

Informed Consent Compliance for Germline Genetic Testing

Name of Practice _____

Practice Address _____

Date ___ / ___ / _____ Account Number _____

Lab _____

I, _____ (physician name), acknowledge that:

- Prior to ordering genetic testing on the patient listed below, I have obtained a signed, written consent form from the patient (or their authorized representative) as required by applicable state law and/or regulations; and
- I will maintain all written consent forms as part of the patient file and make them available to Athena Diagnostics upon reasonable request.

Patient Name _____

DOB ___ / ___ / _____ Gender M/F Collection Date ___ / ___ / _____

Tests Ordered _____

Signature of medical practitioner _____

NPI _____

Background

Some state laws require that individuals (or their authorized representative) provide written informed consent to the physician ordering germline genetic testing and/or releasing test results.

The individual (or authorized person) must sign and date a consent form that includes:

- Statement of test purpose and description
- Statement that prior to testing, the physician ordering the test discussed with the individual the reliability of positive/negative test results and the level of certainty that a positive result for the disease or condition serves as a predictor of such disease
- Statement that the physician informed the individual about availability and importance of further testing, physician consultation and genetic counseling, and provided written information identifying a genetic counselor or medical geneticist
- General description of each disease or condition for which a test is ordered
- The name of the person or persons to whom the test results may be disclosed

This signed consent form should accompany test order and patient specimen UNLESS TEST ORDER CONSENT HAS BEEN SIGNED.

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