

## 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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