100% Connectivity in Point of Care Testing is Achievable

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Disclaimer

* Duke Health Point of Care Testing Program uses the Alere RALS® Web3 interface. Disclosed because several screen captures are included in the presentation. Not intended as a commercial endorsement.

* Former member of the Alere RALS® Advisory Board (2013 to 2015).

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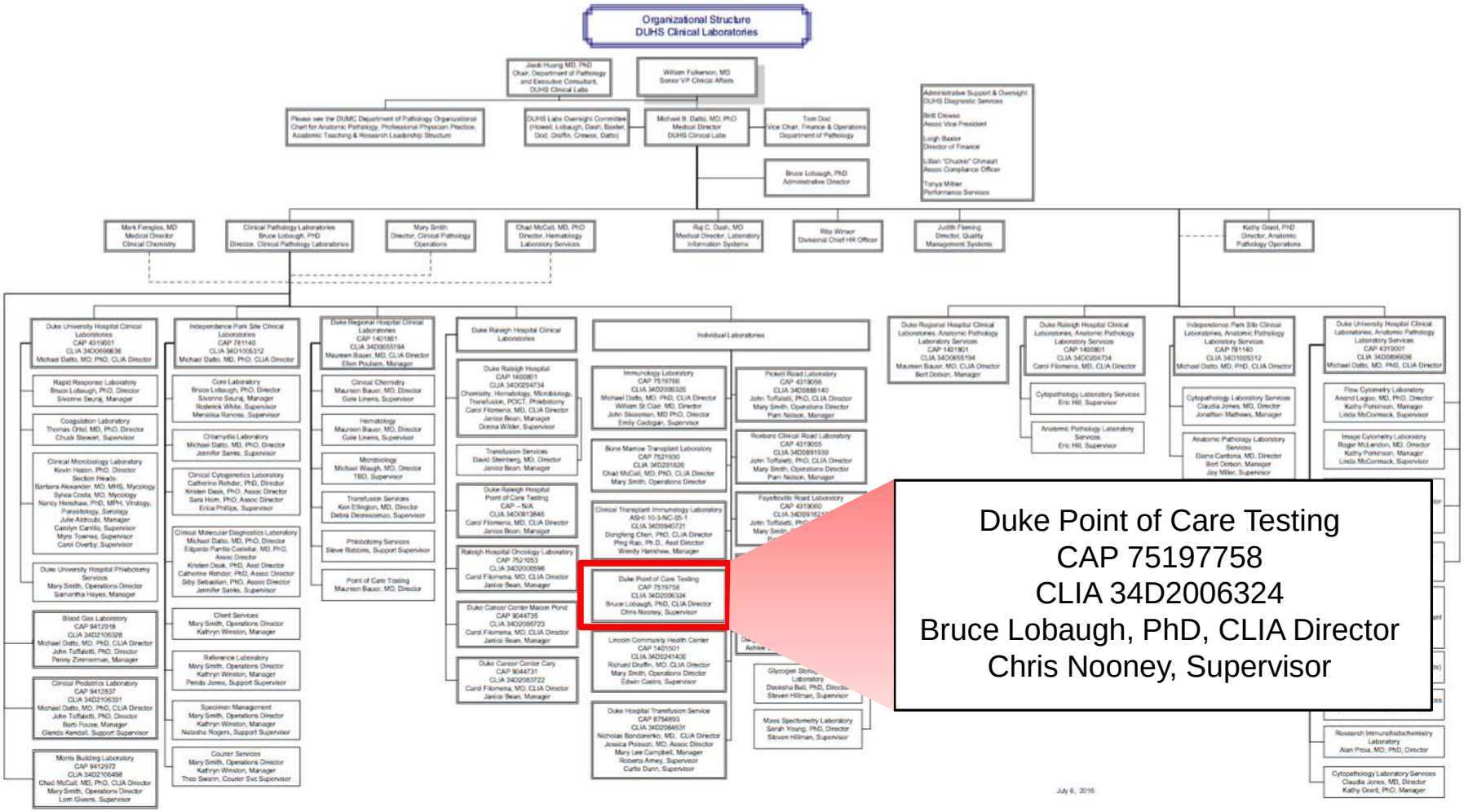
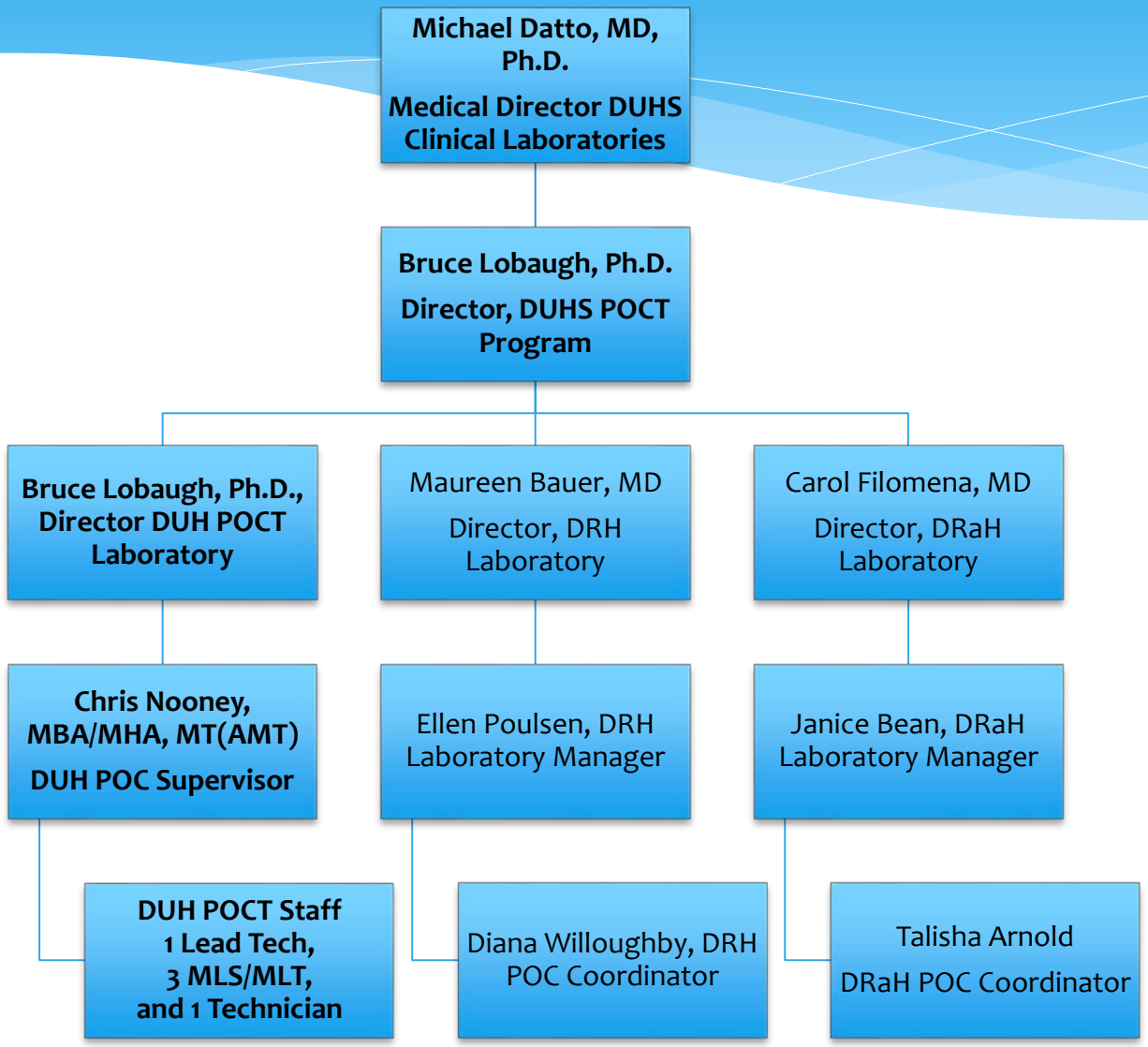
* Located in Durham, NC, Duke University Hospital is ranked nationally in 13 adult and 10 pediatric specialties
* The Hospital is a 905-bed general medical and surgical facility
* The POCT Staff consists of 6 FTEs

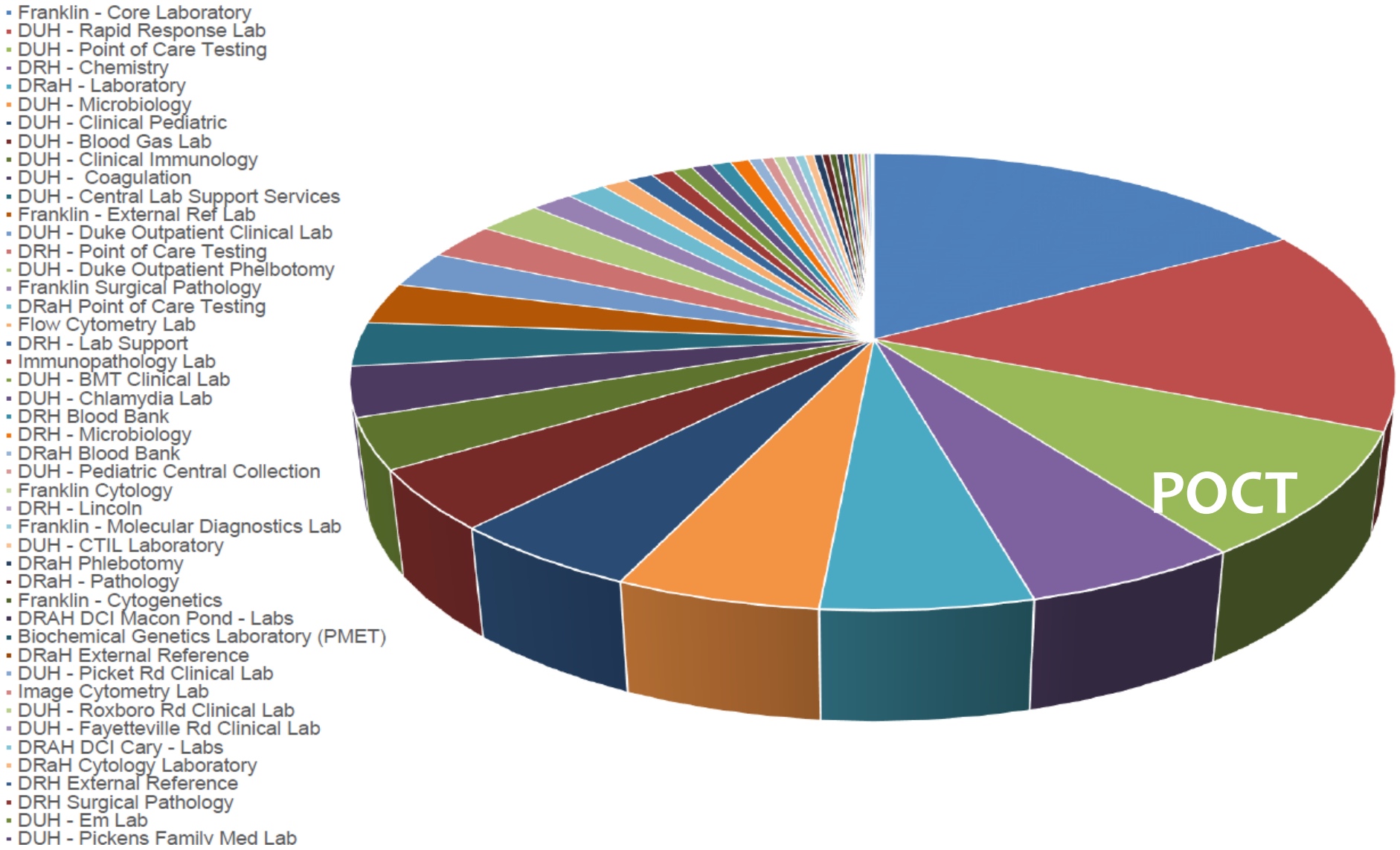
DUHS Clinical Laboratories Organization



DUHS Point of Care Testing Program



FY2016 DUH POCT Had the 3rd highest test volume for DUHS Clinical Labs



The journey begins……

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Beginning your journey…. ask yourself?

* What are your connectivity goals?
* What is your current state?
* What is your 5-year growth plan?
* What is your 10-year growth plan?
* What Health Information System are you using?
* What Laboratory Information System are you using?

What are your connectivity goals?

* Operator/End User management?
* Flow of patient's results from the instrument to the patient's Electric Medical Record (EMR)?
* Quality Management? (QC review, reports, etc.)
* Improved documentation of Compliance?
* Instrument management?
* Interface all instruments?
* **What about Manual Test results?**

What is your current state?

* What is your current state?
  * What types of instruments do you have?
    * How many of each?
  * What are your connectivity options ?
    * Ports
    * Computers
    * Wireless
  * How many locations?
  * How many operators/end users?
  * Do you want to report your manual testing results?
  * Are there connectivity solutions limitations with any of instruments?

What are your growth expectations?

* Are you expecting to add new locations?
* Are you expecting to add multiple facilities?
* Additional instrument options?
* Change instruments?
* Adding non-waived testing?
* POCT Staffing?

Information solutions

* Are there any limitations connecting to your Laboratory (LIS) or Hospital Information Systems (HIS)?
* Are there limitations with the POCT middleware connecting to your current instruments or LIS/HIS systems?
* Can operator/end users competency information be pulled from your current employee training system?

You've gathered all information
Now what?

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Research the Options:

See what middleware solutions are out there. This field is constantly changing.

- What options do each have to meet your goals?
- Do you want a very flexible or rigid system?
- How robust of a system do you need?
- Cost
  - What is the upfront cost?
  - What is the cost to maintain?
  - What is the cost to add modules or instruments?
- What type of support does the vendor offer?
- Do they customize or one size fits all?

Manual Test Results

* Some glucose meters offer the option of entering these results.
* Some middleware solutions offer modules to enter your results.

Both options have good and bad points. You need to decide which is the best option for your program/hospital. Could be a combination of both.

Now sell it to management….

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Gather Key Players

You will need support and "buy in" from key players. This is a journey and will take several different groups to make it a smooth process. Invite or include individual or a representatives from:

- Laboratory Medical Director
- POCT Director
- POCT Lead
- LIS and HIS
- Finance
- Procurement
- Compliance

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Expect the money talk…. …
Focus on the benefits:

* POCT Staffing needs (overtime, number of staff, etc)
* Automatic billing
* Compliance issues
  * Training
  * Reporting results
  * Less transcription errors

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Choose your system

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Narrow your options…

Visit like institutions using your top two choices.

* How long have they had the system?
* How do they use the system?
* Does it meet their needs?
* Ask what they like about the system and what they don't?
* What would they change about the system?
* How often does the system go down?

Build your system

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Preplan before you build…

Once your system is built, you might not be able to easily change it. Build for the future…..

- Floor vs unit?
- Do your instruments move between units? Assign to general location or units?
- Do your Operators float to different units? Assign to general location or unit?
- Do you want to name your instruments or use serial numbers?
- Manage Operator/End User competency in the system or outside the system?
- Make sure each location/unit has the required ports or wireless access and electrical outlets needed. If not who will pay for it?

Test Environment

* Build your Test Environment to match exactly what you want your Live environment to look like.
* Look at:
  - Result ranges
  - Evaluation criteria
  - Comments
  - Reagent lock out
  - Operator lock out
  - QC lock out
* Run tests on every instrument type to test: result ranges, comments, settings, evaluation criteria, location vs meter assignment, patient's not at that location at the test date/time, patient IDs when not valid.

Now try to beat the system.

Go Live

Rome wasn't built in a day, start small.

* Pick one instrument/test and a few locations to bring up.
* Once you determine everything is working as it should, things are stable, and you are comfortable add more locations.
* Then add other testing/instruments.

As you add tests/instruments you will know your system and may be comfortable adding all of those remaining at once. You set the pace…

Advantages to POCT Connectivity

- Entire Care Team has rapid and ready access to POC results via the Electronic Medical Record to make informed care decisions.
- Automated billing.
- Facilitates maintenance of Operator database and certifications/competency.
- Allows central control/oversight of QC, device maintenance/configuration/upgrades, troubleshooting device and interface errors.
- Enhances productivity of the POC Staff.

Challenges to Achieving POCT Connectivity

* Institution Must Implement Electronic Medical Record (EMR)
* Required Capital Investment in POC Connectivity Middleware and Support
* Development of Business Associates and Data Security Agreements between Institution and Vendor
* Available Institutional IT Resource(s) and Coordination Among POC Staff, Institutional and Vendor IT Resources to Develop a Plan, Maintain Momentum and Reach Project Milestones on Schedule (Assigned Project Manager)

Lessons Learned

* *"There will be bumps in the road."*
* *"You can't prepare for everything."*
* *"This is a journey, not a race."*
* *"Celebrate your victories."*
* *"No single middleware solution will be perfect, select based on your priorities."*

Vendors

* Must haves:
  * Compatibility with all middleware programs.
  * Bi-directional connectivity.
  * Operator lockout controlled at the middleware.
  * Reagent lockout controlled at the middleware.
  * Quality Control lockout.
* If special software needed, should be compatible with all middleware programs. (Sit quietly in the background).

Duke Health's Journey to 100% Connectivity

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Flash back to August 1999

DUH POC Testing Program had Oversight At:

* Duke University Hospital (DUH)
* Duke Clinics (Hospital-based Clinics)
* Duke Children's Hospital
* Duke Private Diagnostic Clinics (PDC)

Our connectivity solution: downloading glucose meters only to a computer in the laboratory. Only glucose results reporting to EMR.

No more "sneaker net"..

Total of 50 locations (10 of which were offsite) and 102 instruments mostly glucose meters and 6 orderable tests

2- FTEs, 1- 0.7 and 1-0.5

June 2004

DUH POC Testing Program had Oversight at:

* Duke University Hospital (DUH)
* Duke Clinics (Hospital-based Clinics)
* Duke Children's Hospital
* Duke Private Diagnostic Clinics (PDC)

Two Instrument types connected and reporting to EMR. Point of Care Testing middleware was now loaded on a server located with the Laboratory Information System (LIS).

Total of 91 locations (23 of which were offsite) and 137 instruments mostly glucose meters and 6 orderable tests

3 FTEs and 1-0.5

March 2016

DUH POC Testing Program had Oversight at:

* Duke University Hospital (DUH)
* Duke Cancer Center
* Duke Clinics (Hospital-based Clinics)
* Duke Children's Hospital and Health Center
* Duke Medicine Pavilion
* Duke Private Diagnostic Clinics (PDC)
* Home Care & Hospice

All Instrument types connected and reporting to EMR. Just starting the process of interfacing the manual test through the meters and middleware module.

Total of 150 locations (40 of which were offsite), spanning 4 counties

19 different orderable tests and 485 instruments.

4 FTEs

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DUH POCT Program Today

Oversight for POC Testing at:

* Duke University Hospital (DUH)
* Duke Cancer Center
* Duke Clinics (Hospital-based Clinics)
* Duke Children's Hospital and Health Center
* Duke Medicine Pavilion
* Duke Private Diagnostic Clinics (PDC & CPDC)
* Home Care & Hospice

All Instrument types connected, all manual testing entered through either glucose meter or middleware module and reporting to EMR.

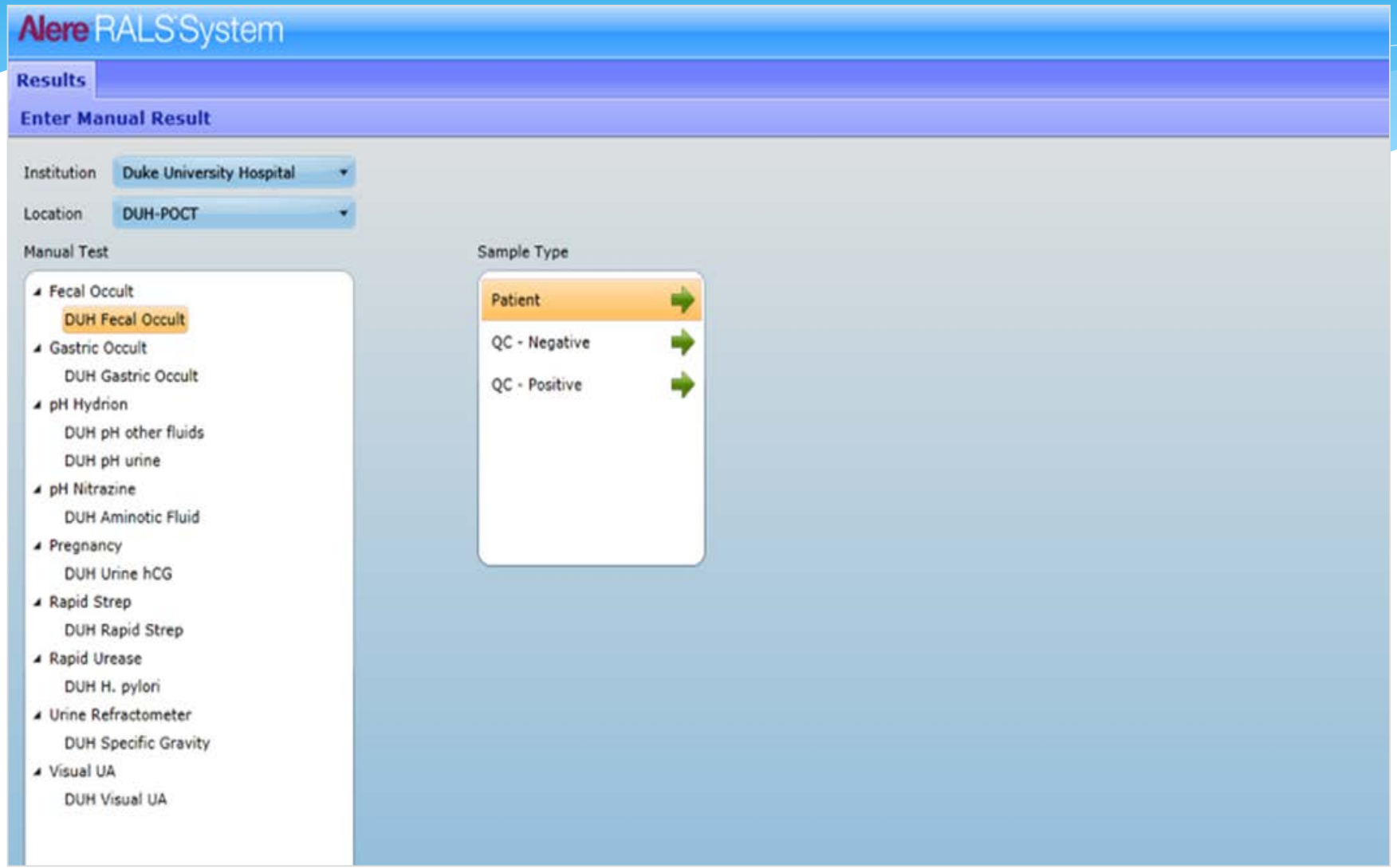
DUH POCT Program Today (contd.)

* 179 locations (65 offsite locations) spanning 5 counties
* Currently supporting 29 different orderable tests
  * Moderately Complex testing
  * Waived testing
* Responsible for 629 instruments (10 separate devices)
* >8,000 certified operators
* 610,546 Units of service as of 3rd Quarter FY2017; 0.01 Worked Hour/Unit of Service (WHUOS)
* Utilize manual test entry through Nova glucose meter and RALS ® MTE module
* Accredited by:
  * DUH hospital-based locations : College of Amercian Pathologists (CAP)
  * PDC's/CPDC's: Joint Commission (TJC)

Test	DUHS	UNC	Mayo	Hopkins	MGH	UPMC
WB Glucose	Nova StatStrip	X	X	X	X	X
Dipstick Urinalysis	Clinitek Status/ Bayer Multistick 10	X	X	X	X	X
Fecal Occult Blood/Gastric Occult Blood	Hemoccult/Hemaprompt/Gastroccult	X		X	X	X
pH/Nitrazine	Paper	X	X	X		X
Urine hCG	Quidel One Step	X	X	X	X	X
BMP	Abbott i-Stat					
Blood Gases/Co-Oximetry	Abbott i-Stat/GEM/AVOXimeter	X	X		X	
Lactate	Abbott i-Stat/GEM	X			X	
Electrolytes	Abbott i-Stat		X			
Ionized Calcium	Abbott i-Stat/GEM	X				
Creatinine	Abbott i-Stat	X		X	X	X
Glycohemoglobin A1c	Siemens Vantage	X		X	X	X
Activated Clotting Time	Hemochron / Abbott i-Stat	X		X	X	
PT/INR	Roche CoaguChek	X	X	X	X	
Urine Specific Gravity	Refractometer					
H pyori	CLOtest	X				
Rapid Strep	Binax Now	X		X	X	
Hemoglobin	HemoCue	X	X	X	X	X
PPM	Fern Test, Wet Prep, KOH Prep	X				
Cholesterol, HDL	Cholestech		X			X
HIV 1/2	OraQuick	X		X	X	X
Tear Fluid Osmolarity	TearLab			X		
Rapid Flu	Alerei				X	
Breath Alcohol			X			
Heparin Assay			X			
Mononucleosis	Henry Schein's One Step Mono Pro +		X			

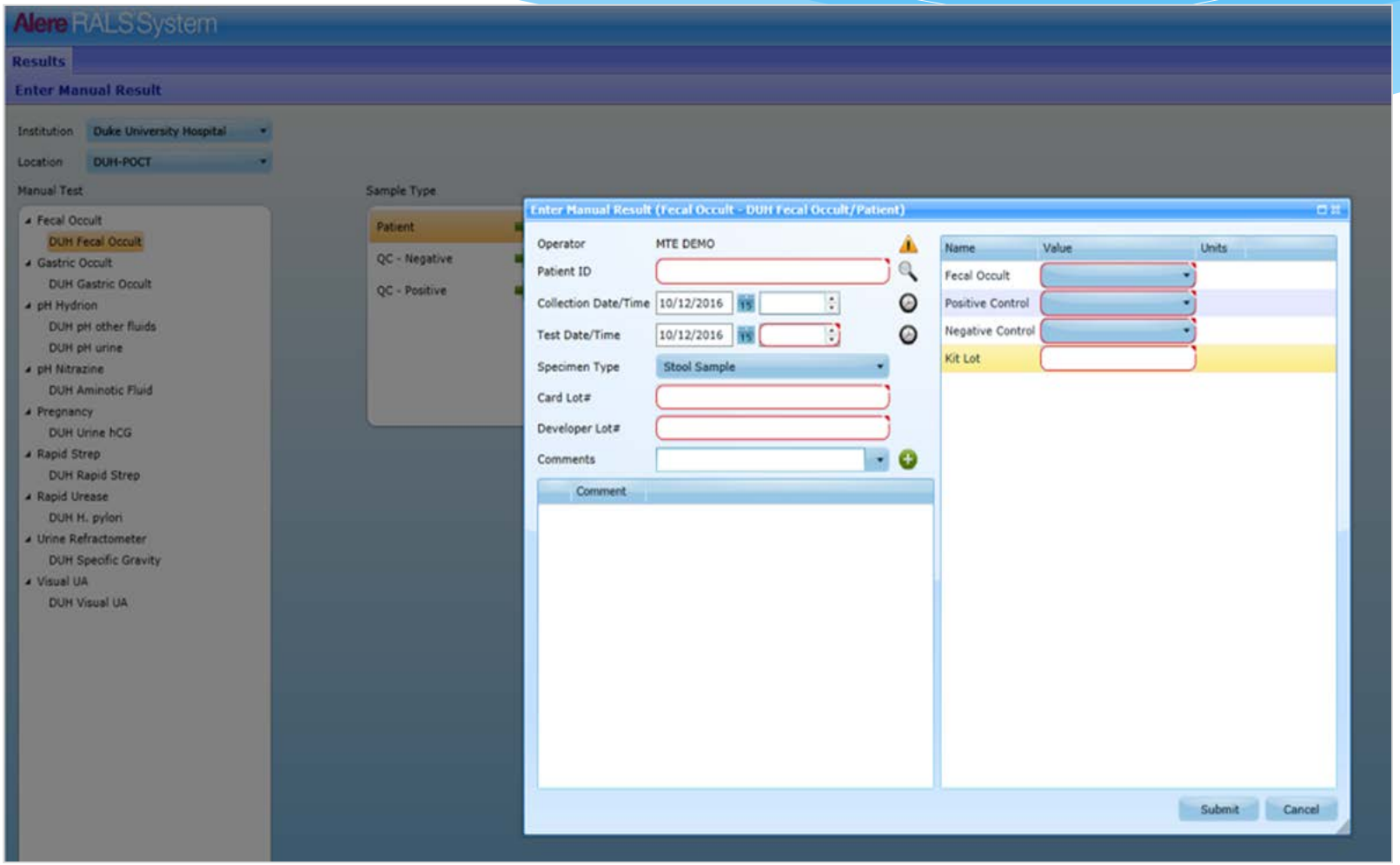
DUH POCT Achieves Full Connectivity to Maestro EHR via Alere RALS ® Web3 - September 2015

Manual Test Entry



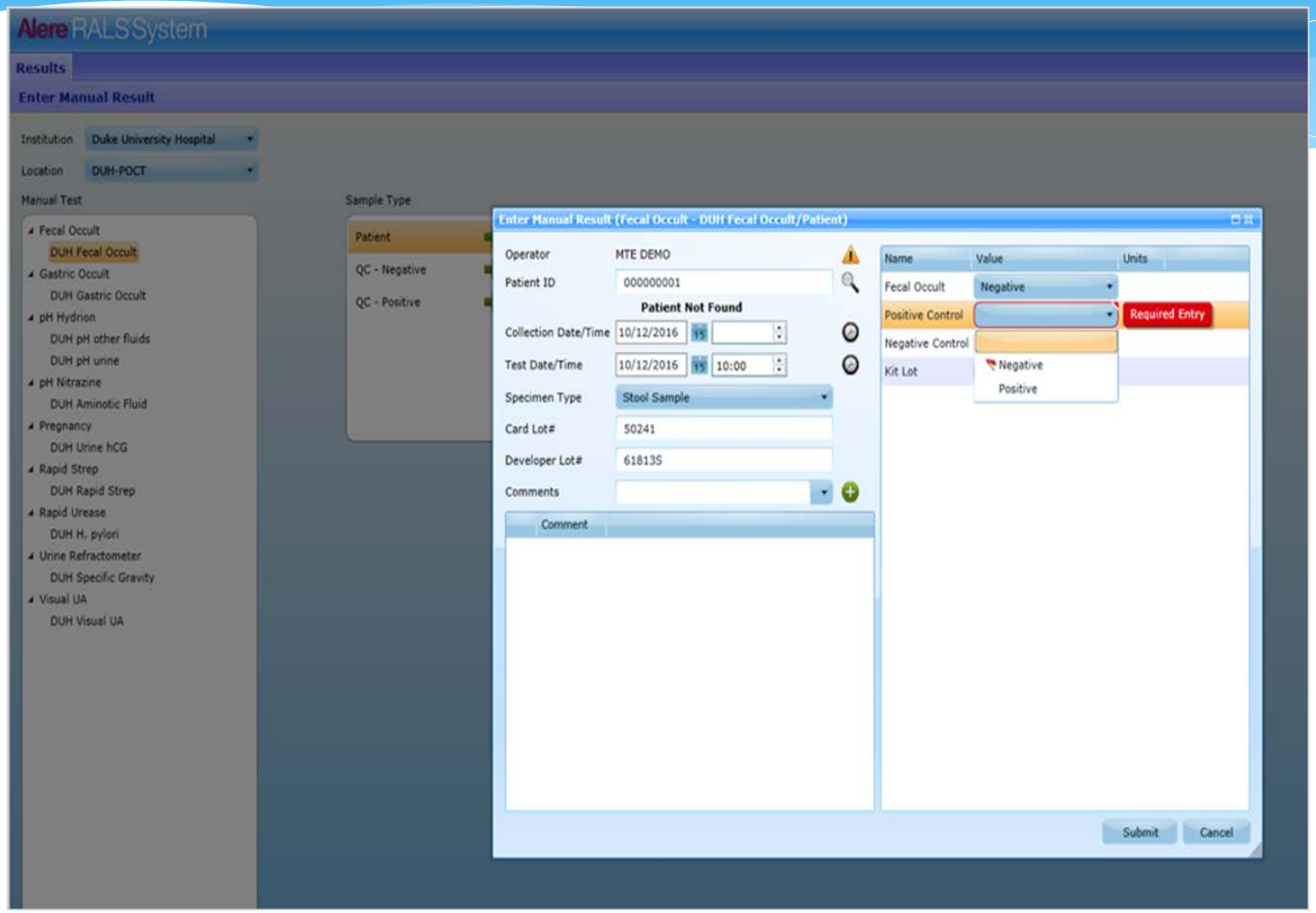
Manual Test Entry

Patient Result Entry: Because we validate each box and place a tracking label on the box, we can drill down to the exact box being used for testing. The Box ID is entered in the Kit Lot field.

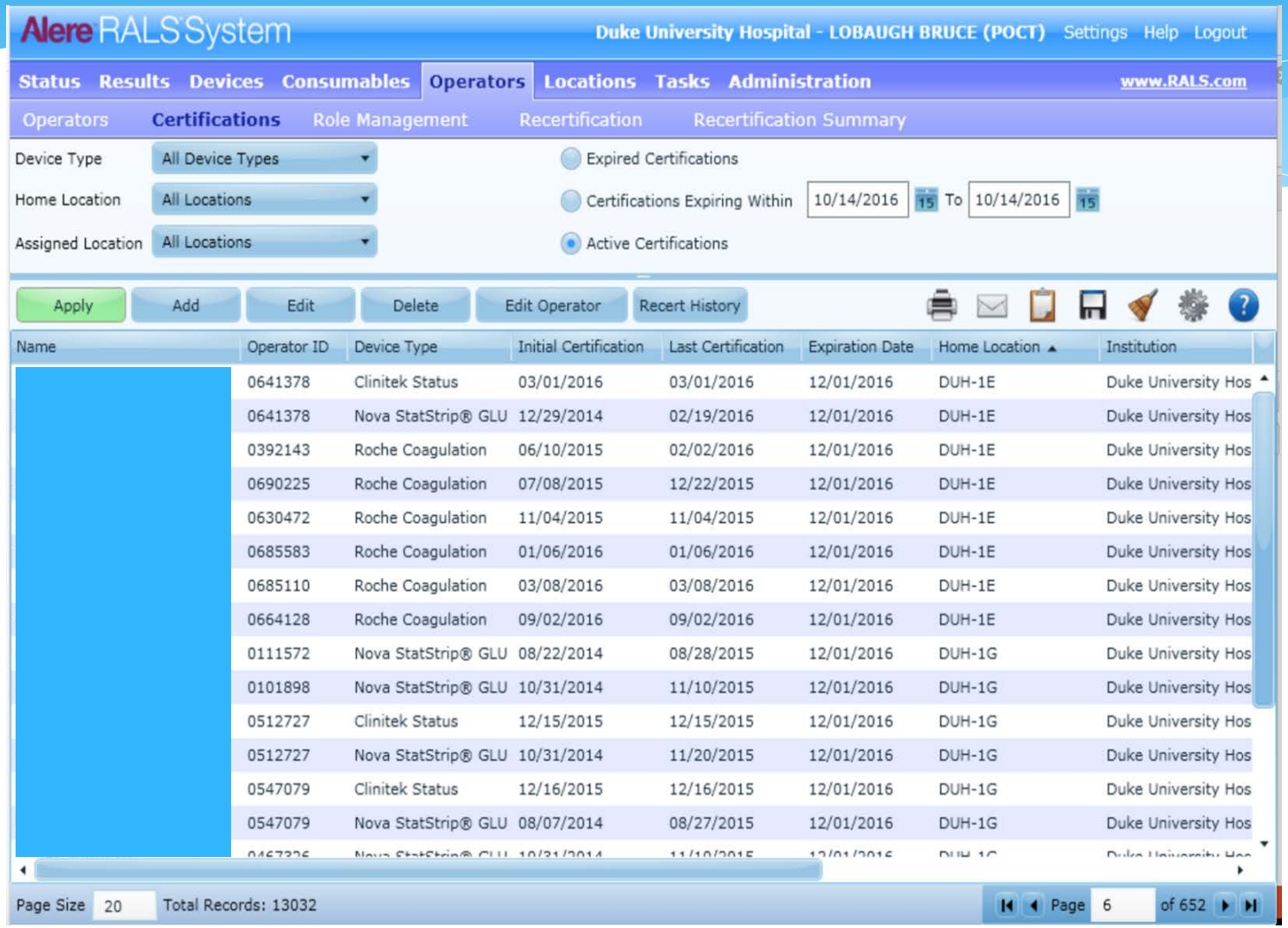


Manual Test Entry

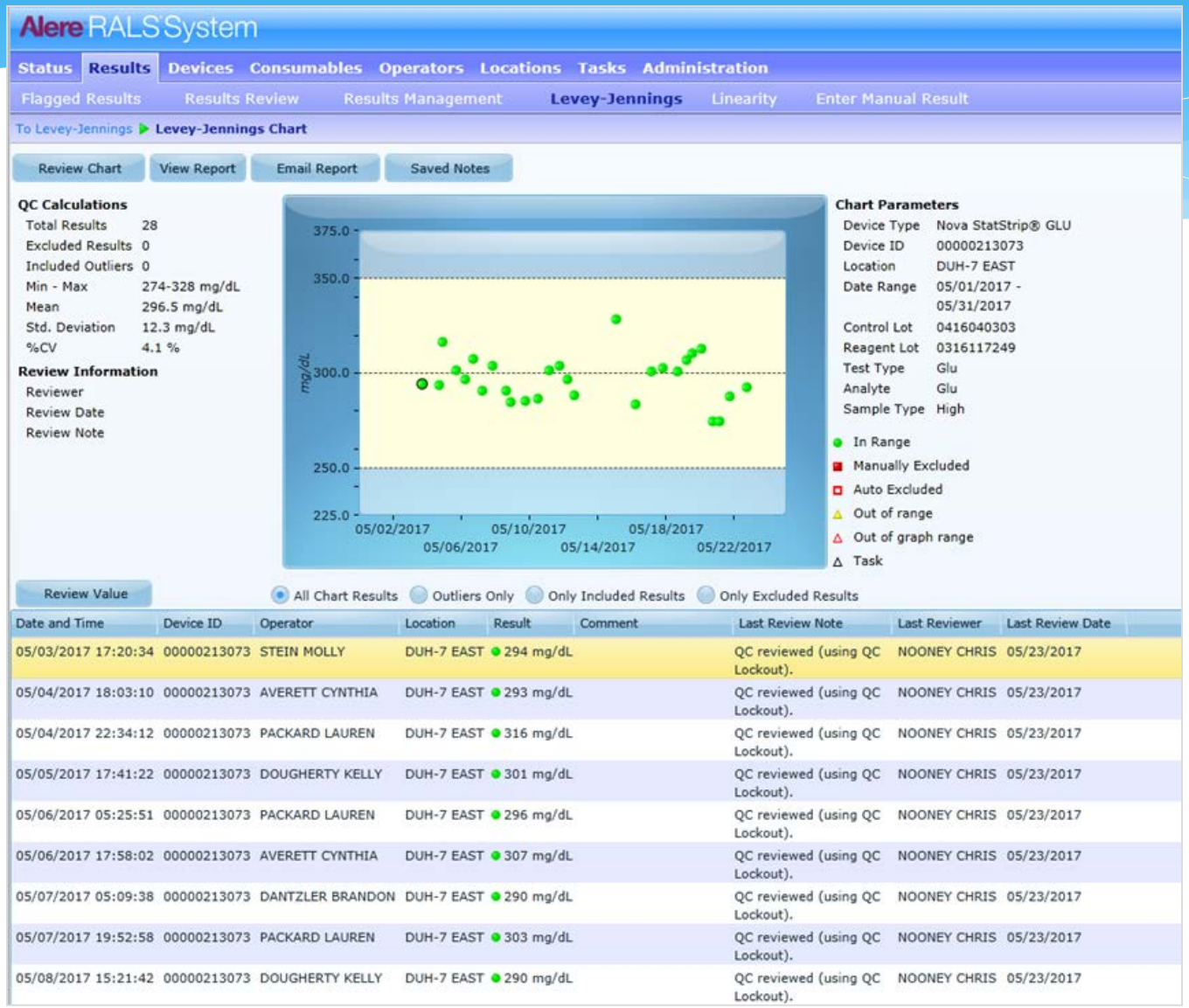
Flagged results are marked, triggering a double check by the operator entering results



Managing Operators



Levey-Jennings



Date and Time	Device ID	Operator	Location	Result	Comment	Last Review Note	Last Reviewer	Last Review Date
05/03/2017 17:20:34	00000213073	STEIN MOLLY	DUH-7 EAST	294 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/04/2017 18:03:10	00000213073	AVERETT CYNTHIA	DUH-7 EAST	293 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/04/2017 22:34:12	00000213073	PACKARD LAUREN	DUH-7 EAST	316 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/05/2017 17:41:22	00000213073	DOUGHERTY KELLY	DUH-7 EAST	301 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/06/2017 05:25:51	00000213073	PACKARD LAUREN	DUH-7 EAST	296 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/06/2017 17:58:02	00000213073	AVERETT CYNTHIA	DUH-7 EAST	307 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/07/2017 05:09:38	00000213073	DANTZLER BRANDON	DUH-7 EAST	290 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/07/2017 19:52:58	00000213073	PACKARD LAUREN	DUH-7 EAST	303 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017
05/08/2017 15:21:42	00000213073	DOUGHERTY KELLY	DUH-7 EAST	290 mg/dL		QC reviewed (using QC Lockout).	NOONEY CHRIS	05/23/2017

Linearity Charts

Alere RALS System

Status | Results | Devices | Consumables | Operators | Locations | Tasks | Administration

Flagged Results | Results Review | Results Management | Levey-Jennings | Linearity | Enter Manual Result

To Linearity ▶ Linearity Chart

Re-Review Chart | View Report | Email Report | Saved Notes

QC Calculations

Total Results	10
Excluded Results	0
Levels Used	5 of 5
Slope	0.97
Y Intercept	0 mg/dL

Review Information

Reviewer	STREMKE KATIE
Review Date	05/23/2017
Review Note	ILQC Level 1: -0.8%, Level 2: -2.7%

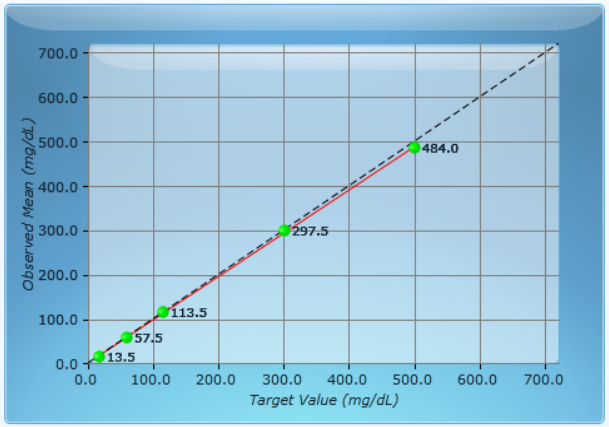


Chart Parameters

Device Type	Nova StatStrip® GLU
Device ID	00026617054
Location	DUH-LIFE FLIGHT
Chart Date	05/23/2017
Product	Glucose
Analyte	Glu
Linearity Lot	Multiple Lots
Reagent Lot	0316117249

- In Range
- Out of range
- Best Fit Line
- Target Line

Review Value | Level: All | All Chart Results | Only Included Results | Only Excluded Results

Date and Time	Device ID	Operator	Location	Level	Result	Target Value	Target Range	Comment	Last Review Note	Last Reviewer	Last Review Date
05/23/2017 14:36:03	00026617054	BALLARD ANDREW	DUH-POCT	Level 1 - 0516153301	14 mg/dL	18 mg/dL	10 - 25 mg/dL	QC Due			
05/23/2017 14:35:09	00026617054	BALLARD ANDREW	DUH-POCT	Level 1 - 0516153301	13 mg/dL	18 mg/dL	10 - 25 mg/dL	QC Due			
05/23/2017 14:38:44	00026617054	BALLARD ANDREW	DUH-POCT	Level 2 - 0516154302	58 mg/dL	59 mg/dL	44 - 74 mg/dL	QC Due			
05/23/2017 14:37:37	00026617054	BALLARD ANDREW	DUH-POCT	Level 2 - 0516154302	57 mg/dL	59 mg/dL	44 - 74 mg/dL	QC Due			
05/23/2017 14:41:53	00026617054	BALLARD ANDREW	DUH-POCT	Level 3 - 0516153303	110 mg/dL	115 mg/dL	95 - 135 mg/dL	QC Due			
05/23/2017 14:40:41	00026617054	BALLARD ANDREW	DUH-POCT	Level 3 - 0516153303	117 mg/dL	115 mg/dL	95 - 135 mg/dL	QC Due			
05/23/2017 14:46:17	00026617054	BALLARD ANDREW	DUH-POCT	Level 4 - 0516154304	297 mg/dL	300 mg/dL	250 - 350 mg/dL	QC Due			
05/23/2017 14:45:11	00026617054	BALLARD ANDREW	DUH-POCT	Level 4 - 0516154304	298 mg/dL	300 mg/dL	250 - 350 mg/dL	QC Due			
05/23/2017 14:48:50	00026617054	BALLARD ANDREW	DUH-POCT	Level 5 - 0516153305	477 mg/dL	500 mg/dL	420 - 580 mg/dL	QC Due			
05/23/2017 14:47:27	00026617054	BALLARD ANDREW	DUH-POCT	Level 5 - 0516153305	491 mg/dL	500 mg/dL	420 - 580 mg/dL	QC Due			

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Conclusion

* Connectivity benefits patients by ensuring the entire medical team can rapidly and readily access test data generated at the point-of-care to render informed decisions.
* Connectivity facilitates quality oversight of even large, complex programs by a relatively small number of knowledgeable and dedicated technologists.
* Achieving a high degree of connectivity requires commitment and coordination of significant financial, technical and IT resources, but the potential rewards can justify the effort.

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