H45-A2
Vol. 25 No. 15
Replaces H45-A
Vol. 18 No. 9

Performance of the Bleeding Time Test; Approved Guideline—Second Edition

This document contains guidelines for performing the template bleeding time test. A descriptive list of variables that can affect the results of the test is also included.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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H45-A2
ISBN 1-56238-571-2
Volume 25 Number 15 ISSN 0273-3099

Performance of the Bleeding Time Test; Approved Guideline—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document H45-A2—*Performance of the Bleeding Time Test; Approved Guideline—Second Edition* is intended for use by those persons responsible for performing the bleeding time test as well as for manufacturers of bleeding time devices. The document describes a procedure for the template bleeding time test. A descriptive list of variables that can affect the results of the test is also included.

Clinical and Laboratory Standards Institute (CLSI). *Performance of the Bleeding Time Test; Approved Guideline—Second Edition*. CLSI document H45-A2 (ISBN 1-56238-571-2). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

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Suggested Citation

(Clinical and Laboratory Standards Institute. *Performance of the Bleeding Time Test; Approved Guideline—Second Edition.* CLSI document H45-A2 [ISBN 1-56238-571-2]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.)

Proposed Guideline
December 1995

Approved Guideline
June 1998

Approved Guideline—Second Edition
June 2005

ISBN 1-56238-571-2
ISSN 0273-3099

Committee Membership

Area Committee on Hematology

Contents

Foreword

For more than 85 years, the bleeding time has been used for the detection of abnormalities of primary hemostasis.[1,2] Over time, various methods for performing the bleeding time have been introduced. Early techniques employing lancets and surgical blades were replaced because of difficulty in standardization of the length and depth of the incision. This document provides guidelines on performing the bleeding time test using the template procedure. The template bleeding time procedure improves the reproducibility of the test by controlling the length and depth of the incision.

The bleeding time test is highly affected by a variety of variables. Because of these many variables, H45 was developed to provide clear guidelines concerning the materials and methods used in the performance of the bleeding time test. H45 provides a list of the variables that can affect the bleeding time test along with recommendations for performance of the test to further improve reproducibility and accuracy.

Although there are questions as to the usefulness of the template bleeding time as a predictor of bleeding in surgical patients,[2] the bleeding time is used in the investigation of severe and moderate von Willebrand disease and severe and moderate congenital and acquired disorders of platelet function.

The procedure outlined in this document essentially has not changed since the previous publication of this document (H45-A). However, the Area Committee on Hematology has revised the document to the second edition of the approved guideline to reflect current CLSI policies. Last published in June 1998, the document now includes the following enhancements:

- definitions have been added consistent with CLSI's policy on harmonization of terminology (see *Note on Terminology* below);
- the photographs in the Appendix have been updated to reflect current safety practices; and
- a summary of the quality management system (as outlined in CLSI/NCCLS documents HS1—*A Quality Management System Model for Health Care* and GP26—*Application of a Quality Management System Model for Laboratory Services*) and how H45 fits into the system with related CLSI/NCCLS documents.

A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. Despite these obstacles, CLSI recognizes that harmonization of terms facilitates the global application of standards and is an area that needs immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In keeping with CLSI's commitment to align terminology with that of ISO, the term a*ccuracy* refers to the "closeness of the agreement between the result of a (single) measurement and a true value of a measurand" and comprises both random and systematic effects, while *reproducibility* describes the "closeness of agreement of results of measurements under changed conditions."

Key Words

Bleeding time, hemostasis, platelet, template

Performance of the Bleeding Time Test; Approved Guideline—Second Edition

1 Scope

This document deals only with the performance of the template bleeding time test, which was developed to improve test reproducibility by controlling the length and depth of the incision. The guideline presents a procedure for performing a template bleeding time. It lists the required materials and equipment, describes affecting variables, defines reference intervals, and deals with the interpretation of results. This document is intended for those who are responsible for performance of the bleeding time test, as well as for manufacturers of bleeding time devices. For a more detailed review of the clinical usefulness of the bleeding time in various disease states, please see the most current edition of CLSI/NCCLS document H51—*Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity.*

2 Introduction

The bleeding time, formerly a commonly used test for assessing primary hemostasis, is an *in vivo* measurement of the interaction of platelets with the walls of small blood vessels. The test may be sensitive to a variety of variables that may produce false-positive and false-negative results. The positive predictive value of the bleeding time with respect to a disorder of the primary hemostasis, is acceptably high only when there is high likelihood of an abnormal result (i.e., when the patient has a history of abnormal bleeding or is taking or receiving a drug known to affect the bleeding time). In general, the bleeding time is not considered useful as a predictive test for surgical bleeding.[2-4] The test should be performed only by individuals who have adequate training and experience in the performance of the procedure.

3 Standard Precautions

Because it is often impossible to know what might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard 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;17(1):53-80 and *MMWR* 1988;37:377-388). For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most current edition of CLSI document M29—*Protection of Laboratory Workers From Occupationally Acquired Infections*.

4 Definitions

accuracy (of measurement) – closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93).[5]

reproducibility (of results of measurements) – closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement (VIM93).[5]

template – a metal or plastic gauge that guides the length and depth of the bleeding time incision.

wick – to draw blood away from the bleeding time incision by capillary action using a sheet of absorbent filter paper.

5 Principle

A standardized superficial incision is made in the skin of the forearm or leg, and the time it takes for bleeding to stop is measured. The length of time of bleeding reflects the effectiveness of platelet-vessel wall interaction.

6 Materials and Methods

The use of a commercial, single-use template device is recommended for assurance of sterility, reproducibility, safety, and convenience. The manufacturer's directions should be followed. Required equipment includes the following:

- gloves;
- template/blade device;
- timing device that measures in seconds;
- sphygmomanometer, also referred to in this document as "cuff";
- Whatman #1 filter paper disc or equivalent;
- alcohol swabs;
- butterfly bandage and a larger bandage (used to cover the butterfly bandage); and
- disposable razor or other shaving device (occasionally required to shave the test site on the forearm).

7 Procedure

The procedure is as follows:

(1) Before performing the test, the person performing the bleeding time test should make certain that the patient's platelet count is not below the laboratory's established limit for performing the bleeding time procedure (see Section 8.9).

(2) Inform the patient about the nature of the test and of the possibility of scarring, keloid formation, and risk of infection. Generally, template bleeding times should not be performed on persons who are unable to cooperate or are known to form keloids.

(3) With the arm supine on a firm support (preferably close to heart level), select a site on the lateral one-third of the forearm, 2 to 3 cm distal to the antecubital crease, in an area devoid of hair (occasionally shaving is required), scars, tattoos, bruises, surface veins, infected skin, moles, or other lesions (see Appendix).

(4) Place a sphygmomanometer cuff on the upper arm.

(5) Clean the test site with an alcohol swab and air dry the site for at least 30 seconds.

(6) Inflate the cuff to 40 mmHg for 30 to 60 seconds before the incision is made and make certain that the pressure is maintained steadily at 40 mmHg during the procedure. Avoid using a sphygmomanometer that has an air leak (i.e., that does not hold a constant pressure). For pediatric patients, see Sections 8.6 and 8.7.

(7) Gloves should be worn when performing the bleeding time procedure.

(8) Place the device firmly, but with as little pressure as possible, on the forearm. Make the incision either perpendicular (vertical) or parallel (horizontal) to the antecubital crease. (One direction—horizontal or vertical—should be used by an institution consistently, since directionality may affect results and, therefore, normal range (see Section 8.1)

(9) Start the timing device. (See Section 8.6 for depth and length appropriate for newborns and pediatric patients.) The incision should be 5 mm long and 1 mm deep for adults.

(10) Wick (do not blot) the drops of blood from the incision with the filter paper every 30 seconds, taking care not to touch the incision, as that might dislodge the developing platelet plug. With excessive bleeding, more frequent wicking may be required. Wick until bleeding ceases. The bleeding time is the time from making the incision until the blood ceases to stain the filter paper red, measured to the nearest 30 seconds. If bleeding continues, the procedure should not be continued indefinitely but discontinued at a time in minutes specified by the institution, such as 20 or 30 minutes.

(11) When the test is completed, remove the cuff. If the area around the incision is to be cleaned, take care to avoid touching the incision with alcohol, because this can induce renewed bleeding and increase scarring.[6] For pediatric patients, refer to Section 8.6.

(12) Place a butterfly bandage on the incision site to bring the edges of the incision together, being careful not to overlap them. A larger bandage may be placed on top of the butterfly bandage to prevent contamination. Both bandages should remain for 24 hours.

(13) The bleeding time device should be disposed of in a puncture-resistant biohazard container and the filter paper in a biohazard bag.

8 Variables

8.1 Direction of Incision

The direction of the incision—horizontal or vertical—is the choice of the laboratory director; however, one direction must be used consistently. A horizontal incision (parallel to the antecubital crease) gives a longer bleeding time when compared to a vertical incision (perpendicular to the antecubital crease). The vertical incision may produce less scarring. Both procedures have a similar degree of reproducibility. The horizontal incision is more sensitive to the effects of aspirin.[7-9]

8.2 Number of Incisions

Usually, a single measurement (using a device that makes one incision or two) is sufficient, although some institutions perform two subsequent measurements and average the two values.

8.3 Depth of Incision

The template improves the reproducibility of the bleeding time test by controlling the length and depth of the incision. However, the depth of the incision still depends to some degree on the operator and the

patient. This is because the dermis is pliable and variations in the pressure applied can lead to variations in penetration.[10] Performing a bleeding time in pediatric patients is one such situation in which a standard adult device generally should not be used (see Section 8.6).

8.4 Ambient Temperature

Extremes of temperature influence results. The test should be carried out at room temperature (22 to 25 °C/72 to 77 °F).[11]

8.5 Venous Blood Pressure

A constantly maintained venous blood pressure of 40 mmHg in adults is recommended for reproducibility of the test. A pressure of 20 mmHg is recommended for newborn and pediatric patients.[11]

8.6 Age and Gender

Shorter bleeding times have been observed with increasing age.[12] Slight differences can be observed between the sexes.[7,9,11,13,14] In elderly patients and other patients with skin atrophy, the results of the bleeding time test may be more difficult to interpret and may be less useful. In such patients, the indications for performance of the bleeding time test should be carefully evaluated.

The procedure for pediatric patients is the same as above but uses a device that makes a smaller 3.5 x 1-mm incision; for the newborn, a template is available that gives a 2.5 x 0.5-mm incision. For both, a pediatric sphygmomanometer must be used that can maintain 20 mmHg.[15,16] The age range and weight in kg that defines "pediatric" may vary between institutions, but is generally in the range of less than 16 years of age or less than 40 kg.

8.7 Drugs

Many drugs can prolong the bleeding time by affecting platelet function[17] (e.g., aspirin, nonsteroidal anti-inflammatory agents, other antiplatelet agents, and antibiotics such as penicillin and cephalosporins). The effect of aspirin on the bleeding time can last up to four days.[18] Usually, anticoagulants such as heparin and coumarin at therapeutic doses do not affect the bleeding time.[3,7,9,11,14,19,20]

8.8 Packed Cell Volume (PCV; Hematocrit)

Prolongation of the bleeding time occurs in patients with moderate to severe anemia (i.e., PCV less than 0.30 [30%]). In such patients, the bleeding time may be shortened following transfusion of red cells or by administration of erythropoietin to raise the hematocrit to greater than 30%.[10,21,22]

8.9 Thrombocytopenia

Thrombocytopenia, which is a decrease in the number of platelets in circulating blood, affects the bleeding time. A weak negative correlation between template bleeding times and platelet counts between 10 x 10^9/L and 100 x 10^9/L (10 000 and 100 000/µL) has been reported.[21] It has been suggested that a disproportionate prolongation of bleeding time for a given platelet count may indicate an accompanying platelet function disorder.[18] There are insufficient data to support the appropriateness or clinical usefulness of performing a bleeding time on patients with platelet counts of 100 x 10^9/L (100 000 µL) or less.

8.10 Other Factors

The presence of an intravenous (IV) catheter, IV infusions, edema, or local hemorrhage involving the potential site of the bleeding time are considered contraindications for doing a bleeding time in that particular arm. These conditions, if present in both arms, could indicate use of the leg for the bleeding time if no contraindications exist, such as peripheral vascular disease.

The leg (the medial aspect of the calf, 6 to 8 cm below the knee) can be an acceptable alternative when it is impossible to use the arm for a bleeding time.[23] For the leg bleeding time, the patient should be in a horizontal (lying flat on the back) position.[23] Apply an appropriately sized pressure cuff to the thigh. The procedure is then the same as for the arm, except that the medial aspect of the calf is the preferred site. The laboratory should establish a separate reference interval for this procedure (see Section 9).

9 Reference Intervals

Each laboratory should establish its own reference interval. The upper limit of most template bleeding times is between 5.5 to 9 minutes. Longer times have been reported. A separate range should be established for pediatric populations and for lower extremities if appropriate for the laboratory. Bleeding times under two minutes can indicate faulty technique. For guidelines on establishing reference intervals, see CLSI/NCCLS document C28—*How to Define and Determine Reference Intervals in the Clinical Laboratory*.

Normal bleeding times may be observed in individuals:

- with mild von Willebrand disease;
- taking aspirin or other nonsteroidal agents; and
- having disorders of primary hemostasis.

10 Interpretation

In subjects with a history of abnormal bleeding, the bleeding time test is useful in detecting moderate and severe hereditary and acquired defects in the interaction of platelets with an injured vessel, such as:

- von Willebrand disease (vWD);
- Glanzmann thrombasthenia;
- Bernard Soulier syndrome;
- aspirin-like platelet dysfunction[2];
- storage pool disease (e.g., Hermansky-Pudlak syndrome)[24]; and
- acquired storage pool disease (e.g., secretion [aspirin-like] defects).[24]

However, in some milder types of platelet dysfunction, such as aspirin-like platelet dysfunction, storage pool disease (e.g., H-P syndrome), and acquired storage pool disease (e.g., secretion [aspirin-like] defects), the bleeding time may lack sufficient sensitivity, and alternative forms of *in vitro* platelet function testing may be necessary.[2,24]

The bleeding time can also be prolonged in afibrinogenemia and other severe coagulation factor deficiencies (i.e., Factor V and VIII). Patients with milder forms of von Willebrand disease often have normal bleeding times. Prolonged bleeding times can be seen in acquired platelet function disorders associated with uremia, multiple myeloma, and myelodysplastic/myeloproliferative syndromes. Bleeding times is one approach to monitoring the effect of therapy with cryoprecipitate, von Willebrand-factor-rich Factor VIII concentrates, and drugs, such as desmopression acetate (DDAVP), although measurement of a

plasma-based analyte, such as von Willebrand factor activity pre- and post-therapy, may be less subjective a measurement.[11]

The bleeding time is not considered useful as a predictive test for surgical bleeding.[2-4,25] Additionally, the finding of a normal bleeding time does not absolutely exclude the possibility of a primary hemostatic defect, and as such may not eliminate the need for other diagnostic procedures if the clinical history dictates. The bleeding time can be of value in the evaluation of patients with a personal or family history of abnormal bleeding.[20,26,27]

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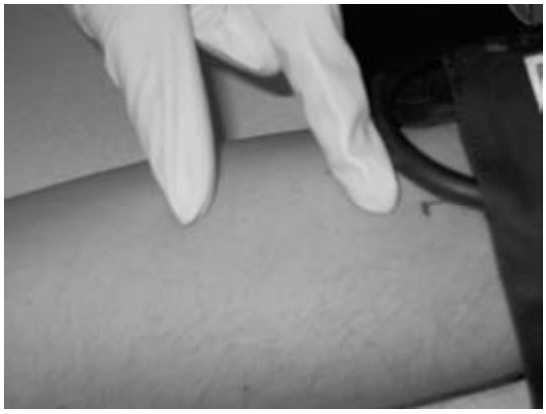
Appendix. Performance of the Bleeding Time Test (For complete details, refer to Section 7 in the main text.)



(1) Select a site for placement of the bleeding time device on the lateral one-third of the forearm, 2 to 3 cm distal to the antecubital crease.

(2) Clean the site with an alcohol swab and air dry for at least 30 seconds.

(3) Inflate the sphygmomanometer cuff and place the device firmly, but with as little pressure as possible, on the forearm. Make the incision.

Appendix. (Continued)

(4) A drop of blood should form. With filter paper, wick (but do not blot) the drops of blood from the incision at least every 30 seconds.

Clinical and Laboratory Standards Institute consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information, contact CLSI or visit our website at www.clsi.org.

Summary of Delegate Comments and Area Committee Responses

H45-A2: *Performance of the Bleeding Time Test; Approved Guideline—Second Edition*

1. Since the bleeding time is a platelet function test, whether or not the patient has had aspirin or other platelet function inhibiting drugs needs to be established before performing the test. The effects of aspirin will destroy the platelet enzyme, cyclo-oxygenase, which will prevent platelets from sticking together and will markedly extend the bleeding time to the point that the test may be cancelled until the platelets return to normal function. If the test is performed anyway, a notation must be included with test results.

- **The committee agrees; hence the warnings in Section 8.7 about the effects of aspirin, as well as other drugs. Unfortunately, in the practical world, patients are not always aware of various over-the-counter drugs that contain aspirin or other drugs affecting platelet function. So even a careful history may not elicit the desired information.**

Section 4, Definitions

2. H45 includes the word accuracy where EP15-A2 is promoting the term trueness instead of accuracy.

- **As stated in the Foreword, "accuracy" refers to the "closeness of the agreement between the result of a *single* measurement and a true value of a measurand"; whereas "trueness" is "the closeness of agreement between the *average value* obtained from *a large series of test results* and an accepted reference value." Accuracy is the appropriate term for this document.**

Section 7, Procedure

3. Point 11. Should a comment be added about performing a bleeding time in pediatric patients (refer to Section 8.6) and that a standard adult device should not be used?

- **The second paragraph of Section 8.6 deals with this issue in sufficient detail. A cross-reference to Section 8.6 has been inserted into Section 7, #11.**

4. Point 11. We suggest a complete procedure for pediatric patients to prevent the use of adult devices and misinterpretation by using pediatric bleeding time instead of adult ones.

- **The second paragraph of Section 8.6 deals with this issue in sufficient detail. A cross-reference to Section 8.6 has been inserted into Section 7, #11.**

Section 7, Procedure, and Section 8.6, Age and Gender

5. In the procedure where there are variations for pediatric patients, it states (See Section 8.6 for...to use with newborns and pediatric patients). This was not included in Step 6 on the proper inflation of the pediatric sphygmomanometer cuff at 20 mmHg for newborns and pediatric patients.

- **This point is explained in Sections 8.6 and 8.7. Cross-references to Sections 8.6 and 8.7 have been added to Step 6 of Section 7 for clarity.**

Appendix

6. Descriptions are very short and if used in isolation could be hazardous (e.g., gloves are not mentioned, the procedure does not indicate when to start timing or the direction of the incision). More details are required.

- **The Appendix is not meant to be used in isolation, but as an adjunct to the specific technique described in greater detail in Section 7. A cross-reference to Section 7 has been added to the Appendix for clarity.**

NOTES

The Quality System Approach

Clinical and Laboratory Standards Institute subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any healthcare service's path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

H45-A2 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X C28						M29

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

H45-A2 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
				H51				

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Related CLSI/NCCLS Publications*

C28-A2 **How to Define, Determine, and Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition (2000).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.

H51-A **Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline (2002).** This guideline describes the following: appropriate test specimens; reagents and materials; methods of platelet agglutination and ELISA; preparation of reference curves; determination of reference intervals; quality control procedures; result interpretation; and sources of error for assays of von Willebrand factor antigen and ristocetin cofactor activity. A brief description of von Willebrand disease and its various subtypes is included, as well as a list of references to more comprehensive reviews of this commonly inherited and rarely acquired bleeding disorder.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on U.S. regulations, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; 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.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

NOTES

NOTES

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