

## Inspecting All Common

<p><b>Proper Use</b></p>	<ul style="list-style-type: none"> <li>• One per lab section-specific packet.</li> <li>• Contains requirements that are applicable to the entire section regardless of the number of discipline-specific checklists and is to be used in conjunction with the discipline-specific checklists</li> <li>• If more than one inspector is inspecting the same section (e.g. core laboratory), inspectors will need to share the All Common Checklist and <b>record their findings</b> on the <b>All Common Checklist ISR Deficiency</b> page for that section.</li> <li>• Never discard any pink or yellow All Common ISR pages; there must be one set for each lab section unit.</li> </ul>
<p><b>Processes/Areas for Observation</b></p>	<ul style="list-style-type: none"> <li>• PT specimen processing (walk through process with lab staff )</li> <li>• Procedure manuals available in work areas</li> <li>• Lab practice matches procedure/ follows manufacturers' instructions</li> <li>• Critical results notification process</li> <li>• Reagents             <ul style="list-style-type: none"> <li>○ Used within expiration date</li> <li>○ Labeled appropriately</li> <li>○ Stored according to manufacturer requirements</li> </ul> </li> <li>• System to detect unusual results</li> </ul>
<p><b>Key Documents to Review</b></p>	<ul style="list-style-type: none"> <li>• Proficiency Testing             <ul style="list-style-type: none"> <li>○ Complete procedure</li> <li>○ CAP-accepted PT data/corrective actions</li> <li>○ Alt PT data/corrective actions</li> <li>○ CAP Activity Menu Report</li> <li>○ Signed PT attestation statements</li> </ul> </li> <li>• Quality Management             <ul style="list-style-type: none"> <li>○ Documented QM/QC Plan</li> <li>○ Specimen collection manual</li> <li>○ Monthly evaluation of instrument maintenance</li> </ul> </li> <li>• Procedure Manual             <ul style="list-style-type: none"> <li>○ Reviewed biennially</li> <li>○ Laboratory Director approves all new and substantially revised procedures</li> <li>○ All personnel are knowledgeable</li> <li>○ Discontinued procedures</li> </ul> </li> <li>• Results Reporting             <ul style="list-style-type: none"> <li>○ Critical result notification with readback</li> </ul> </li> <li>• Reagents             <ul style="list-style-type: none"> <li>○ New lots and shipments verified</li> </ul> </li> <li>• Test Method Validation             <ul style="list-style-type: none"> <li>○ Signed summary statement by laboratory director or designee</li> <li>○ Validation data</li> <li>○ Listing of Lab Developed Tests</li> </ul> </li> <li>• Instruments and equipment             <ul style="list-style-type: none"> <li>○ Sampling of instrument/equipment policies, procedures, function checks, and performance verification records</li> <li>○ Sampling of maintenance logs and repair records</li> <li>○ (Thermometers) Records of traceability of NIST Standards</li> <li>○ Sampling of temperature logs (refrigerator, freezer, water bath, heat block, incubator ambient, etc.), including corrective actions</li> </ul> </li> </ul>