

Box 84

theranos

QUALITY SYSTEMS PRESENTATION

Q1/Q2 2014 Review

Present By: Langly Gee

July 10, 2014



AGENDA

- Mission and Core Value Statements
- Laboratory Licensures
- Sample Volume versus Forecast
- 12 Quality System Essentials
 - Organization
 - Process Improvement
 - Process Control
 - Occurrence Management
 - Audits – External & Internal
 - Documents
 - Personnel
 - Customer Service
- Information Management
- Equipment
- Facilities & Safety
- Purchasing and Inventory



MISSION AND CORE STATEMENT

Mission: Our mission is to make actionable health information accessible to people everywhere in the world at the time it matters, enabling early detection and intervention of disease, and empowering individuals with information to live the lives they want to live.

Core Values: We as employees of the CLIA Laboratory at Theranos put the patient first and in support of that goal will promote the highest quality of laboratory services and adhere to our company's policies and procedures at all times. We adopt performance standards which will ensure the delivery of superior health care services.



THERANOS LABORATORY LICENSURES

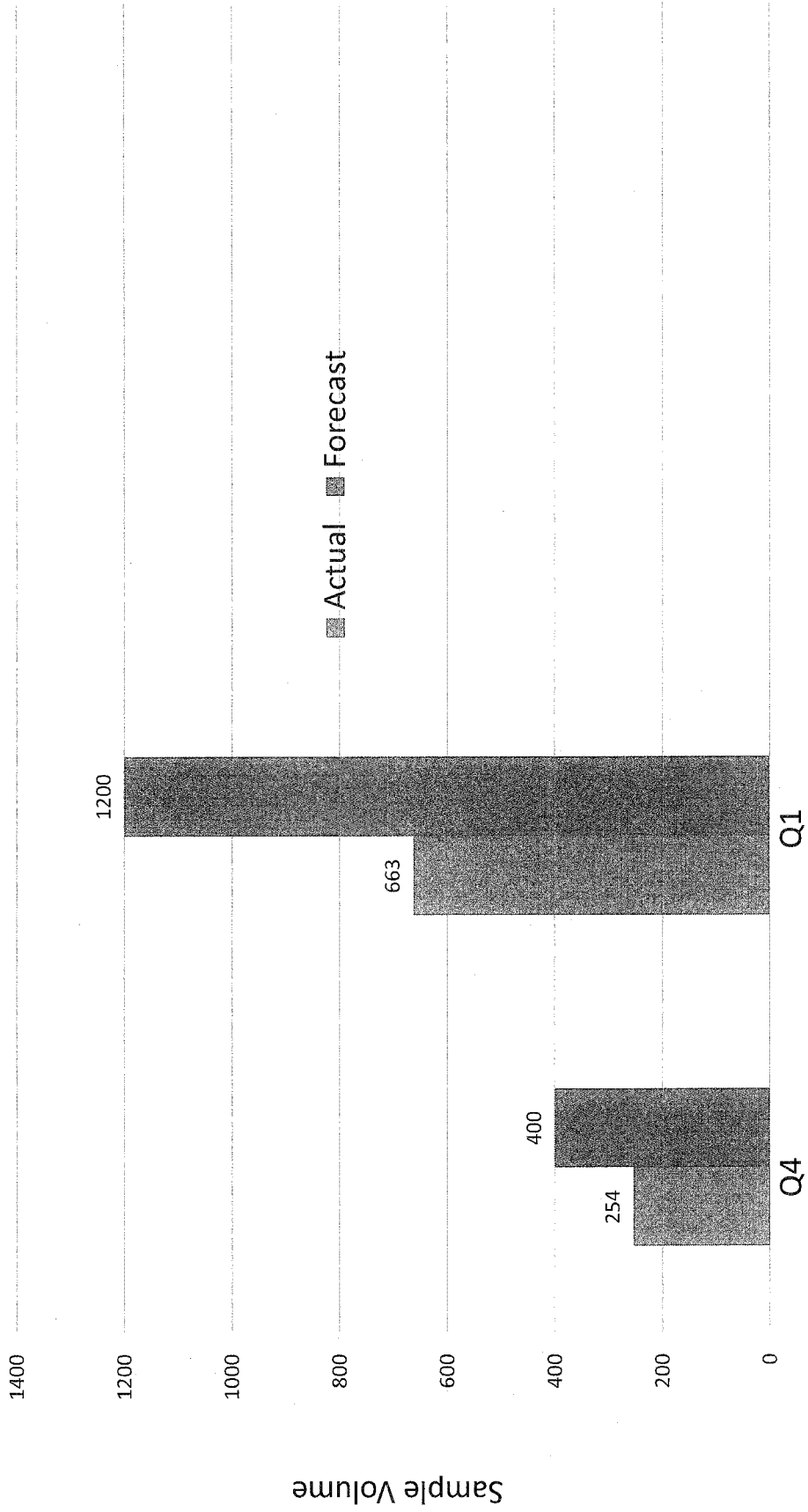
- CLIA 1601 – June 14, 2015
- CLIA EMC – Application pre-qualified 6/27/14 Pending Inspection
- CLIA ARIZONA – Temporary License received 6/24/14, can begin testing
- CMS – January 8, 2016
- Florida – October 21, 2014 (In process)
- Maryland – June 30, 2014 (Application received in Maryland 6/18/14, No lapse, License in 6-8 weeks)
- New Jersey – December 31, 2013 (In-process)
- New York – Pending Approval
- Pennsylvania – August 15, 2014 (License forthcoming)
- Rhode Island – December 30, 2014
- Santa Clara Department of Environment Health –February 28, 2015

REFERENCE LABORATORY LICENSURES

- ARUP – February 8, 2015
- UCSF – November 8, 2014

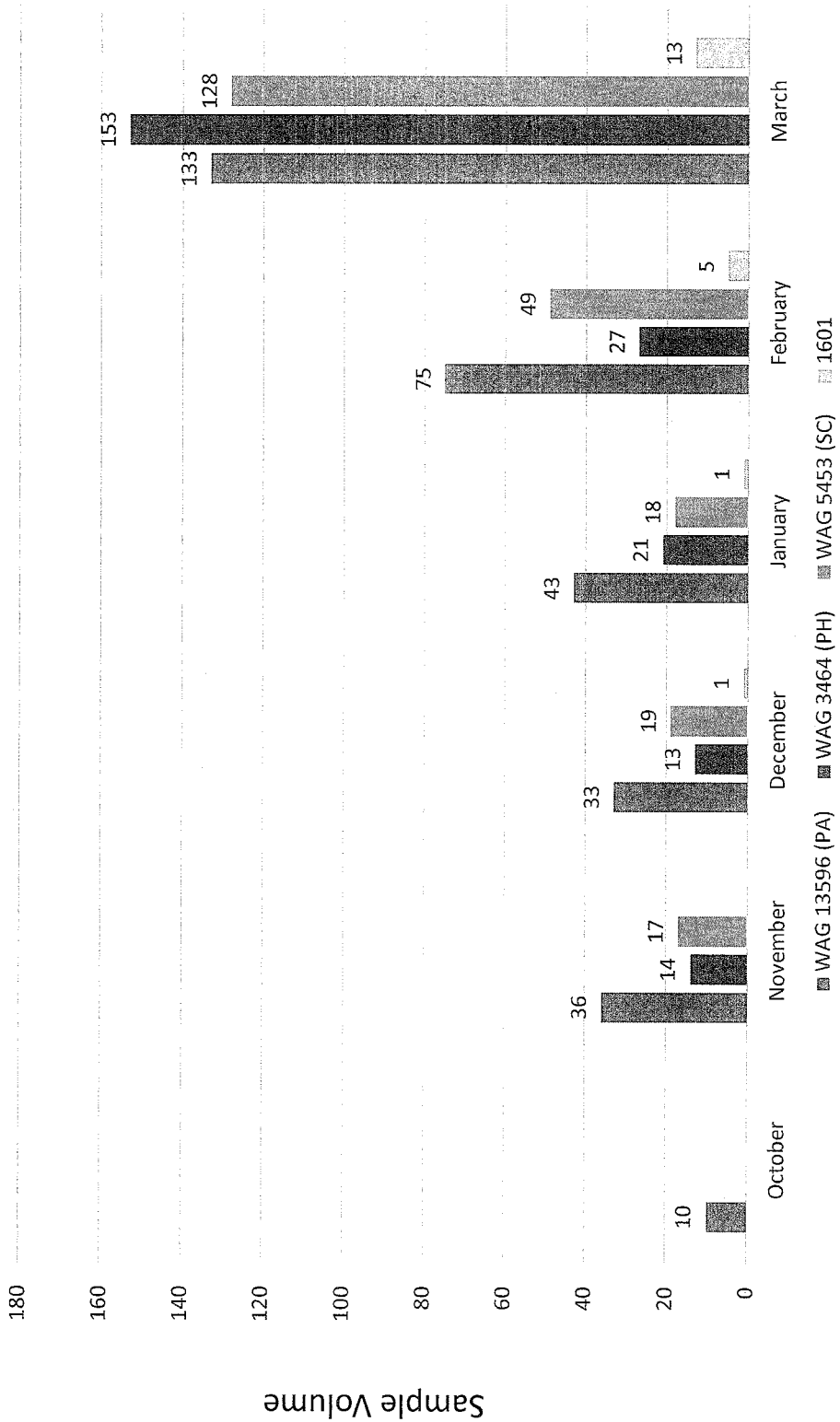


SAMPLE VOLUME VERSUS FORECAST



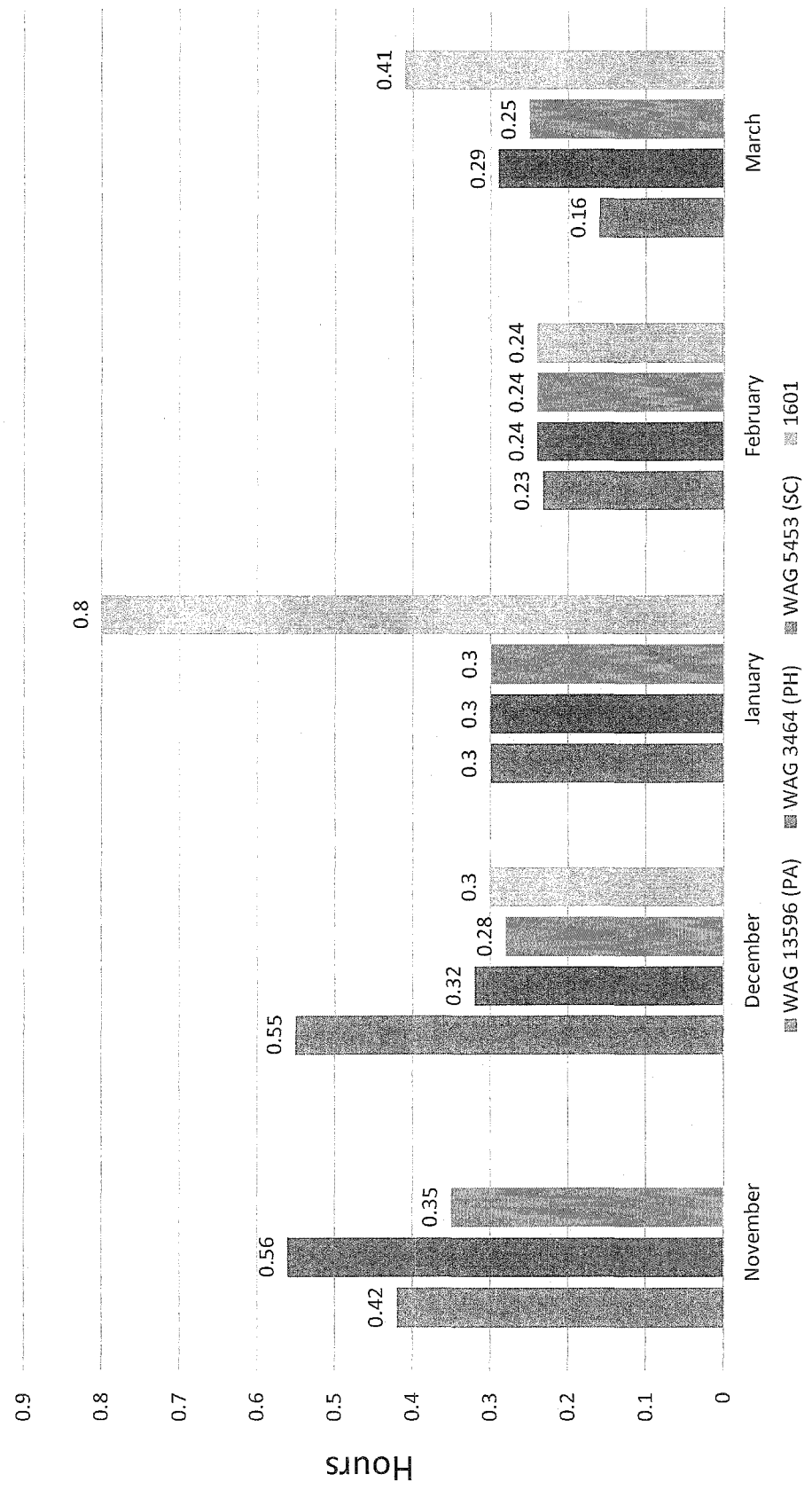


Walgreens / Theranos Samples By Store



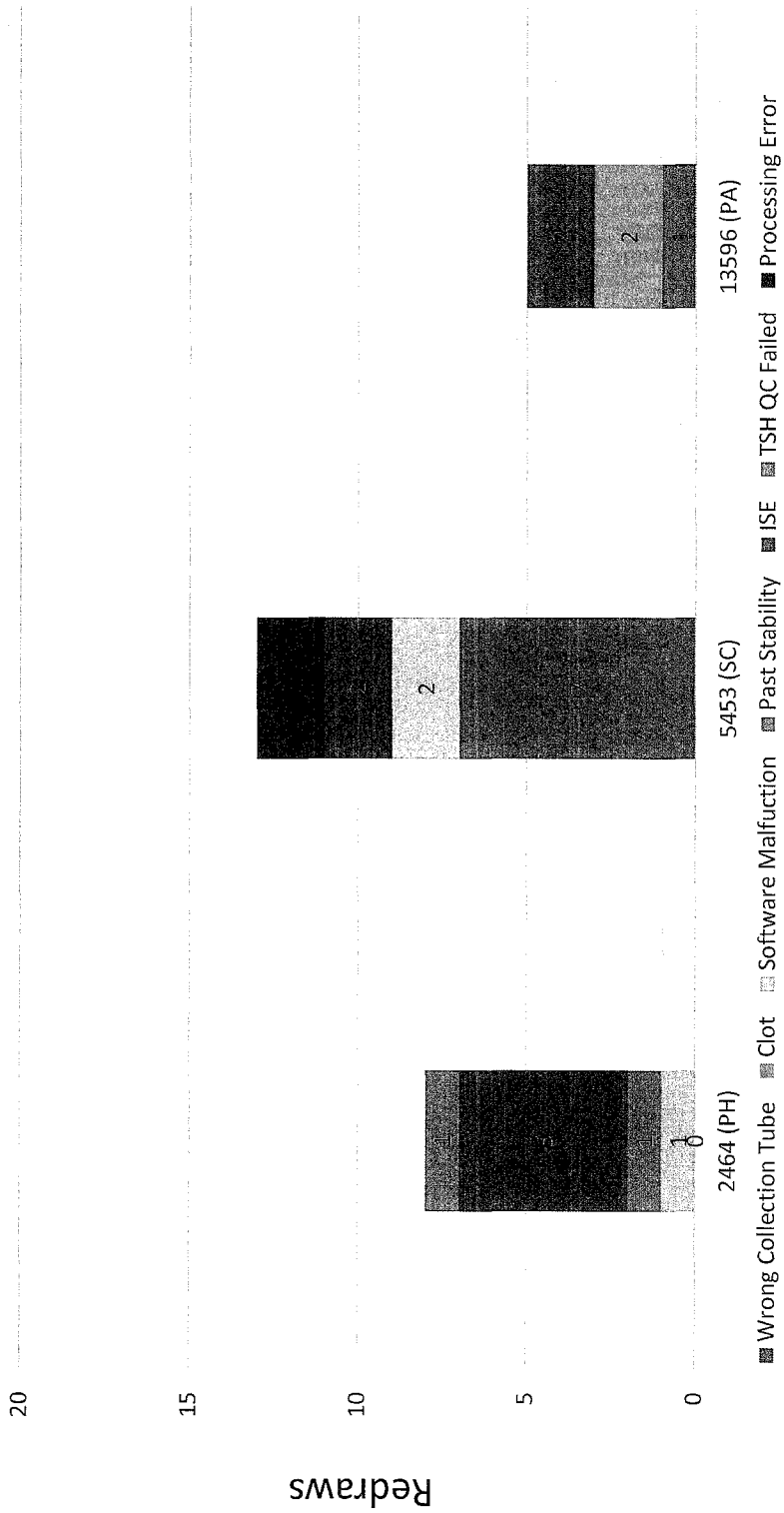


Average Patient Waiting Time At Walgreens Store / Theranos



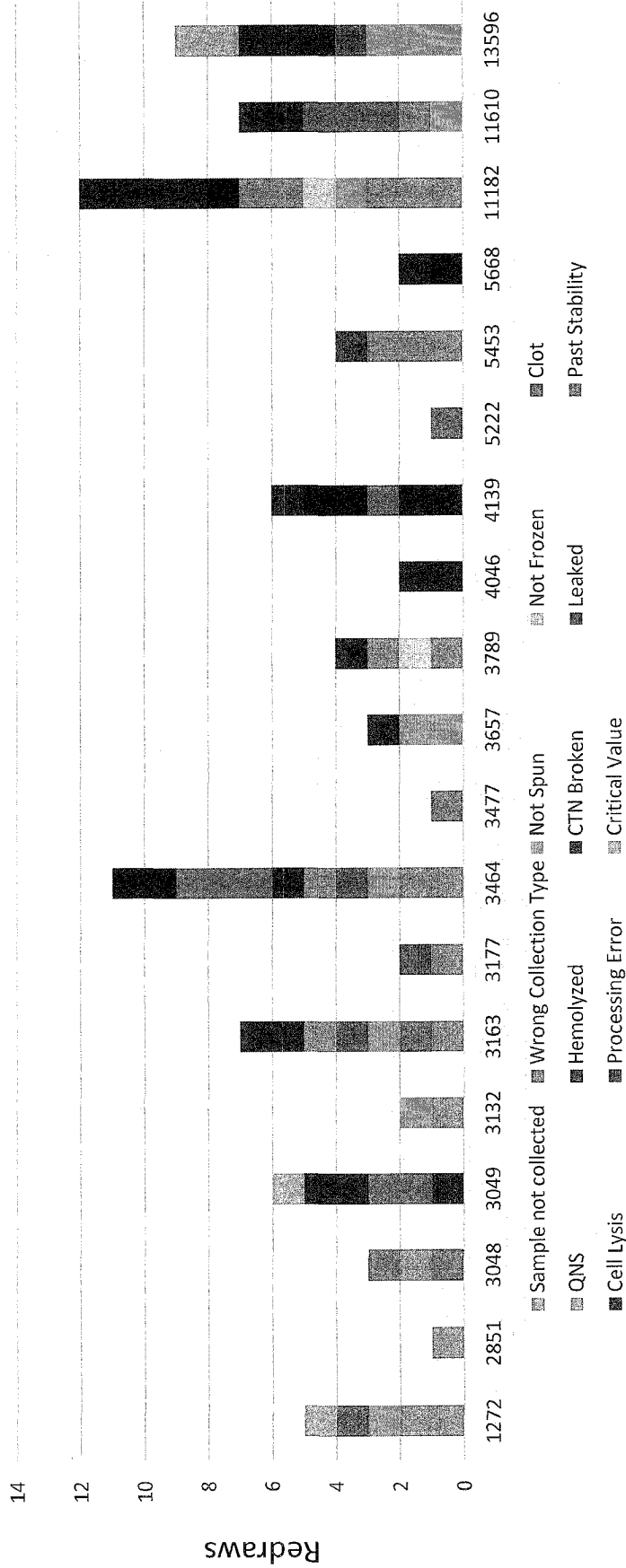


Redraws by Store Location (Q1)





June 2014 Redraws



Hoda, Nereyda, Kim, Melissa	Accessioning
Hoda, Chi, Nereyda	BD Phoenix Automated Microbiology System & BD EpiCenter
Hoda, Melissa, Kim	DiaSorin ETI-MAX 3000
Hoda, Nereyda, David, Kim, Jamie	DiaSorin Liaison
Hoda, Bryon, Kim	Idaho Technology Film/Array
Hoda, Chi, Heather, Stella, David, Kim	Immulite 2000 XPI
Hoda, Chi, David, Stella, Gurbir, Kim	Iris
Hoda, David, Gurbir	OraQuick HCV
Hoda, Chi, David, Stella, Gurbir	OraQuick HIV 1/2
Hoda, Kim, Bryon	Roche Triage
Hoda, Chi, David, Stella, Kim, Bryon	Ruby Cell Dyn
Hoda, David, Bryon, Ellen	Siemens Advia 1800
Hoda, Chi, David, Maria	Siemens BCS
Hoda, Chi, David, Stella	Siemens DCA
Hoda, Chi	Siemens RapidPoint 400/405/500
Hoda, Chi, Nereyda, David, Stella	Streck ESR
Hoda, Stella, Gurbir	BD Macro Vue RPR
David, Bryon Ellen	Siemens Advia 1800
Kim, Nereyda, Romina, Aurelie	CBC
Aurelie, Erika, Jamie, Romina	ELISA
Maria, Bryon, Ellen	PT

Black -- Upstairs
Red - Normandy

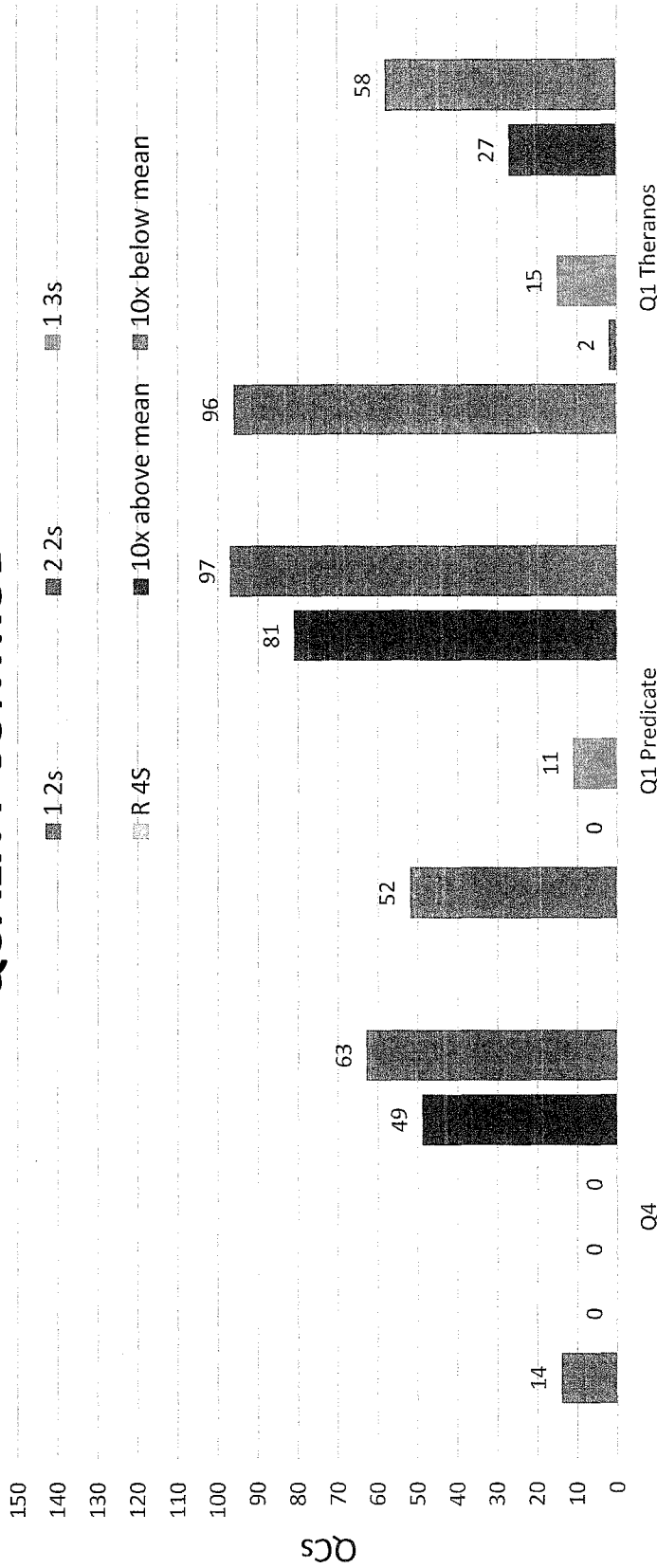


PROCESS IMPROVEMENT

- Improvements to LIS: Pending Lab Review, Fax capability from LIS, Critical Review Screen, 1 Visit/2 Doctor Orders, Viewing Scanned Orders, patient TAT (See Max email 3/28/14 and 6/26/14)
- Increased staff by 12 employees
- Inventory Management Training
- Inventory Monitoring Assignments
- Color Blind test up to date
- Competency Forms
- Edison Levey-Jennings charts created by Karthik
- Transferred four assays to Normandy - Total of 8 (6-tip) assays
 - TT3
 - TT4
 - Testosterone
 - HCG



QUALITY CONTROL



Q4

- 172 Assays Performed
- 10192 Controls Analyzed
- 0.14% Controls Failed
- 10x (CBC and Multiquel)

Q1 Predicate

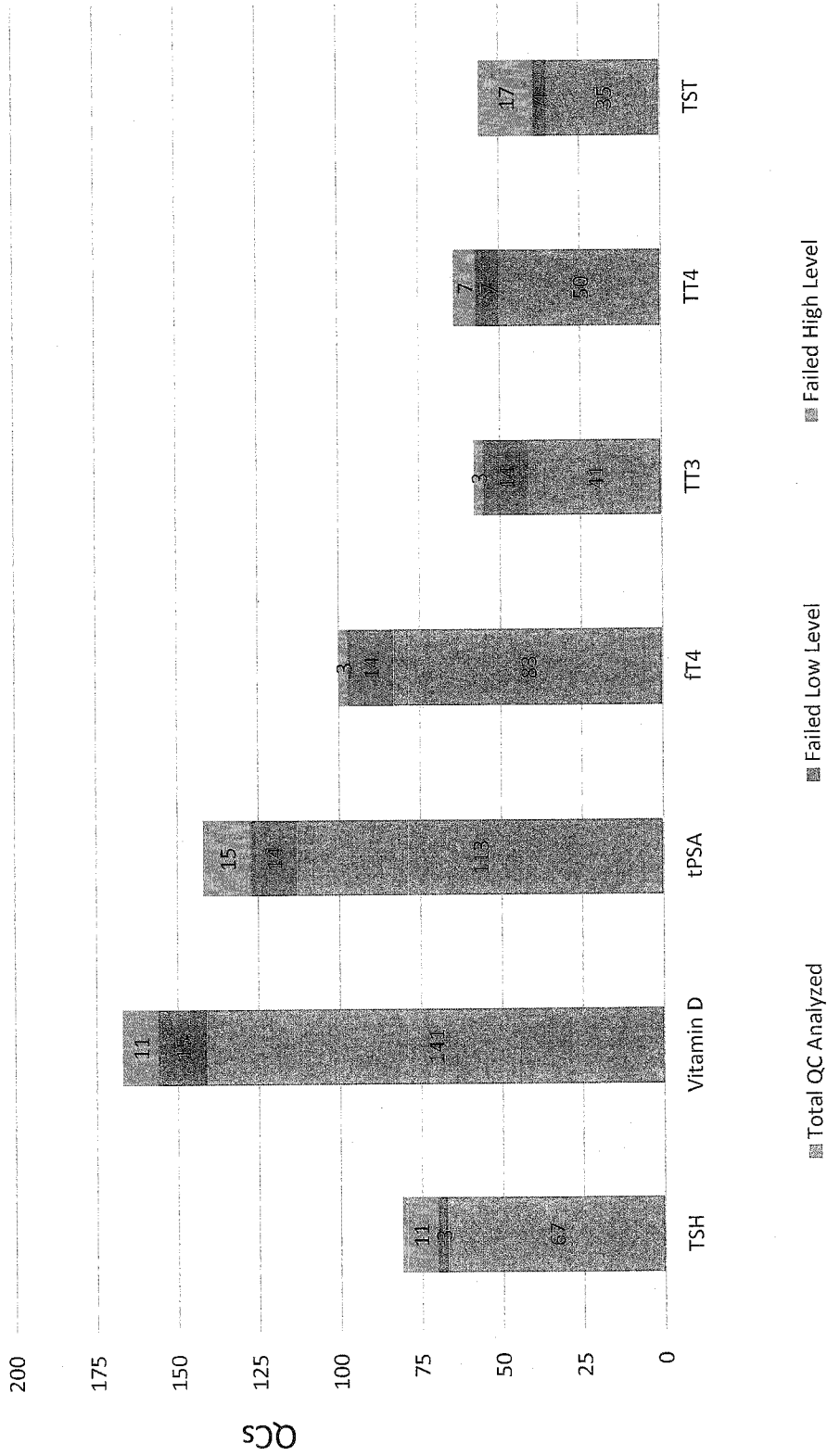
- 132 Assays Performed
- 8458 Controls Analyzed
- 0.75% Controls Failed
- 10x (CBC and Multiquel)

Q1 Theranos

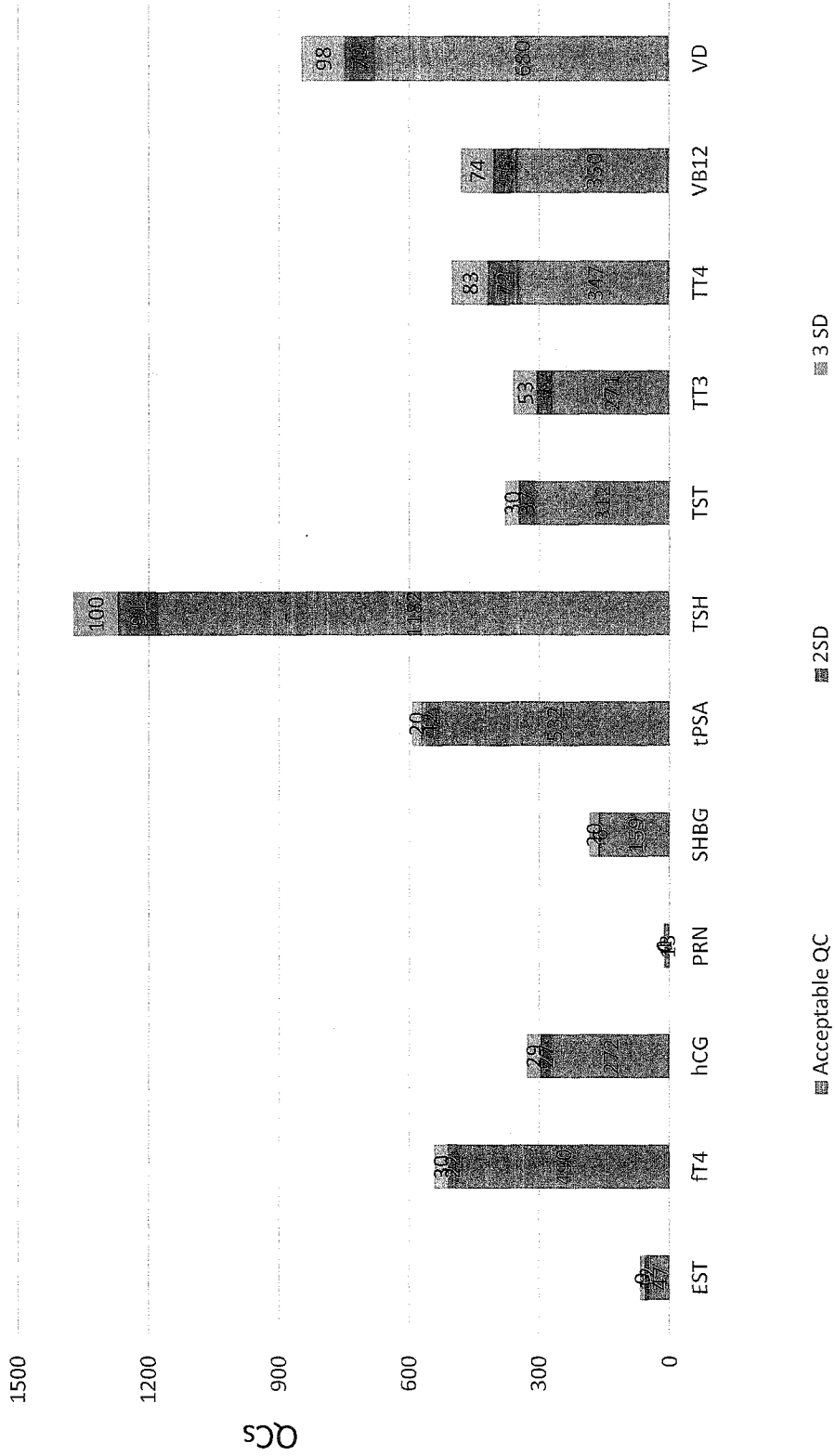
- 52 Assays Performed
- 3879 Controls Analyzed
- 2.9% Controls Failed
- 10x (Multiquel)



ELISA FAILED QUALITY CONTROL (Q1)

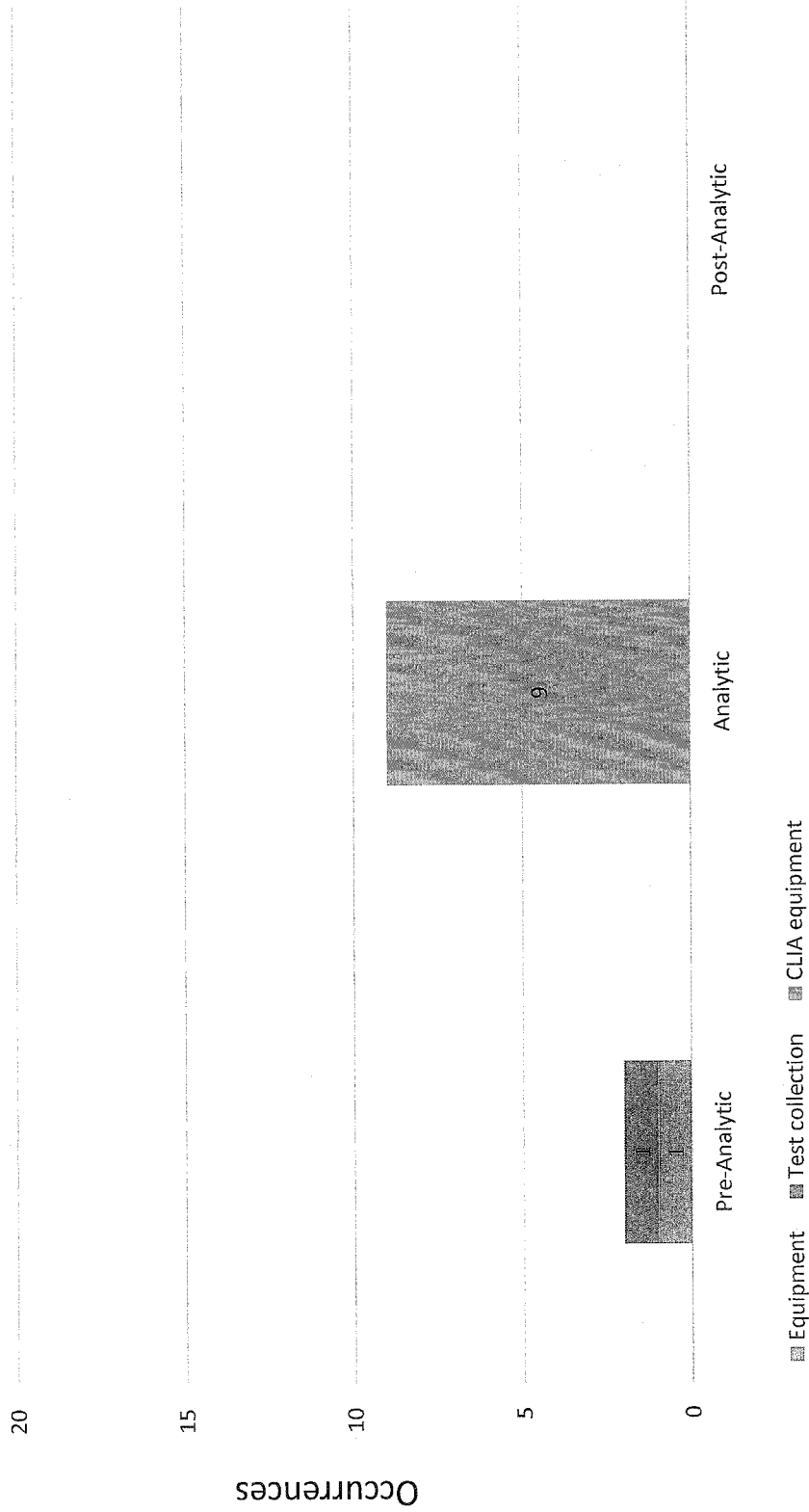


EDISON QUALITY CONTROL (Q3)

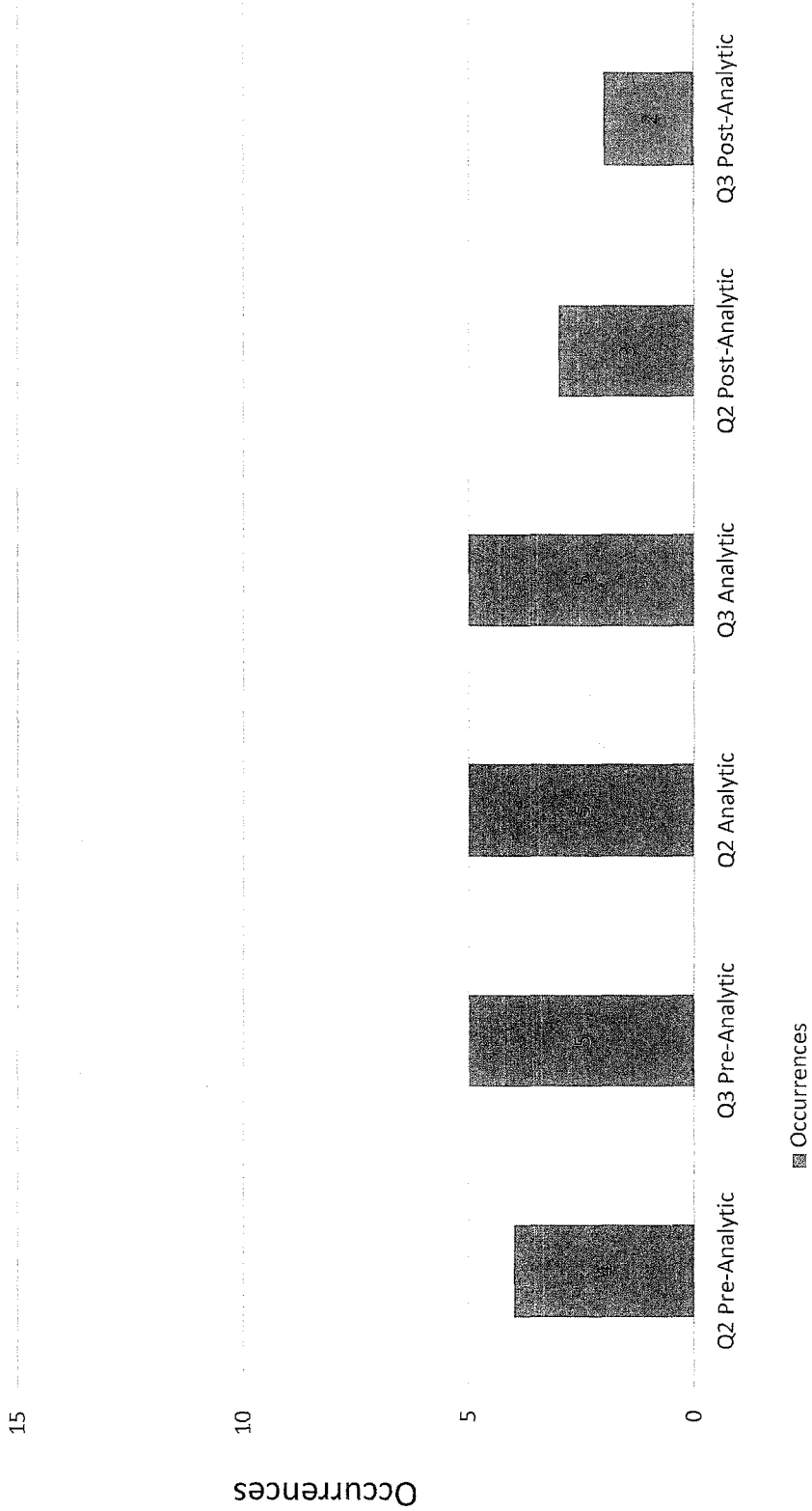




OCCURRENCE (Q1)



OCCURRENCE (Q2 and Q3)





OCCURRENCE Q2

Pre-Analytic

- 10 New Stores
- Shipment Delays
- CTN aliquoting
- New receiving app

Analytic

- New Equipment: FruitFly, Centaur1 & 2, Taylor
- Manufacturer Visits: ELGA filters, Immulite Rubella IgG
- Backorders: hCG
- ISE analyzed neat → 2.5x
- Edison hCG

Post-Analytic

- LabDAQ Bridge
- CBC results bias correction
- Server down preventing fax service



OCCURRENCE Q3

Pre-Analytic

- 20 New Stores
- Shipment Delays
- Abbott tube aliquoting
- Customer scans TRFs
- Expired CTNs used

Analytic

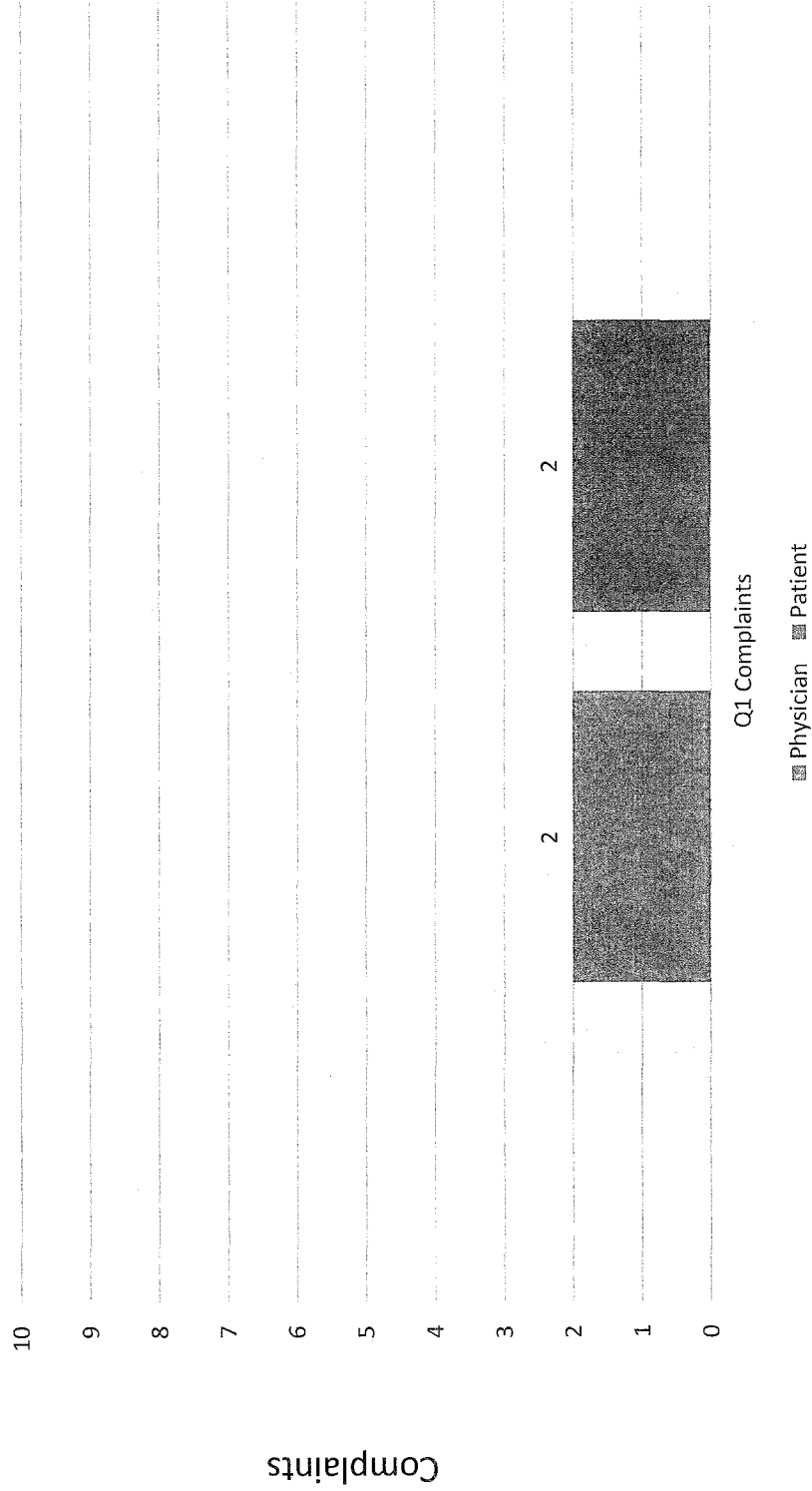
- New Equipment: ThunderBolt, Drew3, TANGO
- Manufacturer Visits: Advia1 probe crash, Immulite elevator and waste, BCS lane sensor and broken sprocket, Advia3 leak sensor, ELGA water filters
- Backorders: ELGA LC136 filter, Siemens HbA1c calibrator, BNP, HBsAg
- Recall: Siemens HbA1c and Calibrator E
- Edison SHBG, Vitamin B12, Estradiol, Prolactin

Post-Analytic

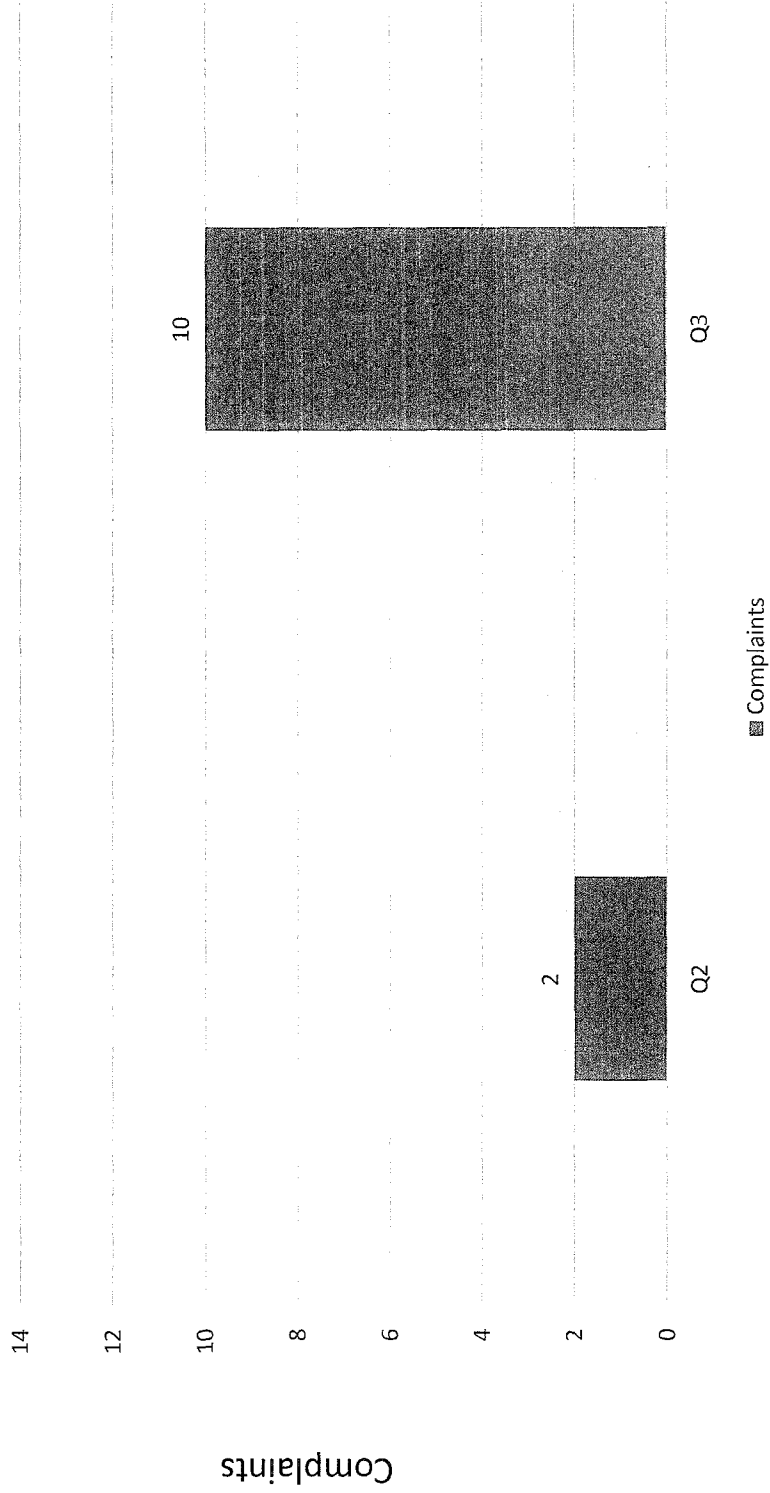
- Corrected Report: PT/INR
- Results faxed to API



COMPLAINTS



COMPLAINTS



COMPLAINTS

Q2

- Physician upset that sales team did not tell her we did not run all tests (E1 and E3)
- Arizona Republic stated that physician's order is needed x 2

Q3

- No one answered phone on Sunday and could not leave voice mail
- Results went to wrong store and test ordered was incorrect
- Bad experience
- Doctor's results went to office instead of personal fax
- Lab ordered wasn't signed
- Testosterone result was wrong
- Results were sent by mail
- Upset it was a venous draw
- Laboratory report stated "Pending Potassium Redraw" and no was alerted
- Results were not received by mail

AUDITS – EXTERNAL AND INTERNAL

External Assessment: None

Internal Assessment: An internal Patient Record Audit was performed for Q1 on April 21 & 22, 2014

1. Ordering Physicians were not providing NPI and ICD9 codes
2. ACTH and IGF-I not offered to ordering physician
3. ISE results not reported, redraw requested, patient has not returned
4. Temperature and Humidity monitoring and Siemens DCA maintenance not performed

Internal Assessment: Personnel Binders was performed on April 23, 2014

1. Various binders did not include current resume, color blind test, media lab and competency training
2. Email sent to CLIA lab to update binder



AUDITS – EXTERNAL AND INTERNAL

External Assessment: None

Internal Assessment: An internal Patient Record Audit was performed for Q2 on July 14, Sept. 3 and 4, 2014

Pre-Analytic

- Test Requisition Form not completed – Customer Service call doctor's for the necessary information
- NPI Number not provided – Customer Service searches for NPI on web site
- Provider did not provide ICD-9 codes – Billing department will call doctor's office if insurance is to be billed

Analytic

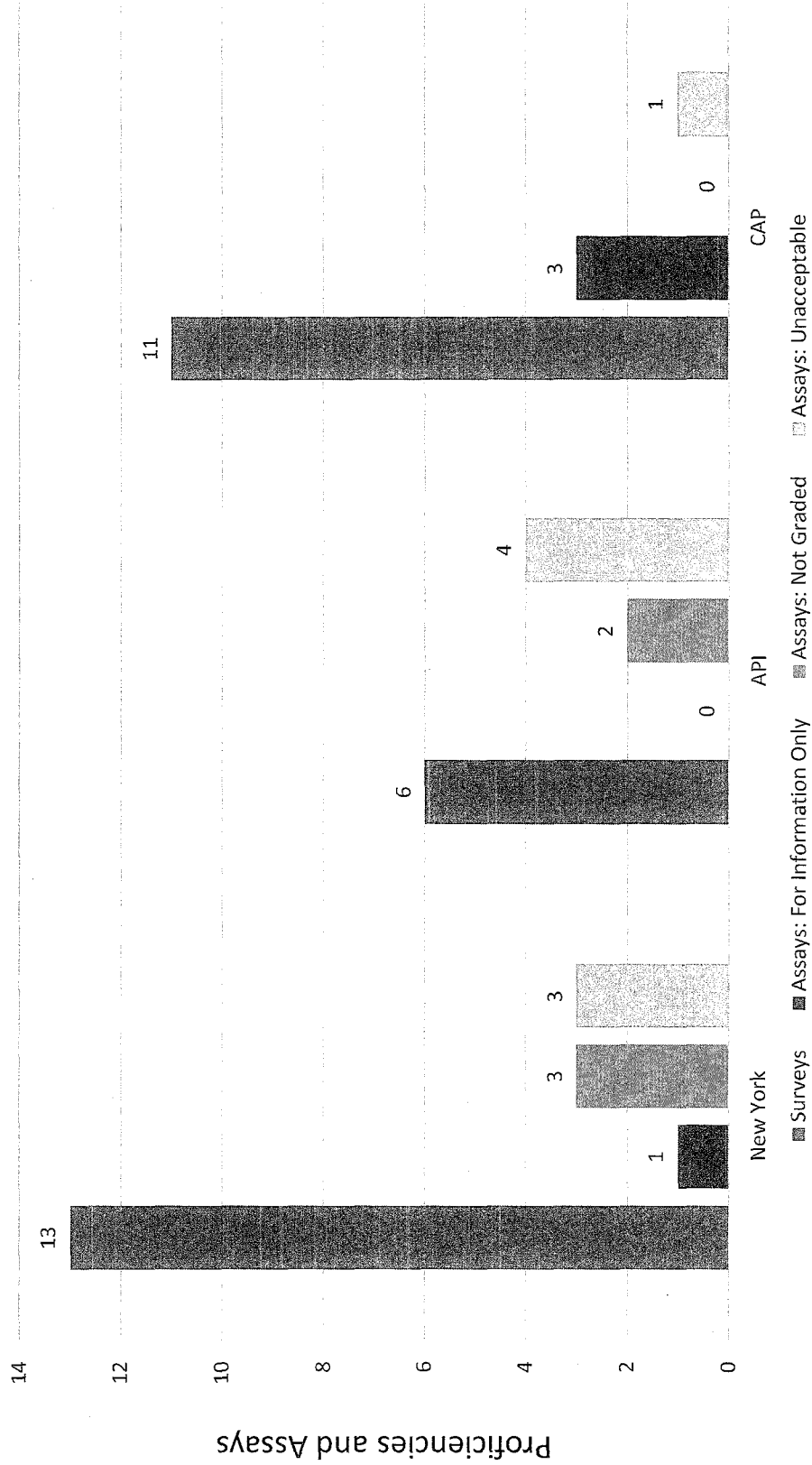
- Temperature and Humidity were not recorded – New temperature / humidity logs created and attached to each refrigerator / freezer. Assigned individuals for daily monitoring
- Daily maintenance for Immulite 2000 XPI was not recorded for 6/15/2014 – Discussed the importance of maintenance in staff meeting

Post-Analytic

- Patient's first name misspelled on laboratory report (Liliana versus Lilliana) – The first name was corrected in LIS and an amended report was sent

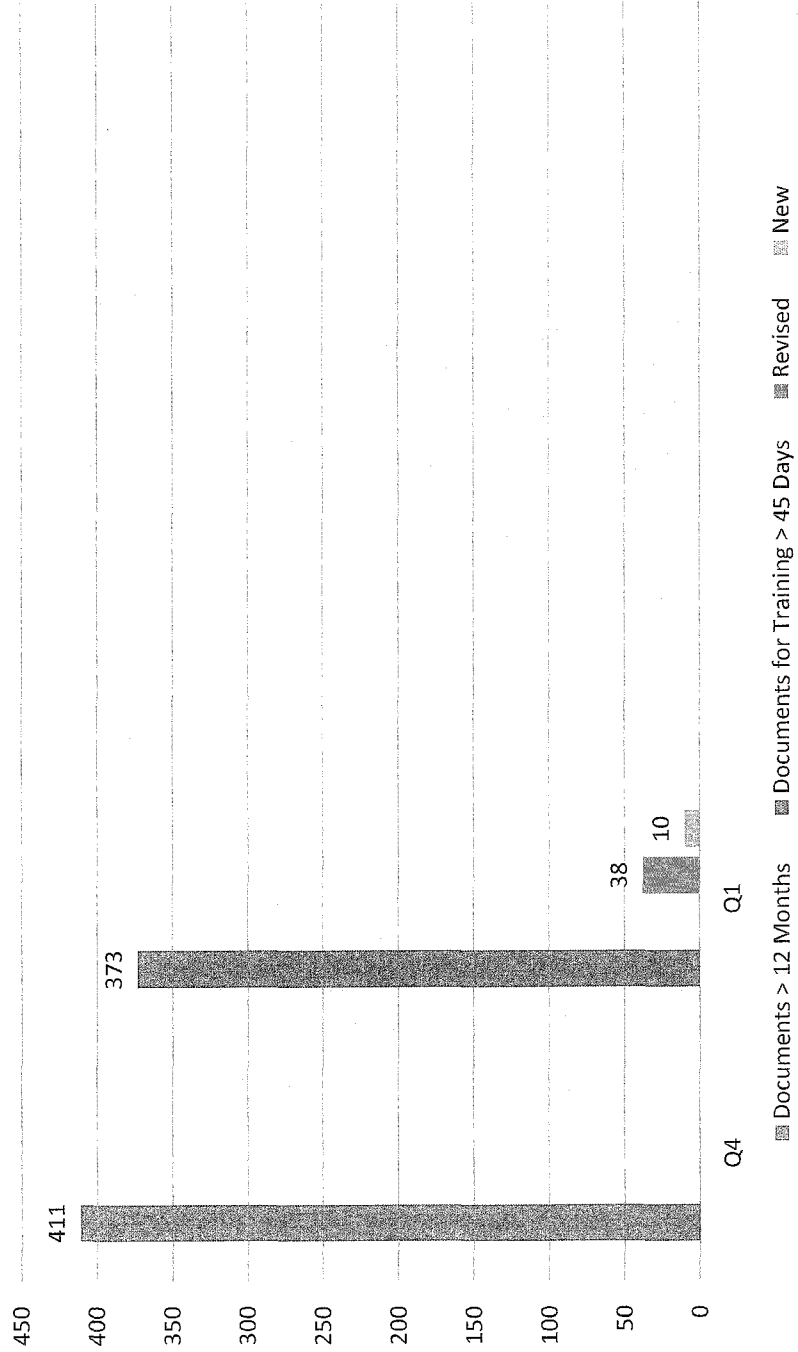


PROFICIENCY TESTING (Q1 and Q2)

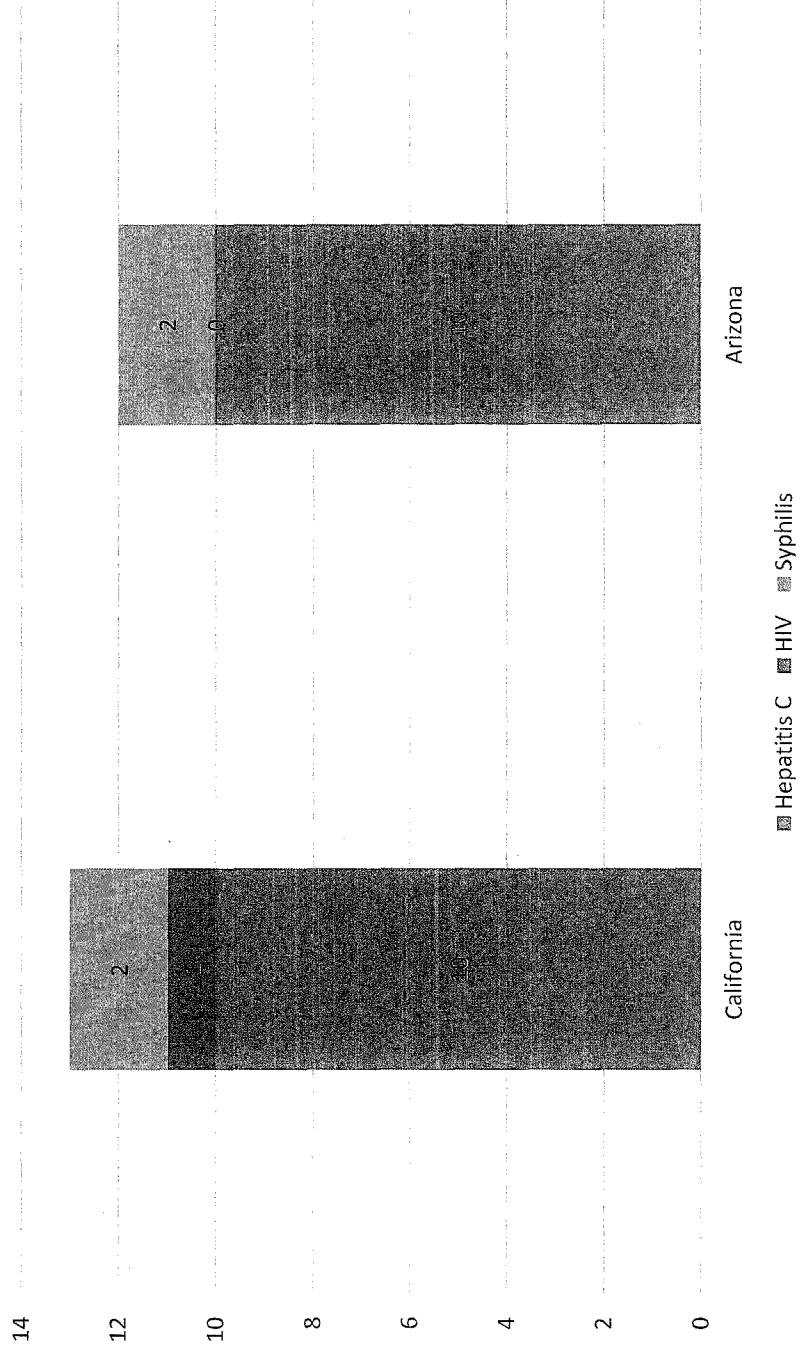




DOCUMENT REVIEW

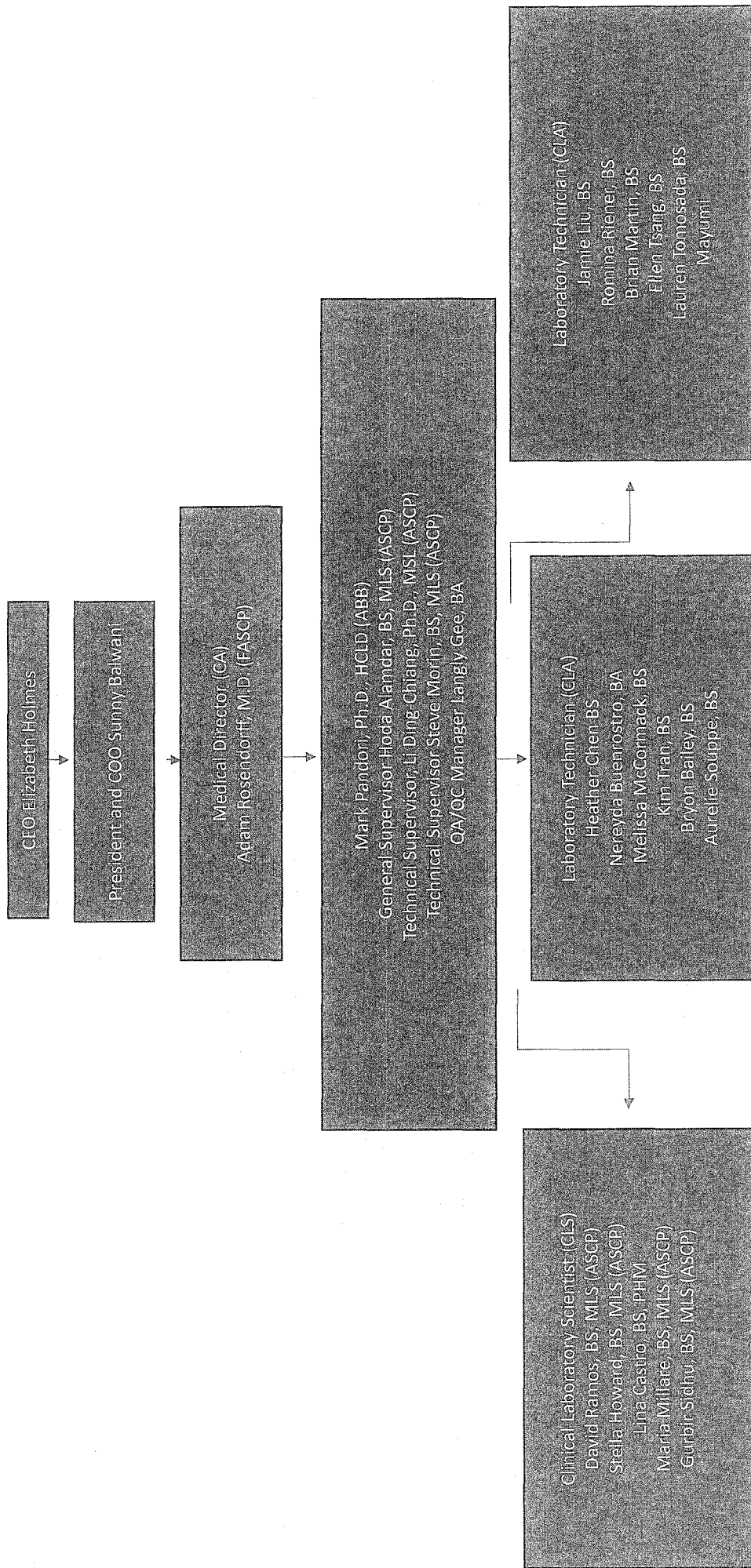


COMMUNICABLE DISEASE CONTROL Q1 and Q2



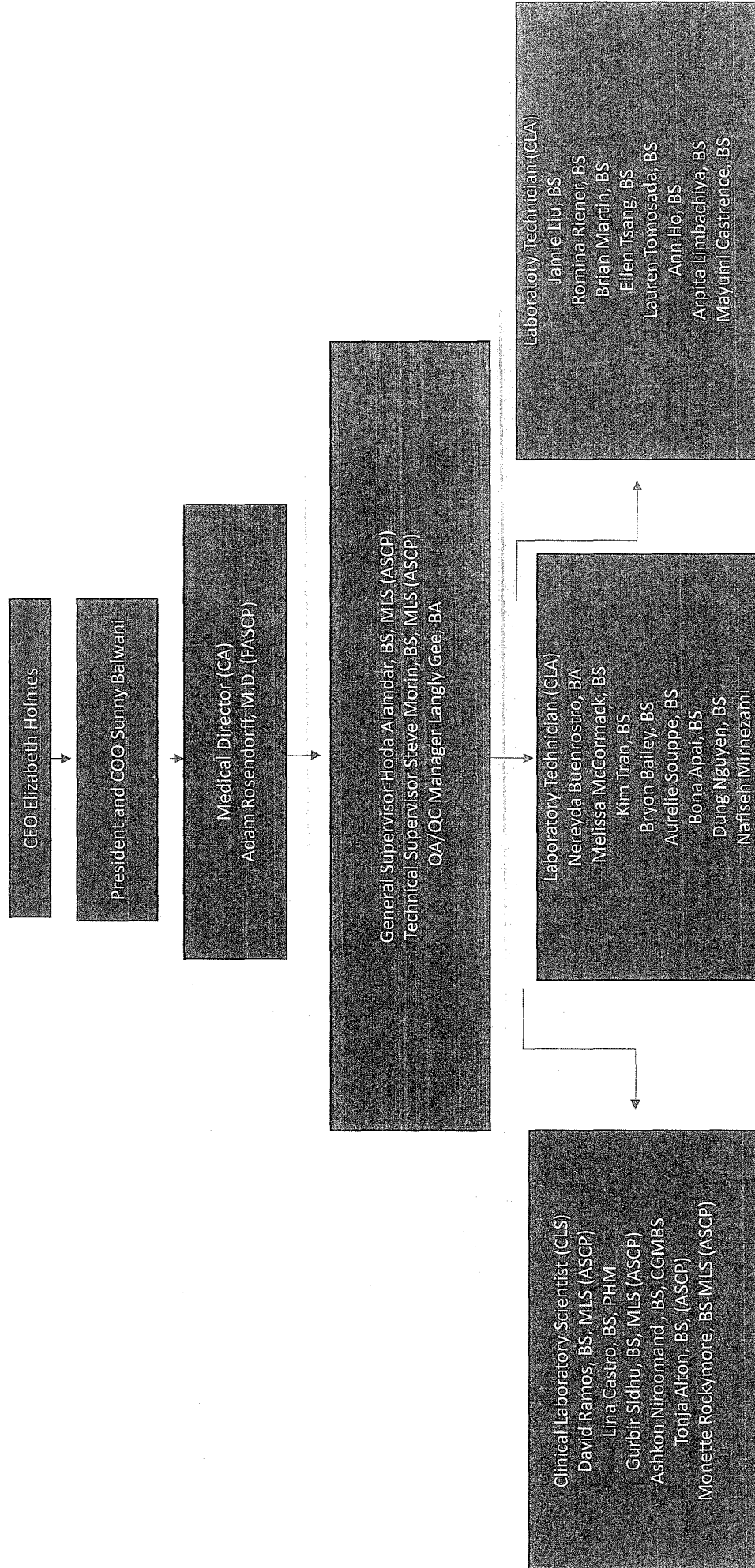


Quality Systems Manual QSM-0001
Section 8 Personnel
ORGANIZATION CHART (3/31/2014)



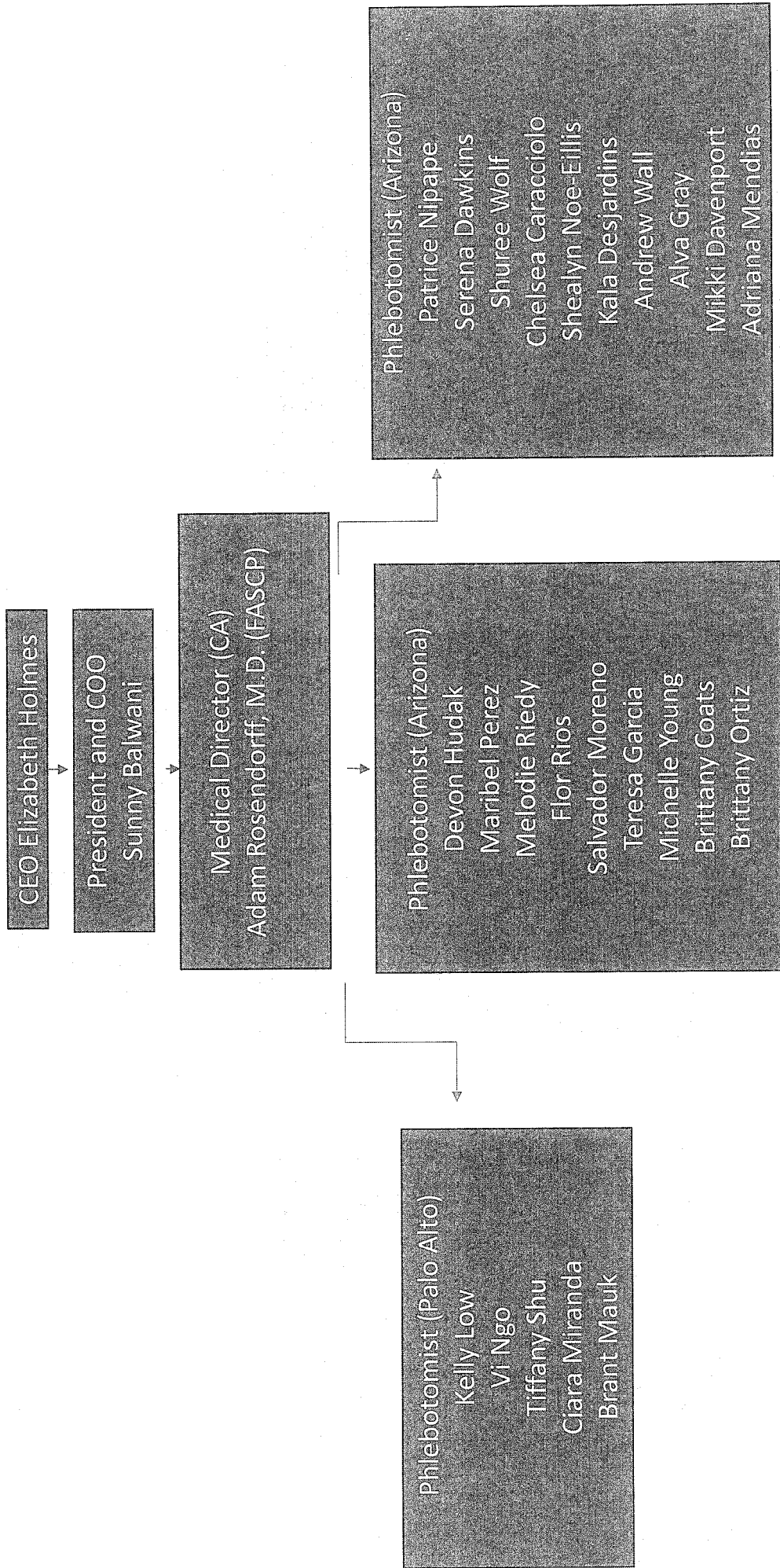


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Section 8 Personnel
ORGANIZATION CHART (6/30/2014)



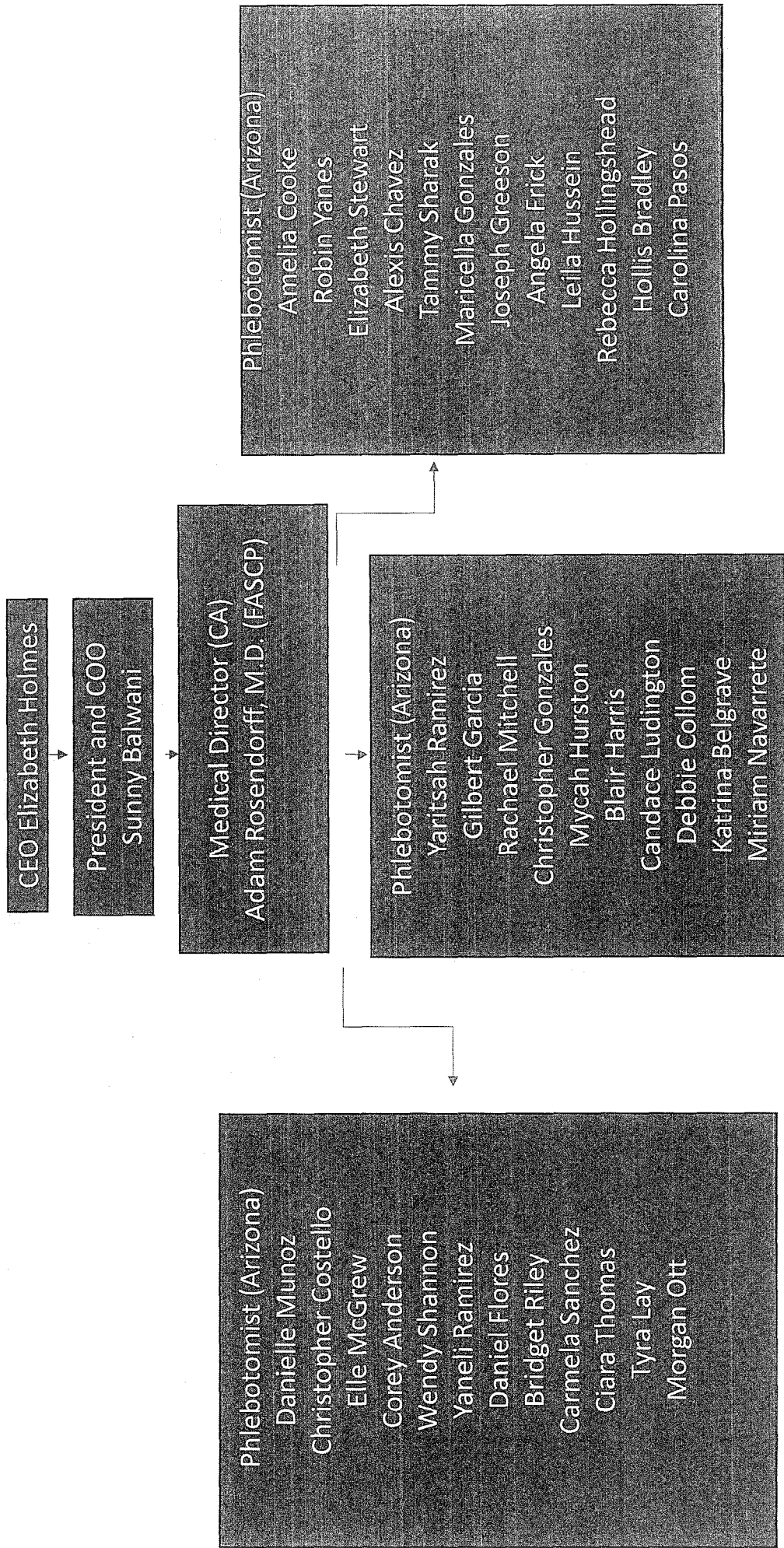


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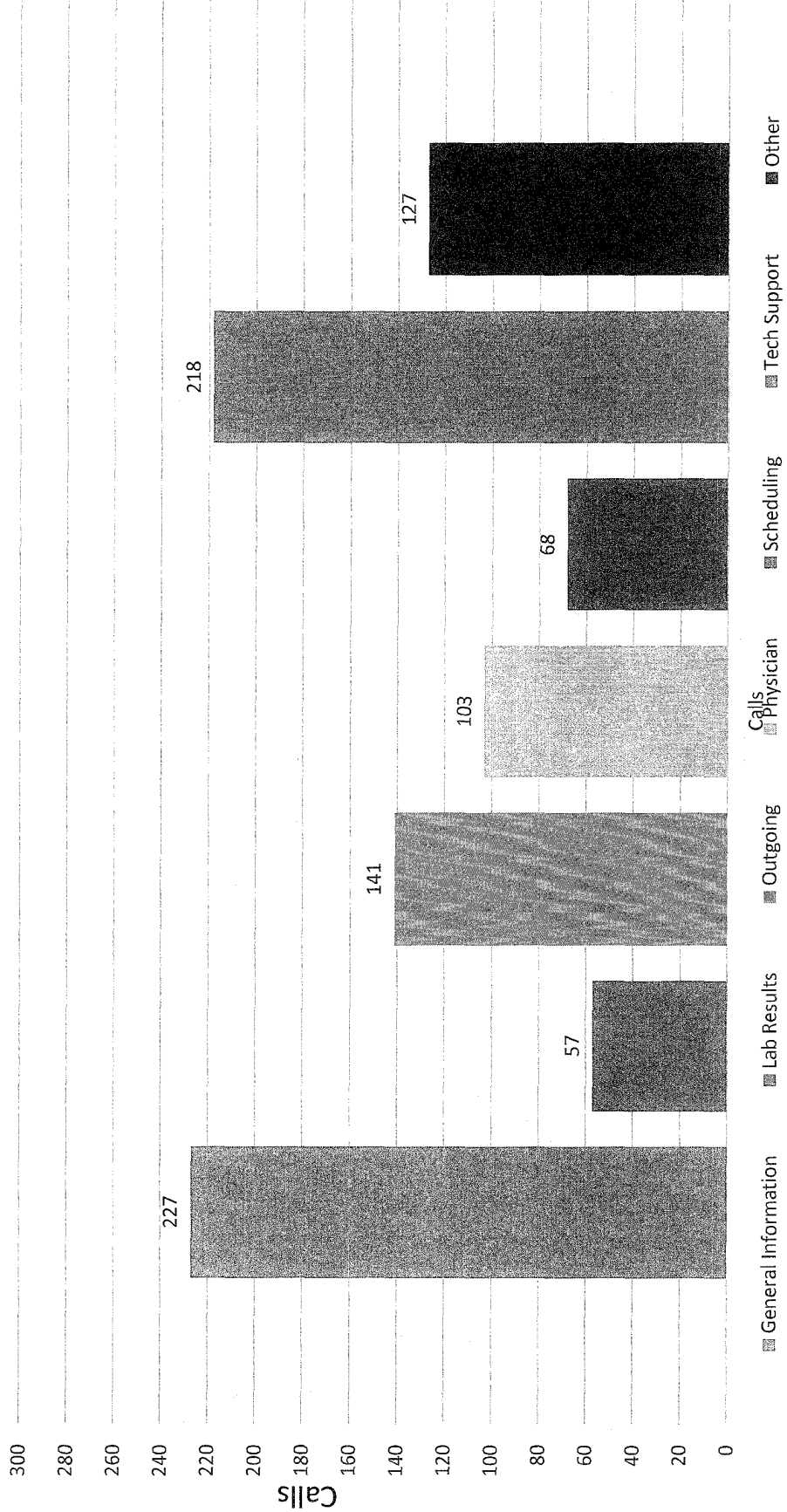


ORGANIZATION CHART (6/30/2014)



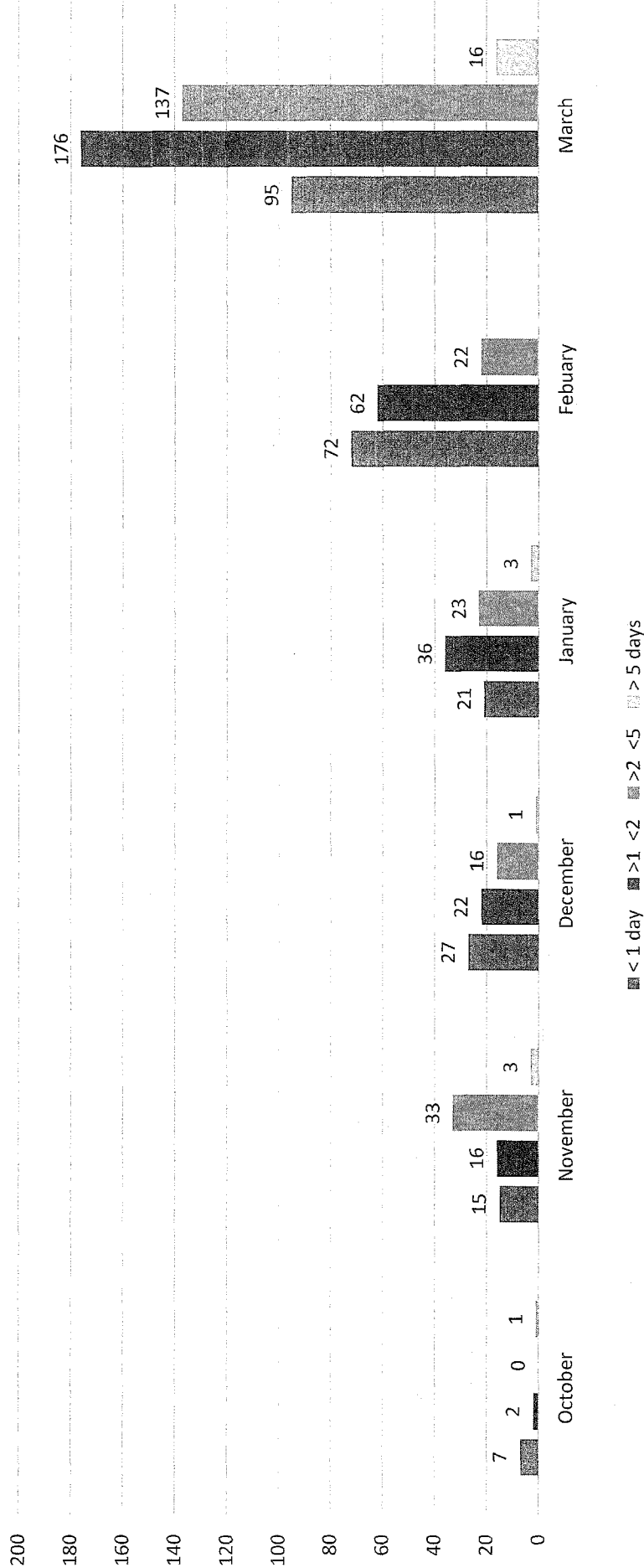


Customer Service Calls Q1

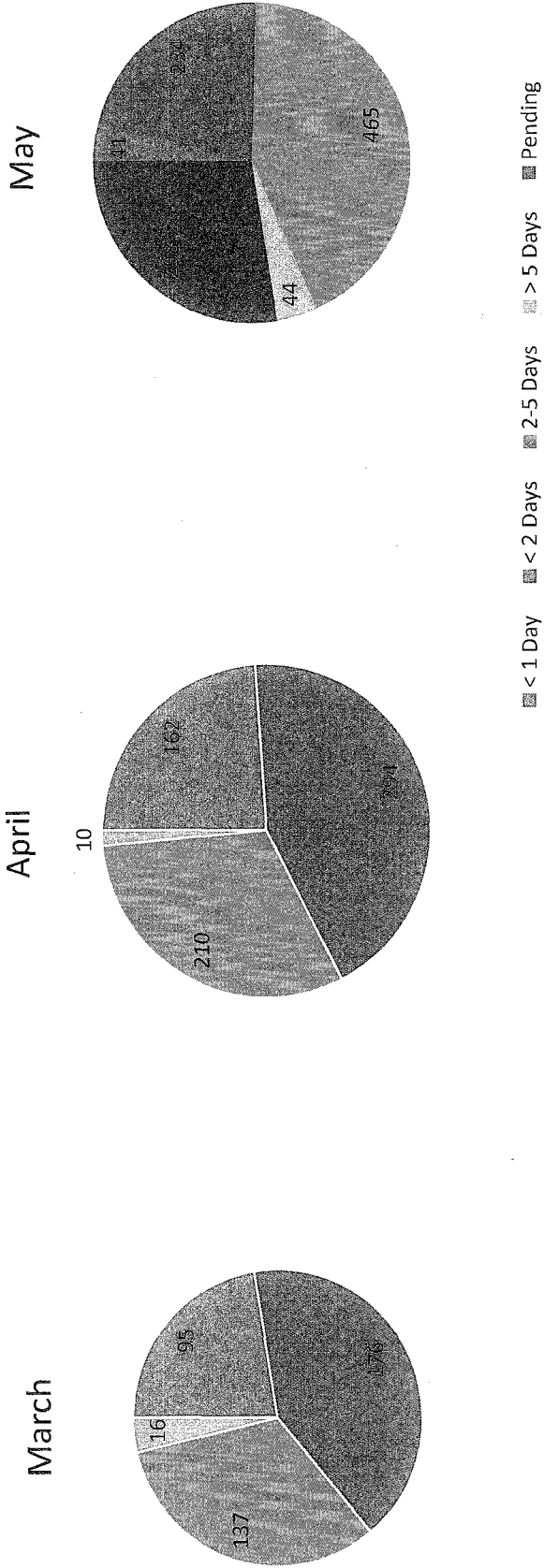




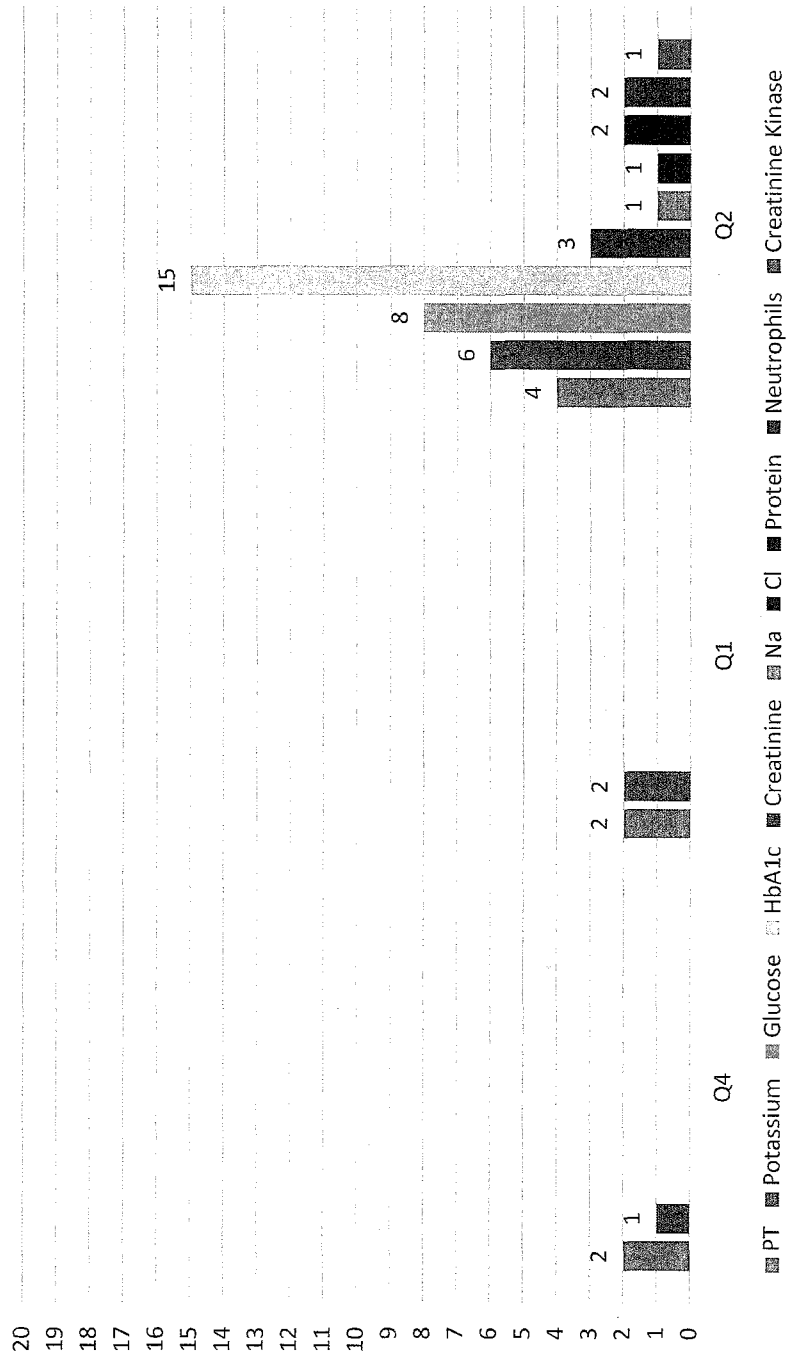
Walgreens Turn Around Time



MARCH, APRIL, MAY 2014 TAT

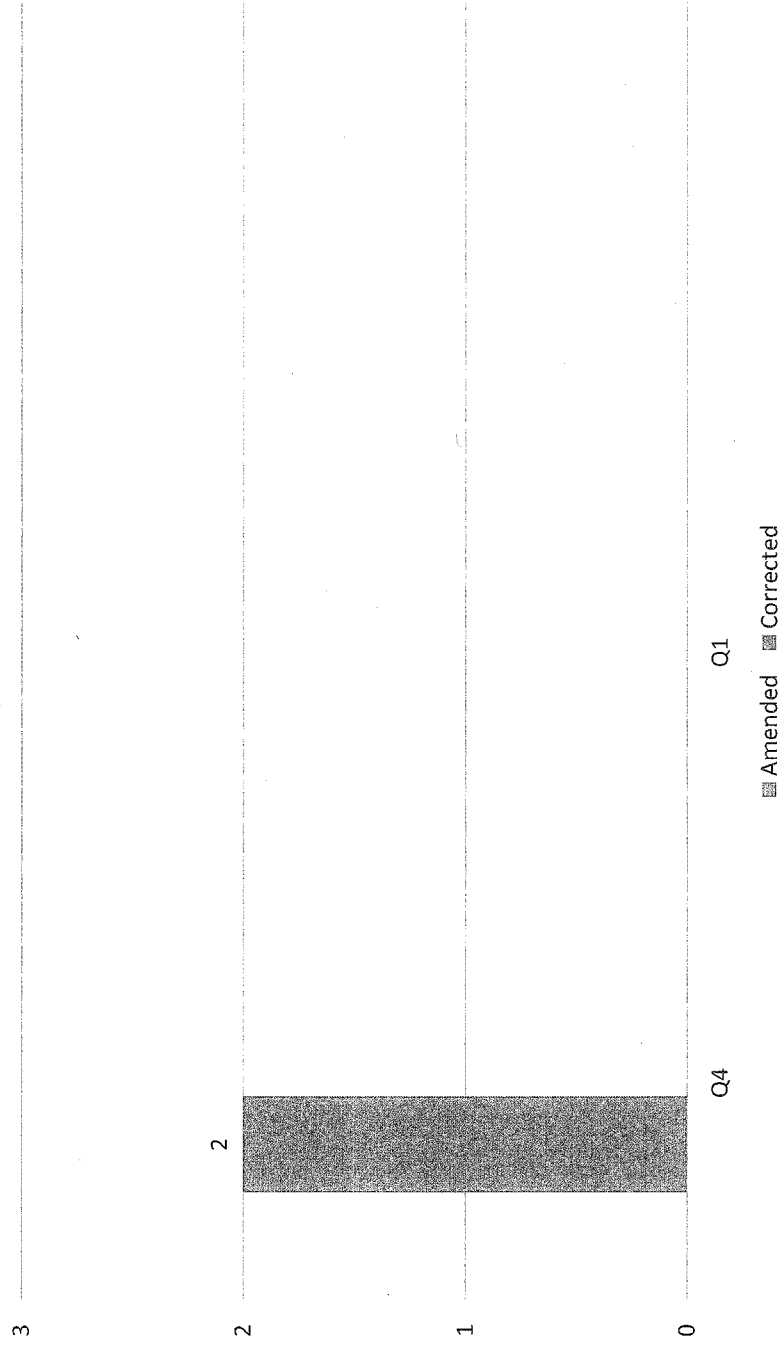


CRITICAL VALUES





AMENDED AND CORRECTED REPORTS



Information Management

Zero HIPAA events through Q2

- IR2488: Walgreens fax transmission cover page needs revision – Sonny D. (In process)
- Improvements to LIS: Pending Lab Review, Fax capability from LIS, Critical Review Screen, 1 Visit/2 Doctor Orders, Viewing Scanned Orders, Patient TAT (See Max email 3/28/14 and 6/26/14)
- Improvements to LIS 6/26/14 – Max to train CLIA staff
- Create a pop-up to prevent patient reporting with missing results – Max (In-process)

CLIA EQUIPMENT

Instruments In-house PM not performed:

- Immulite – Weekly
- BCS – 6 month
- Liaison – Weekly
- IRIS – Monthly

Manufacturer Service Calls:

- Siemens ADIVA 1 and 3 (Air in line causing over dilution, probe crash)
- Siemens Immulite (Rubella IgG controls failing)
- DiaSorin ETI-MAX (ANA assay failure, 6 month PM and training)
- DiaSorin Liaison (6 month PM and in-house training)
- ELGA (Water leak)

Temperature and Humidity monitoring inconsistent, training more staff

BioSafety Cabinet – past due Lina

Eye Wash Stations - June not done

13 pipettes calibrated, all passed as found

6 Timers past calibration, replacements ordered



FACILITIES & SAFETY

Zero on the job accidents through Q2 2014 – 273 Days No Lost Time

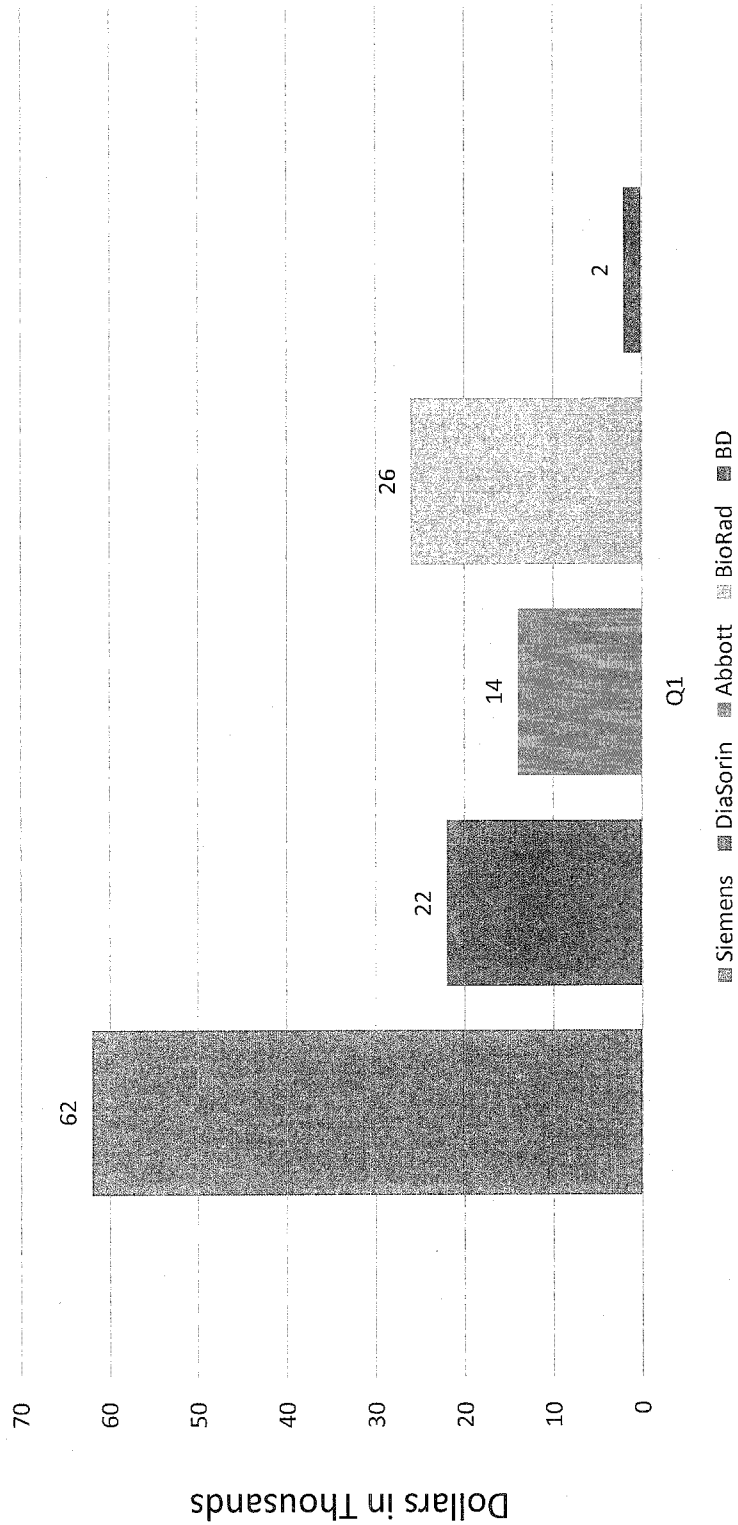
OSHA 300 Log Due 02/01/2014 – Mona (In-process)

Theranos Elevator Requires State Certification – Past due 10/12/2013* - Tom

* A letter from the Department of Industrial Relations posted stating their awareness of situation



DOLLARS SPENT IN PURCHASE ORDERS





COSTS PER TEST BY VENDOR (Q1)

Total Tests and or QC Analyzed By Vendor

Siemens*	13677
DiaSorin	259
Abbott	10156
Bio-Rad	5970
BD	30

Vendor	Dollars Spent	Cost / Test
Siemens	\$61,563.80	\$4.50
DiaSorin	\$21,788.56	\$84.13
Abbott	\$13,629.64	\$1.34
Bio-Rad	\$25,681.57	\$4.30
BD	\$2,083.96	\$69.47

*Siemens HbA1c calibrators on back order until July 21, 2014

CONCLUSION

As improvements are being introduced to ensure Theranos' mission is achieved, the current systems and procedures in place are adequately suited to promote and monitor quality of laboratory services.