TECHNOLOGIST/SCIENTIST COMPETENCY ASSESSMENT

UPLC-MS/MS - Immunosuppressant Drugs Assay

Employee Name	Position	Date

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

1. Direct observations of routine patient test performance	**Pass**	**Fail**	**N/A**	**Assessor intials/date**
Patient identification				
Specimen handling				
Sets up test sequence				
Verify expiration date of reagents, calibrators and QCs				
Procedural precautions during sample preparation				
Instrument operation and function checks				
2. Monitoring the recording/reporting of results	**Pass**	**Fail**	**N/A**	**Assessor intials/date**
MSDRUG incomplete worksheet				
LHR report				
MSDRUG complete worksheet				
Comparison of previously analyzed specimens, internal blind testing samples or external proficiency testing samples				
3. Review of intermediate test records, worksheets, QC, PM	**Pass**	**Fail**	**N/A**	**Assessor intials/date**
MSCheck or tune report				
System suitability check and/or column check results				
Reagent check results				
Batch worksheet				
Instrument print-out (TargetLynx report)				
Entry and tech review of QCs in Unity				
Instrument maintenance log				
Equipment maintenance log (centrifuge)				
Calculation/dilution worksheet				
Troubleshooting log				
4. Direct observations of performance of instrument maintenance (for annual assessment select at least one procedure per year)	**Pass**	**Fail**	**N/A**	**Assessor intials/date**
Xevo TQ MS maintenance				
Acquity UPLC maintenance				
Equipment Maintenance (gas system, centrifuge)				
Replacement of column				

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5. Written evaluation of problem-solving skills and basic knowledge

Question 1:
What is the purpose for calculating and monitoring ion ratios? Using the data below from a cyclosporine analysis, calculate the ion ratios for sample F2513.

Name	Sample Text	Type	RT	IS RT	Area	IS Area	1° Area	ng/mL
01-29-15run1	F2513	Analyte	0.99	0.99	289705	153787	45496	349.8

Question 2:
Data from a recent FK506 analysis is provided below.

Identify the error in this data set and describe the necessary corrective action.

FK506

	#	Name	Sample Text	Type	Std. Conc	RT	IS RT	Area	IS Area	Response	ng/mL	%Dev
1	1	09-04-12run1_01	water	Blank								
2	2	09-04-12run1_02	CAL0060512	Standard	198.400	1.04	1.04	56073.109	36013.500	1.557	178.50	-10.0
3	3	09-04-12run1_03	WB033012	Blank		1.02	1.02	17.077	34163.820	0.000		
4	4	09-04-12run1_04	QC3041812	QC	103.500	1.04	1.04	29317.531	32263.689	0.909	102.70	-0.8
5	5	09-04-12run1_05	QC1041812	QC	2.100	1.04	1.02	711.892	35106.242	0.020		
6	6	09-04-12run1_06	M55167/	Analyte		1.04	1.04	3314.393	35356.789	0.094	7.42	
7	7	09-04-12run1_07	M55384/	Analyte		1.04	1.04	39.007	44770.297	0.001		
8	8	09-04-12run1_08	M55505/	Analyte		1.06	1.04	19.748	42464.914	0.000		
9	9	09-04-12run1_09	T64028/	Analyte		1.04	1.02	5462.640	44369.965	0.123	10.85	
10	10	09-04-12run1_10	T64049/	Analyte		1.04	1.04	2616.220	42821.719	0.061	3.60	
11	11	09-04-12run1_11	CAL0060512	Analyte		1.04	1.04	88584.969	45728.555	1.937	222.95	12.4
12	12	09-04-12run1_12	T64264/	Standard	0.000	1.04	1.04	2541.832	41937.203	0.061	3.54	
13	13	09-04-12run1_13	T64310/	Analyte		1.02	1.02	3227.921	42652.332	0.076	5.31	
14	14	09-04-12run1_14	T64323/	Analyte		1.04	1.04	5583.380	43584.934	0.128	11.43	
15	15	09-04-12run1_15	T64336	Analyte		1.04	1.02	23.203	43909.496	0.001		
16	16	09-04-12run1_16	QC2041812	QC	51.700	1.04	1.04	22007.020	46389.734	0.474	51.92	0.4
17	17	09-04-12run1_17	CAL0060512	Standard	198.400	1.04	1.04	79559.250	41931.043	1.897	218.30	10.0
18	18	09-04-12run1_18	water	Blank			1.18		61.584			

Note: Medical record numbers are purposely concealed in this report.

Question 3:
A number of data quality flags are in place to prevent reporting of erroneous results. When present, technologists must take steps to investigate the failure and apply appropriate corrective actions.

Consider a scenario where for a single patient result, the ion ratio failed and the internal standard area is below the acceptable limit. Describe 3 possible steps to take and associated corrective actions to be made before reporting the result.

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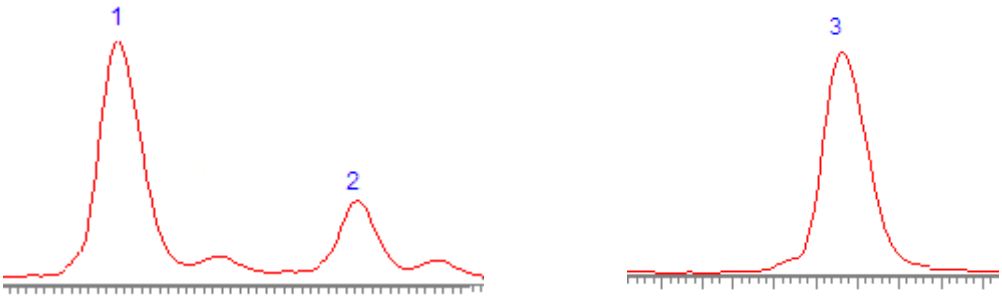
1.	2.	3.

Question 4:

Integration of chromatographic peaks (determination of height, area, and retention time) is the first and most important step in the data analysis of all chromatography-based analytical methods. To ensure accuracy in situations where manual peak integration is warranted, it is important that technologists use the appropriate technique.

Draw lines and shade the peak area to show how you would integrate peaks 1, 2 and 3 below.



Question 5:

Upon performing system function check prior to an immunosuppressant drugs analytical run, the pressure recording in the ACQUITY UPLC Console shows a pressure of 75 bars, which exceeds the acceptable limit and must be resolved. Rank the following steps based on the order you would take when troubleshooting this scenario of a high system backpressure failure.

- ☐ Confirm the flow path is correct (i.e. flow is diverted to waste).
- ☐ Remove the column.
- ☐ Check for blockage in the post-column tubing leading to the MS divert switch valve.
- ☐ Check for blockage in divert switch valve.
- ☐ Check the LC method and perform visual inspection of the column manager.
- ☐ Check for blockage in the pre-column tubing (i.e. tubing from the injector to the column switch valve).

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 competency assessment acceptable: Yes □ No □

Employee Signature:	Date:
Assessor Signature:	Date: