

510(k) Summary

A. Device Name - 807.87(a)

1. Trade Name

VeriSure Pro West Nile Virus (WNV) RNA External Quality Controls:

- VeriSure Pro WNV RNA Positive External Quality Control
- VeriSure Pro WNV RNA Negative External Quality Control

2. Common Name

AcroMetrix WNV External Quality Controls

B. Statement of Indications of Use

The VeriSure Pro WNV RNA External Quality Controls (EQC) are intended for use with the Procleix System for the detection of West Nile Virus (WNV) in human plasma from donations of whole blood and blood components for transfusion. The VeriSure Pro WNV RNA External Quality Control is intended to provide a means of estimating precision and reproducibility of the Procleix Assay and has the potential for detecting systematic deviations of the Procleix assay for the qualitative determination of WNV.

C. Establishment Registration Number - 807.87(b)

The AcroMetrix Establishment Registration Number is 2954316.

D. Device Classification - 807.87 (c)

As an unassayed quality control material used in conjunction with nucleic acid tests that are intended for use in screening the blood supply, the VeriSure Pro WNV RNA External Quality Controls are considered a Class II medical device and requires submission of a 510(k) premarket notification.

To our knowledge no special controls or performance standards have been established for a product of this type.

E. Substantial Equivalence Statement and Data - 807.87(f)

1. Predicate Device

The VeriSure Pro WNV RNA External Quality Controls are substantially equivalent to the VeriSure Pro HIV-1 RNA, HCV RNA and Negative External Quality Controls (BK 040060).

2. Description of Device Function

The VeriSure Pro WNV RNA External Quality Controls are unassayed controls prepared using processed human plasma and are intended for use with the Procleix System for the detection of WNV. The VeriSure Pro WNV RNA External Quality Controls are designed to monitor assay performance. Frequent testing of independent quality control samples provides the analyst with a means of monitoring the performance of laboratory assays. Routine use of controls enables laboratories to monitor day-to-day test variation, lot-to-lot performance of test kits and operator variation, and can assist in identifying increases in random or systematic error.

3. Description of Device Components

The VeriSure Pro WNV RNA External Quality Controls are supplied in 1.4 mL tubes. Recommended storage conditions are -20°C to -80°

4. Comparison to Predicate Device

Nine (9) lots of each VeriSure Pro WNV RNA External Quality Control were tested in the Procleix assay during product release and real-time stability testing. A total of 539 VeriSure Pro WNV RNA Positive EQCs and 546 VeriSure Pro WNV RNA Negative EQCs were tested.

The mean, standard deviation (SD) and percent coefficient of variation (%CV) for Relative Luminescence Units (RLU) and Signal to Cutoff Ratios (S/CO), as well as the ± 3 SD ranges for these values, were calculated for each lot of each VeriSure Pro WNV RNA External Quality Control. These statistics were compared to the same statistics (based on 3 lots of each EQC) presented in the 510(k) submission for the predicate device (BK 040060) and are summarized in Tables 1 and 2. The calculations of these statistics for the product release testing are presented in Appendices A - E.

Table 1: Summary Statistics for the VeriSure Pro WNV RNA Positive External Quality Controls					
Variable	Product	Mean	SD	%CV	Result Range (± 3 SD)
RLU	VeriSure Pro HIV-1 RNA Positive	668,797	156,781	23.4%	198,454 to 1,139,140
	VeriSure Pro HCV RNA Positive	389,986	28,490	7.3%	304,516 to 475,456
	VeriSure Pro WNV RNA Positive	1,282,235	162,706	12.7%	794,117 to 1,770,353
S/CO	VeriSure Pro HIV-1 RNA Positive	18.99	3.34	17.6%	8.97 to 29.01
	VeriSure Pro HCV RNA Positive	10.56	0.91	8.6%	7.83 to 13.29
	VeriSure Pro WNV RNA Positive	30.55	3.39	11.1%	20.39 to 40.72

Table 2: Summary Statistics for the VeriSure Pro WNV RNA Negative External Quality Controls					
Variable	Product	Mean	SD	%CV	Result Range (± 3 SD)
RLU	VeriSure Pro HIV-1/HCV Negative	6,087	1,476	24.2%	1,659 to 10,515
	VeriSure Pro WNV Negative	1,400	1,746	125%	0 to 6,638
S/CO	VeriSure Pro HIV-1/HCV Negative	0.16	0.04	25.0%	0.04 to 0.28
	VeriSure Pro WNV Negative	0.03	0.05	157%	0 to 0.17

The VeriSure Pro WNV RNA External Quality Controls performed in a manner that was substantially equivalent to the performance of the predicate device.

5. Lot-to-Lot Comparison

Table 3 shows the means and SDs for the RLUs and S/CO values for nine (9) lots of each VeriSure Pro WNV RNA External Quality Control. The data were collected during product release and real-time stability testing. All tested controls gave the correct qualitative result, i.e., all of the WNV RNA Positive EQCs gave positive results, and all of the WNV RNA Negative EQCs gave negative results in the Procleix WNV Assay. The S/CO data are graphed using standard box-and-whisker plots in Figures 1 and 2. The boxes range from the first to the third quartiles. The

inter-quartile range (IQR) is the distance between the first and third quartiles, i.e., the height of the box. The whiskers are drawn to the furthest data point that is within 1.5 times the IQR from the box. Values further from the box than 1.5*IQR are plotted individually.

Table 3: Lot-to-Lot Summary of VeriSure Pro WNV RNA External Quality Controls							
External Quality Control	Lot Number	N	Reactivity Rate (Percent Positive)	RLU Mean	RLU SD	S/CO Mean	S/CO SD
WNV RNA Positive	310602	140	100	1,319,183	107,636	29.85	1.864
	318802	130	100	1,249,446	172,190	30.35	4.016
	325202	149	100	1,354,122	188,652	32.45	3.615
	402302	20	100	1,234,092	20,488	31.47	0.522
	406502	20	100	1,230,494	70,068	26.72	1.522
	426002	20	100	1,141,157	167,992	28.95	4.261
	507303	20	100	1,088,039	90,028	28.69	2.374
	518202	20	100	1,216,393	54,350	29.65	1.325
	524502	20	100	1,202,165	81,011	29.95	2.018
WNV RNA Negative	310601	140	0	1,486	2,268	0.03	0.070
	318801	139	0	1,081	1,141	0.02	0.025
	325201	149	0	1,107	1,080	0.02	0.024
	402301	20	0	1,001	646	0.02	0.018
	406501	20	0	3,433	2,346	0.07	0.052
	426001	20	0	847	903	0.02	0.022
	505902	20	0	2,226	3,162	0.05	0.081
	518201	20	0	1,074	622	0.02	0.016
	524501	18	0	3,861	1,186	0.09	0.030

Figure 1: Comparison of Distribution of S/CO for Nine Lots of Positive WNV EQCs

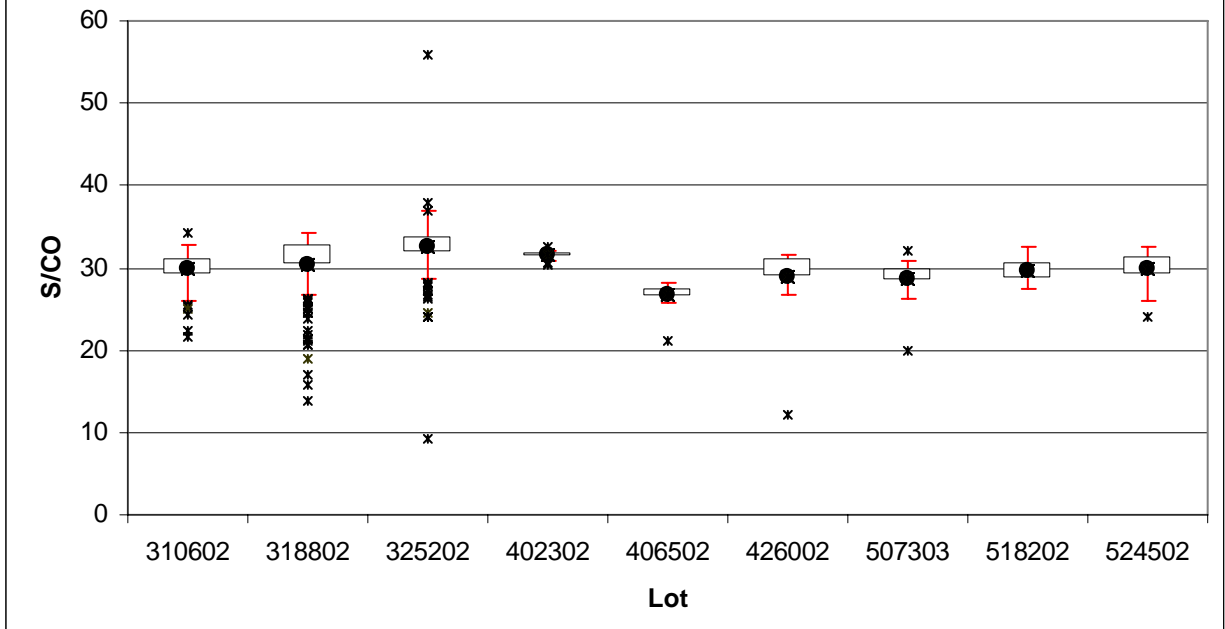
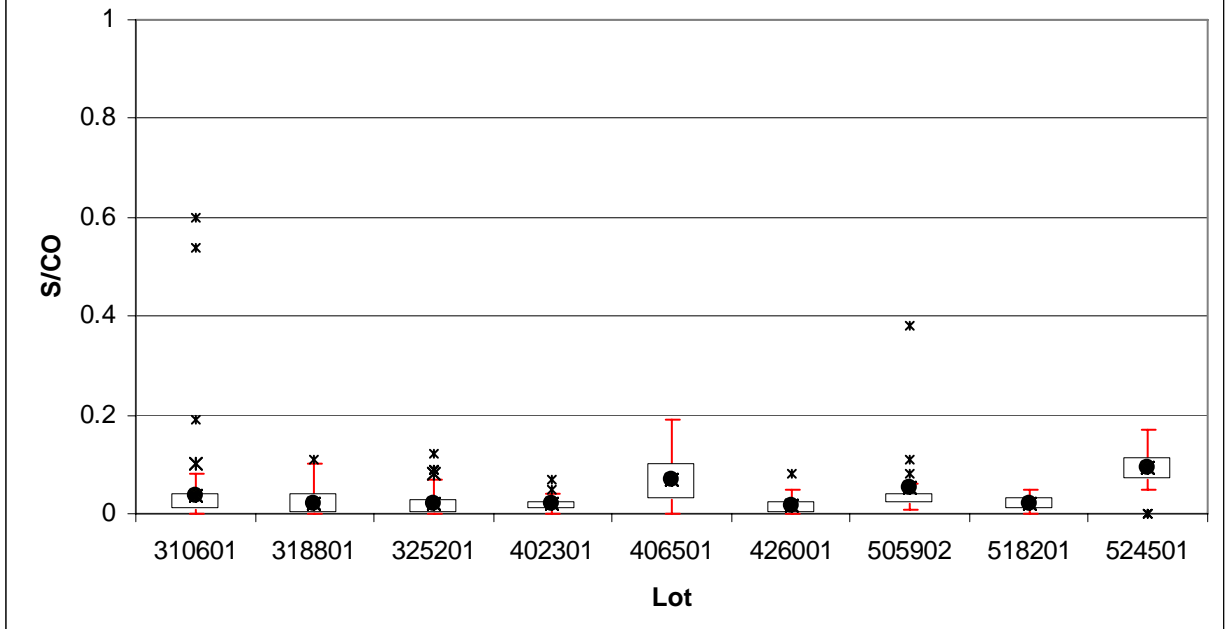


Figure 2: Comparison of Distribution of S/CO for Nine Lots of Negative WNV EQCs



The performance characteristics of the three lots of each VeriSure Pro WNV RNA External Quality Control are consistent with each other indicating lot-to-lot uniformity.

6. Clinical Data

In order to evaluate the performance of the VeriSure Pro WNV RNA External Quality Controls (EQCs) in the routine blood testing laboratory environment, one (1) lot of each VeriSure Pro WNV RNA EQC was provided to Gen-Probe, the developer of the Procleix Blood Testing System, for use in the clinical evaluation of the Procleix WNV assay at one of their clinical trial sites.

The performance of the VeriSure Pro WNV RNA Positive and Negative EQCs in the Procleix WNV assay is summarized in Table 4.

Table 4. Clinical Performance of VeriSure Pro WNV RNA EQCs in Procleix WNV Assay				
External Quality Control		WNV Positive	Negative	
N		184	184	
Reactivity	Number	184	0	
	Percent	100	0	
RLU	Mean	1,266,729		
	SD	68,436		
	%CV	5.4		
S/CO	Mean	30.49		
	SD	2.14		
	%CV	7.0		
S/CO Range	Minimum	25.44		0.000
	Maximum	38.53		0.512

The performance of the VeriSure Pro WNV RNA EQC in this clinical evaluation was comparable to the performance observed in pre-clinical testing at AcroMetrix. In addition, the test results are similar to those observed for the predicate device.

Due to the limitations of Gen-Probe’s IND study design, additional lots of the VeriSure Pro WNV RNA EQCs could not be tested at the clinical trial sites. It was for this reason that multiple lots (a total of 9 lots of each control) were evaluated in pre-clinical studies at AcroMetrix (see Sections IX.F and IX.G above).