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Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition

This document provides guidance on performing the fibrinogen assay in the clinical laboratory. Topics addressed include reporting of results and *in vivo* and *in vitro* conditions that may alter results.

A guideline for global application developed through the NCCLS consensus process.

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Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition

Abstract

Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition (NCCLS document H30-A2) is a performance guideline for laboratory and/or clinical healthcare professionals responsible for the routine performance of fibrinogen assays. This guideline describes a technique, based on the method described by Clauss,[1] that is practical, precise, and widely used in the clinical laboratory. Preanalytical and analytical factors and conditions that may alter results are discussed.

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Foreword

One of the major physiological roles of the coagulation system is to stop the loss of blood by generating a fibrin meshwork at the site of trauma or injury by converting the plasma glycoprotein fibrinogen to the fibrin polymer mesh. Numerous pathological conditions can induce decreased levels of fibrinogen rendering the coagulation system unable to generate sufficient fibrin to halt the blood loss. Increased levels of fibrinogen have been associated with cardiovascular disease and thrombosis. Decreased or increased levels of fibrinogen are clinically relevant and must be accurately determined. Laboratories should establish a normal reference interval for fibrinogen measurements. Generally, the normal reference interval is 150 to 350 mg/dL (1.5 to 3.5 g/L).

Fibrinogen, a β-globulin, is deficient in congenital afibrinogenemia and hypofibrinogenemia; in some cases of dysfibrinogenemia; and in a variety of acquired states, such as disseminated intravascular coagulation, systemic hyperfibrinolysis, severe hepatic dysfunction, and after treatment with L-asparaginase or sodium valproate. Spontaneous bleeding is usually not seen in patients with selected hypofibrinogenemia, i.e., fibrinogen levels of 50 to 100 mg/dL (0.5 to 1.0 g/L); however with certain types of hemostatic stress (surgery, trauma) bleeding may occur at levels up to 100 mg/dL (1.0g/L).

Fibrinogen is an acute phase reactant (i.e., a variety of physiologic stimuli or stresses such as pregnancy, inflammatory states, or estrogen use cause elevation of the plasma fibrinogen). Sustained progressive increases in fibrinogen within the upper 50th percentile of the normal reference interval or persistently elevated fibrinogen levels have increased risk of arterial and venous thrombosis (a prethrombotic state or a hypercoagulable state). Elevated fibrinogen levels have been implicated as a possible risk factor for the development of arterial and venous thrombotic complications.[2-11] Consequently, fibrinogen levels may be more widely used in the future for the assessment of the risk of developing thrombotic complications.

A number of assays of plasma fibrinogen have been described which are based on measurements of total clottable fibrinogen by protein assay,[7,8] changes in turbidity or light scattering,[9] salt precipitation,[10] and fibrinogen antigen by various immunologic methods.[2,11]

This document also describes a specific technique for the determination of fibrinogen concentration based on the Clauss thrombin clotting rate assay.[1] This assay is practical, precise, and widely used in the clinical laboratory. This document is primarily directed toward laboratory and/or clinical personnel responsible for obtaining and processing blood specimens, performing the fibrinogen assay and quality control procedures, and reporting fibrinogen assay results. It is also intended as a guide for manufacturers of the reagents and instruments. Preanalytical and analytical factors and conditions that may alter results are discussed.

Other international standards procedures have been established for determination of fibrinogen in plasma. This guideline was separately from standards for fibrinogen determination prepared by the Deutches Institut für Normung (DIN).[12,13] On comparison, the documents appear to be essentially the same. Some differences do occur based on available and standard reagents. Use of either should allow determination of fibrinogen concentration. NCCLS will work toward harmonization in the next revision of H30.

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; aids in defining document structure; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS document GP26—*A Quality System Model for Health Care*.

Foreword (Continued)

The quality system approach applies a core set of "quality system essentials," basic to any organizational process, to all operations in the healthcare service's path of workflow. The quality system essentials are: organization; personnel; equipment; purchasing and inventory; process control; documents and records; occurrence management; internal assessment; process improvement; service and satisfaction; facilities and safety; and information management. The path of workflow for the clinical laboratory consists of three process areas: preanalytical; analytical; postanalytical.

NCCLS document H30-A2—*Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition* describes the preanalytical and analytical aspects of the path of workflow for the clinical laboratory by specifically providing guidance on the collection, transportation, handling, and storage of the specimen or sample and on performing fibrinogen assays in the laboratory.

Key Words

Afibrinogenemia, Clauss method, disseminated intravascular coagulation (DIC), dysfibrinogenemia, fibrin, fibrinogen, hypofibrinogenemia

Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition

1 Introduction

This document specifies a technique to assay fibrinogen in plasma, based on the method of Clauss.[1]

2 Scope

H30-A2 contains guidelines for the collection, transportation, handling, and storage of blood specimens or plasma samples and general guidelines for performing the fibrinogen assay by the Clauss method.[1] It is primarily directed toward laboratory and/or clinical personnel responsible for obtaining and processing blood specimens, performing the fibrinogen assay and quality control procedures, and reporting fibrinogen assay results. It is also intended as a guide for manufacturers of the reagents and instruments. The guideline does not cover prothrombin-time (PT)-derived fibrinogen determination which can be performed using various automated coagulation instruments.[14]

3 Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are new guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80.), [MMWR 1987;36(suppl 2S):2S-18S] and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*.

4 Definitions[a]

Control (plasma), *n* - A batch of citrated plasma used to monitor the stability of the laboratory test system, which includes reagents, instruments, reconstituting and diluting fluids, and pipettes; **NOTES**: a) "Normal control plasma" gives test results within the range of the reference interval; b) "Abnormal control plasmas" for factor assays should contain factor concentrations below the reference interval values due to abnormally low factor concentrations; c) If factors are clinically elevated, the "abnormal control plasma" should contain factor concentrations above the reference interval; d) Normal and abnormal control plasmas may be prepared in the laboratory or obtained commercially.

Reference curve, *n* - A line, typically a straight line, that defines the quantitative relationship between an independent variable and a dependent variable; **NOTE**: From this line the observed output of an analytic procedure (e.g., APTT test) can be converted to the units of measurement of the analyte of interest (e.g., coagulation factor activity).

[a] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents*. For complete definitions and detailed source information, please refer to the most current edition of that document.