Both Sides of the Accreditation Experience: A Surveyor's Story

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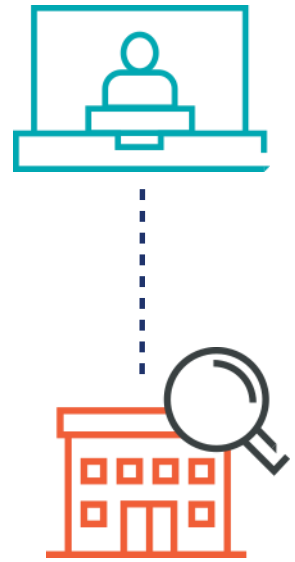
The Joint Commission

Role as a Joint Commission Surveyor

- Perform a meaningful assessment of your laboratory
- Help you identify risks
- Assist you on your journey to high reliability
- Ensure compliance with Joint Commission standards and CLIA requirements
- Be educational and collaborative

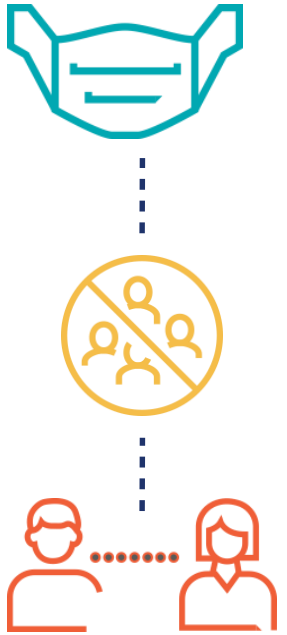
Changes due to Public Health Emergency

- Virtual surveys approved for initials and reaccreditation surveys utilizing zoom technology.
- All virtual surveys will have an onsite follow-up survey.
- Laboratories are contacted to check if they are wanting to participate via a virtual survey.
- Joint Commission Central Office monitors whether a surveyor can physically go to a location, as safety for all is of utmost importance.



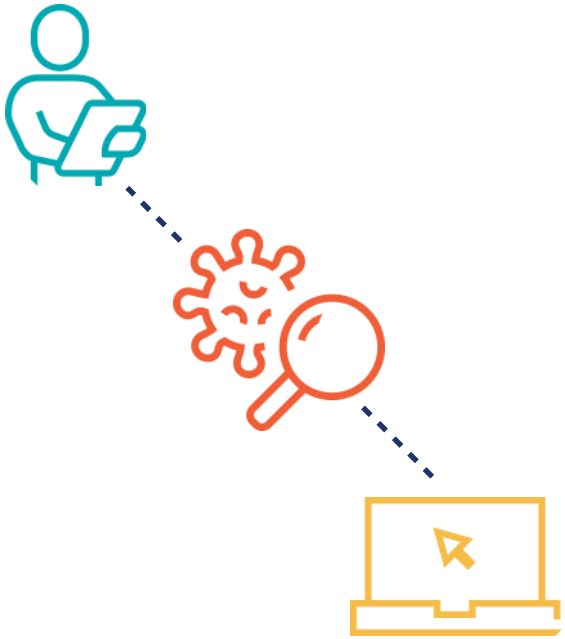
Process Changes if Surveyor Onsite

- Use of masks as routine practice/follow PPE and risk reduction strategies as established by CDC
- Physical social distancing
- Limiting number of individuals in group sessions/limiting observers to avoid additional exposures
- Maximizing use of technology
- Will not enter an at-risk or confirmed COVID-19 room/area



Process Changes if Surveyor Onsite

- Limited physical review of high-risk/ aerosol generating procedures
- Review of Infection Control policies/management
- Emergency management policies implemented
- Education of staff for these new processes
- Implementation and compliance to these new policies
- Ensure awareness of COVID-19 resources available on the Joint Commission website



Where Do Laboratories Struggle During Survey?

And What are the Greatest Challenges We See?

Challenge: Required Documents for Survey

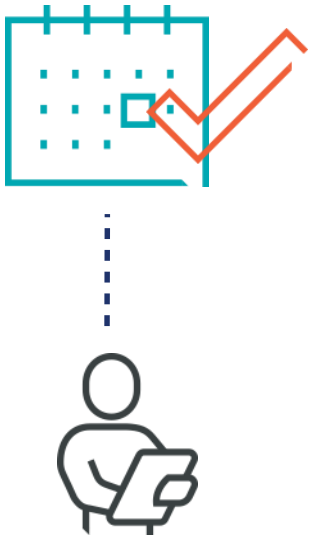
- CMS-209 completed (refer to CMS website to obtain)
- Current CLIA Certificates (all), with Specialties/ Subspecialties
- State Licenses, as appropriate
- List of specialties/subspecialties with test menu for each
- List of major instruments in lab, include all other ancillary, and Point-of-Care sites performing laboratory tests, kits used in the lab

Challenge: Required Documents for Survey

- Proficiency data **by** CLIA number for past 24 months (required for all surveys), including all worksheets, attestations, corrective actions (last six completed events)
- Include scorecard (if available) for all regulated/non-regulated analytes)
- List of tests that do not use Proficiency Testing for verification of accuracy/precision (alternative PT)
- Results of alternative Proficiency Testing

Challenge: Required Documents for Survey

- Process Improvement data for last 24 months
- Results of periodic lab environment inspections
- Emergency Operations Plan (evaluations/actual responses)
- Documentation of errors, accidents, complaints
- Internal/external audits, PI monitors
- Culture of safety data



Challenge: Required Documents for Survey

- Credentials, contract for Lab Director, how contract monitored (OPPE)
- Personnel licenses or certification if required by state or policy of the organization
- List of all testing personnel qualifications, hire date, training and competency records for last two years
- Proof of highest level of education for personnel

Challenge: Required Documents for Survey

- IQCPs for all applicable test systems with all 3 required sections (RA, QCP, QAP) approved and signed, implementation date, documentation of review
- Be able to retrieve testing records for patients who have had lab tests for past 24 months
- List of new instruments implemented since last survey with validations studies
- Temperature charts, maintenance records, QC records
- Policies and procedures
- Normal patient Prothrombin Time mean for your current lot of thromboplastin reagent and the ISI value specific to the reagent lot in use

Challenge: CMS-209 and CLIA Roles

- Surveyors will ask to see your CMS-209. Why?
- We need to see who holds the CLIA roles and delegated to perform certain duties
- Most labs struggle with this form because the CLIA roles do not necessarily “match” the titles used in the laboratory
- Review of CLIA roles:
  - Moderate Complexity Lab: Lab Director, Clinical Consultant, Technical Consultant, Testing Personnel
  - High Complexity Lab: Lab Director, Clinical Consultant, Technical Supervisor, General Supervisor, Testing Personnel

Moderate Complexity Laboratory Director

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- MD, DO, or DPM with current medical license in state of lab's location **AND** laboratory training/experience consisting of (only one required)
  - One year directing or supervising non-waived tests
  - 20 CME credit hours in laboratory practice commensurate with director responsibilities (after 09/01/1993)
  - Equivalent laboratory training (20 CMEs) obtained during medical residency
- PhD in chemical, physical biological, or clinical laboratory science **AND** certification by ABMM, ACBB, ABB, ABMLI

Moderate Complexity Laboratory Director

- PhD in chemical, physical, biological, or clinical laboratory science **AND** one year directing or supervising non-waived testing
- Masters in clinical laboratory science, medical technology or chemical, physical or biological science **AND** one-year laboratory training/experience **AND** one-year supervisory experience in a non-waived testing laboratory
- Bachelors in medical technology or chemical, physical or biological science **AND** two years laboratory training/experience **AND** two years supervisory experience in a non-waived testing laboratory
- **ON OR BEFORE 02/28/1992**: Qualified or could have qualified as a director under the laboratory regulations published March 14, 1990
- **ON OR BEFORE 02/28/1992:** Qualified as a director by the **state** in which the laboratory is located

Moderate Complexity Clinical Consultant

- MD, DO with current medical license in state of lab's location and certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- MD, DO, DPM with current medical license in state of lab's location and laboratory training/experience consisting of (only one needed)
  - One year directing or supervising nonwaived testing
  - 20 CME credit hours in laboratory practice commensurate with director responsibilities (effective 8/2/93)
  - Equivalent laboratory training (20 CMEs) obtained during medical residency
- Doctorate in chemical, physical, biological or clinical laboratory science **AND** certification by ABMM, ABCC, ABB, ABMLI
- MD, DO, DPM with current medical license in state of lab's location

Moderate Complexity Technical Consultant

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications **OR**
- MD, DO, or DPM with current medical license in state of lab's location **AND** one-year laboratory training/experience in a non-waived testing laboratory in **the designated specialty/subspecialty of responsibility OR**
- PhD or Master's degree in chemical, physical, biological or clinical laboratory science or medical technology **AND** one-year laboratory training/experience in a non-waived testing laboratory in the **designated specialty/subspecialty of responsibility OR**
- Bachelors in chemical physical, biological (*BSRN qualifies) or clinical laboratory science or medical technology **AND** two years laboratory training/experience in the **designated specialty/subspecialty of responsibility**

Moderate Complexity Testing Personnel

- MD, DO, DPM with current medical license in state of lab's location
- PhD in laboratory science, chemical, physical, or biological science
- Masters in medical technology, laboratory science, chemical, physical, or biological science
- Bachelors in medical technology, laboratory science, chemical, physical, or biological science
- Associate degree in chemical, physical or biological science, or medical laboratory technology
- High school graduate or equivalent and successfully completed military training of 50 or more weeks and served as a medical laboratory specialist

Moderate Complexity Testing Personnel

- High school diploma or equivalent and appropriate training/experience which includes:
  - The skills required for proper specimen collection
  - The skills required for implementing all standard laboratory procedures
  - The skills required for performing each test method and for proper instrument use
  - The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed
  - A working knowledge of reagent stability and storage
  - The skills required to implement the quality control policies and procedures of the laboratory
  - An awareness of the factors that influence test results
  - The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results

High Complexity Laboratory Director

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP, AOBP, or equivalent qualifications
- MD, DO, DPM with current medical license in state of lab's location **AND** one-year laboratory training during medical residency
- MD, DO, DPM with current medical license in state of lab's location **AND** two years of experience in directing/supervising high complexity testing
- PhD in chemical, physical, biological, or clinical laboratory science **AND** certification by the HHS-approved boards (effective 02/24/2003)

High Complexity Laboratory Director

- Hold an earned PhD in chemical, physical, biological, or clinical laboratory science from an accredited institution **AND** until 12/31/2002 must have served or be serving as director of a laboratory performing high complexity testing **AND** must have at least two years of laboratory training or experience or both **AND** two years of experience directing or supervising high complexity testing. (Directors meeting this qualification will be "grandfathered" in by CMS.)
- **ON OR BEFORE 02/28/1992:** Serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under laboratory regulations published 03/14/1990
- **ON OR BEFORE 02/28/1992:** Qualified as director by the state in which the laboratory is located

High Complexity Clinical Consultant

- MD, DO with current medical license in state of lab's location and certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- MD, DO, DPM with current medical license in state of lab's location and laboratory training/experience consisting of (only one needed)
  - One year directing or supervising nonwaived testing
  - 20 CME credit hours in laboratory practice commensurate with director responsibilities (effective 8/2/93)
  - Equivalent laboratory training (20 CMEs) obtained during medical residency
- Doctorate in chemical, physical, biological or clinical laboratory science AND certification by ABMM, ABCC, ABB, ABMLI
- MD, DO, DPM with current medical license in state of lab's location

High Complexity Technical Supervisor

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic **AND** clinical pathology by ABP, AOBP, or equivalent qualifications **OR**
- MD, DO, DPM with current medical license in state of lab's location **AND** certified in clinical pathology by ABP, AOBP, or equivalent **OR**
- MD, DO, DPM with current medical license in state of lab's location **AND** one year of training/experience in **high complexity testing in the respective specialty OR**
- PhD in clinical laboratory science, chemical, physical, biological science **AND** one year of training/experience in **high complexity testing in the respective specialty OR**
- Masters in medical technology, clinical laboratory science, chemical, physical, or biological science **AND** two years training/experience **in high complexity testing in the respective specialty OR**
- Bachelors in medical technology, chemical, physical, or biological science **AND** four years training/experience in **high complexity testing in the respective specialty**

***** Technical Supervisor qualifications are NOT the same for Immunohematology, Histology, and Cytology**

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High Complexity Technical Supervisor

Immunohematology

- MD, DO with current medical license in state of lab's location **AND** certified in clinical pathology by ABP, AOBP, or equivalent qualifications
- MD, DO with current medical license in state of lab's location **AND** have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology

Cytology

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic pathology by ABP, AOBP, or equivalent qualifications
- MD, DO with current medical license in state of lab's location **AND** be certified by the American Society of Cytology to practice cytopathology or equivalent qualifications

Histopathology

- MD, DO with current medical license in state of lab's location **AND** certified in anatomic pathology by ABP, AOBP, or equivalent qualification

High Complexity General Supervisor

- Qualify as laboratory director of high complexity testing
- Qualify as technical supervisor of high complexity testing
- MD, DO, DPM with current medical license in state of lab's location **AND** one year training in high complexity testing
- PhD in clinical laboratory science or chemical, physical, biological science **AND** one year of training/experience in high complexity testing
- Masters in clinical laboratory science, medical technology, or chemical, physical, biological science **AND** one year of training/experience in high complexity testing
- Bachelors in medical technology or chemical, physical, biological science **AND** one year of training/experience in high complexity testing

High Complexity General Supervisor

- Associate Degree in laboratory science or medical laboratory technology **AND** have at least two years of laboratory training or experience, or both, in high complexity testing
- Education and training equivalent to an Associate Degree in laboratory science or medical laboratory technology **AND** have at least two years of laboratory training or experience, or both, in high complexity testing
  - Education – 60 semester hours including either 24 semester hours of medical laboratory courses or 24 semester hours of science courses (6 hours chemistry; 6 hours biology; and 12 hours in chemistry, biology, or medical laboratory technology, or any combination
  - Training – either completion of an approved/accredited clinical laboratory or medical laboratory training program, which may be included in the 60 semester hours specified above or three months of documented laboratory training in each specialty in which the individual performs high complexity testing

High Complexity General Supervisor

- **Cytology**
  - Be qualified as a Cytology Technical Supervisor
  - Be qualified as a cytotechnologist **AND** have at least three years of full-time experience (2,080 hours per year) as a cytotechnologist within the preceding 10 years

- General supervisor requirement is met in **histopathology, oral pathology, dermatopathology, and ophthalmic pathology** because all tests and examinations must be performed by someone qualified as a technical supervisor

High Complexity Testing Personnel

- MD, DO, DPM with current medical license in state of lab's location
- PhD in clinical laboratory science or chemical, physical, or biological science
- Master's in medical technology, clinical laboratory science or chemical, physical, or biological science
- Bachelor's in medical technology, clinical laboratory science or chemical, physical, or biological science
- Associate Degree in laboratory science or medical laboratory technology

High Complexity Testing Personnel

- Education **AND** training equivalent to an Associate Degree in laboratory science or medical laboratory technology:
  - Education – 60 semester hours including either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses (6 hours of chemistry; 6 hours of biology, and 12 ours in chemistry, biology or medical laboratory technology, or any combination)
  - Training – either completion of an approved/accredited clinical laboratory training program, which may be included in the 60 semester hours specified above or at least three months of documented laboratory training in each specialty in which the individual performs high complexity testing
- **ON OR BEFORE 02/28/1992:** Qualified or could have qualified as a technologist under laboratory regulations published 03/14/1990. **Does not apply after 09/01/1997.**

High Complexity Testing Personnel

- **On OR BEFORE 04/24/1995:** With a high school degree of equivalent **AND** either one below**:**
  - Have graduated from an approved or accredited medical laboratory or clinical laboratory training program
  - Have successfully completed at least a 50-week official U.S. military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician)
- **AFTER 09/01/1997** the high school diploma route can no longer be used for new employees

Cytology Testing Personnel

- A cytotechnologist working in a non-licensure state must have graduated from “ a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation, or other organization approved by HHS; or be certified in Cytology by a certifying agency approved by HHS”; 493.1483(b)

Challenge: CLIA Roles and Delegation

Once you understand the required CLIA roles for laboratory personnel, the Laboratory Director may want to delegate certain duties.

- Ensure you have a letter of delegation as required in the Joint Commission standards. Ensure **all** duties delegated are included.
  - It is helpful to not write the delegation letter with individual names, identify the individuals by CLIA role.
  - There is no special format; it is up to the organization, but ensure it is signed and dated by the Laboratory Director.

What Can be Delegated by the Lab Director

- To the Clinical Consultant: ensuring test reports include pertinent information for interpretation; availability for consultation
- To the Technical Consultant: appropriate test method selection; enrollment in CMS-approved PT program; training and competency of personnel; review of policies and procedures with no changes; acceptable analytical test performance maintained; quality control and quality assessment programs established and maintained
- To the High Complexity General Supervisor: remedial actions when deviations found; routine review of quality control and quality assessment activities ensuring problems are identified and corrected (if there are no problems, do investigate to make sure); orientation and documentation of testing personnel competency

ALL DELEGATED DUTIES MUST BE IN WRITING!!!!

Delegated Duties

- Although the Lab Director can delegate certain duties, these remain ultimately the responsibility of the LD
- Establish a system to remain **ACTIVELY** involved in the operations of the laboratory to ensure delegated duties are being performed, such as effective communication, resolution of complaints. It may be necessary to make changes.
- Review sampling of PT results to ensure all is done correctly, including corrective action performed
- Review sampling of results, policies, and procedures

All these practices may assist in avoiding Leadership RFIs

Challenge: Who Performs Competency Assessment

- Moderate Complexity Testing
  - Technical Consultant
  - Anyone who meets the regulatory requirements for Technical Consultant
- High Complexity Testing
  - Technical Supervisor for each specialty
  - Delegated, **in writing**, to a General Supervisor as long as the individual meets the regulatory (CLIA) requirements for a General Supervisor

Be aware that only a pathologist or other physician with at least one year of immunohematology training qualifies as a technical supervisor of immunohematology.

Competency Assessment

- If a qualified individual performs any TC, TS, or GS functions including competence assessment, their names must be listed as TC, TS, or GS on the CMS Form 209 regardless of their job title in the laboratory. If a TS assesses competence for both high and moderately complex testing, he/she must be listed on the Form 209 as both TC and TS. If they test patients, they must also be listed as testing personnel.
- If an individual is not TC or TS qualified and will be gathering competence data, the policy and delegation document **must** state that the individual has been delegated to gather data for performance assessment.
- **It is ultimately the responsibility of the Laboratory Director to ensure competency is performed timely and appropriately**.

Competency Assessment

- ***Six elements per testing platform required by CLIA***
  - Direct observation of routine patient testing
  - Monitoring the reading and reporting of test results
  - Review of intermediate test results, quality control (QC), proficiency testing (PT), and preventive maintenance
  - Direct observation of instrument maintenance and function checks
  - Assessment of test performance
  - Assessment of problem-solving skills

Pitfalls of Competency Assessment

- For Non-Waived Testing: The person assessing the competency does not meet the requirements of a TC, TS, or GS. (often seen for POCT and Respiratory)
  - Take the time to ensure that staff doing the assessment meet the qualifications required
  - Have someone from the lab who meets TC qualifications perform the assessment
  - Waived/moderate complexity kits based on type of sample used - **Know your test menu and complexity level!**

Other Errors Found in Competency Assessment

- The six methods are not used to evaluate competency for every platform used
  - The policy should include the six methods
  - The policy should identify when a method is not applicable for a test
  - Include all six methods on the competency assessment form; cannot pick and choose methods
- For new hires, the sixth month competency assessment is either not done or not done on time
  - Schedule this on your calendar
  - Hold the employee accountable to get this done
  - Six months plus or minus 15 days from the date of the orientation assessment
  - Waived test kits being used not following manufacturer instructions/components change complexity to **HIGH**!

Other Errors Found in Competency Assessment

- For PPM testing, using credentialing and privileging for documentation of physician qualifying to perform non-waived testing at site. This **CANNOT** be used in lieu of documentation of competency using the six required procedures as applicable to testing performed for instrument based waived testing.

Challenge: Proficiency Testing

- Laboratories are required to participate on a CMS-approved proficiency testing program for each regulated analyte performed.
- Non-regulated analytes (or analytes not included in a formal PT program) are **NOT** required to have proficiency testing. However, **it is required** labs evaluate accuracy and reliability of results for these analytes with criteria for acceptability. This must be performed at least every 6 months. If performance verification is unacceptable, a thorough investigation must be performed and documented.
- All unsatisfactory results must have **thorough** corrective action of all potential causes, perform corrective action and provide evidence of review. Do not just document "repeated and OK, QC OK " or "random error" (remember "random error" by definition is random, not consistent because it is not thoroughly investigated.) When you conduct the investigation, ensure patient tests performed during that same time were not affected.

- **Note: for information on approved proficiency testing providers see *http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_providers.asp***

Proficiency Testing

- The laboratory maintains records of its participation in a proficiency testing program.
- The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.
- The laboratory retains proficiency testing records for at least two years from the date of participation.
- The laboratory performs PT for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) certificate for each regulated analyte.
- PT samples are integrated into normal workflow, tested by and rotated amongst staff who perform patient testing and are tested the same number of times as patient samples.
- The laboratory staff and laboratory director (or QUALIFIED designee) sign the attestation statement.
- The laboratory does **NOT** send proficiency testing samples to another laboratory for analysis (this is **REFERRAL**). **Please be careful when you have multiple CLIA numbers. The PT kit is specific to the CLIA!**

Challenge: Correlations

- The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations. Do not forget manual method correlations to instrument correlations.
- Correlations are performed at least once every six months and documented.
- The laboratory has a policy for performing correlations and the Lab Director defines tolerance limits for agreement when performing correlations.

Challenge: IQCPs

- Ensure you have approved IQCPs for all systems applicable or the system/test automatically defaults to CLIA regulations – required Quality Control levels and frequency every day of patient testing
- IQCPs must include a Risk Assessment, Quality Control Plan, and Quality Assurance Plan. Ensure all your potential risks are included (sometimes these arise as systems are in use and “you experience things”).
- From July 2017 forward, all revised or new IQCPs must have Laboratory Director signature and date for each of the three sections.
- Evidence of review like any other procedure
- Available to the laboratory staff – not placed in an office where they are “forgotten”.

Challenge: Coagulation

- Ensure automated coagulation Quality Control is performed every 8 hours (a range may be specified in writing in your policy, such as +/- 15 minutes before performing the test or after the 8-hour mark, giving you a 30-minute window.
- Remember D-dimer performed on the Triage meter is still a coagulation test and if IQCP is not used, coagulation quality control rules apply.
- Each new lot of thromboplastin reagent used requires the lab to establish the new normal patient mean (new lot=new geometric mean).

Challenge: Coagulation (cont.)

- Ensure **correct** ISI is set in the instrument. Remember for PT results, the INR calculation incorporates the normal patient PT mean and the ISI specific to the lot number of thromboplastin reagent in use.
- During the survey, the surveyor will ask you to display the ISI set in the instrument and compare to the ISI stated in the package insert for lot in use. If incorrect, the new mean must be recalculated while surveyor is onsite. It must be approved by the Laboratory Director and determine if incorrect results may have been previously reported. **All this must be completed prior to end of survey.**

THANK YOU.

QUESTIONS?

The Joint Commission