

CLARITAS  
GENOMICS

# Lessons Learned at Claritas from Simultaneous Accreditation to CLIA and ISO 15189: Combining the World's Most Accepted QMS with CLIA

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# Overview

- A2LA
  - Background
  - Application process
  - Pre-assessment
  - Assessor qualifications
  - On-site Expectations
  - Reporting and Corrective actions
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- Claritas
  - Background
  - Preparations
  - Pre-assessment
  - Claritas assessor interaction
  - On-site perspectives
  - Reporting and corrective actions
  - Accreditation Value



# A2LA Background

- Non-profit, non-governmental, membership organization
- Provide accreditation and training
- Established in 1978
- International Laboratory Accreditation Cooperation (ILAC) Recognized
- Deemed Status achieved in 2014
- Only AO in **world** holding both ILAC and CMS Recognitions!

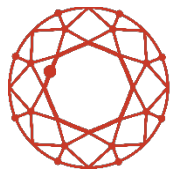


# Claritas Genomics Background

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Claritas combines the world's best pediatric specialists with innovative patient-centric diagnostics to advance precision care.

- Commercial molecular diagnostics laboratory
- Spun out of Boston Children's Hospital in 2013
- Large Test Menu including, the Claritas Clinical Exome, several region of interest exome tests, single gene assays, deletion/duplication assays, Chromosomal Microarray, and PCR/Gel bases assays.
- Hold CLIA and ISO:15189 accreditations and licenses with MA, CA, FL, MD, NY\*, PA, and RI.

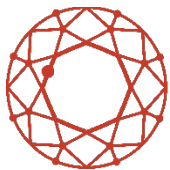


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# Why ISO?

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- A robust QMS is essential to a molecular sequencing lab
- Perfect time to implement processes that were based in QMS concepts reflected in ISO 15189
- Prepares company for additional accreditations and licensure
- Future of regulatory landscape
- Support from Executive Level of Organization

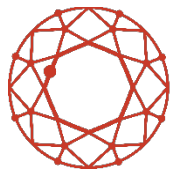


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# Why A2LA?

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- A2LA reaches an organizational depth that other AO's do not reach
- Results in a deeper corporate quality audit
- A2LA's CMS deemed status makes process more efficient
- High level of engagement and support from A2LA
- International recognition of the ISO:15189 accreditation



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# A2LA Application

- Complete application including:
  - Completed application form
  - Organization chart and Technical Matrix
  - Credentials of key staff members
  - PT Plan, PT data, Corrective actions for any PT Outliers
  - Quality Manual and supporting SOPs
  - Completed assessor checklist
  - Equipment list, floor plan
  - Scope Selection List



# A2LA Application Process

- Upload to CAB Portal
- A2LA Accreditation Officer Reviews Submittal
- Accreditation Officer Proposes Assessor/Assessment Team
- Schedule assessment dates





# Assessor Planning

- Prior Document Review
- Prepare notes and questions
- Send notification to lab informing them of gaps or questions/clarifications
- Provide agenda



# Application Process

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November 2013

- Began Discussions considering ISO 15189 and A2LA

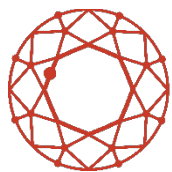
May 2014

- Obtained Application for ISO 15189 Accreditation

December 2013

- First gap analyst performed of QMS

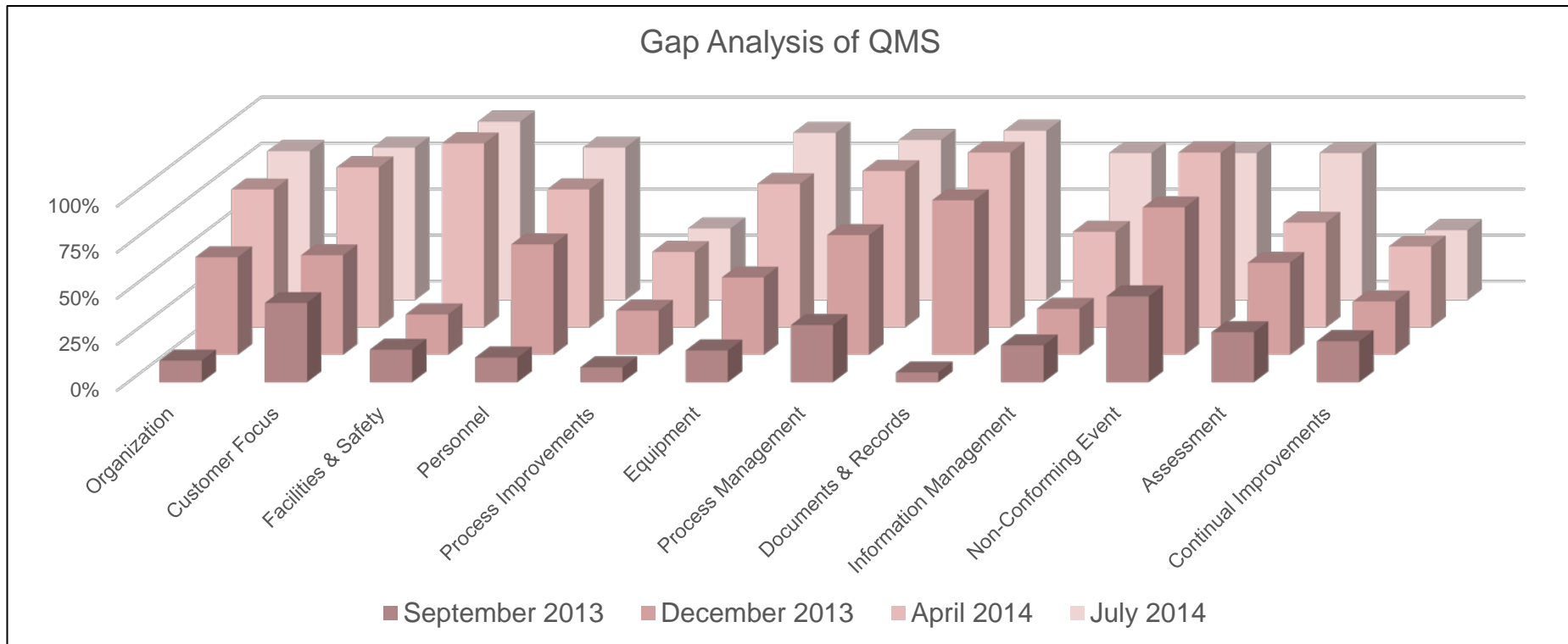
July 29,  
2014  
Application  
Submitted

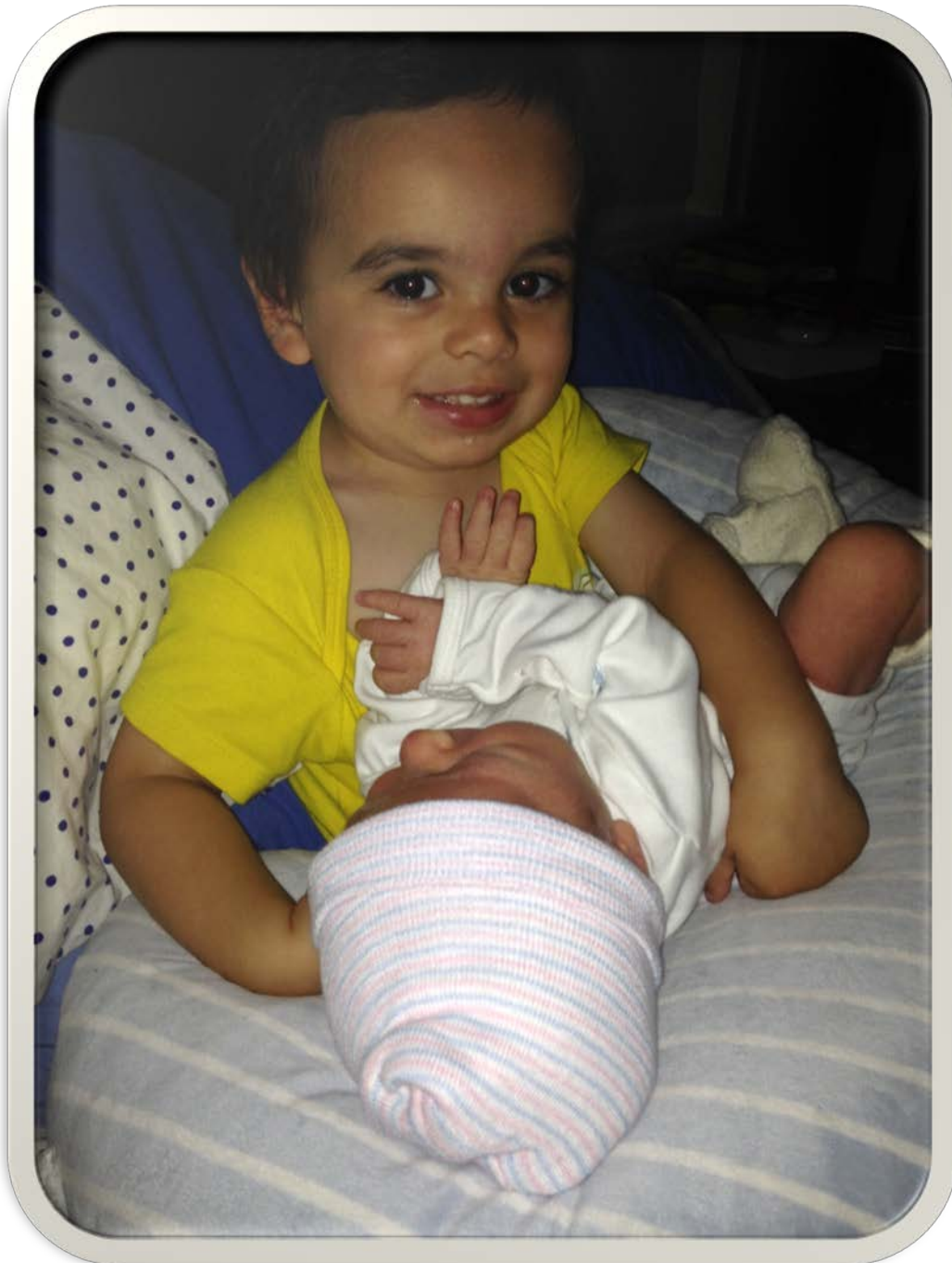


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# Document Review Preparation

- Significant amount of process planning and policy writing
- Optimization of document control process
- Continual internal auditing, gap analysis of QMS





# Pre-Assessment

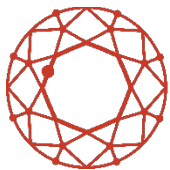
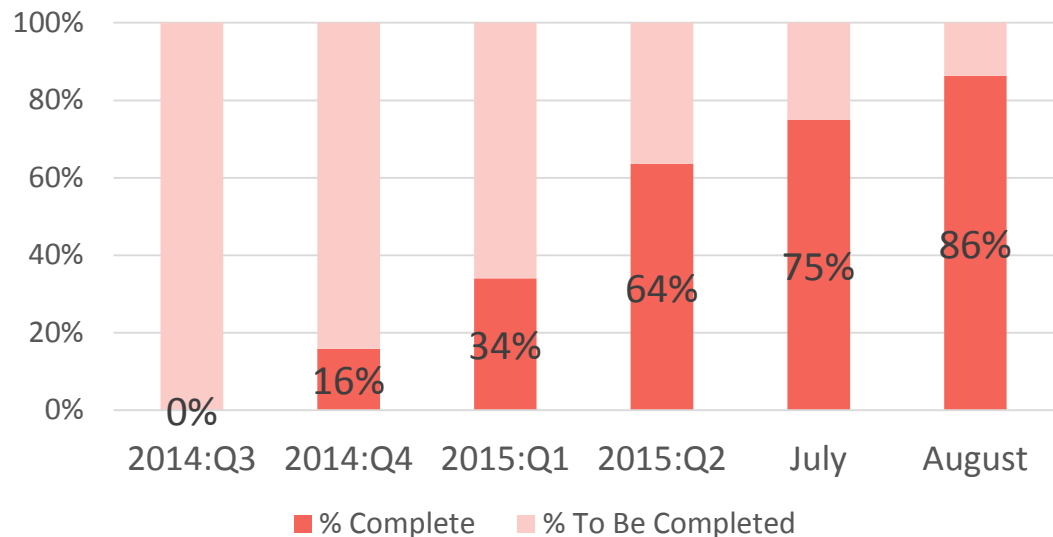
- Optional
- Provides an opportunity to explain the requirements, policies, and expectations
- Normally lasts one day on-site
- Assessor provides lab a listing of items to work on



# Pre-Assessment

- Valuable tool to prepare for on-site assessment
- Exhaustive review of most documents and processes
- Used report as audit tool for the next 11 months
- Useful validation of expectations of standards
- Allowed to become accustomed to how A2LA would inspect

ISO 15189:2012 Preparedness



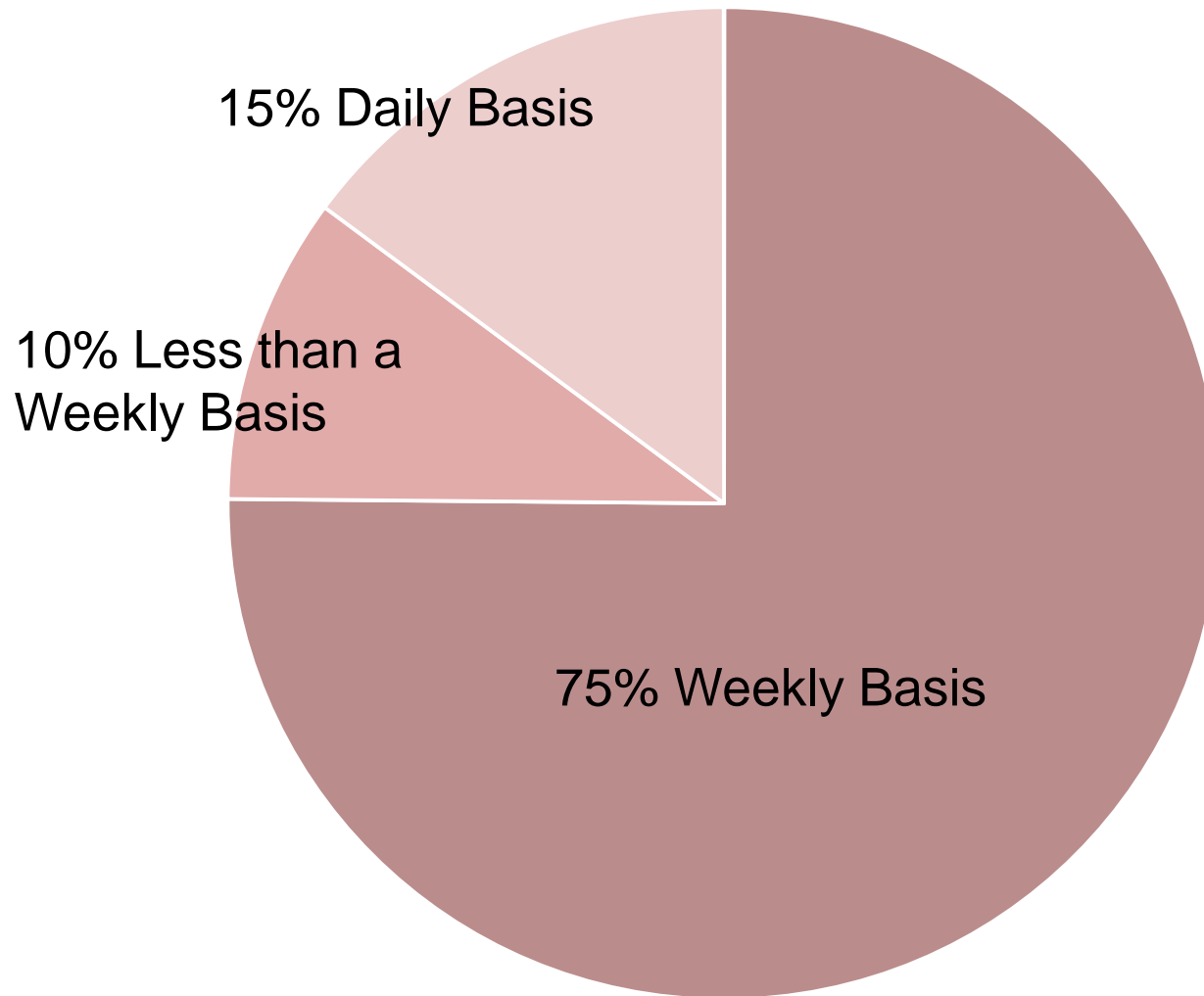
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# Assessment Preparation

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- 5 formal audits against pre-assessment report
- 1 full audit of ISO:15198
- Filling the gaps identified in the pre-assessment
- Constant process improvements
  - Implementing new processes
  - Improve documentation of current processes
- 100 Documents put under document control
- 83 External References put under document control
- QRR Committee met twice a month

# Percent of Company Actively Working on the Planning and Implementation of QMS





# Assessors

- Assessor Qualifications
  - Technical expert with minimum of 10 years experience in the technology
  - A2LA provides 5 day training course
    - ISO 15189 Requirements
    - ILAC Policies
    - Assessment approach
    - Interviewing/Interpersonal skills
    - A2LA policies
    - Must pass a written exam
  - Technical match with Lab's Scope



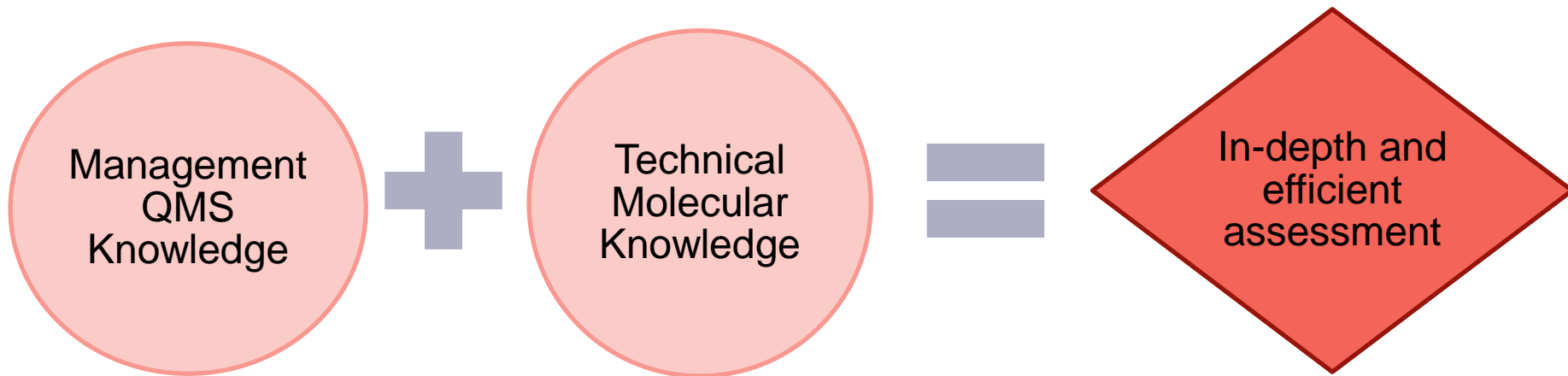
# Assessors

- Assessor Qualifications continued:
- Annual Technical Forum – refresher training
- Assessor monitoring
  - Staff assessor oversights
  - Staff evaluations (each assessment)
  - Lab feedback (each assessment)
  - Accreditation Council evaluates assessors



# Two Assessors for On-Site Inspection

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# On-site Assessment

- Focus more on implementation than documentation
- Fact-finding mission
- Transparency-no surprises
- Findings must be cited to a requirement (ISO 15189, CLIA, labs own procedures not to an assessor opinion!)



# On-site Assessment

- Management system review
  - Management review
  - Internal audits
  - Corrective and preventive actions
  - Document and record control
  - Areas “outside the lab” – procurement, customer feedback, complaints, reference labs



# On-site Assessment

- Technical review
  - Observe tests
  - Interview personnel
  - Review records
  - Evaluate equipment
  - Proficiency testing results



# On-Site Assessment

## Management System

Assessor + QA Manager  
at a desk

Review of Documents  
and Records

Reviews evidence of  
following requirements  
and internal policies

## Technical

Assessor and Lab  
Management in the Lab

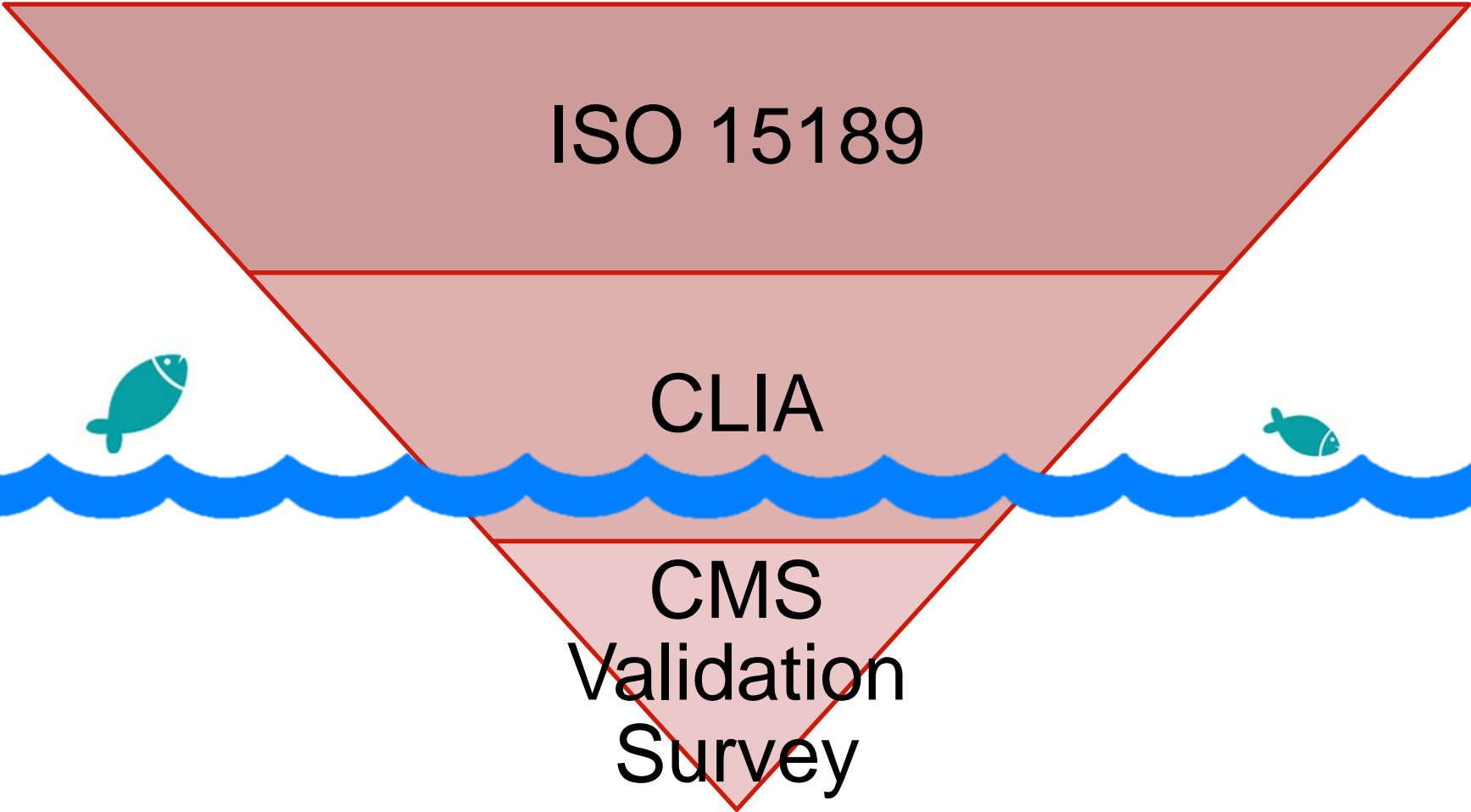
Interview Technologists

Reviews validations

Performed Tracer Audit

# On-Site Assessment

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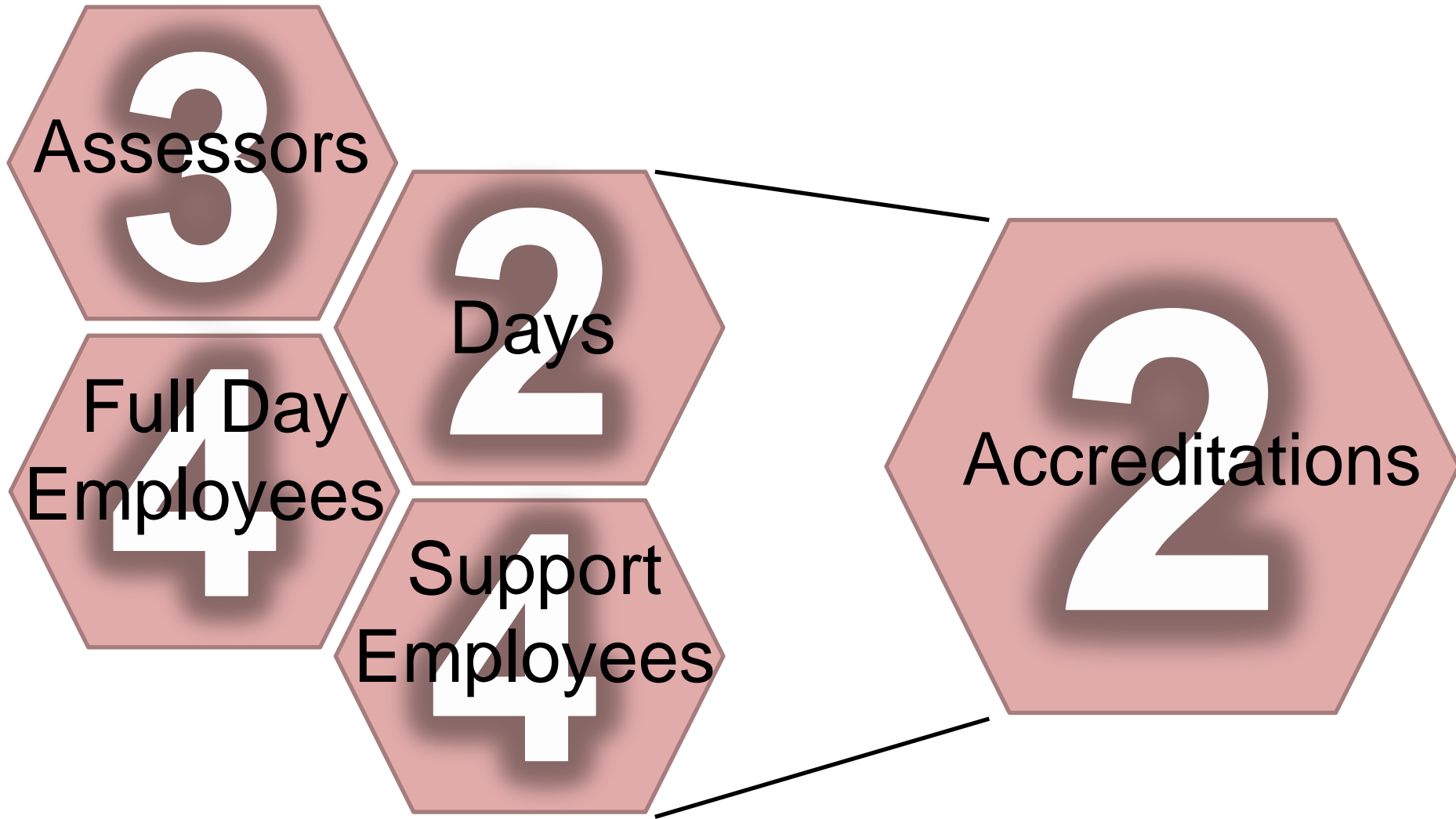
ISO 15189

CLIA

CMS  
Validation  
Survey



# On-Site Assessment by the Numbers



# Reporting

- Exit briefing
- Final, written report provided at exit
- Instructions provided on responding to findings



# Reporting

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- Prior to citing a deficiency and completing report, assessors consulted regional CMS with discordant opinions
- Exit briefing was extremely thorough with evidence of what regulation was being cited
- Full official report given prior to departure
- List of Observations, optional, also provided, on ways to improve current practice or documents.

# Corrective Action Process

- A2LA Requires:
  - Root cause investigation
  - Corrective action
  - Objective evidence demonstrating that deficiency has been closed
  - Past tense not “we will”



# Corrective Action Process

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- Explicit directions on how they want to see CAPA process
- Worked within internal policies of Non-conforming event and CAPA reporting and management
- Quick turn around time for feedback of submission
- Independent Accreditation Counsel reviews the objective evidence and determine whether to grant accreditation

# Recognitions

- A2LA is the only Accreditation Organization in the World that holds both:
  - CMS Deemed Status
  - International Laboratory Accreditation Cooperation (ILAC) Recognition



# Recognitions

- A2LA maintains and operates a management system similar to our customers
- ISO 15189 Program is recognized
- ILAC recognition means labs results can be accepted internationally



# Accreditation Value

## Internal

Thorough prep and audit greatly improved our QMS

Improved Culture of Quality Enterprise-wide

Improved Regulatory Readiness

Prepared us for future of FDA Oversight of LDTs

## External

Identifies us Early Adopter of Future Climate of QMS

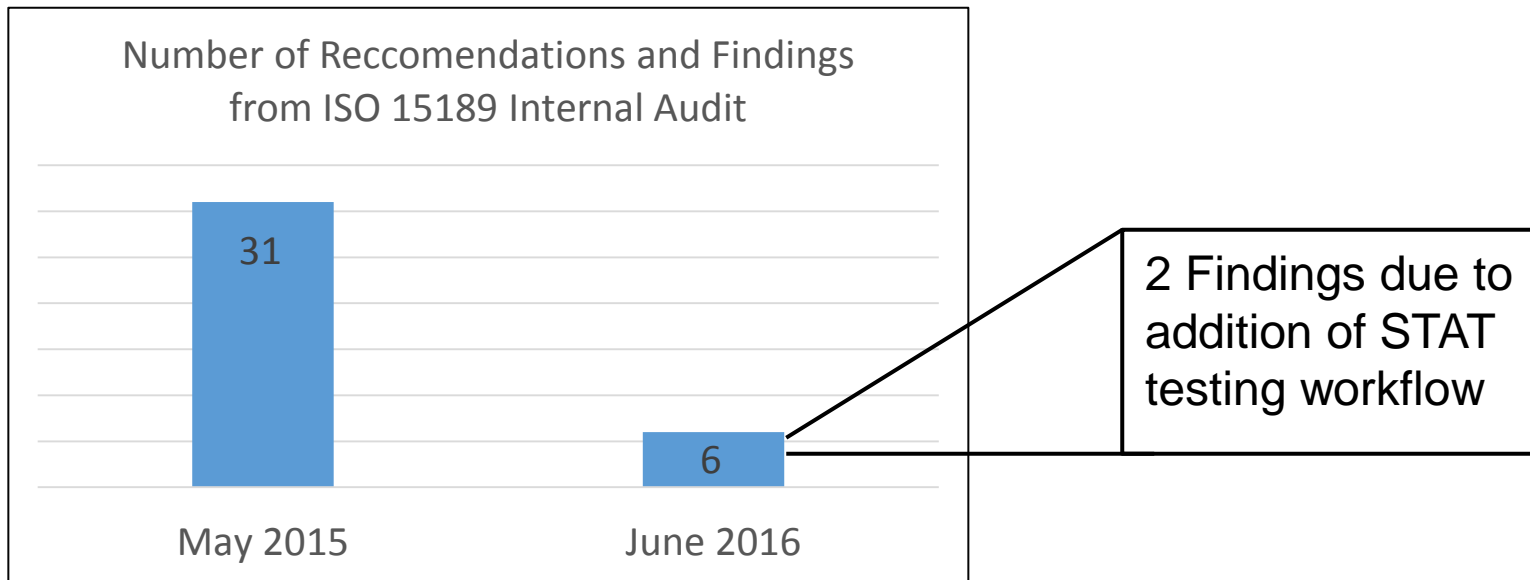
Marketing Opportunity

Insurance Company Noted Accreditation as a sign of lower risk



# Improved Regulatory Readiness

- Increased number and variety of internal audits
  - Required to perform ISO:15189 and CLIA annually, and Management Review semiannually.
- Increased number of qualified internal auditors
  - Gaining more unbiased audit results



# Improved Regulatory Readiness

Since gaining our ISO:15189 and CLIA accreditation we've had several successful on-site inspections, including:

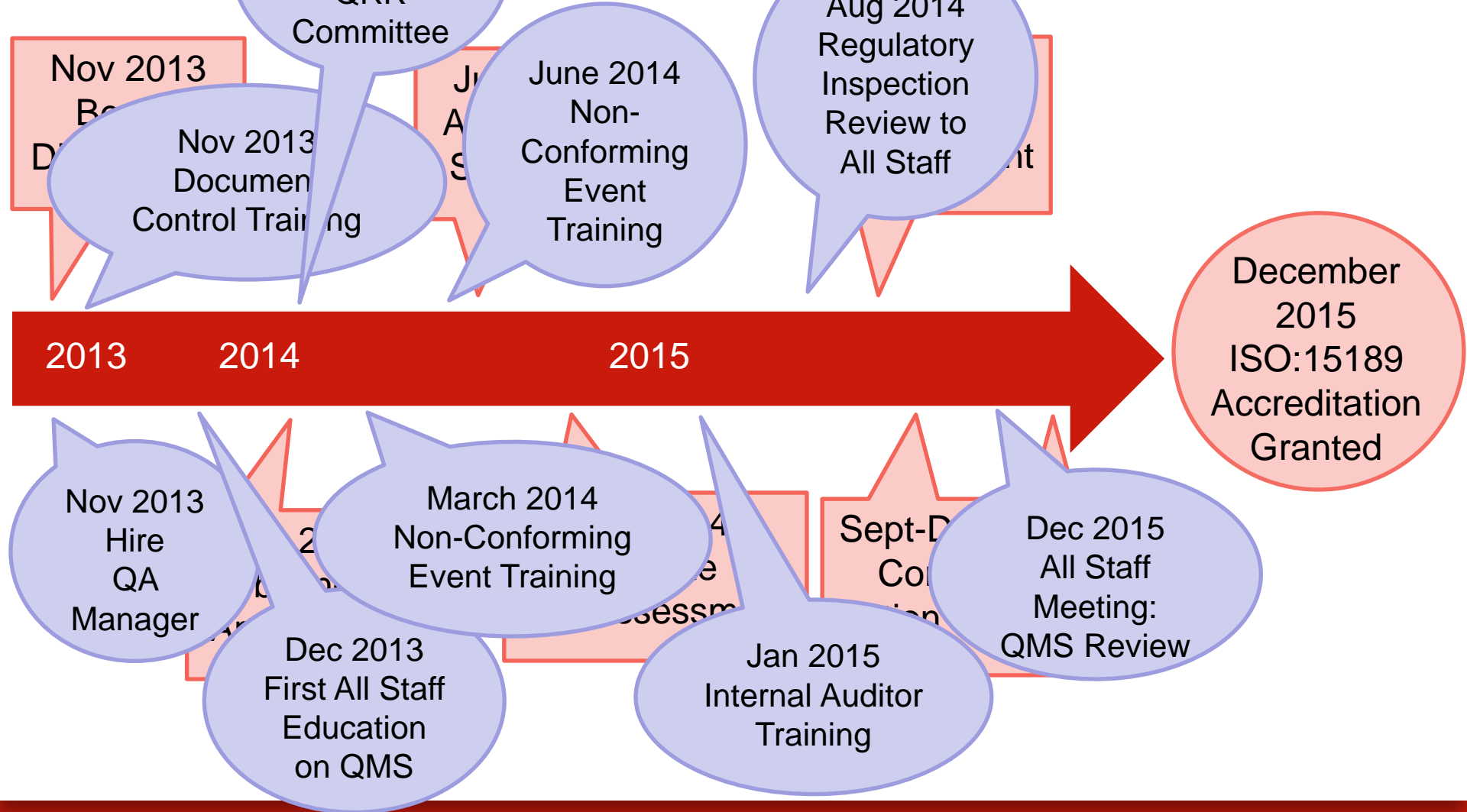
New York State Clinical Laboratory Evaluation Program

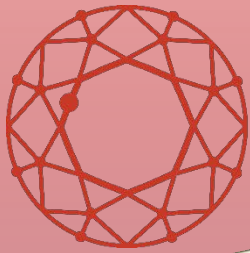
Unannounced follow up to CMS Validation Survey

State of California Department of Public Health

Also renewed their license with: CA, MA, MD, PA, and RI

# Timeline of Accreditation Process and Development of Culture of Quality





# CLARITAS GENOMICS

CENTERS FOR MEDICARE & MEDICAID SERVICES  
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS  
CERTIFICATE OF ACCREDITATION

LABORATORY NAME AND ADDRESS  
CLARITAS GENOMICS  
99A ERIE ST  
CAMBRIDGE, MA 02139

LABORATORY DIRECTOR  
MARK D KELLOGG PHD, MT(ASCP)

CLIA ID NUMBER  
22D0

EFFECTIVE DATE  
03/01/2016

EXPIRATION DATE

11 CMS-2-032916

If you currently hold a Certificate of Compliance or Certificate of Accreditation for the above named laboratory located at the address shown herein (and other approved locations) used for the purpose of performing laboratory examinations or procedures, this certificate shall be valid until the expiration date above, but is subject to re-evaluation, suspension, or revocation of the Act or the regulations promulgated thereunder.

Seal of the Department of Health and Human Services

Kenneth W. Davis  
Division of Laboratory Survey and Compliance  
Center for Medicare & Medicaid Services

LAB CERTIFICATION (CODE)  
ROUTINE CHEMISTRY (310)

EFFECTIVE DATE  
03/01/2016

LAB C

FOR MORE INFORMATION ABOUT THIS ACCREDITATION OR CONTACT YOUR LOCAL ACCREDITATION OFFICE, PLEASE CONTACT YOUR STATE AGENCY.

ILAC-MRA A2LA

**ISO 15189:2012  
Internationally-Recognized  
Accredited Laboratory**

A2LA has accredited  
**CLARITAS GENOMICS, INC.**  
Cambridge, MA

for technical competence in the field of  
**Clinical Testing**

This laboratory is accredited in accordance with the recognized International Standard ISO 15189:2012 Medical laboratories - Requirements for quality and competence. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated January 2015).

Presented this 22<sup>nd</sup> day of December 2015.

*[Signature]*  
Senior Director of Quality & Communications  
For the Accreditation Council  
Certificate Number 371201  
Valid to December 31, 2017  
Revised: March 1, 2016

Seal of the International Accreditation Forum for Laboratory Accreditation  
A2LA  
SEAL 15189  
INTERNATIONAL ACCREDITATION FOR LABORATORY ACCREDITATION

For the tests to which this accreditation applies, please refer to the laboratory's Clinical Scope of Accreditation.

ISO 15189 ACCREDITED  
A2LA Clinical  
Raising the Bar in Laboratory Quality

