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Verification of the Reference Range for POCT Platelet Function Testing: Evaluation of Normal Donors for the VerifyNow PRU Test

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Background: The Accriva VerifyNow PRU Test is a point-of-care assay to determine response to anti-platelet medication targeted to the platelet P2Y12 receptor, such as clopdigorel. The effect of these medications is clinically relevant to patient outcomes, optimal timing of surgical procedures, and utilization of platelet-based blood products. The Instructions for Use (IFU) published "off-drug" reference range of 194 – 418 PRU requires verification or validation prior to result reporting. This 95% confidence interval was determined on subjects with a history of cardiovascular disease prior to the planned administration of a P2Y12 inhibitor and is calculated according to the recommendations contained in the CLSI C28-A2 guideline. In clinical practice, it is often difficult to obtain blood samples from this population in order to validate or verify the reference range; alternatively, blood samples from healthy volunteers are used. The purpose of this study is to compare the range of PRU results obtained on healthy volunteer subjects to the reference range reported in the VerifyNow PRU Test package insert.

Method: Whole blood samples were obtained from normal volunteers at sites performing validation studies on the VerifyNow PRU Test (formerly P2Y12 test) from January through December 2011. Blood used for testing was collected into 3.2 percent sodium citrate using a 21 gauge needle following blood collection into a sodium citrate or no-additive discard tube. Samples were allowed to equilibrate at room temperature for 10 minutes, and all tests were completed within 4 hours. Volunteers were questioned and self-reported any use of an anti-platelet agent within 10 days prior to sample collection, and any volunteer who reported such exposure was excluded from the validation or verification activities. Each sample was collected according to individual institution policies and practices, and no donor identifiers were recorded.

Results: There were 779 individual donor results obtained from 176 VerifyNow instruments at 158 hospital sites during the time period, representing data obtained from 21 test device lots. The mean PRU result of the normal subjects was 324.5 PRU, slightly greater than the mean IFU reference range of 306.7 PRU. The 95% confidence interval of the normal donor data was 248 – 406 PRU, as compared to the 95% IFU reference range interval of 194 – 418 PRU for subjects with a history of cardiovascular disease. One value (0.1%) was below and 10 values (1.2%) were above the reference range of 194 – 418 PRU.

Conclusions: The 95% confidence interval of the normal donor is within the wider reference range contained in the IFU. That reference range was developed from a population with a history of cardiovascular disease, with increased age and potential comorbidities and concomitant medications. This study demonstrates that It is acceptable to utilize normal donors to validate or verify the reference range. It is important to note that results from a normal donor population may not span the entire reference range from the typical patient population.