CLIA is a Federal Program that requires laboratories to follow standards ensuring accurate and reliable test results. Anytime a facility performs a test and used that result to treat or diagnosis an individual and CLIA certificate is required.

To perform SARS-CoV-2 antigen testing using the Sofia or BD Veritor System a facility must have a CLIA certificate of waiver.

The only requirement for CLIA certificate of waiver is to follow manufacturer’s instructions.

Good lab practice:

* Read manufacturer package insert. When instructions are not followed it can affect the accuracy of the results.
* **Specimen collection:**
  + Both of these test systems require use of specific swabs
  + Sofia test system if transport media is used, requires specific media
  + Both test systems have specimen stability requirements, read manufacturer’s instruction.
* **Quality Control**
  + Ensures testing system is working properly.
  + Both systems have external controls (pos and neg swab) and internal (built in controls)
    - External controls should be performed w/each lot and shipment
    - Internal controls with each patient
    - If either external or internal controls do not work test is invalid
    - Control results should be documented
  + Sofia has a calibration check which is required to be performed every 30 days
* **Storage and Expiration requirements**
  + Both of these test system have test kit storage requirements and expiration dates.
  + Test kits must be stored at appropriate temperatures (temp must be documented)
  + Test kits must not be used past their expiration date
* **Performing test**
  + Must follow timing steps specifically. If require 15 min before reading result, then must wait the entire 15 min
  + Test results are not meant to be read visually. Must use the test system analyzer.
  + For both test systems negative results are meant to be presumptive. If a negative result does not fit clinical history or is questionable; then a sample should be sent for confirmation by an EUA approved molecular method.
* **Training**
  + All personnel performing testing, should have document training.
* More information and example logs
  + Most manufacturer’s package inserts can be found on-line
  + Google Ready, Set, Test
    - CDC educational tools for waived labs. Both a workbook and an on-line course
    - Email me any questions: [kristine-rotzoll@uiowa.edu](mailto:kristine-rotzoll@uiowa.edu)