPERIMENT: 0000001304

Remarks | Remarks

Removed: True False

Displayed: Yes

Entry Code: 2395

Created By: ADEGROOT_ROLE

Created On: 29/MAR/2016 00:00:00

Requires Action: True False

Description:

Flag Comment:

Object Name: 0000001304

C Test Process: EIA_PREF_M-16-00016

C Rel Object Id: 0

C Rel Object Name: Pre-F Elisa Manual/Sheet1

C Rel Object Type: SHEET



End to End flow – ondersteunende functies

EIA_PREF_M-15-00048 | P10223

- Workflow Log [ELISA / ELIS]
 - [1] [START] [DLIMAMA]
 - [2] [ELN] [DLIMAMA]
 - [3] [COVER] [DLIMAMA]
 - [4] [PICK] [DLIMAMA]
 - [1] [INACT] [DLIMAMA]
 - [2] [BATCH] [DLIMAMA]
 - [3] [ADD_WB] [DLIMAMA]
 - [4] [CRT_PLATES] [DLIMAMA]
 - [1] [STOP] [DLIMAMA]
 - [1] [STOP] [DLIMAMA]
 - [1] [TECH] [DLIMAMA]
- Sample Analysis Assay # 3
 - [F] [JBO7-068] [JBO7-4]
 - [F] [PHU1-003] [PHU1-037]
 - [F] [PHU1-037] [PHU1-037]
- Batch # 1
 - [True] [Inact-151210-1]
- Experiment # 1
 - [True] [0000001195]
- Plate Protocol # 1
 - [True] [EIA_PREF_M-15-00048]
- Request # 1
 - [CHK00307] [DLIMAMA]
- QC Analysis # 4
 - [INT-0004-00022] [ELISA]
 - [INT-0004-00022] [ELISA]
 - [INT-0005-00015] [ELISA]
 - [INT-0005-00015] [ELISA]
- Investigation # 0

Test Process


Flags						
Template	Object Name	Object Type	Comment	Description	Impact	
	Inact-151210-1	BATCH		Result for : Heat block is out of spec	Yes	
	Inact-151210-1	BATCH			Yes	
	Inact-151210-1	BATCH	not used	heat blok added	Yes	
	0000001195	EXPERIMENT		Not in calibration: RSVREF_MAN_EIA_PREP/INSTRUMENTS/JV_3958	Yes	
	0000001195	EXPERIMENT		Not in calibration: RSVREF_MAN_EIA_PREP/INSTRUMENTS/JV_6966	Yes	
	0000001195	EXPERIMENT		Not in calibration: RSVREF_MAN_EIA_PREP/INSTRUMENTS/JV_7917	Yes	
	0000001195	EXPERIMENT		Results entered manually for 7 tests	Yes	
	EIA_PREF_M-15-00048	PLATE_PROTOCOL		Out of Spec result for : Max 1 out of 4 ICs at the start are OoS	Yes	
	EIA_PREF_M-15-00048	PLATE_PROTOCOL		Out of Spec result for : Max 1 out of 4 ICs at the end are OoS	Yes	

QC Samples									
Spec Type	Component	Limits	Result	In Spec	Analysis	Status	Label ID	Inv. Type	
HIGH	IC50	2000.0 <= Result <= 30000.0	5000	T	ELISA_RSV_PREF	C	INT-0004-00022	IC	
HIGH	IC50	2000.0 <= Result <= 30000.0	3000	T	ELISA_RSV_PREF	C	INT-0004-00022	IC	
MEDIUM	IC50	1000.0 <= Result <= 2000.0	1000	T	ELISA_RSV_PREF	C	INT-0005-00015	IC	
MEDIUM	IC50	1000.0 <= Result <= 2000.0	1200	T	ELISA_RSV_PREF	C	INT-0005-00015	IC	

End to End flow – ondersteunende functies

- [EIA_PREF_M-15-00048] [PLUZZS]
- Workflow Log [ELISA / ELIS
 - [1] [START] [DLIMAMA]
 - [2] [ELN] [DLIMAMA]
 - [3] [COVER] [DLIMAMA]
 - [4] [PICK] [DLIMAMA]
 - [1] [INACT] [DLIMAMA]
 - [2] [BATCH] [DLIMAMA]
 - [3] [ADD_WB] [DLIMAMA]
 - [4] [CRT_PLATES] [DLIMAMA]
 - [1] [STOP] [DLIMAMA]
 - [1] [TECH] [DLIMAMA]
- Sample Analysis Assay # 3
 - [F] [JBO7-068] [JBO7-068]
 - [F] [PHU1-003] [PHU1-003]
 - [F] [PHU1-037] [PHU1-037]
- Batch # 1
 - [True] [Inact-151210-1]
- Experiment # 1
 - [True] [0000001195] [0000001195]
- Plate Protocol # 1
 - [True] [EIA_PREF_M-15-00048]
- Request # 1
 - [CHK00307] [DLIMAMA]
- QC Analysis # 4
 - [INT-0004-00022] [ELISA]
 - [INT-0004-00022] [ELISA]
 - [INT-0005-00015] [ELISA]
 - [INT-0005-00015] [ELISA]
- Investigation # 0

Assays



Results

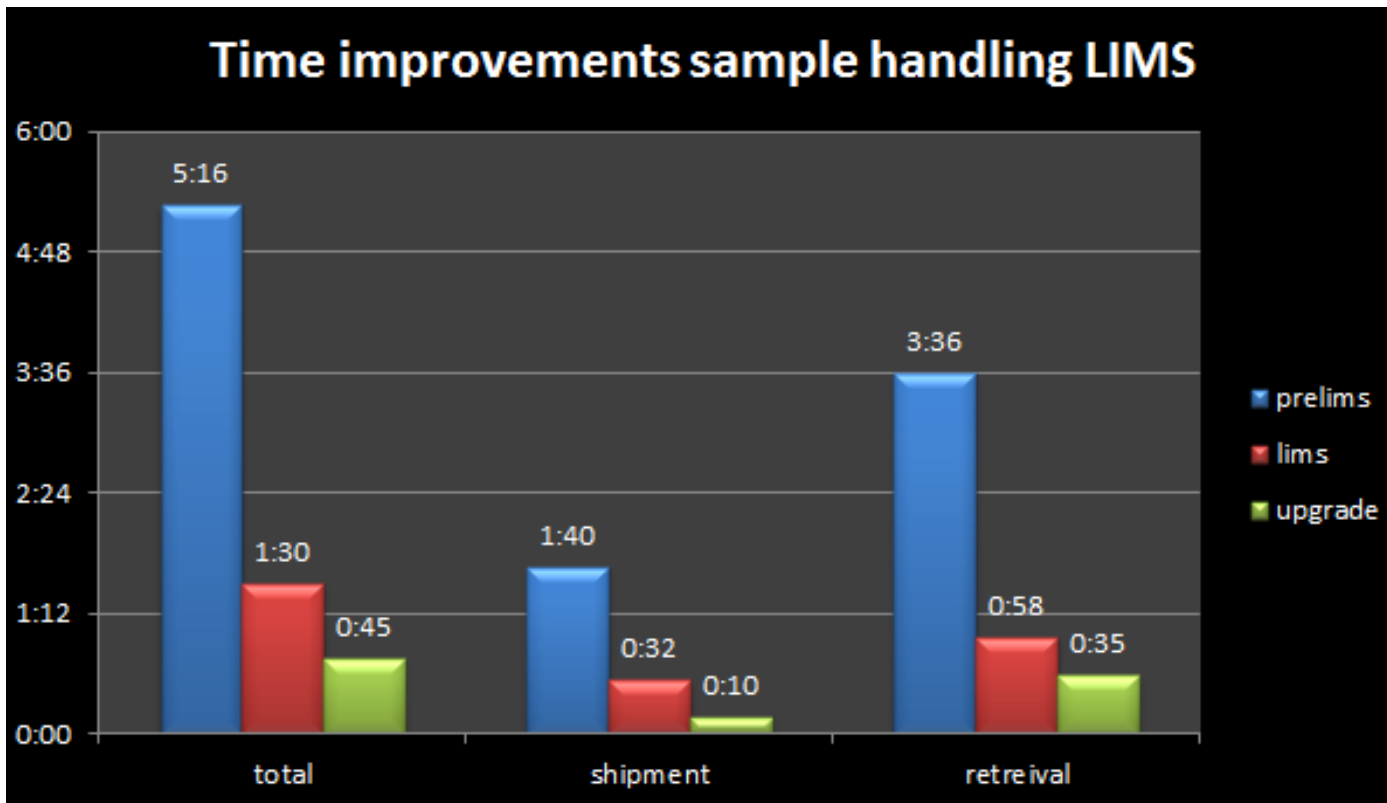
Aliquot #	Has Flags	Consent	Subject ID	In Spec	Canceled Out	Investigated	Released	Current	Set Reason
JBO7-068	E	Y	JBO7-68	T	F	F	F	Impacted	<input type="button" value="Hold"/>
PHU1-003	E	Y	PHU1-001	T	F	F	F	Impacted	<input type="button" value="Hold"/>
PHU1-037	E	Y	PHU1-004	T	F	F	F	Impacted	<input type="button" value="Hold"/>



LIMS Gains

	prelims	lims	upgrade
total	5:16	1:30	0:45
shipment	1:40	0:32	0:10
retrieval	3:36	0:58	0:35

Calculate improvement		update
Pre LIMS	317	
LIMS	91	45
percentage profit	71%	85.79%



LIMS Gains

- 60% Tijdwinst op de assays alleen
- 85% Tijdwinst maximaal op andere features

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