POC COVID-19 TESTING
CLIA CERTIFICATE OF WAIVER

- **Federal Regulations**
- **Update (anything on certificate) within 30 days**
- **Renew certificate every two years ($180 fee)**
- **Follow MI instructions**
- **Does not limit who can be tested**
- **CLIA@dhhs.nh.gov**
STATE LICENSURE

- **151:2 License Required**
- **(C) Laboratories performing tests or analyses of human samples, or collection stations operated by laboratories.**
- **State Rules**
  - **He-p 808 Laboratories**
  - **He-p 817 Collection Stations**
REGULATION AND GUIDANCE

- Manufacturer’s Instructions
- He-p 808 Laboratory Rules
- He-p 817 Collection Station Rules
- Public Health Guidance and Recommendations
- CFR 483 Long Term Care Facilities Regulations
MANUFACTURER’S INSTRUCTIONS

- Precautions
- Storage and Stability
- Quality Control
- Procedure
- Specimen Collection and Handling
- Result Interpretation
- Limitations
WAIVE THE REQUIREMENT FOR LAB/COLLECTION STATION LICENSURE DURING THE PANDEMIC

- Create and implement policies and procedures to address requirements for collection, storage, and transport of specimens for COVID-19 testing. Such policies and procedures shall be in line with the manufacturer’s instructions and CDC laboratory guidance and updated as needed.
- Create and implement policies and procedures for reporting results as required to the National Healthcare Safety Network (NHSN), NH Division of Public Health Services, Ordering Physician, and the patient.
- Create and implement policies and procedures for handling positive results. Such policies and procedures shall be in line with NH Division of Public Health Services guidance.
- Follow the manufacturer’s required and recommended instructions.
- Testing shall not be administered without a physician’s order.
- Specimens are to be collected and tested following CDC guidelines, CLIA requirements and manufacturer’s instructions.
- Records must be kept of all testing and test results. Results must be kept confidential in compliance with state and federal HIPAA regulations.
- Maintain a clean and clutter free work environment. Specimen collection, processing, and test analysis areas for COVID-19 shall not be shared with other specimen types and shall include at a minimum three feet of linear counter space. Equipment, work surfaces, and flooring within areas used for collection and processing patient specimens shall include only non-porous material suitable for disinfection.
- Maintain any and all records pertaining to personnel training and specimen collection logs for 4 years.
PUBLIC HEALTH GUIDANCE

• Health Alert Network (HAN) Messages
  • HAN #20
  • HAN #22
  • HAN #23
LONG TERM CARE FACILITIES REGULATIONS (LABORATORY)

• F770 Laboratory Services (meet CLIA requirements)
• F773 Lab Services physician Order/Notify of results
• F775 Lab reports in record/Lab name/address (system for recording results)
LONG TERM CARE FACILITIES REGULATIONS (CON’T) F886

• CMS MEMO QSO-20-38-NH
• TESTING FREQUENCY
• COUNTY POSITIVITY RATE (CMS DATA)
• CONDUCT TESTING IN A MANNER CONSISTENT WITH STANDARD OF PRACTICE
• DOCUMENT
• PROCEDURES
LABORATORY ORDER FOR TESTING

- Written policies should cover the use of standing orders.
- Specific criteria clearly identified in the protocol
- Standing order approved by MD
LABORATORY REPORT

- Patient Name/Identification Number
- Where the laboratory test was performed
- Test Date
- The Test performed
- Specimen Source
- The test result, units of measurement or interpretation or both
TRAINING

• INTENDED FOR THE USE BY TRAINED PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN TECHNIQUES OF IN VITRO DIAGNOSTIC PROCEDURES AND PROPER INFECTION CONTROL PROCEDURES

• HAVE EVIDENCE OF TRAINING.