Reveal® G4 Rapid HIV-1/2 Antibody Test Customer Letter

Dear Customer:

Thank you for choosing the Reveal® G4 Rapid HIV-1/2 Antibody Test (Reveal® G4). By purchasing this test as an agent of a clinical laboratory, you are agreeing that you and any of your consignees will abide by the following **RESTRICTIONS** regarding the use, sale, and distribution of the device. You are also agreeing that you have read and understand the following **WARNINGS**.

RESTRICTIONS:

- **Sale of Reveal® G4 is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met[1-3] and where there is assurance that operators will receive and use the instructional materials.**
- **Reveal® G4 is approved for use only by an agent of a clinical laboratory.**
- **Test subjects must receive the *Subject Information Brochure* prior to specimen collection, and appropriate information when test results are provided.**
- **Reveal® G4 is not approved for use to screen donors of blood, plasma, cells or tissues.**

WARNINGS:

IVD **For *In Vitro* Diagnostic Use**

- **Read the package insert completely and carefully prior to use of Reveal® G4. If the directions are not followed exactly, inaccurate test results may occur.**
- **The United States Food and Drug Administration has approved this test for use with whole blood (venipuncture and fingerstick), serum, and plasma specimens only. Use of this test with specimens other than those specifically approved for use with Reveal® G4 may result in inaccurate test results.**
- **Perform Reveal® G4 at room temperature (15-27°C, 60-80°F).**
- **Perform Reveal® G4 on a flat work surface to ensure that reagents and specimens uniformly flow through the test device.**

This is not an exhaustive list. Further instructions are provided in the package insert that accompanies Reveal® G4. The package insert also contains the intended use of the test, a summary and explanation of the test and how it works, precautions and storage instructions, instructions on how to use the test and interpret the results, and limitations of the device.

The *Subject Information Brochure* contains general information on HIV and AIDS, the need for HIV testing, and its importance, and the meaning of a Reactive and Non-Reactive test result with Reveal® G4. You should review both the package insert and *Subject Information Brochure* prior to using the test.

If you have any questions, please contact our Customer Service Department at (902) 450 1588, or toll free at 1-877-MEDMIRA (telephone), (902) 450 1580 (fax) or support@medmira.com (email).

Sincerely,

Hermes Chan
Chief Executive Officer
MedMira Laboratories Inc.

1. CLSI Document QMS02-A6, Quality Management System: Development and Management of Laboratory Documents, 6th Edition
2. CLSI Document GP27-A2, Using Proficiency Testing to Improve the Clinical Laboratory, 2nd Edition
3. CLSI Document POCT 04-A2, Point-of-Care *In Vitro* Diagnostic (IVD) Testing, 2nd Edition

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