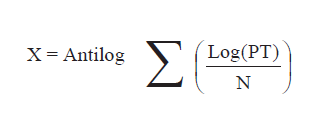
**INR Verification Plan**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being validated) | | |
| **Date:** |  | |
| **Laboratory Name:** |  | |
| **City, Country:** |  | |
|  | | |
| **Instrument/Method/Reagent:** |  | |
|  | ☐ Primary ☐ Back-up | |
| Serial Number(s): |  | |
| **INR Certified Plasma:**  (name) |  | |
| Lot Number: |  | |
| Expiration Date: |  | |
| **Reason for Verification:** | ☐ Initial Verification | ☐ Re-verification (choose one below)  ☐ Instrument move  ☐ Instrument modified  ☐ Method change  ☐ Other: ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Regulatory Status:**  (check all that apply) | ☐ FDA Approved ☐ FDA Cleared ☐ CE Marked  ☐ EUA ☐ None | |

1. **Overview:**
   1. This verification will be conducted on the above INR Verification method and INR Certified Plasma.
   2. This plan was written using “VAL 2009\_INR Verification Guidelines” as a reference, please refer to this document if more details are needed.
   3. All raw data reports will be saved in (insert location)
   4. The plan includes the following sections:

* Geometric Mean
* INR Verification with Certified Plasma
* Method Approval

1. **Geometric Mean**
2. Geometric mean is calculated from the PT results obtained from at least 20 normal patients. The sample of normal patients should include equal numbers of men and women. Women should not be on any type of hormone therapy.
3. The following equation is used for calculation:



1. Geometric mean can be calculated using a computer-based statistical program such an Excel formula option. See VAL 2010\_INR Calculators Worksheet.
2. **Verification of INR Results Using Certified Plasma**
3. Enter the average calculated INR for each sample below. (If Certified Plasma has a worksheet included in the kit, please use it.) Only if a worksheet is not provided with kit, use the INR Calculator worksheet. Complete the form for as many days that the verification plasma is run.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Result | Calculated INR | Expected INR | Expected INR Range | Acceptable  Yes/No |
| Sample 1 |  |  |  |  |
| Sample 2 |  |  |  |  |
| Sample 3 |  |  |  |  |
| Sample 4 |  |  |  |  |
| Sample 5 |  |  |  |  |

1. Acceptance Criteria - +/- 15% or as indicated in the package insert of the Certified Plasma. (Note acceptance criteria may differ depending on kit used. Use criteria for your kit.)
2. **Method Approval**
3. The final decision on INR verification and acceptance is made after a careful review of all the studies performed as part of the complete verification process. The Laboratory Director shall make the ultimate decision on INR verification. INR acceptance is based on the results from the above studies.

|  |  |
| --- | --- |
| **Prepared By:** |  |
| **Date:** |  |

References

* CLSI H54-A, Vol. 25 No. 23 Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline. 2005
* CLSI H47-ED3, One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline. 2023