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. Make the required reagents | Yes ⃝ | No ⃝ |
| 1. Perform the RNA isolation procedure, adhering to CLIA006 | Yes ⃝ | No ⃝ |
| 1. Quantify the RNA | Yes ⃝ | No ⃝ |
| 1. Check the quality of the RNA | Yes ⃝ | No ⃝ |

Check Results

The Observer/Lead must verify the results for the Competency Run. Observer/Lead should initial that the results have been verified.

|  |  |  |  |
| --- | --- | --- | --- |
| rna batch ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Bioanalyzer batch ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Competent? | | Initials/Date |
| 1. Check the concentration of TL and NTC controls are acceptable | Yes ⃝ | No ⃝ |  |
| 1. Check the batch is completed in VeraLIS | Yes ⃝ | No ⃝ |
| 1. Check bioanalyzer profiles | Yes ⃝ | No ⃝ |
| 1. Check quantity and quality of previously analyzed specimen. Ideally this would be a PT specimen, but can also be a TL or NTC   ID\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes ⃝ | No ⃝ |

Conclusion

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ is competent to perform the duties of CLS RNA Isolation 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. Explain how you would qualify a new Qiagen kit lot. Please cite the SOP.

Situation: Concentrations of 10 of your samples are too high to be read on the Tecan.

Questions:

1. How much sample and how much 1xTE do you need to make a 1:10 dilution?
2. How much sample and how much 1xTE do you need to make a 1:15 dilution?
3. How much Quant-it solution do you need to read these 10 samples? (Do not include any buffer volume or extra standards)
4. You do not have enough Quant-it to test these 10 samples. Why can’t you use the same standard curve used previously?

*True or False: Circle True or False. Correct the statement if it is false.*

1. True or False: When checking the quant, you add 1.0 µL of the QC aliquot sample to the Quant-It solution in the plate.
2. True or False: When checking the quant, you add 1.0 µL of standard to the Quant-It solution in the plate.
3. True or False: You need to check the labels of the FNA tubes correspond to the IDs in your batch.
4. True or False: You need to check the labels of the elution tubes correspond to the IDs in your batch.
5. True or False: It is okay if the IDs of the FNA tubes are not in the same order as the IDs in your batch.
6. True or False: 70% ethanol is added to the flow through of the Qiashredder column.
7. True or False: RW1 is added to the flow through of the DNA column.
8. True or False: To make the QC aliquot, you only need to add 5 µL of sample to the aliquot tube.

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