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