Product(s): **Reveal G4 Rapid HIV-1 Antibody Test**

Subject: **Validation Requirements in Transitioning from Reveal G3 to Reveal G4 LAB S/P**

Dear Customers & Partners,

MedMira's Reveal® G4 Rapid HIV-1 Antibody Test (Reveal G4) has recently been approved by the United States Food and Drug Administration (FDA) and will replace the Reveal G3 Rapid HIV-1 Antibody Test (Reveal G3).

The Reveal G4 Rapid HIV-1 Antibody Test (Reveal G4) is an advanced version of the Reveal G3 Rapid HIV-1 Antibody Test (Reveal G3). The updated test design incorporates a new buffer and redesigned casings for the test cartridge and InstantGold cap. The new G4 Universal Buffer is very similar to the G3 Universal Buffer, differing slightly in formulation by the addition of surfactants to lyse red blood cells when using whole blood, and by the replacement of the preservative agent. The redesigned cartridge and cap casings serve to improve the product usability and user interface. The biological principles of Reveal G4 are identical to Reveal G3. The Reveal G4 test procedure for serum or plasma specimens and the interpretation of test results also remain unchanged from Reveal G3.

To demonstrate the performance equivalency of Reveal G3 with the new Reveal G4, and thereby to validate that the improved features of Reveal G4 do not affect the performance characteristics with serum or plasma specimens, an equivalency study was performed. A summary of the study is provided below.

Equivalency Study

The study involved testing repository serum and plasma samples on both Reveal G3 and Reveal G4; the reactivity of all samples used in the study had been verified using FDA approved screening tests, as well as FDA approved confirmatory assays for reactive samples. Overall, 660 serum samples (330 HIV-1 positive and 330 HIV-1 negative) and 220 plasma samples (110 HIV-1 positive and 110 HIV-1 negative) were tested on three lots of Reveal G4 and one comparative lot of Reveal G3 in a blinded manner, such that the users could not anticipate the sample reactivity.

Three operators performed panel testing using the assigned lots of Reveal G3 and Reveal G4 and the assigned serum/plasma panel sets. Serum and plasma panel members were tested as per the serum/plasma test procedure in the package insert. A set of test controls (one HIV negative and one HIV positive) was tested by each operator on each testing day prior to Panel testing. Test results were interpreted according to the product literature. The testing records were then forwarded to an independent study manager for decoding and compilation of data.

The data demonstrated that the Reveal G3 and Reveal G4 performance was equivalent for all serum and plasma specimens, with both tests providing 100% specificity for all HIV-1 non-reactive specimens tested and 100% sensitivity for all HIV-1 reactive specimens tested, as summarized in Table 1 below.

Table 1: Comparative performance characteristics of Reveal G3 and Reveal G4 with serum and plasma

Specimen Type	Reference Results	Performance Characteristics				Equivalency
		Reveal G3		Reveal G4		
		Reactive	Non-Reactive	Reactive	Non-Reactive	
Plasma	HIV-1 Reactive	110	0	110	0	100%
	HIV-1/2 Non-Reactive	0	110	0	110	
Serum	HIV-1 Reactive	330	0	330	0	100%
	HIV-1/2 Non-Reactive	0	330	0	330	

Based on the results of the equivalency study, it is the opinion of MedMira that further correlation studies are not required by customers currently using the Reveal G3 product who now wish to cross over to Reveal G4 for testing of serum or plasma. However, as regulations can vary from state to state, county to county, or from facility to facility, users should consult regulatory bodies to ensure continued compliance.

Should you have any questions regarding this Customer Advisory Notice or Reveal G4 please contact our Customer Support Team at G4@medmira.com or +1 877 633 6472.