

**TECHNOLOGIST/SCIENTIST DIRECT OBSERVATION CHECKLIST**  
**UPLC-MS/MS - Immunosuppressant Drugs Assay**

Employee Name	Position	Date

Type of Assessment:  6 month     Annual     New     Other

<b>Did the employee correctly and completely:</b>	<b>Yes</b>	<b>No</b>
Identify the location of the procedure, worksheets and user manual?	<input type="checkbox"/>	<input type="checkbox"/>
Identify test requirements including acceptable specimen type and volume, internal standards, MRM transitions?	<input type="checkbox"/>	<input type="checkbox"/>
Locate and describe utility of MassLynx method files including MSTune, MSMethod, Inlet Method, TargetLynx Method?	<input type="checkbox"/>	<input type="checkbox"/>
Identify the storage location(s) of reagents, supplies, QC, and calibrators?	<input type="checkbox"/>	<input type="checkbox"/>
Clean glassware and prepare mobile phase and LC solutions?	<input type="checkbox"/>	<input type="checkbox"/>
Verify lot number, expiration date and wherever appropriate the concentrations of QC samples, reagents and calibrators?	<input type="checkbox"/>	<input type="checkbox"/>
Locate pending patient samples and utilize SMART workflow?	<input type="checkbox"/>	<input type="checkbox"/>
Perform sample preparation procedure? Follow procedure to prevent contamination?	<input type="checkbox"/>	<input type="checkbox"/>
Perform dilution procedures as needed? Calculate concentration after dilution?	<input type="checkbox"/>	<input type="checkbox"/>
Perform start-up procedure and monitor read backs?	<input type="checkbox"/>	<input type="checkbox"/>
Perform MS Tune or MS Check?	<input type="checkbox"/>	<input type="checkbox"/>
Determine LC/MS system suitability prior to running patient samples?	<input type="checkbox"/>	<input type="checkbox"/>
Check column(s) and replace as necessary following maintenance procedure?	<input type="checkbox"/>	<input type="checkbox"/>
Create and verify sample list table?	<input type="checkbox"/>	<input type="checkbox"/>
Perform data analysis?	<input type="checkbox"/>	<input type="checkbox"/>
Inspect chromatograms and verify run performance (including internal standard peak area, carryover and failed ion ratio tolerance)?	<input type="checkbox"/>	<input type="checkbox"/>

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Perform manual integration when necessary? Provide and document explanation for modification?	<input type="checkbox"/>	<input type="checkbox"/>
Evaluate and document QC data (including observed values, retention time and peak area)?	<input type="checkbox"/>	<input type="checkbox"/>
Verify levels outside the technical range?	<input type="checkbox"/>	<input type="checkbox"/>
Follow up and troubleshoot common problems as needed by repeat injection or re-extraction?	<input type="checkbox"/>	<input type="checkbox"/>
Perform post-flush and shutdown procedures? Complete maintenance log sheets?	<input type="checkbox"/>	<input type="checkbox"/>
Call clinicians with alert values and document patient results with appropriate comments as needed?	<input type="checkbox"/>	<input type="checkbox"/>
Clear pending logs and ensure that reports are released successfully?	<input type="checkbox"/>	<input type="checkbox"/>
Review completed worksheets?	<input type="checkbox"/>	<input type="checkbox"/>
Store completed samples and utilize SMART workflow?	<input type="checkbox"/>	<input type="checkbox"/>
Replenish supplies and reagents at start and end of shift?	<input type="checkbox"/>	<input type="checkbox"/>
Store documentation in designated binders?	<input type="checkbox"/>	<input type="checkbox"/>

**Dates observed:**                 

**COMMENTS/CORRECTIVE ACTION/FOLLOW-UP:**

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By signing and dating this form you certify that correct actions or responses were provided for the competency assessment tools above. In the event that errors were made, the correct action or response was reviewed with the employee followed by repeat evaluation with an acceptable response.

Employee Signature:	Date:
Assessor Signature:	Date: