**Example of a PT or PTT Reagent Lot Parallel Testing Form**

Date of Testing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

New Reagent

Manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Lot #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ISI Value (For PT reagent only): \_\_\_\_\_\_\_\_\_\_\_\_\_

Old Reagent

Lot #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Establishment of Geometric Mean with New PT Reagent Lot**

|  |  |
| --- | --- |
| **Normal Population PT Results** | Geometric Mean: \_\_\_\_\_\_\_\_\_Date Analyzer Programmed: \_\_\_\_\_\_\_\_\_\_\_Tech: \_\_\_\_\_\_\_\_\_\_\_ |
| 1 | 6 | 11 | 16 |
| 2 | 7 | 12 | 17 |
| 3 | 8 | 13 | 18 |
| 4 | 9 | 14 | 19 |
| 5 | 10 | 15 | 20 |

**PT/INR/PTT Correlation Study**

|  |  |  |  |
| --- | --- | --- | --- |
| Old Lot  | New Lot  | Old Lot  | New Lot  |
| 1 |  | 11 |  |
| 2 |  | 12 |  |
| 3 |  | 13 |  |
| 4 |  | 14 |  |
| 5 |  | 15 |  |
| 6 |  | 16 |  |
| 7 |  | 17 |  |
| 8 |  | 18 |  |
| 9 |  | 19 |  |
| 10 |  | 20 |  |

Patient Correlation Results: R=\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Validation of Reference Range with New Reagent Lot**

**Normal Patient PT/PTT Results**

|  |  |
| --- | --- |
| 1 | 11 |
| 2 | 12 |
| 3 | 13 |
| 4 | 14 |
| 5 | 15 |
| 6 | 16 |
| 7 | 17 |
| 8 | 18 |
| 9 | 19 |
| 10 | 20 |

Reference range criteria – at lest 90% of samples should be within the current range.

Enter range to be validated: \_\_\_\_\_\_\_\_\_\_\_\_\_

Reference range validated?: Yes No (circle one)

Reference range for the New Lot #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reference range for the Old Lot #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the reference range changed? Yes No (circle one)

**Manual INR Check**

**INR = (Patient PT/mean normal range PT)ISI**

|  |  |  |
| --- | --- | --- |
| Patient ID # | Analyzer Result  | Manual Calculation Result  |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |

New lot # PT reagent acceptable for use?: Yes No (circle one)

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Supervisor’s Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_