XII. 510(k) Summary

A. Device Name - 807.87(a)

1. Trade Name

   VeriSure Pro HBV DNA External Quality Control

2. Common Name

   AcroMetrix HBV External Quality Control

B. Statement of Indications of Use

The VeriSure Pro HBV DNA External Quality Control (EQC) is intended for use with the Procleix Assay and no other HBV assay for the detection of hepatitis B virus (HBV) DNA in human plasma from donations of whole blood and blood components for transfusion. The VeriSure Pro HBV DNA 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 HBV DNA.

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 HBV DNA External Quality Controls is considered 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

1. Predicate Device

   The VeriSure Pro HBV DNA External Quality Control is substantially equivalent to the VeriSure Pro HIV-1 RNA and HCV RNA External Quality Controls (BK 040060).

2. Description of Device Function

   The VeriSure Pro HBV DNA External Quality Control is an unassayed control prepared using processed human plasma and is intended for use with the Procleix Assay for the detection of HBV DNA. The VeriSure Pro HBV DNA External Quality Control is 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 HBV DNA External Quality Control is supplied in 1.4 mL tubes. Recommended storage conditions are -20°C to -80°C.

F. Clinical Data

Each VeriSure Pro HBV DNA EQC lot was evaluated in the Procleix Ultrio HIV-1/HCV/HBV Screening Test and in the Procleix Ultrio HBV Discriminatory (dHBV) Assay.

The performance of the VeriSure Pro HBV DNA EQC in the Procleix Ultrio HIV-1/HCV/HBV Screening Assay, and in the HBV Discriminatory Assay, is summarized in Table 10.

Table 10. Performance of VeriSure Pro HBV DNA EQC in Procleix Ultrio Assay

Assay		HIV-1/HCV/HBV	dHBV
N		585	96
Reactivity	Number	585	96
	Percent	100	100
RLU	Mean	1,163,323	1,123,411
	SD	104,605	82,797
	%CV	9.0	7.4
S/CO	Mean	14.83	25.00
	SD	1.08	1.15
	%CV	7.3	4.6
S/CO Range	Minimum	6.09	20.87
	Maximum	25.63	28.52

The performance of the VeriSure Pro HBV DNA 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.