



## ACKNOWLEDGMENT

Innovative Genomics LLC ("Innovative Gx") agrees to place a specimen collector in a physician's office to collect, package, process, and handle the submission of patient specimens only for testing performed at Innovative GX Laboratories. This Acknowledgment is intended to provide (i) a brief background of the applicable federal laws when a laboratory places a specimen collector in a physician's office and (ii) a non-exclusive list of tasks a specimen collector may not perform for a physician's office.

**Background.** Federal regulations, including the Anti-kickback statute (42 U.S.C. §1320a-7b), the Stark Law (42 U.S.C. §1395nn), and Clinical Laboratory Improvement Amendments (42 U.S.C. §263a), have been interpreted to allow clinical laboratories to place specimen collectors in physicians' offices under certain, limited circumstances. In compliance with these federal regulations and absent any State law prohibitions, a laboratory may make available to a physician's office a specimen collector who collects specimens from patients for testing by an outside laboratory; however, the **collector may not perform any additional tasks that are normally the responsibility of the physician's staff**. Where the collector performs clerical or clinical functions not directly related to the collection or processing of laboratory specimens for the lab, a strong inference arises that he/she is providing a benefit in return for the physician's referrals to the laboratory.

**Non-Exclusive List of Prohibited Tasks.** Tasks which a collector of Innovative Gx may NOT perform for the physician or physician's office staff include, but are not limited, to the following –

1. Take vital signs or other nursing functions;
2. Specimen collection services for testing performed by physician's office lab;
3. Conduct, or assist with, the testing for physician's office laboratory;
4. Registration of patient's demographics into physician's computer system;
5. Preparation of paper requisitions for laboratory test ordering;
6. Filling out and completing the test-specific forms for the ordering of test(s);
7. Collate, file, or enter results into physician's record system;
8. Answering the office phone for results or other matters; and
9. Call patients for appointments.

**Compliance is the cornerstone of Innovative GX.** We are committed to providing innovative molecular genomics tests and other services in a professional and ethical manner that complies with federal and state laws in order to enhance to patient care. We appreciate your cooperation and assistance and ask that your staff be made aware that our collector may not perform tasks for them so that both you, your office staff, and Innovative GX are compliant with applicable laws and regulations.

By signing this Acknowledgment, you acknowledge and understand a collector may not perform any additional tasks that are normally the responsibility of the physician's staff and in the event adherence to this Acknowledgment cannot be maintained, we will unfortunately need to discontinue providing this voluntary collection service in your office. Should you have any questions or need to report concerns, please contact Innovative Gx directly at [jg@innovativegx.com](mailto:jg@innovativegx.com) or at 210-352-5175, ext. 8.

By: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_