CLIA GUIDELINES FOR QUALITY CONTROL

To monitor compliance to the federal CLIA regulations, each area of the clinic that performs patient testing using equipment and/or test kits should be inspected 3 times per year by the district laboratory manager. The following are guidelines to follow to ensure compliance in your area:

CENTER NAME		DEPARTMENT	SUPERVISOR	
#	Question			Score
1	Record temperatures of refrigerators, freezers and incubators daily. **Comments:**			
2	Record room temperature and humidity daily. **Comments:**			
3	Run urine dipstick quality control on Multistix and Chemstrips each day of use. **Comments:**			
4	Run urine pregnancy test control each time a new box is opened. Also, record whether control line appears each day of use. **Comments:**			
5	Run Strep control each time a new box is opened. Also, record whether control line appears each day of use. **Comments:**			
6	Run Hemocue glucose controls each day of use. **Comments:**			
7	Run Hemoglobin Controls once a month and with every new delivery of reagents, also perform maintenance/cleaning/self-cal and check off on QC Log. **Comments:**			
8	If gram stains are used at your facility, run gram stain control each week of use or if new reagents are opened. **Comments:**			
9	Run HIV controls with each new box opened, or if storage area exceeds room temperature during storage. **Comments:**			
10	Run lead controls once per month, with each new lot number of test kits, each new shipment of test kits, and each change of operator if it has been more than two weeks since the last time they performed QC. **Comments:**			
11	Run lipid controls. Must be performed with each new shipment or lot number of cassette and with each new location of analyzer set up in an acceptable environment. **Comments:**			
12	Run HbA1c controls every 30 days, with each new shipment of HbA1c test kits, each new lot of test kit, new operator in correct use of the HbA1c Analyzer and any time an unexpected test result is obtained. **Comments:**			
13	Run Influenza controls each time a new box is opened, once for each untrained operator, once for each new shipment of kits and each lot received in the shipment is tested. **Comments:**			

14	Run urine drug of abuse card test controls with each new lot, each new shipment of material even if it is the same lot previously received, each new operator, monthly as a check on continued storage conditions, when problems are suspected or identified. **Comments:**	
15	Run Syphilis controls with each new lot #, each new shipment (even if from the same lot previously received), monthly, as a continued check on storage conditions, with each new operator or whenever problems are identified (storage, operator or other). **Comments:**	
16	Check off maintenance sheet each day. **Comments:**	
17	Check for expired reagents and tubes weekly. **Comments:**	
18	Be sure to keep a CLIA log or send-out log on all laboratory specimens including paps. You may pull logs off the computer or keep them manually. Check that all patient results are entered and mark off any pending results as they are completed. **Comments:**	
Some Tips: **Inspection Performed By:** **Date:**		