Inherent Risk Assessment

Impact				
Rating	**Financial**	**Reputational**	**Test Menu**	**Laboratory Oversight**
5	>500K	CLIA sanctions could cause long-term impact to OSU/OSUP/OSUWC Brand	Test menu includes high complexity testing, including with laboratory developed testing	No direct nor indirect oversight for compliance/accreditation
4	100K - 500K	CLIA sanctions could cause significant impact to OSU/OSUP/OSUWC Brand	Test menu includes high complexity testing	Minimal oversight through CLIA Compliance
3	10K-100K	CLIA sanctions could cause Negative publicity, capable of being managed	Test menu includes moderate, PPM and waived testing only	Monitored through CLIA Compliance Process
2	1K-10K	CLIA sanctions would cause minimal publicity, but no action would be necessary	Test menu includes moderate and waived testing only	Directly monitored by OSUP Laboratory Management or Laboratory Compliance
1	<1K	CLIA sanctions would cause no publicity	Test menu includes only waived testing	Directly monitored by OSUP Laboratory Management or Laboratory Compliance, plus laboratory has designated individual for overseeing compliance/accreditation

Controls Assessment					
Rating	**Policies / Procedures**	**Safety (Patient and Laboratory)**	**Quality Control**	**Director Oversight**	**Testing Process Observed During Walkthrough**
25	No policies or procedures	More than one incident of patient and/or safety incident in the laboratory	No routine testing nor documentation of quality control	No laboratory director involvement	Performing additional or deviating from package insert (moderate or high testing)
20	Policies/procedures exists but need updating, not consistent with the most current manufacturer guidelines	At least one instance of patient and/or safety incidence in laboratory	Deviating from manufacturer guidelines; inconsistent documentation	Minimal director involvement	Performing additional or deviating from package insert (waived testing)
15	Updating of existing policies and procedures in progress	Laboratory in process of improving safety practices	Following manufacturer guidelines with inconsistent or missing documentation	Laboratory director understands laboratory requirements, but takes limited action	minimal deviation from packing insert that does not impact patient care
10	Applicable policies / procedures established but not regularly updated or signed	No present negative impact on patient outcomes, but small improvements can be made in laboratory and patient safety	Following manufacturer guidelines with consistent documentation; no process in place for review	Laboratory director understands and completes necessary requirements.	Working on adapting procedures and process to meet all package insert guidelines
5	Policies / Procedures established and regularly updated signed by medical director	Employs safety laboratory practices through process and procedures; evidence of thorough and accurate patient results	Following manufacturer guidelines with consistent documentation; signed review	Laboratory director actively involved with all laboratory operations	Follows package insert and only performs test within limitation of CLIA certificate

Walkthrough Schedule	
Total Score	**Walkthrough Schedule**
<175	Annually
175-399	Biannually
400-499	Quarterly
>499	Monthly