# IMPLEMENTING NEW POINT OF CARE TESTING

## A PRACTICAL GUIDE

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# TRICORE REFERENCE LABORATORIES

- Regional medical laboratory providing diagnostic testing for patients and providers
- Located throughout New Mexico
- 13 Million Test Per Year (not POC tests)
- 1.3 Million interfaced POCT tests per year
- 99% Volume Performed On-site
- 85+% of Clinical Data for NM

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# TRICORE POINT OF CARE PROGRAM

**3 SEPARATE HOSPITAL SYSTEMS**

16 hospitals

160 clinics/Urgent Care

2 hybrid ED UC

18 instrument types

16 manual kits/tests

10,000 total operators

2200 non-waived operators

800+ individual devices

1.3 million tests/year (interfaced only)

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# TRICORE POCT STAFF

POC manager

6 POC technical supervisors

21 POC techs

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# REQUEST FOR POC TESTING

How is this handled at your site?

- Laboratory decides what can be implemented
- Unit decides and lab implements
- You come across POC devices or kits that you didn’t even know about and must implement after the fact
- Your program has a collaborative POCT committee to receive and vet all requests

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# POINT OF CARE COMMITTEES

One committee per system-members:

POC staff

Medical directors

Hospital and Tricore Quality

Infection Prevention

Purchasing

Hospital administration

Unit/clinic directors

# COMMITTEE RESPONSIBILITIES

- Receive requests for new/additional testing
- Review quality indicators for each month
- Review corrective action plans for non-conforming events
- Notify of adverse events: product recalls, device issues
- Collaborate with Infection Prevention on relevant issues
- Address standardization within the system
- Notify of IT projects, go live, and other issues

# POINT OF CARE SYSTEM WORKGROUP

Tricore POCT Workgroup-members:

POC supervisors

POC medical directors

Tricore Quality

Assay development

# WORKGROUP RESPONSIBILITIES

- Standardize devices/kits for Tricore POC program
- Standardize processes such as validations, reference ranges, etc.
- Work with POC medical directors for technical issues
- Regulatory issues
- Recalls of devices or reagents, decide on corrective actions

# HAS THIS EVER HAPPENED TO YOU?

Unknown to you, the cardiac cath lab director has a meeting with Sam Salesrep to see their latest device.

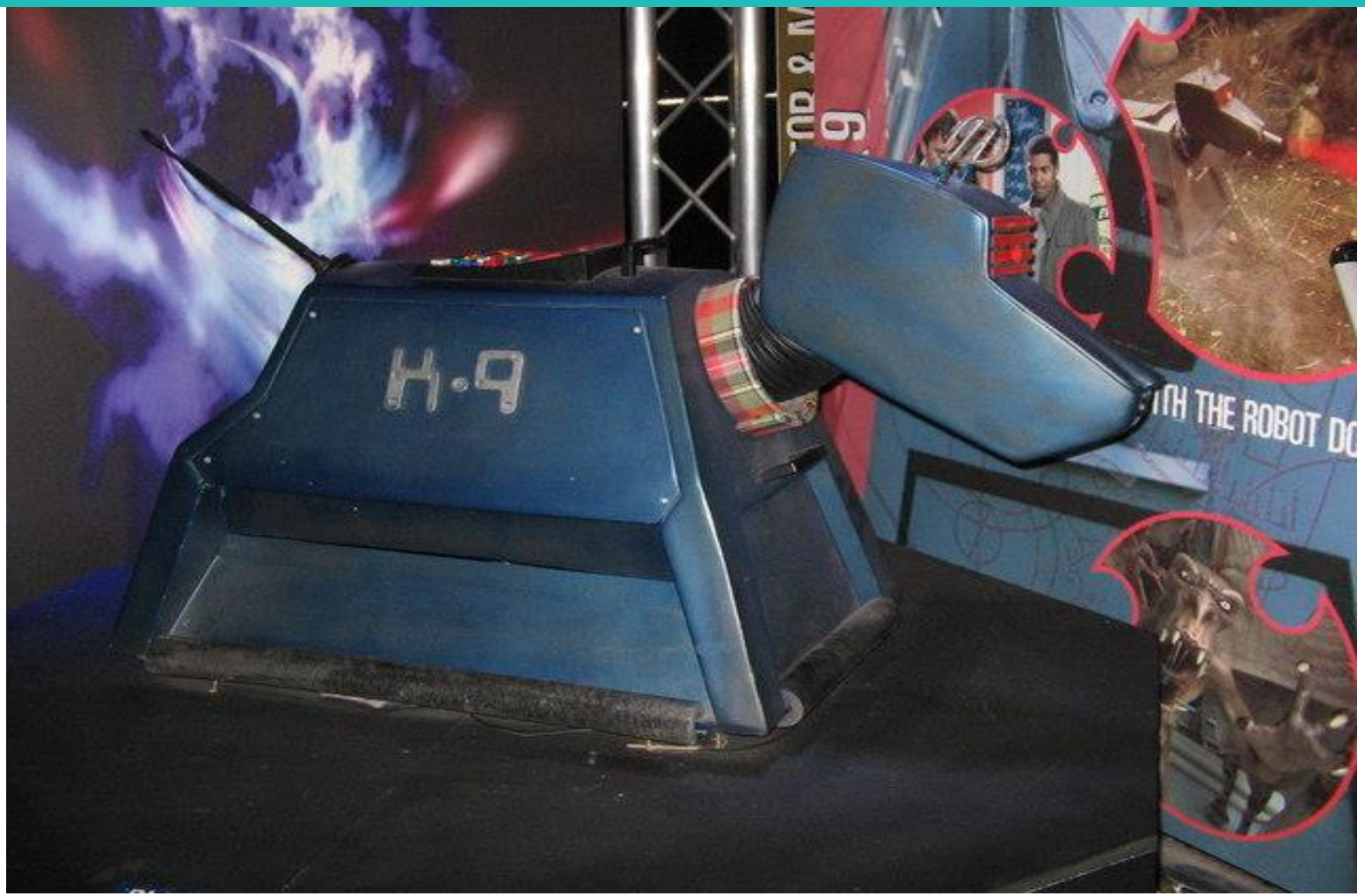
The CCL director was very impressed and now wants to bring it into her department.

Poctalyzer Ultra

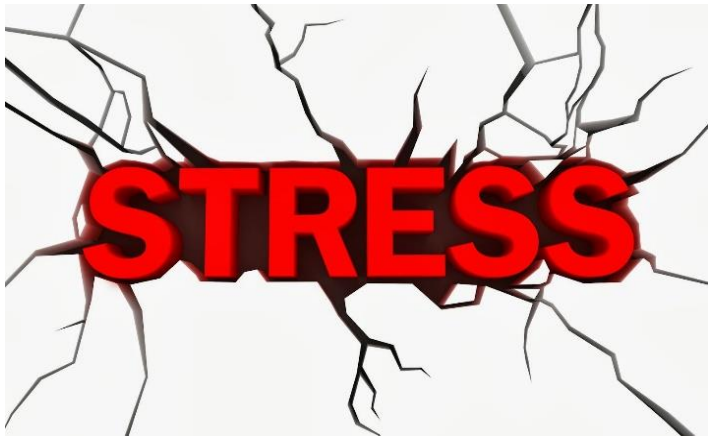
Pro Plus-Enzymatic

or

# PUPP-E!



# NOW WHAT?!




# FIRST THINGS FIRST

- Check FDA website for approval and CLIA complexity, EUA
- Do internet research on device, methodology, limitations
- Ask for package insert, user's manual, other information from manufacturer
- Check with POC listservs

# …AND HOW ABOUT…

- Physical specs-will it fit? Temp/humidity?
- Is renovation needed in the department?
- Electrical needs—do you have enough plugs?
- Are there ports available for connectivity?
- Are there appropriate staff to perform testing?

# HAVE YOU CONSIDERED?

- How will the device be connected?
- New server or device management system needed?
- Does it fit with the rest of the POCT program?
- Can the central lab do the test as quickly and accurately?

# POCT REQUEST-SAY PLEASE!

- Do you have a form for all POC testing requests?

- Should contain:

  Test requested (device, kit, etc.)

  Justification for testing-why the test is needed

  Who will be responsible for testing (nurses, perfusionists, etc.)

  Capital approval obtained?

  Signature of unit/clinic director

  Space for POCT committee approvals

# DO YOU HAVE A PRE-APPROVAL PROCESS?

A checklist makes sure none of the steps are missed

- VAT or Products & Standards Committee
- IT Security
- Capital/budgeting
- Administrative approval
- Standardization
- Medical Director approval
- POCT committee

# PUPP-E IS APPROVED!

## Checklist for implementation

- Write procedure
- Develop electronic learning program
- Determine ports, Wi-Fi, IT infrastructure
- IT build: middleware, LIS, HIS, EMR
- QC process; IQCP if indicated
- Logs

# PUPP-E IS IN THE HOUSE!

- Determine placement
- Environmental concerns
- Electrical
- Connect to ports/Wi-fi and test

# INFORMATION TECHNOLOGY

- Build test(s) in middleware
- Build test(s) in LIS
- Build test(s) in EMR
- Determine date of go live

# NEXT STEPS

- Instrument clinical validations
  - Vendor assistance
  - Gather and crunch data
  - Medical director sign-off
- IT testing
- Interface validation
- Medical director approval

# DOES EVERYONE KNOW HOW TO DO THE TEST?

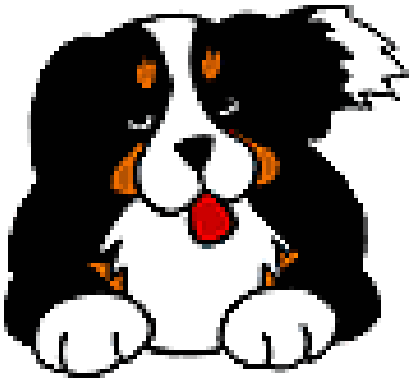
- Vendor training assistance
- Manufacturer's resources: videos, checklists, etc.
- Train the trainer model
- Ensuring access to the new device

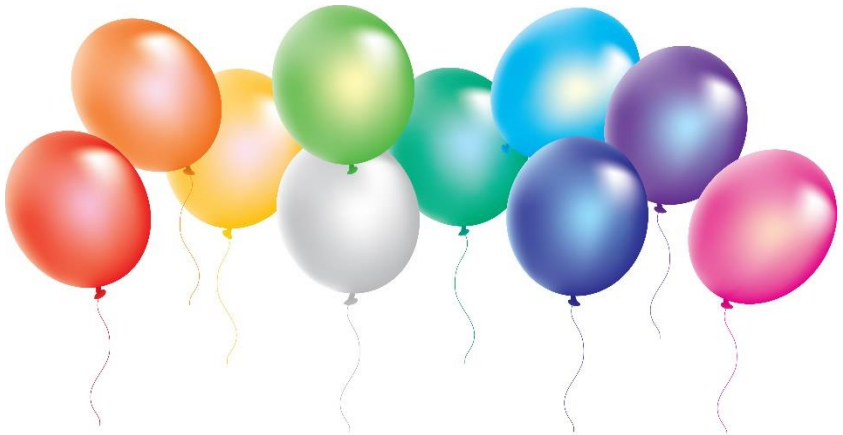
# ALMOST THERE!

- Plan post go-live IT validation
- Establish ongoing competency schedule
- Add to Activity List
- Purchase proficiency testing

# CELEBRATE!

## PUPP-E is implemented!



# Questions?
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