REGULATORY CONSIDERATIONS IN DEPLOYING POC COVID-19 TESTING IN NON-TRADITIONAL TESTING SITES

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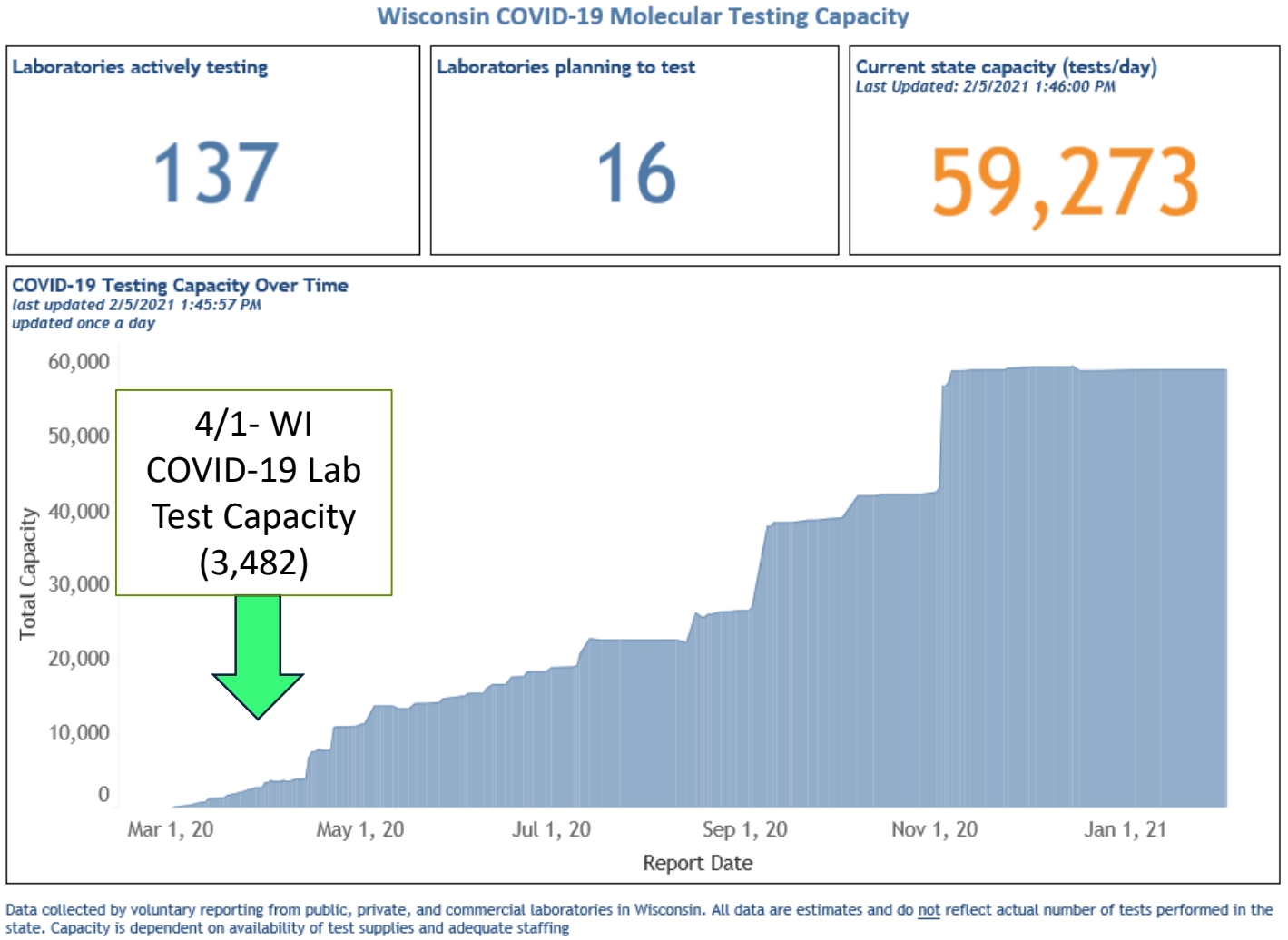
Laboratory Operations Manager

APHL QIF Call February 16TH, 2021

BACKGROUND

- March 2020- Abbott receives EUA for the fastest available molecular point-of-care (POC) test for detection of COVID-19
- April 2020
  - HHS provides Abbott ID Now instruments to public health jurisdictions to best meet testing priorities
  - Milwaukee makes national news as COVID cases & deaths rise disproportionately in minority populations
  - WI DHS, WSLH & MHDL strategize utilization of ID Now POC units within Milwaukee areas and communities



MHD's Mission & Approach

Advance the health and equity of Milwaukeeans through science, innovation, and leadership.

Innovation

- Identify non-traditional sites for analyzer deployment
- Sites that support high risk and/or underserved populations to advance the health and equity of Milwaukeeans

Science

- Provide training, supplies and resources

Leadership

- Educate on best practices, work flows and reporting
- Monitor site testing patterns and demands

Quality

- Continuously improve and adapt to create sustainable and positive health outcomes

Planning

Team Selection

- Administration (Clinical Services Deputy Commissioner, Laboratory Director)
- Preparedness/Testing Coordinator
- Laboratory Operations Manager
- Technical Staff/Laboratory Scientists

Training

- Attended Abbott Virtual ID Now Training Session
- Reviewed Manuals, Instructions for Use, EUA and package inserts
- Developed a standard training guide
- Reviewed CLIA Waived Testing Guidance documents

Tools

- Modified/created user friendly quality logs (temperature, QC) per CLIA requirements
- Created competency assessment documentation and FAQ for non-traditional settings
- Developed a standard site survey for use in assessing physical space

Outreach

- Reached out to other state PHL's to learn about their deployment approach
- Pre-screen calls with partners to gauze partner interest and applicability to their setting
- Focus on local partners to increase access to diverse, high risk and underserved populations
- Upon completion of survey, setup visits to confirm site appropriateness and address issues

Site assessment tool

1. Certification, Oversight, and Educational Considerations

Does the site have a CLIA license?	☐ Yes ☐ No
If yes, what is their CLIA certificate #?	
Is there medical oversight?	☐ Yes ☐ No
If yes, name and credentials?	
What is the educational/training background for "super-user"?	

2. Operational Location Considerations

Does the facility have a designated work space that is clean, flat, level and stable within reach of 120V electrical outlet?	☐ Yes ☐ No
Can the work space accommodate ID Now unit and safety hood?	☐ Yes ☐ No
Is the workspace out of direct sunlight?	☐ Yes ☐ No
Does the workspace have a temperature range within 50º - 86ºF, and room relative humidity 10-80%, non-condensing?	☐ Yes ☐ No
Can the unit remain in the same location for an extended period of time? *(QC must be done every time unit is moved.)*	☐ Yes ☐ No
Will the unit be secluded and away from high traffic areas?	☐ Yes ☐ No

Initial site identified….

Site identified at same building after quality/safety and test training visit…

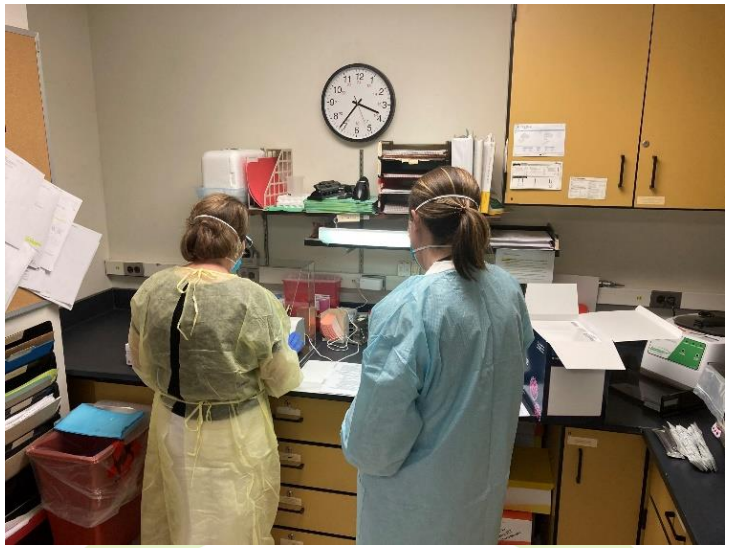
SITE ASSESSMENT CONTINUES.....

3. Safety Considerations

Does the facility have appropriate PPE for the operators collecting specimens and performing the test? (e.g. gloves, disposable coats, masks, protective eye wear, etc.)	☐ Yes ☐ No
Does the facility have the ability to dispose of biohazardous waste?	☐ Yes ☐ No

4. Reporting

Does the facility have the ability to fax or email daily count of tests performed including positive/negative/invalid patient results?	☐ Yes ☐ No
Does the facility have access or a mechanism in place for reportable result reporting to MHD/DHS/WEDSS? *Testing facilities **are required** to report all positive and negative results to the appropriate health authorities.*	☐ Yes ☐ No



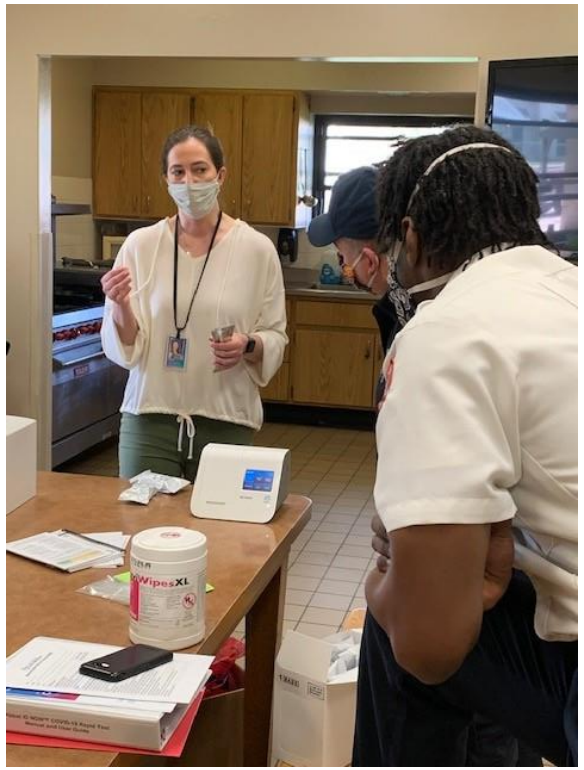
Partners Understanding on site specs

5. Partner Acknowledgement

Partner acknowledges that all requirements above have been, or will be, implemented prior to system installation and training.	☐ Yes ☐ No
Partner acknowledges that all testing will follow manufacturer's guidelines for performing COVID-19 testing on the Abbott ID NOW instrument.	☐ Yes ☐ No
Partner acknowledges that testing is intended only for persons that may have been exposed to the virus based on signs and symptoms, and/or because an individual: • has lived in or has recently traveled to a high prevalence COVID-19 location • has been in close contact with a suspected or confirmed case of COVID-19	☐ Yes ☐ No
Partner acknowledges that ***a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions***, especially if the patient's medical, travel, or contact history suggests a strong likelihood of infection. Negative results must be combined with clinical observations, patient history, and epidemiological information.	☐ Yes ☐ No

If any of the previous questions are answered "no", review will be performed to determine what measure(s) may be taken to qualify a site for placement. A "no" response does not automatically disqualify the facility from receiving a unit.

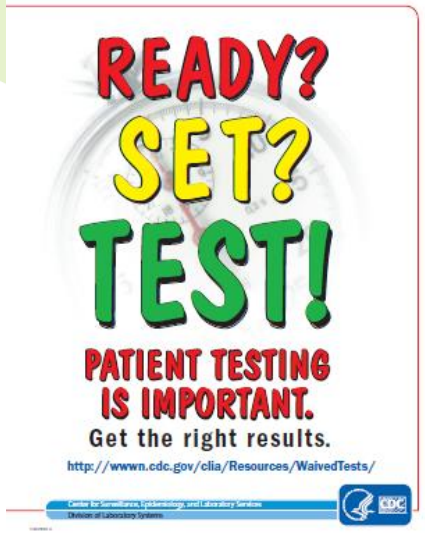
TRAINING



Provided on-site training utilizing standard training guide

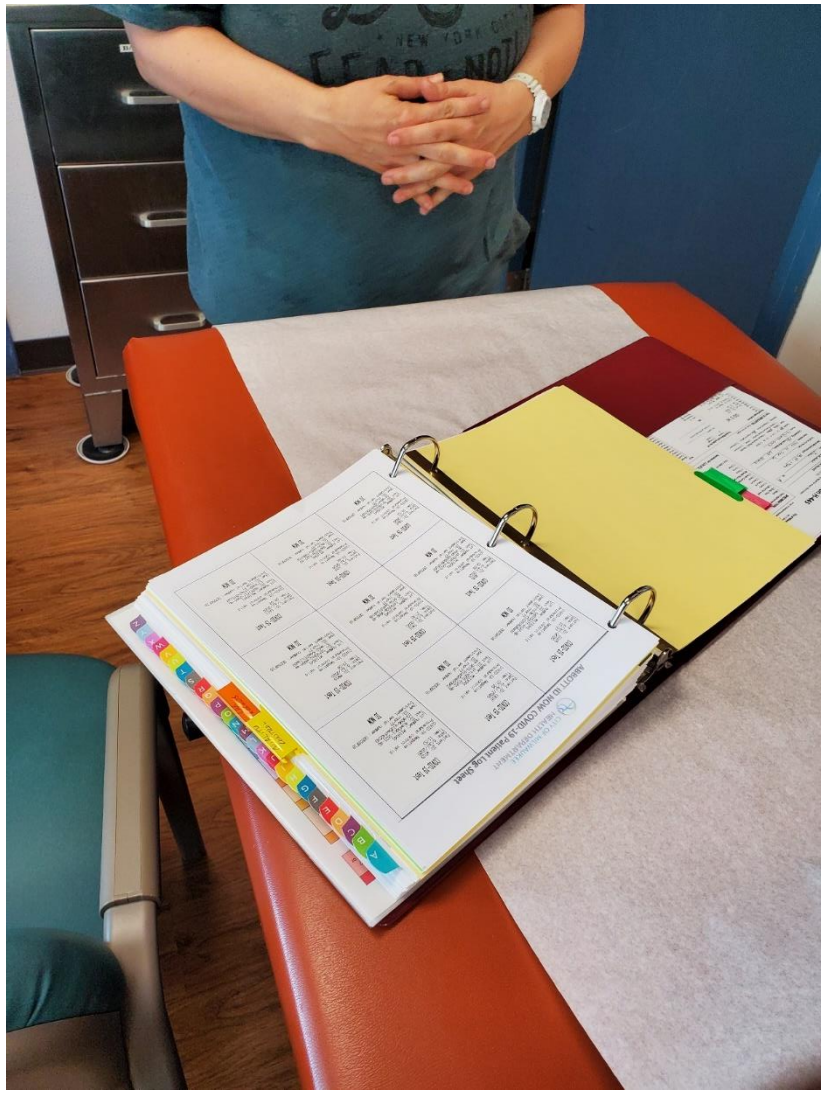
- During training, completed initial competency documentation
- Issued a binder with instrument manual and printed resources including CLIA & Waived Testing Booklet, Abbott training links

Coordinated with WI state lab to establish Web-based Laboratory Reporting and training



https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf

CITY OF MILWAUKEE
HEALTH DEPARTMENT



Week	Pos	Neg	Inval
8	1	308	25
9	2	201	38
10	1	307	42
11	3	290	17
12	2	256	5

DEPLOYMENT SITES

Location Type	# of locations	Population Served
Homeless Shelter/ Isolation Facility	2	Residents and staff at shelters
Student Health Center	2	College students including those in dorm setting
Correctional Facility	2	Inmates and staff
Fire Department	1	Emergency personal
Clinical Service Provider	4	Un- & Underinsured, employees caring for vulnerable populations

Lessons learned

- Important to establish that the site is a considered a LAB- especially important for state reporting obligations (especially for sites accustomed to CLIA Certificate of Waiver)
- Routine Communication and on-site training is key to compliance success
- Strength in numbers- Flexibility- learning from each site to modify training & documents and overall improve for all
- Everything works best of there is a site owner!!!
- Ideal to have a dedicated POC Coordinator to manage the process

Thank you!

QUESTIONS!

kschieb@Milwaukee.gov

CITY OF MILWAUKEE
HEALTH DEPARTMENT

CLIA REGULATORY CONSIDERATIONS DURING COVID

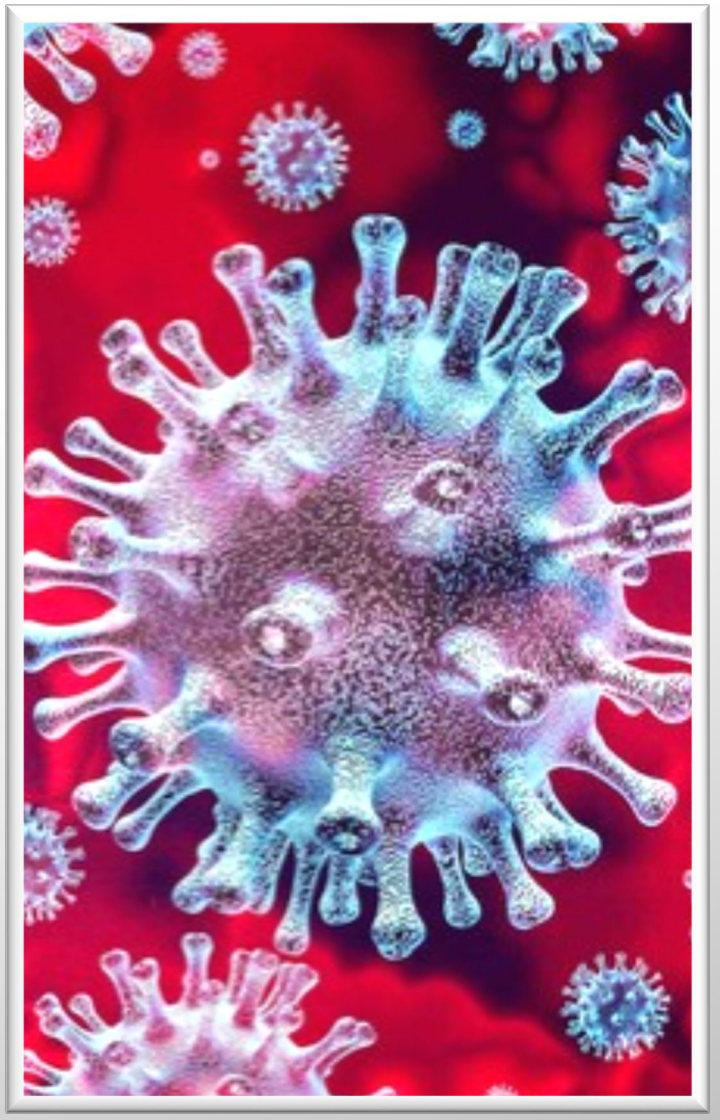
JEFF GROFF

CLIA PROGRAM MANAGER

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT (CDPHE)

DO THE CLIA REQUIREMENTS APPLY DURING THE COVID PANDEMIC?

YES!



FDA EMERGENCY USE AUTHORIZATION (EUA) FOR COVID TESTING

- DEVELOPERS OF COVID TESTS SUBMIT THE TEST DATA TO THE FDA FOR REVIEW.
- THE FDA EVALUATES THE TEST METHOD TO DETERMINE THE COMPLEXITY RATING UNDER THE EUA.
- TESTS ARE BEING APPROVED ALMOST DAILY AND A CURRENT LISTING OF THOSE APPROVED TESTS UNDER THE EUA MAY BE FOUND ON THE FDA'S WEBSITE AT
- HTTPS://WWW.FDA.GOV/MEDICAL-DEVICES/CORONAVIRUS-DISEASE-2019-COVID-19-EMERGENCY-USE-AUTHORIZATIONS-MEDICAL-DEVICES/VITRO-DIAGNOSTICS-EUAS
- THE COMPLEXITY RATINGS ARE ASSIGNED AS FOLLOWS;
  - W-WAIVED
  - M-MODERATE
  - H-HIGH

WHAT DEFINES A LABORATORY

- ANY FACILITY PERFORMING TESTING ON A SAMPLE DERIVED FROM A HUMAN BEING FOR THE PURPOSES OF DIAGNOSIS, TREATMENT OF DISEASE OR ASSESSMENT OF HEALTH IS DEFINED AS A LABORATORY.
- A CLIA CERTIFICATE MUST BE ISSUED TO THE LABORATORY PRIOR TO TESTING AND REPORTING PATIENT RESULTS.
- THE LEVEL OF COMPLEXITY OF TESTING THAT WILL BE PERFORMED (WAIVED, MODERATE, HIGH) DICTATES WHAT TYPE OF CLIA CERTIFICATE IS ISSUED.
- THERE ARE FOUR TYPES OF CLIA CERTIFICATES
  - CERTIFICATE OF WAIVER
  - CERTIFICATE OF PROVIDER PERFORMED MICROSCOPY PROCEDURES (PPM)
  - CERTIFICATE OF COMPLIANCE
  - CERTIFICATE OF ACCREDITATION

CLIA CERTIFICATE OF WAIVER

- LABORATORIES ONLY PERFORMING RAPID COVID TESTS THAT HAVE BEEN GIVEN THE "CLIA WAIVED" DESIGNATION BY THE FDA MUST HAVE A CLIA CERTIFICATE OF WAIVER ISSUED BY THEIR CLIA STATE AGENCY.
- THE TERM "WAIVED" MEANS THE LABORATORY IS "WAIVED" FROM ALL OF THE CLIA REQUIREMENTS LABS PERFORMING NON-WAIVED TESTING MUST ADHERE TOO.*
  - *SOME STATES HAVE ADDITIONAL STATE LICENSING REQUIREMENTS BEYOND THE FEDERAL CLIA REQUIREMENTS.
- AS OF 2.8.2021, THERE ARE ONLY NINE RAPID COVID TESTS THAT HAVE BEEN GIVEN THE CLIA WAIVED DESIGNATION.
- OTHER THAN HAVING AN ACTIVE CLIA CERTIFICATE, THE LABORATORY MUST DO TWO THINGS WHEN PERFORMING COVID TESTING.
  1. THE MANUFACTURER INSTRUCTIONS MUST BE FOLLOWED
  2. THE LABORATORY MUST REPORT THEIR TEST RESULTS TO THEIR STATE FOR TRACKING PURPOSES

CLIA CERTIFICATE OF PROVIDER PERFORMED MICROSCOPY PROCEDURES (PPM)

- A PPM CERTIFICATE IS DESIGNED FOR PHYSICIAN PRACTICES AND SMALLER CLINICS.

- A PPM CERTIFICATE ALLOWS FOR ANY CLIA WAIVED TEST TO BE PERFORMED IN ADDITION TO A LIMITED MENU OF MICROSCOPIC EXAMINATIONS THAT MAY BE PERFORMED BY A MID-LEVEL OR HIGHER PROVIDER.

CLIA CERTIFICATE OF COMPLIANCE AND CERTIFICATE OF ACCREDITATION

- THESE TWO TYPES OF CERTIFICATES ALLOW THE LABORATORY TO PERFORM ANY CLIA WAIVED TEST, THE PPM TESTS AND BOTH MODERATE AND HIGH COMPLEXITY TESTS.
- THE PRIMARY DIFFERENCE BETWEEN THESE CERTIFICATE TYPES IS WHO IS THE REGULATORY OVERSIGHT FOR THAT LAB (E.G. ONSITE INSPECTIONS).
- A CLIA CERTIFICATE OF COMPLIANCE, THE CLIA STATE AGENCY PERFORMS THIS FUNCTION AND WILL HOLD THE LABORATORY TO THE FEDERAL CLIA REQUIREMENTS
- A CLIA CERTIFICATE OF ACCREDITATION, THE LABORATORY MAY CHOOSE ONE OF THE ACCREDITATION ORGANIZATIONS THAT HAVE BEEN GIVEN DEEMED STATUS BY CMS (E.G. CAP, COLA, JOINT COMMISSION, A2LA, ETC.)
- THERE ARE CURRENTLY SEVEN APPROVED ACCREDITING ORGANIZATIONS THE LAB MAY CHOOSE FROM.

MODERATE COMPLEXITY TESTING

- A LABORATORY PERFORMING MODERATE COMPLEXITY TESTING MAY PERFORM COVID TESTING AS WELL.
- AS OF 2.8.2021, THERE ARE ONLY 17 COVID TESTS THAT HAVE BEEN GIVEN THE MODERATE COMPLEXITY RATING.
- THE LAB DIRECTOR AND TESTING PERSONNEL QUALIFICATION REQUIREMENTS ARE NOT AS STRINGENT WHEN MODERATE COMPLEXITY TESTING IS BEING PERFORMED.
- ALL OF THE OTHER CLIA REQUIREMENTS MUST BE MET TO INCLUDE ANY ACCREDITATION STANDARDS ESTABLISHED BY THE ACCREDITING ORGANIZATION IF THE LAB HOLDS A CLIA CERTIFICATE OF ACCREDITATION.

HIGH COMPLEXITY TESTING

- MOST OF THE COVID TESTS APPROVED BY THE FDA UNDER THE EUA HAVE BEEN GIVEN THE HIGH COMPLEXITY RATING.
- AS OF 2.8.2021 A TOTAL OF 209 TESTS HAVE BEEN APPROVED FOR USE UNDER THE EUA.
- MOST OF THE TESTS GIVEN THE HIGH COMPLEXITY RATING ARE REAL-TIME PCR METHODS.
- THE QUALIFICATION REQUIREMENTS FOR THE LABORATORY DIRECTOR AND TESTING PERSONNEL ARE MORE STRINGENT WHEN HIGH COMPLEXITY TESTING IS BEING PERFORMED.

WHAT ARE THE STEPS NEEDED PRIOR TO PERFORMING PATIENT TESTING AND REPORTING RESULTS?

1. CONTACT YOUR CLIA STATE AGENCY TO INFORM THEM THAT COVID TESTING IS GOING TO BE PERFORMED. THIS IS BEING TRACKED IN THE FEDERAL CLIA DATABASE, SO THAT INFORMATION WILL NEED TO BE UPDATED.
2. ENSURE THAT THE LABORATORY DIRECTOR AND TESTING PERSONNEL MEET THE MINIMUM QUALIFICATION REQUIREMENTS.
3. VALIDATE THE METHOD TO INCLUDE;
    1. ACCURACY
    2. PRECISION
    3. ANALYTICAL SENSITIVITY
    4. ANALYTICAL SPECIFICITY TO INCLUDE INTERFERING SUBSTANCES
    5. REPORTABLE RANGE

WHAT ARE THE STEPS NEEDED PRIOR TO PERFORMING PATIENT TESTING AND REPORTING RESULTS?

4. ESTABLISH WRITTEN PROCEDURES FOR THE TEST METHOD AND HAVE THE LAB DIRECTOR SIGN AND DATE THOSE PROCEDURES.
5. PERFORM AND **DOCUMENT** COMPETENCY ASSESSMENTS ON ALL TESTING PERSONNEL PRIOR TO REPORTING ANY PATIENT TEST RESULTS. THIS MUST BE DONE AT LEAST SEMIANNUALLY DURING THE FIRST YEAR AND ANNUALLY THEREAFTER UNLESS THE METHOD OR INSTRUMENTATION CHANGES, IN WHICH CASE THE INDIVIDUALS PERFORMANCE MUST BE REEVALUATED.
6. COMPETENCY ASSESSMENTS MUST INCLUDE AT MINIMUM;
    I. DIRECT OBSERVATION OF ROUTINE PATIENT TEST PERFORMANCE TO INCLUDE PATIENT PREPARATION, IF APPLICABLE, SPECIMEN HANDLING, PROCESSING AND TESTING;
    II. MONITORING THE RECORDING AND REPORTING OF TEST RESULTS;
    III. REVIEW OF INTERMIDIATE TEST RESULTS OR WORKSHEETS, QC RECORDS, PT TEST RESULTS, AND PREVENTATIVE MAINTENANCE RECORDS.
    IV. DIRECT OBSERVATION OF PERFORMANCE OF INSTRUMENT MAINTENANCE AND FUNCTION CHECKS;
    V. ASSESSMENT OF TEST PERFORMANCE THROUGH TESTING PREVIOUSLY ANALYZED SPECIMENS, INTERNAL BLIND TESTING SAMPLES OR EXTERNAL PROFICIENCY TESTING SAMPLES; AND
    VI. ASSESSMENT OF PROBLEM SOLVING SKILLS;

ARE THERE ANY OTHER SPECIAL REQUIREMENTS FOR PERFORMING COVID TESTING?

- YES AND NO.
- YES BECAUSE ALL COVID TEST RESULTS MUST BE REPORTED TO PUBLIC HEALTH OFFICIALS FOR EPIDEMIOLOGICAL PURPOSES.
- NO BECAUSE THE CLIA REQUIREMENTS REMAIN IN EFFECT FOR ANY TEST BEING PERFORMED BY THE LABORATORY TO INCLUDE COVID TESTING METHODS.
- MANY PUBLIC HEALTH LABS ARE ALREADY PERFORMING HIGH COMPLEXITY TESTING AND HAVE THE INFRASTRUCTURE TO ADD A NEW TEST TO THEIR MENU.

WHAT CAN WE EXPECT DURING THE BIENNIAL ONSITE INSPECTION?

- MANY LABS HAVE ENDURED THE BIENNIAL INSPECTION PROCESS OVER TIME BY FEDERAL CLIA REGIONAL OFFICERS (RO'S) AND/OR BY THEIR ACCREDITING ORGANIZATION.
- IT CAN BE EXPECTED THAT ADDITIONAL SCRUTINY WILL BE GIVEN TO THE COVID TESTING METHODS DURING THE SURVEY PROCESS TO ENSURE ALL OF THE REGULATORY REQUIREMENTS HAVE BEEN MET.
- MANY SCHEDULED ONSITE SURVEYS HAVE BEEN DELAYED DURING THIS CYCLE DUE TO THE PANDEMIC.
- CLIA HAS EXTENDED THE CERTIFICATION PERIOD TO THE END OF MARCH 2021, SO IF YOU HAVE NOT HAD YOUR ONSITE SURVEY AS ANTICIPATED, THE CLIA CERTIFICATE WILL NOT BE TERMINATED ON THE EXPIRATION DATE. THIS DATE MAY BE EXTENDED BY CMS AS THEY EVALUATE THE OUTBREAK LEVELS.

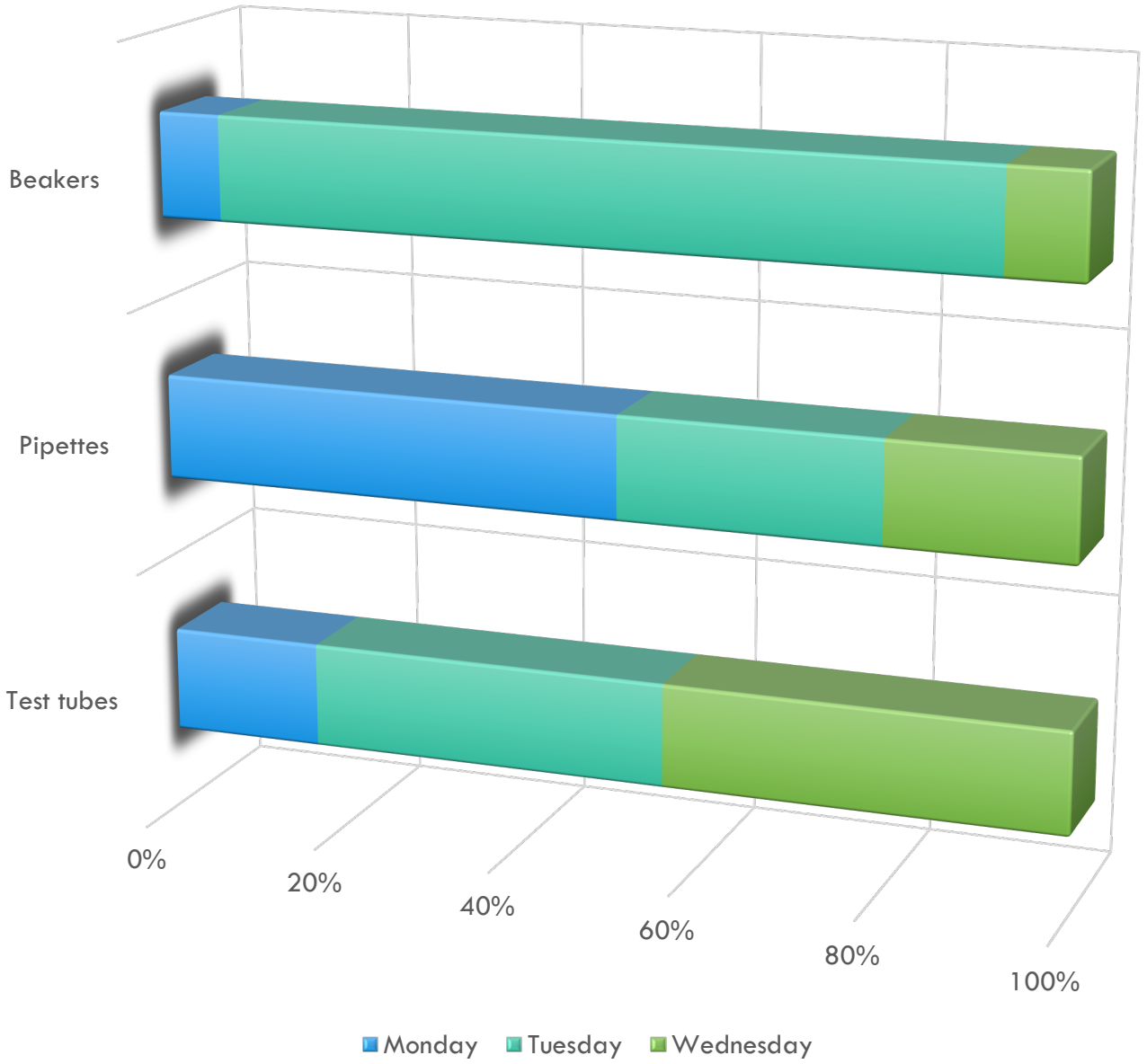
WHAT CAN WE EXPECT DURING THE BIENNIAL ONSITE INSPECTION?

- COVID METHOD VALIDATION DATA AND SUMMARY.
- WRITTEN PROCEDURES SIGNED AND APPROVED BY THE LAB DIRECTOR.
- DOCUMENTATION OF COMPETENCY ASSESSMENT FOR ALL TESTING PERSONNEL.
- AN ACTIVE QUALITY ASSURANCE PROGRAM THAT IS CAPABLE OF IDENTIFYING ERRORS WHEN THEY OCCUR, CORRECTING PROBLEMS AND MONITORING OVER TIME THE EFFECTIVENESS OF ANY CORRECTIVE ACTIONS TAKEN.
- IT IS VITAL THAT **ALL** OF THESE ACTIVITIES ARE DOCUMENTED.

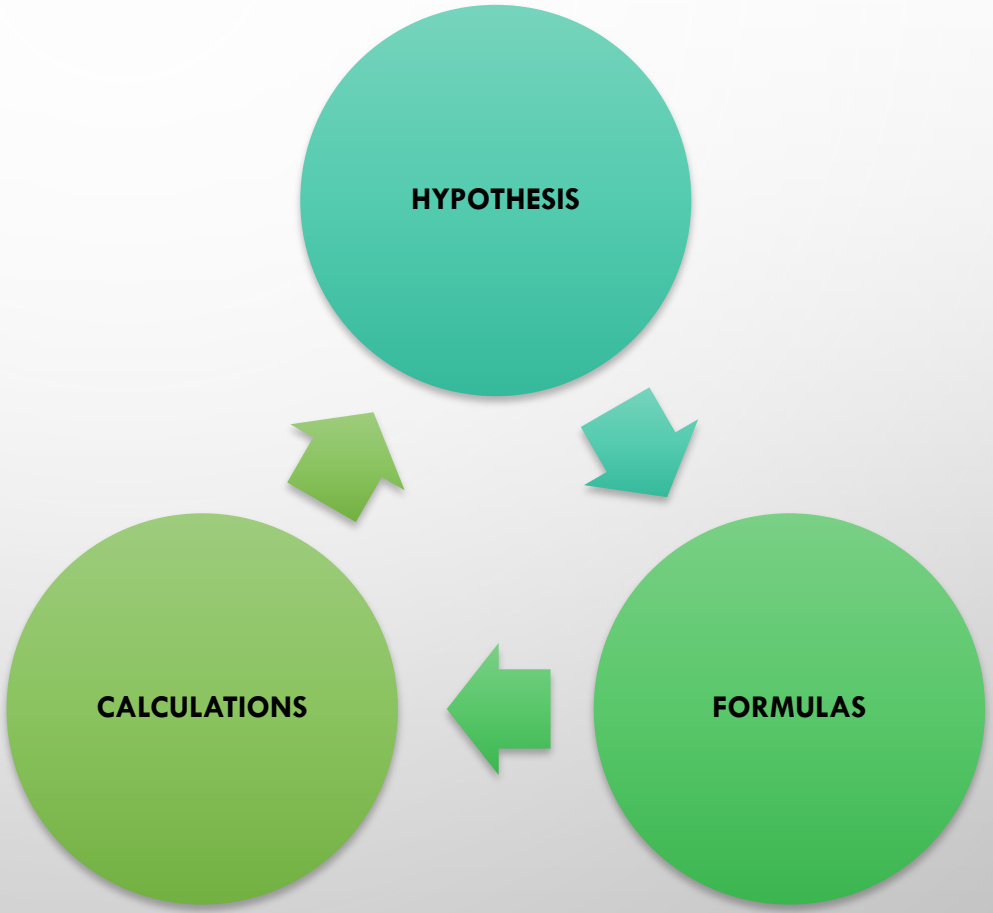
ELEMENTS

- Atoms
- Chemical Testing
- Formulas

INVENTORY BY DAY



SUCCESSFUL TESTING



CONTACTS

WWW.CMS.HHS.GOV/CLIA

FDA.GOV