

# Progress on the Path to Clinical Lab 2.0

---

*How TriCore's Multi-Site CAP 15189<sup>SM</sup> Accreditation Accelerates and Sustains Our Lab's Culture Change While Improving Quality and Productivity*

*Jane Smith  
Director of Compliance & Quality Systems  
October 2017*



# TriCore Reference Laboratories

Financial Strength	State of the Art Diagnostics	Quality & Expertise	Major Provider for New Mexico
New Mexico leader in diagnostic testing	Full-service reference laboratory offering 1,700 highly specialized tests	45+ Pathologists, Scientists, and Clinicians	10.9 Million diagnostic tests per year
Proven track record for financial stability and growth	98% of testing is performed at our facilities	12 clinical specialties	1350+ Employees 42 courier routes across New Mexico
Scalable business model	Nationally recognized Hematopathology consult service	99% patient satisfaction	18– Hospital Laboratories 24 – Patient Care Centers
Clients across New Mexico, the Southwest and the United States		The first multi-site laboratory to earn CAP 15189 <sup>SM</sup> accreditation	12 – Branch Laboratories 195,000 – Surgicals
		One of only 21 labs nationwide to achieve the rigorous CAP 15189 <sup>SM</sup> quality standards	86,450 – Cytologies 7,600 – Cytogenetics
		The only New Mexico lab recognized for achieving this prestigious accreditation	10,200 – Molecular 900,000 – Infectious Disease



# TriCore Lab Operations

- *Serving 2 Million New Mexico Citizens*



## Sole Source Laboratory Providers

- Nine hospitals in Greater Albuquerque area
  - Academic Hospital (Cancer Centers, Children's Hospital), Heart Hospital, Community Sponsor Hospitals
- Five sponsor hospitals in rural New Mexico
- Lab Managed Services for hospital system and a cancer center (Four hospitals)

## Reference Laboratory Service

- Across the entire state of New Mexico
- New Mexico is the 5<sup>th</sup> largest state in land area (121,589 sq. mi)

# Volume to Value

## **TriCore's Vision:**

*To drive improvements in patient and population health through real time targeted intervention to positively affect patient lives.*



Reshaping the way medicine is delivered:

- Right test at the right time
- Data converted to actionable information
- Proactive

# Lab Service Requirements-Clinical Lab 1.0

Lab services are essential to patient care. Clinical Lab 1.0 is the supporting structure. TriCore must be available to meet the needs of all patients and clinical personnel responsible for the care of those patients.

## Services Include:

- Orders for testing
- Patient prep and identification
- Collection, transportation and storage of samples
- Processing and exam of clinical specs
- Interpretation, reporting and advisory services
- Accurate and timely results
- Safety and ethics in medical lab work

# TriCore's CAP 15189<sup>SM</sup> Journey

- 2006 - Initially looked at obtaining the CAP 15189<sup>SM</sup> accreditation. Timing and environment were not right.
- 2009 - Environment changed and new executives were highly supportive and engaged.
- 2010 - CAP 15189<sup>SM</sup> performed an initial *gap analysis*.
- 2011 - First multi-site lab to received accreditation.

# Quality Management System

**A Quality Management System (QMS)** is the organization's structure, its responsibilities, procedures and resources for ensuring the quality of a product or service.

# QMS Essentials

- Organization
- Service and Satisfaction
- Facilities and Safety
- Staff and Resources
- Purchasing and Inventory
- Equipment
- Process Control



- Documents and Records
- Information Management
- Occurrence Management
- Assessments and Compliance
- Process Improvement
- Contract Management



# ISO 15189<sup>SM</sup> Requirements Assessed

- Personnel Training & Competencies
- Standard Operating Procedures
- Proficiency Testing
- Document Control
- Good Documentation Practices
- Validations



# ISO 15189<sup>SM</sup> Requirements Assessed

- Continuous Improvement of Processes
- Quality Control (Analytic Systems)
- Patient Test Management (Pre through Post Analytic Systems)
- Assessing Quality (Audits, Monitors, Corrective/Preventive actions by determining root cause, Client and Patient Surveys)
- Non-Conforming Events Management

# TriCore's CAP 15189<sup>SM</sup> Journey

ISO 15189<sup>SM</sup> is the standard we are accredited to

CAP 15189<sup>SM</sup> is the program that administers the accreditation to the standard

CAP 15189<sup>SM</sup> assesses the maturity of the Quality Management System (QMS)

Based on a three year cycle:

- ✓ First year, full surveillance of the entire ISO 15189<sup>SM</sup> standard
- ✓ Second year, surveillance of the Management requirements of the ISO 15189<sup>SM</sup> standard
- ✓ Third Year, surveillance of the Technical requirements of the ISO 15189<sup>SM</sup> standard

# TriCore's CAP 15189<sup>SM</sup> Journey

Progress in maturing the QMS program during first six years

- ✓ At the start focus was on performing better root cause analysis
- ✓ Root causes improved and then focused on better corrective action
- ✓ Better effectiveness checks and preventive action
- ✓ Continual striving for better communication and educating the ISO 15189<sup>SM</sup> standard down to the front end
- ✓ Created an Internal Audit Dept. and Program

# TriCore's CAP 15189<sup>SM</sup> Journey

## Internal Audit Program

- Finding opportunities through audits
- Auditing is an invaluable tool in helping define areas of opportunities to promote quality in the lab.
- Audits help identify regulatory risk, gaps in standardization, and improvement through best practices.
- Ensures awareness of updates to regulatory standards.



# TriCore's CAP 15189<sup>SM</sup> Journey

- Beginning our third cycle of CAP 15189<sup>SM</sup> accreditation.
- Areas of strength includes management review report, physician advisory services, client engagement services, and maturity of Internal Audit Program.
- This year tipping point for changing our culture.
- Very positive quality culture! Staff at all levels feel that CAP 15189<sup>SM</sup> has helped them be more conscientious and patient oriented. Staff feel empowered, a part of the vision and are looking for opportunities for improvement.

# Benefits to TriCore

- Transformed culture of “mistakes” that were punitive to one where  
“ Every defect is a treasure”
- Focus on the process, not the person
- Non-conformities identified provided an opportunity for improvement
- Gaining efficiencies
- Streamlined processes

# Benefits to TriCore

- Internal audits now perceived as tools for identifying OFIs
- Adoption of CAP 15189<sup>SM</sup> became foundation to achieve standardization of both systems and processes used in all testing locations operated or managed by TriCore
- Standardization of P&Ps and processes, and aligning with our Strategic Initiatives, helped tremendously as we have started implementing lab management services to other hospitals in an efficient and streamlined manner



# Benefits to TriCore

- TriCore has ~ 90% of the longitudinal health information of the population of NM and we provide lab support for the bulk of the largest organizations in NM.
- Acquisition of Rhodes, access to more data, creating more data driven products has helped TriCore to expand their business model to include population health management

# Benefits to TriCore

- Diagnostic Optimization- by using the data in the eMPI (enterprise master patient index), allowed TriCore to use actionable results to develop Targeted Intervention Models

Prenatal Care

Hepatitis C

Diabetes

# Benefits to TriCore

- Quality has permeated to our non-technical areas of the organization (client engagement, risk management, strategy) and are aligned with our vision.
- Staff feel empowered and an important part of the QMS and TriCore.
- Moved away from one test at a time and fee for service to support value based care

# Quality Measurements/Metrics Required by CAP 15189<sup>SM</sup>

## Quality Indicator Tracking

- ✓ Department metrics measuring performance

## Incident Tracking (Non-Conformities)

- ✓ Records of errors, complaints or process/system failures

## Corrective Actions and Preventative Actions

- ✓ CAPAs with thorough root cause analysis and follow-ups

## Quality System Internal Audit

- ✓ Internal Audits measure compliance with our QMS

## Proficiency Testing Surveys

- ✓ Measures analytical performance

## Patient Satisfaction Surveys

- ✓ Surveys and complaint resolution



# What Do We Measure and Monitor?

- Collect patient and provider complaints-track and trend and provide feedback
- Client Engagement liaisons works with clients, sponsors and providers on issues, questions that come up.
- Internal Audit performs audits and follow ups to look for OFI
- Internal Audit summaries are reported up to Quality Committee of the Board and the Compliance and Internal Audit Committee of the Board
- TATs, Patient Wait Times, Business/Financial metrics, Growth

# What Do We Measure and Monitor?

- Identification and Control of Non-conformities- pre-analytical, analytical, and post analytical, customer related and HIPAA areas are measured.
- Created and monitoring 2017 Systemic QI- Reducing % of Unrecoverable Samples
- Annual Management Review Report is created and reported to TriQual and the Quality Committee of the Board

# Value for Measuring

- Helps in identifying areas for opportunities for improvement (OFI) in the future as a system
- Use quality oversight to identify systemic issues
- Helps in standardizing processes and policies
- Internal Audits present a unique way of identifying OFI
- Become proactive, rather than reactive
- Proactive-finding issues before an external agency comes in

# Value for Measuring

- Improved on our CAP LAP inspections since becoming accredited. 2016 Reduced the % of deficiencies by 14% from 2014 for the 14 CAP accredited sites
- By using the CAP 15189<sup>SM</sup> as our foundation, and using the principles from it, we have not only enhanced our QMS, but in the last year have enhanced both our Compliance Program and our Safety Program for TriCore



# Value for Measuring

History of last three cycles  
15189<sup>SM</sup> Assessments

2011

Major NC

4

Minor NC

8

2014

Major NC

4

Minor NC

5

2017

Major NC

0

Minor NC

2

# Alignment with Strategic Objectives

- Pioneers in integrating improvements in quality, risk management, and operational systems into a complex, statewide environment
- Being accredited, standardizing methodologies, and sustaining our culture has given us a scalability that allows TriCore to continue to grow efficiently in the current and future healthcare environment

# Alignment with Strategic Objectives

- Identified efficiencies and opportunities for improvement and created a culture of quality which has created the foundation for delivering the new model of clinical labs services in the era of value (quality) based reimbursement, integrated care and precision medicine...Lab 2.0
- By standardizing methodologies, and having this database across the environment, we can tap into health data to provide targeted, predictive and personalized care for patients and assist providers in positively affecting their patient's care

# What Have We Done Well?

- Persistence with our goal of achieving and sustaining our CAP 15189<sup>SM</sup> accreditation.
- Continued support by leadership and focusing and aligning with the companies vision.
- Built a expansive Internal Audit Dept.- not only doing quality audits, but also compliance, HIPAA, billing and other business related audits.
- Took ownership of our "errors" and turned it into a process focus, the lessons we learned enabled us to get better. Never ending!
- By having a better understanding of where we were, and where we are now, will help us sustain the culture we have built, and help us in our goal of where we want to be in this unsettling healthcare environment.

# What Could We Have Done Better? Lessons Learned

- Communication to all staff. Leadership had the vision but staff wasn't seeing it
- Showed staff how important their job was, no matter what the job!
- Getting staff involved in identifying opportunities for improvement
- Empowered staff to do the best job they could
- Made staff more knowledgeable about the actual requirements of the ISO 15189<sup>SM</sup> standard
- Educated more upon hiring



Jane Smith, Director of Compliance & Quality Systems  
TriCore Reference Laboratories  
1001 Woodward Place NE  
Albuquerque, NM 87102

[Jane.Smith@tricore.org](mailto:Jane.Smith@tricore.org)

505-938-8880