TOPIC	QUICK OVERVIEW	SLIDES
What is inspection readiness?	● Important to produce high quality patient results and to save time, money and stress ● Previous citations addressed ● Current on all rule changes ● Check with mock inspections ● Compliant with regulations ○ Occupational Safety and Health Administration (OSHA) ○ Office of Civil Rights (OCR) - HIPAA ○ The Joint Commission (TJC) ○ College of American Pathologists (CAP) ○ Food and Drug Administration (FDA) ○ Centers for Disease Control and Prevention (CDC)	Why Worry About Inspection Readiness? What Does Inspection Readiness Mean? Best Assessment Process Be Compliant With Whom?
How can I manage regulatory compliance and inspection readiness on an ongoing basis?	● Knowledge of the regulatory process ● Awareness of how regulatory standards are currently interpreted ○ Accept changes over time ○ Changes might come from: ■ Technological advancements ■ Enhancements in industry ■ Evolving understanding of regulatory process ■ Changes in clinical utilization of information produced ● Use of best management practices ○ Make sure every person in	Successful Strategies

	organization understands, fulfills role in compliance ○ Consider regulatory concerns in everyday decisions, such as: ■ Staffing ■ Equipment ■ Reagents ■ Controls	
What is the first thing I should do to become inspection-ready?	● Review previous inspection results ● Re-evaluate deficiencies and corrections made ● Revisit notes from close calls ● Review results, corrective actions from internal audits ● Consider suggestions from previous inspectors ● Verify follow-up	Step One: Study Prior Survey Results
What next?	● Determine commonly-cited deficiencies for industry ○ Personnel requirements, qualifications according to highest complexity assay ■ Create crosswalk of job descriptions with personnel standards ■ Check test complexity database when implementing updated tech or changing assays ○ Personnel files available, complete ○ Competency requirements ■ Develop clear policy ■ Thoroughly document training, reassessments ○ Proficiency testing ■ Treat PT samples as patient samples	Step Two: Identify Common Deficiencies Most Commonly Cited 1-6 Identify Hot News Topics Example 1: Alternative Quality Control Example 2: Evolving Technologies Look Forward & Stay Apprised

	■ Sign attestation forms properly ○ Proper storage of reagents, specimens ■ Consistent with manufacturer instructions ■ Monitored, documented ○ Expired reagents, materials ■ Establish procedures, schedules ■ Random audits ○ Standard operating procedures ■ Must be current, comprehensive, signed by director ■ Must include site-specific info ● Double check proper documentation ● Deficiencies can be either standard or condition-level (more serious) ● Actively monitor potential industry advancements ○ Shows commitment to continual improvement ○ Provides enhanced patient experience ● Individualized Quality Control Plans, voluntary alternative quality control option ● Point-of-Care-Testing evolving with advances in technologies	
How can I minimize health and safety risks and hazards?	● Visually inspect facility ● Most hazards are chemical, biological, or physical ● With chemical hazards, you must: ○ Identify hazards ○ Determine employee exposures ○ Develop chemical hygiene	Step Four: Safety Checklists Chemical Biological Physical

	plan ○ Define standard operating procedure addressing hazards and precautions ○ Provide material safety data sheets ○ Provide employee training ● Highly important with biological hazards: ○ Create containment procedures ○ Identify potential biological effect ● Most prevalent biological hazards are simple allergens from laboratory animals ● Physical hazards are most common, including: ○ Slips, trips, falls ○ Ergonomic hazards of lifting, pushing, pulling, performing repetitive tasks ○ Electrical ○ Mechanical ○ Acoustic ○ Thermal ● To avoid injury: ○ Monitor posture ○ Keep storage neatly organized ○ Install ground-fault circuit interrupters ○ Limit use of flexible extension cords ○ Protect light fixtures ○ Perform walk-throughs ○ Measure for compliance ○ Ensure proper storage for hazardous materials, chemicals, liquids ○ Offer eye, face protection ○ Check, practice exit routes	Tips to Avoid Common Physical Injury Tips to Avoid Physical Injury from Electrical Hazards Tips to Avoid Physical Injury in Walkways Tips to Avoid Physical Injury from Hazardous Materials Summary of Tips to Avoid Physical Injury
What should I do for the actual inspection?	● Familiarize yourself and staff with requirements ● Have the following items organized and ready for inspector	Step Five: The Actual Inspection

	○ Copy of current CLIA Certificate ○ Previous survey report and corrective actions taken ○ Personnel files, including complete documentation for licenses, certifications, job descriptions, proof of education (diplomas and transcripts), training records (initial and continuing), annual performance evaluations, annual competency assessments, and confidential vaccination records ○ Properly documented standard operating procedures (SOPs) for all the processes being performed in your facility ○ Documentation of participation in proficiency testing program appropriate for your test menu and specialties ○ Instrument and equipment installation, calibration, validation study maintenance records, temperature and humidity records, service reports, and quality control performance records ○ Verify the security of LIS (Laboratory Information System) as well as the accuracy of data entered and stored ○ All quality control records, charts and logs involved in quality assessment ● Keep watch for written report from surveyor, to be received within a few days with detailed instructions	

	on how and when to respond	
What should I do after the inspection?	• Stay apprised of latest developments in technology • Use insights to strategize for future compliance • Show inspectors you've adopted a culture of quality patient care with continual improvement	Step Six: Look Ahead & Stay Engaged