ALLIANCE LABORATORIES

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Factor II (Prothrombin) Informed Consent

1. **What is Factor II (Prothrombin) Genotyping?** The Factor II (prothrombin) G20210A mutation is the second most common genetic abnormality of the coagulation system, after Factor V (Leiden), occurring in approximately 1-2% of random Caucasians and 5-7% of Caucasian venous thrombosis patients. Factor II (prothrombin) genotyping detects a mutation associated with familial or recurring venous thrombosis. It is recommended for patients for whom a hypercoagulable disorder is suspected, including: family history for venous thrombosis, individual history of recurrent thrombosis, thrombosis during pregnancy or oral contraceptive use, thrombosis appearing at an atypical site in an otherwise healthy adult and thrombosis at age less than 45 years or pediatric stroke.

2. **What is the purpose of this test and what are its limitations?** Everyone has two copies of the Factor II gene. An individual may have two normal copies, two abnormal copies, or one normal and one abnormal. This test detects the presence of a specific genetic change (mutation) which has been shown to predispose people to develop deep vein thrombosis. Two abnormal copies have been found in 5-7% of all Caucasians with venous thrombosis. If this mutation is not found by the testing procedure, it does not mean that the risk of carrying or developing deep vein thrombosis is not present. It simply means that this specific mutation has not been found, although other mutations may be present. It is also possible that such a patient may have secondary deep vein thrombosis due to non-genetic causes that would not be detected by this test. A person with one copy of the mutation has an approximate 3-fold increase in risk for venous thrombosis. The increase in risk for a person with two copies of the mutation is not known.

3. **What is required to perform this test?** You will be asked to provide 5 mL of blood, which is equal to about one tablespoon. DNA will be extracted from this blood sample and tested. The only discomfort that you may feel is the stick of the needle in your arm. You may also experience a small bruise at the site of the needle puncture. You will also be asked to provide information regarding your medical history, which is necessary for proper interpretation of your test result. In the unlikely event that you should be injured in the course of being tested, your physician will provide any necessary medical care. However, you would be expected to bear the cost of such medical care. Compensation will not be provided in the event of any injury.

4. **Is there a cost for this test?** This is a routine clinical laboratory test and the results may aid in your diagnosis; thus, you or your health insurer will be billed for this procedure.

5. **What will happen to the DNA once the test is complete?** If you consent by initialing below, your sample might be used for laboratory quality control purposes after identifiers are removed and will be stored for longer than 60 days. If you do not initial the box below, the sample will be destroyed within 60 days of collection and not used for any other purposes.

☐ I consent to my DNA sample being used for laboratory quality control activities and storage of my DNA past 60 days. *Please initial.*

6. **How will I obtain results from this test?** DNA testing and interpretation of results are complex. The information from this test will be provided in the form of a written report to your physician who will inform you of the results. The laboratory will not provide results directly to patients. Your physician may suggest genetic counseling prior to performing this test or if your results are abnormal. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without your written authorization.

Patient Attestation of Informed Consent:
My signature below indicates that I have received information about this test, **Factor II,** and that I have read and understood the material in this document. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues. I agree to undergo this testing.

_____ _____
Patient Signature Date

_____ _____
Signature of Parent/Guardian if Patient is a minor Print Name of Parent/Guardian

For the Physician:
As the referring physician, I understand the benefits and limitations of this study and have requested that the above-named patient be tested. I attest to the fact that I have provided the patient with the information contained above and fully answered any questions. I believe that the patient understands the information and is voluntarily signing this informed consent.

_____ _____
Signature of Physician/Health Care Professional Print Name of Physician/Health Care Professional