|  |  |
| --- | --- |
| **Validation Plan**  To be completed before validation begins | **Description of the Method/Technology Being Validated** |
| Click or tap here to enter text.  *\*Include manufacturer model/version numbers* |
| **Purpose of the Validation** |
| Click or tap here to enter text.  *\*Why validate this method/technology?* |
| **Performance Characteristics and Expected/Desired Results (Specification Requirements)** |
| |  |  | | --- | --- | |  | Measurement range | |  | Accuracy | |  | Measurement uncertainty of the results | |  | Limit of detection | |  | Limit of quantification | |  | Selectivity of the method | |  | Linearity | |  | Repeatability | |  | Reproducibility | |  | Robustness |   Click or tap here to enter text.  *\*What is the Lab’s accepted tolerance with this method/technology? What will Lab accept? What won’t Lab accept? Setting a threshold/expected performance before performing the validation will reduce the opportunity for the Lab to anchor acceptability to the results of the validation.* |
| **Project Plan/Milestones** |
| Click or tap here to enter text.  *\*Setting milestones and timelines will help with achieving the completion of the project in a timely manner and for it to not end up on the backburner. With incremental milestones formed, it is also less daunting of a task.* |
| **Essential Equipment/Software Required** |
| Click or tap here to enter text. |
| **Validation Assigned to the Following Individual(s):** |
| Click or tap here to enter text. |
| **Validation Summary**  To be completed throughout and after validation is completed | **Validation Procedure Used** |
| Click or tap here to enter text. |
| **Results Obtained** |
| Click or tap here to enter text.  *\*This should neatly summarize the results obtained for each of the performance characteristics.* |
| **Summary** |
| Click or tap here to enter text.  *\*Findings from the validation. What did Lab learn about the method/technology? What is going to be the final accepted method/procedure that Lab will implement based on the results and needs?* |
| **Validity of the Method** |
| |  |  | | --- | --- | |  | The results of the validation are acceptable, and the method/procedure detailed in the Summary section is fit for its intended use | |  | The results of the validation are NOT acceptable and/or the method/procedure is NOT fit for its intended use | |
| **Limitations** |
| Click or tap here to enter text.  *\*What are the limitations of the method/technology? What can’t it do or do well?* |

|  |  |
| --- | --- |
| **Approved by:** |  |
| **Title of approver:** |  |
| **Date approved:** |  |