**INR Verification Summary Report**

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| --- |
| (Please fill in the table with your laboratory’s informationand 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

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| **Geometric Mean** |
|  |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Result | Calculated INR | Expected INR | Expected INR Range | AcceptableYes/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:** |  |