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| **Determination of Geometric Mean and ISI Value** |
| **Purpose** |  International Normalized Ratio ( INR ) is a system established by the World Health Organization ( WHO ) and the International Committee on Thrombosis and Hemostasis for reporting results of blood coagulation tests. The INR should be the same even if different thromboplastins and instruments are used. This international standardization permits a patient on Coumadin to travel and still obtain comparable test results.With each new lot number of PT reagent ( Innovin ), there are certain tasks that must be done:1.) Establishing a new normal patient geometric mean.2.) Patient correlations between the new and old lots of Innovin.3.) Programming the ISI and normal patient geometric mean into the coagulation analyzer.4.) Documenting the manual check of the INR calculation.Modules to complete these tests are found in EP Evaluator. |
| **Definitions** | **ISI ( International Sensitivity Index ):**The available thromboplastins used for measuring Prothrombin Time ( PT ) vary in their sensitivity to factor depletion. The ISI value indicates how a particular reagent compares to an internationally standardized sample. The ISI is usually between 0.8 and 1.4. The specific value is provided in the reagent’s package insert ( Innovin ).**Normal Patient Mean:**The geometric mean PT value in healthy subjects. The geometric mean of N results is the Nth root of the product of the individual values.**INR:**INR is calculated from the PT value, normal patient mean and ISI:INR = ( PT / Normal Patient Mean )^ISI |
| **Policy Statements** | * This procedure applies to all laboratory technologists performing hematology testing, the section supervisor, and section pathologist.
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| **Procedure** | **Geometric Mean and Verification of Reference Interval ( VRI )****( Data is entered in VRI module in EP Evaluator )**• A minimum of 20 healthy subjects is required.• The normal patient mean is the geometric mean of the PT results.• The proposed PT reference interval is verified by the same procedure in the VRI module – the reference interval is verified if no more than 10% of the values fall outside the interval.• INR is computed for each PT result, based on the ISI from the product insert and the normal patient mean determined in this module. The proposed INR reference interval is verified if no more than 10% of the computed INR values fall outside the interval.**Method Comparison****( Data entered in EP Evaluator )**• INR method comparison compares PT and INR values from two methods (new reagent vs. old reagent).Data for this analysis should include 20-40 PT values, distributed across the full range of expected results ( the quality of the analysis depends more on the ranges of the results than the number of values ). Only PT values are input; INR values are computed by EP Evaluator. Two method comparison studies are performed; one for PT and a second for INR.Slope, Intercept and their confidence intervals;When two methods are statistically identical, the 95% confidence interval for slope includes 1.00, and the 95% confidence intercept includes 0.0.Example: If the 95% CI for the slope is 0.92 to 1.02 1.00 is included in the interval. However, if the CI IS 0.82 to 0.92, 1.00 is not included in the interval.**Manual INR Check****•** This is performed monthly as part of routine maintenance. An INR is obtained from the analyzer and verified manually by using the formula; INR = ( PT / Normal Patient Mean )^ISI.The ISI used in this equation has been verified with a Siemens representative with each new lot of Innovin. |
| **References** | 1. Innovin Product Insert, Siemens Healthcare Diagnostics Inc., Newark DE 19714 USA August 2016 B4212T50E3108 ( 5747 ) 22. EP Evaluator Clinical Laboratory – Children’s Hospitals and Clinics of Minnesota |
| **Materials** | **Equipment** | **Reagents** | **Supplies** |
| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Al Quigley | 09/15/17 | Initial version, post CAP inspection. |