LA4-A4
Vol. 23 No. 21
Replaces LA4-A3
Vol. 17 No. 16

Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition

This document addresses the issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

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

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LA4-A4
ISBN 1-56238-503-8
Volume 23 Number 21 ISSN 0273-3099

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Abstract

NCCLS document LA4-A4—*Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition* addresses the issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper. The purpose of these considerations is to produce a functional standard that will result in uniform techniques for collecting the best possible specimen for use in newborn screening programs. Issues addressed in the standard include: (1) procedures for applying blood collected by heel-stick onto the preprinted circles of filter paper; (2) recommendations on the source of blood; (3) techniques for direct collection, and alternative collection procedures of specimens; (4) specifications for the filter paper, handling, and the mailing package; (5) specifications for the specimen collection device; and (6) the handling of blood spots collected on filter paper for DNA analysis.

NCCLS. *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition*. NCCLS document LA4-A4 (ISBN 1-56238-503-8). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

Suggested Citation

(NCCLS. *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition.* NCCLS document LA4-A4 [ISBN 1-56238-503-8]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Proposed Standard
September 1982

Tentative Standard
March 1985

Approved Standard—First Edition
December 1988

Approved Standard—Second Edition
July 1992

Approved Standard—Third Edition
October 1997

Approved Standard—Fourth Edition
July 2003

ISBN 1-56238-503-8
ISSN 0273-3099

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NCCLS would like to extend its appreciation to W. Harry Hannon, Ph.D., Chairholder of the Area Committee on Immunology and Ligand Assay for his leadership of the Working Group on Neonatal Screening Programs.

In addition, NCCLS gratefully acknowledges the following individuals for their contributions to the revision of LA4-A4:

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Oklahoma State Department of Health
Washington State Department of Health
Schleicher & Schuell BioScience, Inc.
National Newborn Screening and Genetics Resource Center (NNSGRC)

Contents

Contents (Continued)

Foreword

This standard has been written for both manufacturers and newborn screening programs, with primary emphasis on the specimen collection centers and the specimen collection device (card). Specimens for newborn screening are usually collected by hospital personnel during the first few days of the neonate's life. This standard informs and instructs collection personnel on the essentials of collecting a high-quality specimen, for handling it after it has been collected, for transporting it to the testing facility, and for storing the residual specimen content after laboratory testing. Furthermore, the standard is applicable to other testing procedures for which blood collected on filter paper is used as a specimen source (e.g., fingerstick collections on filter paper to test for specific antibodies and for DNA diagnostic testing). See the most current edition of the NCCLS standard H4 —*Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture*, for an essential reference document for use with this standard.

The present standard replaces the third edition approved standard, LA4-A3, which was published in 1997. Several changes have been made in this edition; chief among them are the modifications (in Sections 3.1, 3.2, and 3.3) of the procedures for applying collected blood onto the preprinted circles of filter paper. Modifications were made that better describe the use of other sources of blood and their collection and application onto the filter paper. The current standard makes recommendations on the source of blood (Section 2), and techniques for the direct blood collection from the puncture site and other collection techniques (Section 3). Extensive enhancements were made to the specifications for specimen matrix and shipment, especially in the printing section (Section 4.1.3). Minimum data set requirements have been updated (Section 5.1). Modifications were made in the specimen collection device section to include quality control aspects for printing (Section 5.2). A new section has been included to cover storage of and access to specimens for biobanking (Section 7). Appendix A was updated and a figure was added to demonstrate drying techniques. This single-page appendix is detachable from the document and can be used as an instructional aid and displayed in the specimen collection center. In addition, a new appendix has been added that illustrates a blood spot drying device (Appendix D).

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 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 for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

Key Words

Biobank, blood collection, DNA diagnostics, dried blood spots, filter paper, heel-stick puncture, neonatal screening, newborn screening

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1 Scope

1.1 Specimen Quality

The primary goal of this standard is to improve and ensure the quality of blood spots collected from newborns.[1] Unacceptable and poor quality specimens place an unnecessary burden on the screening facility, cause unnecessary trauma to the infant and anxiety to the infant's parents, potentially delay the detection and treatment of the affected infant, and could contribute to a missed or late diagnosed case. When the screening laboratory receives an unacceptable specimen, it should request another specimen according to criteria established by the testing laboratory. In all newborn screening programs, the turnaround time for analytic results is critical if treatment to prevent the adverse consequences of the condition (such as irreversible mental retardation or death) is to begin on time.

1.2 Specimen Acceptability

The only justification for refusing to analyze a specimen and declaring it unacceptable is that its analysis might yield unreliable, misleading, or clinically inaccurate values for a particular analyte. Since, by this definition, an unacceptable specimen gives no usable information, such specimens should not be analyzed, and those responsible for collecting the original specimen should be notified with all due haste so that an acceptable specimen can be obtained as soon as possible. If a specimen is analyzed, the laboratory is, in effect, acknowledging that the specimen is suitable for testing and is assuming responsibility for the reliability of the analytic values. Program-specific rules should be written and followed consistently with respect to handling specimens of insufficient quantity, especially for multianalyte test panels.

1.2.1 Other Considerations

The secondary goals of this standard are to delineate the minimum necessary information for the specimen collection form; to standardize the components of this form; to describe minimal requirements for the filter paper matrix on which the blood spots are collected; and to define the handling, shipping, and storage conditions for dried blood spot specimens.

1.3 Applications

This standard specifically addresses the collection of blood specimens for newborn screening programs[1] and applies to the collection of specimens used to detect such congenital disorders as primary hypothyroidism, phenylketonuria (PKU), galactosemia, congenital adrenal hyperplasia, biotinidase deficiency, maple syrup urine disease (MSUD), hemoglobinopathies and homocystinuria, among others. Many aspects of this standard are also appropriate and useful for the collection of dried blood spots used for DNA diagnostics, home collection devices, and a variety of new tests. In addition, most elements of this standard are applicable to blood collection on filter paper from fingerstick punctures of adolescents and adults. With older children (greater than one year of age) and adults, the palmar surface of the finger's last phalanx is most frequently used. (See the most current edition of NCCLS document H4—*Procedures and Devices for Collection of Diagnostic Blood Specimens by Skin Puncture*.)