TECHNOLOGIST/SCIENTIST TRAINING CHECKLIST

UPLC-MS/MS – Immunosuppressant Drugs Assay

Employee Name	Position	Date

Type of Assessment: ☐ 6 month ☐ Annual ☐ New ☐ Other

Task/Activity	Comments	Trainer/Date
• Locate procedures (hard and electronic copies) • Locate instrument user manual • Locate reagents (including QC, calibrators, tuning, LC/MS Check and stock solutions including backups) and supplies • Review procedure process • Review sample requirements • Review schedule for cutoff and turnaround times		
• Locate and identify test components in system o Mobile phase o Weak and strong needle wash, seal and fluidics wash solvents o Guard column o Column position o Nitrogen and argon gas o Ion source • Locate and identify test components in MassLynx o Project folder o Method files (MS Tune, MS Method, Inlet Method) o Sample list table o Quantification method • Describe the test sequence steps for analyzing samples		
• Generate worksheet for patient samples. • Locate pending patient samples; follow SMART workflow • Perform universal precaution when handling specimens • Verify patient sample volume • Verify calibrator and QC expiration dates • Warm up specimens, calibrators, QCs, sample blank, zinc sulfate and precipitation solution to room temperature. • Demonstrate dilution procedure on samples exceeding the upper analytical measurable range • Prepare 15 patient samples that were previously analyzed (Criterion for acceptability is <10% mean difference)		
• Pipette 40µL of 0.2M zinc sulfate to microcentrifuge tubes. • Accurately transfer 80 µL of calibrators, QC, sample to the microcentrifuge tubes. • Vortex mix for 5-10 seconds. • Add 200 µL of the precipitation solution. • Resuspend precipitate and vortex mix for approximately 45-60		

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seconds. • Centrifuge at 9015 rcf or higher for 1 minute at room temperature. • Transfer supernatant into labeled maximum recovery vials for analysis. • Load samples in the sample manager		
• Prepare and validate precipitation solution. • Prepare mobile phases, wash needle, and seal wash solvents. • Perform daily maintenance/system check and document in maintenance logsheets • Perform start-up procedure • Verify column injections and if necessary, replace columns • Perform MS Check • Perform LC/MS check • Create and verify sample list table with correct injection sequence, injection volume, concentration, sample type and method files • Perform post-run procedure (i.e. LC flush, replacement of column)		
• For data analysis, use correct quantify method in TargetLynx • Verify internal standard peak area and perform repeat injection if necessary • Verify carryover in whole blood blank • Evaluate peak retention time, shape and integration of analyte and internal standard in all chromatograms. • Review QCs and enter data in Bio-Rad Unity program • Verify and troubleshoot samples with failed ion ratio tolerance • Complete maintenance log sheets		
• Report patient data via MEH function in Sunquest • Perform dilution and calculate the new concentration • Report correctly values outside the AMR or CRR		
• Review completed worksheets • Perform column wash and shutdown procedure • Store completed patient samples; follow SMART workflow • Store printouts and completed worksheets in designated binders and follow Record and Specimen Retention policy		
• Replenish disposable supplies and reagents • Take inventory of consumables for sample prep reagents, calibrator and QCs. • Empty waste and prepare for removal.		
• Troubleshoots common problems (i.e. missed or partial injections, retention time, IS area and ion ratio failures) and document corrective actions		

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• Describe back up plan (primary and secondary)		
• Locate and describe utility of analyte-specific information table(s)		

COMMENTS/CORRECTIVE ACTION/FOLLOW-UP:

By signing and dating this form, you certify that training was provided in adequate detail in compliance with the operating procedure(s) with appropriate time for questions and that questions have been answered.

Employee Signature:	Date:
Assessor Signature:	Date: