Customer Advisory Notice

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

Subject: IQCP Risk Assessment and Quality Control Plan

Dear Customer,

MedMira has compiled this information to aid in the preparation of your laboratory's IQCP Risk Assessment and Quality Control Plan for Reveal G4 Rapid HIV-1 Antibody Test (Reveal G4). This information is not intended to replace the Package Insert provided with the test. Information has been abstracted from the Reveal G4 Package Insert (IRIPYZIS0001EN, Rev 1/1) and the Reveal G4 HIV-1 Antibody Test Controls Package Insert (IRICPIS0001EN, Rev 0/1).

Failure	Cause	Failure Type	Reveal G4 Risk Mitigation Features	Reveal G4 Package Insert Section	Potential Effect(s) of Failure	Laboratory Risk Mitigation	Severity	Frequency	Laboratory Documentation
Inappropriate sample	Substances interfering with sample flow into the Test Cartridge	Specimen	None	Limitations of the Test					
	Substances interfering with product formulation/biologics	Specimen	None	Performance Characteristics > Interfering Substances and Unrelated Medical Conditions					
	Non-validated sample type collected	Operator	None	Specimen Handling/ Collection and Use					
	Non-validated anticoagulant used during sample collection	Operator	None	Specimen Handling/ Collection and Use					

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Incorrect sampling procedure	Sample contaminated with other body fluids/materials during collection	Specimen	None	Precautions					
	Incorrect or non-validated sample type tested	User	None	Specimen Handling/Collection and Use					
	Unapproved patient category collected	User	None	Specimen Handling/ Collection and Use					
	Inadequate sample volume collected	User	None	Specimen Handling/ Collection and Use					
	Incorrect technique for sample collection	User	None	Specimen Handling/ Collection and Use					
Incorrect sample handling	Sample contaminated after collection	User	None	Specimen Storage section of PI					
	Sample stored at incorrect temperature	Environment	None	Specimen Handling/ Collection and Use					
	Sample stored for too long prior to testing	Environment	None	Specimen Handling/ Collection and Use					
	Whole blood specimen frozen	User	None	Specimen Handling/ Collection and Use					
	Frozen serum/plasma specimens mishandled during thawing	User	None	Specimen Handling/ Collection and Use					
	Serum/plasma samples frozen and thawed more than twice	User	None	Specimen Handling/ Collection and Use					
	Samples tested before equilibrating to room temperature	User	None	Specimen Handling/ Collection and Use					

Failure	Cause	Failure Type	Reveal G4 Risk Mitigation Features	Reveal G4 Package Insert Section	Potential Effect(s) of Failure	Laboratory Risk Mitigation	Severity	Frequency	Laboratory Documentation
Operator failure	Package insert instructions not followed	User	None	Package Insert					
	Incorrect sample volume added to the Test Cartridge (Plasma) or Universal Buffer vial 1 (fingerstick Whole Blood) or Sample Tube (venipuncture Whole Blood)	User	None	Specimen Handling/ Collection and Use, Test Procedure					
	Patient sample used as external control material	User	None	Test Procedure					
	External control material substituted as patient sample	User	None	Test Procedure					
Reagent handling	Product damaged during shipment	Environment	None	Precautions > Handling Precautions					
	Storage temperature outside specified range (2-30°C)	Environment	None	Precautions > Handling Precautions					
	Used Mylar pouch from which Silica packet was missing	User	None	Precautions > Handling Precautions					
	Used Mylar pouch which was punctured or opened in advance of use	User	None	Precautions > Handling Precautions					
	Used Mylar pouch which has been used was damaged	User	None	Precautions > Handling Precautions					
	Reused Test Components (excluding Universal Buffer)	User	None	Precautions > Handling Precautions					
	Used Test Cartridge with contaminated or damaged immunoreactive membrane in Test Cartridge	User	None	Precautions > Handling Precautions					
	Used Expired reagents	User	Expiration printed on reagents and packaging	Precautions > Handling Precautions					

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	Used reagents from different lots	User	Lot number printed on reagents and packaging	Precautions > Handling Precautions					
Reagent Test Procedure	General Reagent Failure	Reagent	Built-in Procedural and Reagent Control is designed to detect general reagent failures.	Quality Control					
	Sample not added to Test Cartridge	User	Built-in Procedural and Reagent Control is designed to detect procedural errors.	Test Procedure, Quality Control					
	Reagent deterioration	Reagent	None	Storage Instructions					
	Test Procedure not followed correctly	User	None	Test Procedure					
	Product used before equilibrating to room temperature	User	None	Test Procedure					
	Reagent contamination	User	Universal Buffer formulation includes preservative agent	Storage Instructions					
	Inappropriate/inadequate volume of Universal Buffer added to InstantGold cap	User	None	Test Procedure					

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Test result Interpretation	Inadequate lighting used to read test results	User	None	Handling Precautions					
	Test Results not read immediately after completion of Test Procedure	User	None	Test Procedure, Test Result Interpretation					
	Misinterpretation of test results	User	None	Test Results and Interpretation of Results					
External Control failure	Shipping temperature outside control's specified range (2-30°C)	Environment	None	Handling and Storage Instructions (Test Control Package Insert)					
	Storage temperature outside specified range (2-30°C)	Environment	None	Handling and Storage Instructions (Test Control Package Insert)					
	External control materials tested before equilibrating to room temperature	User	None	Directions for Use > General Test Preparation (Test Control Package Insert)					
	Reactive and Non-Reactive Test Control misused	User	None	Directions for Use (Test Control Package Insert)					
	External control materials expired	User	Expiration printed on reagents and packaging	Directions for Use > General Test Preparation (Test Control Package Insert)					

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.