Appendix C: Initial / Annual Laboratory Compliance Walkthrough			
Laboratory:		**Inspector:**	**Date:**
Lab Address:			
CLIA number:	**CLIA expiration date**		
Name of Director on the CLIA license:			

INHERENT RISK				
CLIA Certificate Type:	**Waived / PPM / COMP / ACC**	**If ACC:**	**TJC / CAP / COLA**	
Test Menu	**FDA Test Complexity (Waived, Moderate, PPM, High)**	**LDT / Off label use**	**Risk rating (1 low-5 high)**	
			Circle the rating: Test Menu	
			5	Test menu includes high complexity testing, including with laboratory developed testing
			4	Test menu includes high complexity testing
			3	Test menu includes moderate, PPM and waived testing only
			2	Test menu includes moderate and waived testing only
			1	Test menu includes only waived testing

INHERENT RISK OVERSIGHT			CONTROL RISK OVERSIGHT	
Laboratory Oversight - POC / Compliance OSUP			**Director Oversight: None / Minimal / Moderate / Thorough**	
Circle the rating			**Circle the rating**	
5	No direct nor indirect oversight for compliance/accreditation		25	No laboratory director involvement
4	Minimal oversight through CLIA Compliance		20	Minimal director involvement
3	Monitored through CLIA Compliance Process		15	Laboratory director understands laboratory requirements, but takes limited action
2	Directly monitored by OSUP Laboratory Management or Laboratory Compliance		10	Laboratory director understands and completes necessary requirements
1	Directly monitored by OSUP Laboratory Management or Laboratory Compliance, plus laboratory has designated individual for overseeing compliance/accreditation		5	Laboratory director actively involved with all laboratory operations.

CONTROL ASSESSMENT

Policies and Procedures		Notes	Met / Not Met	Risk rating (5 low - 25 High)	
				Circle the rating: Policies and Procedures	
Policies and Procedures	Documentation of initial & annual review of package insert/procedure by laboratory director			**25**	No policies or procedures
	A procedure is available in addition to the package insert			**20**	Policies/procedures exists but need updating, not consistent with the most current manufacturer guidelines
	Follow manufacturers' clinical guidelines / package insert			**15**	Updating of existing policies and procedures in progress
	Procedure states the manufacturer's frequency of QC.			**10**	Applicable policies / procedures established but not regularly updated or signed
	Procedure matches the manufacturer's package insert			**5**	Policies / Procedures established and regularly updated signed by medical director
	Timing in procedure matches manufacturer's package insert				
	Incubation temperatures match manufacturer's package insert				

Safety (Patient and Laboratory)		Notes	Met/ Not Met	Risk rating (5 low-25 High)	
				Circle the rating: Safety (Patient and Laboratory)	
Specimen handling and processing	Specimen labeled with two identifiers			**25**	More than one incident of patient and/or safety incident in the laboratory
	Specimen collection follows Universal precautions			**20**	At least one instance of patient and/or safety incidence in laboratory
	Specimen type follows manufacturer's guidelines			**15**	Laboratory in process of improving safety practices
	Specimen is stored per manufacturer guidelines			**10**	No present negative impact on patient outcomes, but small improvements can be made in laboratory and patient safety
Report Results	Results are interpreted per manufacturer's recommendations			**5**	Employs safety laboratory practices through process and procedures; evidence of thorough and accurate patient results
	Test results are documented in the patient's (participants') records				
	References ranges are available to staff				
	Personnel understand action to take with a critical result or unusual result				
	Traceability to reagent lot (Product recalls)				
	Laboratory tracks patient safety reports (indicate number if applicable)				
	Laboratory tracks misidentification occurrences (indicate number if applicable)				
	Effective process for entering results (Manual / Electronic) - Manually entered tests are verified				
	For manual tests the patient log includes documentation of: internal QC, reagent lot numbers, patient name and Identifiers, date, and who performed the test.				

Instrument function checks and maintenance/ EOC	There is documentation of current maintenance / function check records			
	There is documentation of corrective action on instruments / equipment			
	Maintenance logs are kept for the life of the instrument			
	There is a list of instrument error codes available			
	Testing process follows manufacturer's guidelines for frequency of maintenance			
	Safety Shield is present			
	Eye Wash Maintenance is documented			
	Documentation of Laboratory Director (or designee) review of maintenance logs			
	Timers and thermometers are calibrated			
	Temperature is recorded daily for all refrigerators, freezers and incubators			
	Laboratory refrigerators are clean; no food or beverage stored with specimens or reagents			
	Reagent / specimen refrigerator and freezers are labeled as biohazard			
	Waste containers are appropriately labeled and utilized			
	Sharps containers are appropriately utilized and secured			
	Safety occurrence tracking is effective. Number of occurrence, as applicable.			

Quality Control		Notes	Met/ Not Met	Risk rating (5 low-25 High)	
				Circle the rating: Quality control	
Quality Control	QC is performed per manufacturer's guidelines			**25**	No routine testing nor documentation of quality control
	There is documentation of internal quality control			**20**	Deviating from manufacturer guidelines; inconsistent documentation
	There is documentation of external quality control			**15**	Following manufacturer guidelines with inconsistent or missing documentation
	QC results are documented and reviewed for acceptability before patient testing			**10**	Following manufacturer guidelines with consistent documentation; no process in place for review
	QC/Kit lot numbers are recorded			**5**	Following manufacturer guidelines with consistent documentation; signed review
	If/when QC fails, there is documentation of QC corrective action				
	Personnel understands and can detail action needed if QC fails				
	QC logs are maintained for 2 years				
	Laboratory Director (or designee) signs QC logs monthly				
Testing Process		**Notes**	**Met/ Not Met**	**Risk rating (5 low-25 High)**	
				Circle the rating: Testing Process	
Kit and Reagent Handling	Reagents are stored per manufacturers' guidelines (compare package insert with temperature logs)			**25**	Performing additional or deviating from package insert (moderate or high testing)
	There are no expired reagents in use			**20**	Performing additional or deviating from package insert (waived testing)
	Kits/reagents are labeled with received, open and expiration dates			**15**	minimal deviation from packing insert that does not impact patient care
	Old lot number reagents are not combined with new lot numbers			**10**	Working on adapting procedures and process to meet all package insert guidelines
Personnel Initial Training and Competency	Medical Director is qualified Lead is qualified			**5**	Follows package insert and only performs test within limitation of CLIA certificate
	Testing Personnel have documentation of initial training				
	Training Checklist(s) are thorough and utilized				

	Testing Personnel have documentation of annual competency			
	Documentation of testing personnel knowledge of package insert or procedure			
	There is documentation of notification to testing personnel with changes			
	Personnel can answer procedural questions and demonstrate testing per manufacturer package insert			
PPM		**Notes**	**Met/ Not Met**	**Risk rating (5 low-25 High)**
Personnel Initial Training and Competency	Documentation of Proficiency Testing for all regulated analytes (Pin worm Prep)			**25** Not meeting minimum PPM laboratory regulations, at risk for patient safety failures
	Documentation of highest education available (PPM Only)			**20** Not meeting minimum PPM laboratory regulations
	Initial Training documentation for all personnel for each test			**15** Inconsistent processes / policies for meeting PPM laboratory regulations
	Annual Competency 6 levels documented			**10** Meets most and is improving processes / policies for meeting PPM laboratory regulations
Maintenance	There is documentation of routine cleaning of the microscope			**5** Meets laboratory regulations for PPM testing
	There is documentation of microscope maintenance / calibration			
Quality Control	Split sample daily peer review documented			
	There is traceability for patient specimens			

Notes:

Action Needed: