**INR Verification Summary Report**

|  |  |  |
| --- | --- | --- |
| (Please fill in the table with your laboratory’s information  and details on the method being validated) | | |
| **Date (s) Verification Performed:** |  | |
| **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 | |

**Results:** All raw data reports and statistical analysis can be found in the (insert instrument name) Validation/verification binder.

1. **Geometric Mean**- refer to raw data

|  |
| --- |
| **Geometric Mean** |
|  |

1. **INR Certified Verification Results** (Note use as many rows as per your kit)

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

Acceptance Criteria- +/- 15% or per package insert of Certified Plasma

**INR Verification Approval**

Approved

Not Approved

|  |  |
| --- | --- |
| **Medical Director:** |  |
| **Date:** |  |

|  |  |
| --- | --- |
| **Prepared by:** |  |
| **Date:** |  |

**Method Approval**

Approved

Not Approved (provide recommendations/corrective actions below)

Additional comments, if needed:

|  |  |
| --- | --- |
| **Laboratory Director:** |  |
| **Date:** |  |