Name of Testing Personnel:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Completed\_\_\_\_\_\_\_\_\_\_\_\_

Name of Observer/Lead:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Instructions:***

1. *Trained Observer (Lead): Please review and score the problem solving questions on the back of this sheet. Sign/date once reviewed. Observe the Testing Personnel and check the results of the patient run.*
2. *Testing Personnel: Please fill in the associated VeraLIS batch IDs.*

**Part I:**

Direct Observation

 Observer/Lead must watch the CLS complete the tasks below and initial/date.

|  |  |  |
| --- | --- | --- |
| Task | Competent? | Initials/Date |
| 1. Testing Personnel uses appropriate PPE.
 | Yes ⃝ | No ⃝ |  |
| 1. Create Hybtarget batch in VeraLIS
 | Yes ⃝ | No ⃝ |  |
| 1. Perform NuGEN Day 1 procedure. Quantify WT product.
 | Yes ⃝ | No ⃝ |  |
| 1. Perform NuGEN Day 2 procedure. Quantify ST product.
 | Yes ⃝ | No ⃝ |  |
| 1. Run Bioanalyzer on WT and Frag/Label products
 | Yes ⃝ | No ⃝ |

Check Results

 The Observer/Lead must verify the results for the Competency Run.

 Observer/Lead should initial/date that the results have been verified.

|  |  |  |
| --- | --- | --- |
| Hybtarget batch ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Bioanalyzer batch ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Scan batch ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Competent? | Initials/Date |
| 1. Check the B and M controls are acceptable for both WT and ST steps
 | Yes ⃝ | No ⃝ |  |
| 1. Check the bioanalyzer profiles for B and M controls
 | Yes ⃝ | No ⃝ |
| 1. Check WT, ST, and AUC of a previously analyzed specimen. Ideally this would be a PT specimen, but it can also be a B or M control.

ID\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes ⃝ | No ⃝ |

Conclusion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is competent to perform the duties of Manual NuGEN Yes ⃝ No ⃝

Further Actions Required? No ⃝ Yes ⃝, if yes, explain below:

|  |  |  |
| --- | --- | --- |
| Observer/Lead Name | Signature | Date |
|  |  |  |
| Testing Personnel Name | Signature | Date |
|  |  |  |

**Part II:** Problem Solving

Grade (0-100%)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by (sign/date)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Testing Personnel: Answer the following questions. You may use any notes and/or SOPs. Passing is answering 70% correct.*

1. True or False: The plate you elute into after your post-SPIA purification is where you add fragmentation master mix.
2. True or False: Samples are eluted three times in Rnase-free water during the whole NuGEN process.
3. True or False: It is important to match the Biotin Frag/Label lot to the microarray lot.
4. True or False: It is important to match the Exon (ST) lot to the microarray lot.
5. True or False: It is important to match the WT lot to the microarray lot.
6. True or False: At the third bead purification step, the operator adds 172.8 uL of beads.
7. How much sample do you need to move forward after SPIA2 (WT Synthesis)?
8. How much sample do you need to move forward after ST Synthesis?
9. Why must you wait to add enzyme to SPIA 2 master mix until you are ready to move to Post-Amp?
10. What is the sense transcriptome? When and where is it made?
11. What is the whole transcriptome? When and where is it made?
12. Draw the B-RNA bioanalyzer profile for Frag/Label and explain why it looks like that.
13. Draw the B-RNA bioanalyzer profile for WT and explain why it looks like that.

**Please attach this sheet to QA form TRAN-001C, Rev. 1, “Competency Training Record Form.”**