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GP20-A2

Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition

This document contains recommended procedures for performing fine needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions/masses, from patient preparation through staining the smear.

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

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For additional information on committee participation or to submit comments, contact CLSI.

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

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Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition

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Nina Dhurandhar, M.D., Chairholder
Harvey Cramer, M.D.
Leza N. Gallo, M.D.
Daniel F.I. Kurtycz, M.D.
Krzysztof Moroz, M.D.
Margaret H. Neal, M.D.
Marianne Prey, M.D.
Gail Radcliffe, Ph.D.
Suzanne M. Selvaggi, M.D.

Abstract

Clinical and Laboratory Standards Institute document GP20-A2—*Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition* describes procedures for collecting, handling, fixing, and staining aspiration biopsy specimens. Equipment and aspects of patient preparation necessary to obtain a fine needle biopsy specimens are also addressed. Interpretation of smears is not included in this guideline.

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Foreword

Fine needle aspiration biopsy (FNAB) begins with obtaining a pertinent history and ends with a documented interpretation of the morphologic findings. NCCLS document GP20-A2—*Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition* is a consensus document on the performance of FNAB. As with any procedure, the quality of the test depends on the adequacy of the specimen and the appropriateness of the biopsy procedure. GP20-A2 provides practical recommendations for the performance of FNAB, including recommendations on obtaining patient consent, performing the biopsy, smearing techniques, and the use of ancillary studies. Particular emphasis is placed on adherence to standard precautions. NCCLS document GP20-A2 is not, however, intended to summarize the morphologic features used for diagnosis.

The revisions in this guideline are intended principally to achieve international harmonization. The previous edition (GP20-A) was published for wide and thorough review in the NCCLS consensus-review process. The objective of this review was to obtain specific input on the utility and applicability of the recommendations provided for fine-needle aspiration biopsy (FNAB) techniques. However, a "Summary of Consensus Comments" has not been included in this approved, second-edition document as all comments received as a result of the consensus review process were editorial in nature.

A Note on Terminology

NCCLS, 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. NCCLS recognizes that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and deserves immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In this document, the term *Accuracy* 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. *Trueness* is used in this document when referring to the "closeness of the agreement between the average value from a large series of measurements and to a true value of a measurand."

Key Words

Cytology, deep-seated lesion/mass, fine needle aspiration biopsy (FNAB), liquid-based cytology, nonpalpable lesion/mass, palpable lesion/mass, superficial lesion/mass

Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition

1 Scope

Fine needle aspiration biopsy is a widely accepted technique for the initial work-up and management of a patient who presents with a superficial, palpable lesion/mass. This technique is also used for a deep-seated, nonpalpable lesion/mass under radiologic guidance. This minimally invasive procedure is safe, accurate, rapid, and cost effective. Patient acceptance is high and complications are minimal. The goal of this guideline is to provide recommendations for performing the procedure and optimal collection, handling, fixation, and staining of aspiration biopsy specimens. Equipment needs and patient preparation issues are addressed. NCCLS document GP20-A2 is not, however, intended to summarize the morphologic features used for diagnosis.

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.*

2 Introduction

This document provides information about key aspects of the performance of fine needle aspiration biopsy (FNAB). FNAB is a diagnostic procedure that uses thin (fine) needles (22-g or narrower) to obtain cytologic specimens. These cellular specimens are then examined microscopically to detect the presence of various diseases, including those of neoplastic or infectious origin. Often, FNAB is the preferred method of diagnostic biopsy because, in well-trained hands, it is rapid, accurate, cost effective, and safe. Extensive training or experience in the technique is necessary to provide cellular specimens that enable a definitive diagnosis. This document addresses both superficial (palpable) and deep-seated (nonpalpable) lesions/masses in separate sections; however, there is significant overlap. (See Appendix A for a flow diagram of the procedure.)

FNAB is a minimally invasive, cost-effective technique with high diagnostic trueness (in the range of 90 to 99%). For example, several studies show that introduction of FNAB resulted in a 50% reduction in the number of surgical procedures performed on the thyroid, accompanied by a corresponding increase in the percentage yield of tumors at thyroid surgery. The total number of neoplasms detected has, therefore, remained stable, even though only half as many patients underwent surgery. The overall result has been a decrease in the cost of medical care associated with management of thyroid disease.[1,2] In many

institutions FNAB has helped reduce the number of open surgical biopsies. Similar results have been demonstrated in the management of palpable breast lesions/masses.

The diagnostic sensitivity and specificity of FNAB depend on several factors, including:

- the site and type of lesion/mass aspirated;
- the experience of the aspirator (the person performing the aspiration);
- the quality of the sample preparation; and
- the diagnostic skills of the pathologist.

The influence of these factors should not be underestimated. In particular, during the performance of deep-seated aspirations, the presence of a cytotechnologist (for slide preparation) or cytopathologist (for preparation and immediate interpretation) decreases the number of unsatisfactory specimens and increases diagnostic yield.[3]

3 Definitions

Accuracy (of measurement) – Closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93)[4]; **NOTE:** See the definition of **Measurand**, below.

Deep-seated lesion/mass - Situated in the thoracic or abdominal organ/cavity; **NOTE:** It is usually not palpable and is visualized radiologically.

Endoscopy - A procedure where an instrument is used for examination of the interior of a canal or hollow organ.

Ipsilateral - On the same side, e.g., arm on the same side as the breast mass.

Measurand – particular quantity subject to measurement.[4]

Superficial mass/lesion - Situated near the surface; **NOTE:** It is palpable.

Trueness (of measurement) - The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value; (ISO 3534-1).[5]

4 Superficial Lesions/Masses

4.1 FNAB Preparation

Prior to the procedure, the person performing the aspiration (the aspirator) should have the following important information:

- pertinent clinical history (review the chart or consult clinical colleagues about, e.g., prior history of malignancy or infection, or previous related/pertinent pathologic results);
- any relevant imaging studies and differential diagnostic considerations;
- the questions the study is attempting to answer;

The Quality System Approach

NCCLS subscribes to a quality 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 through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality 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. 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

GP20-A2 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related 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
											M29-A2

Adapted from NCCLS document HS1— *A Quality 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, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

GP20-A2 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Preanalytic					**Analytic**		**Postanalytic**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
X	X	X GP15-A2 GP23-A	X GP15-A2 GP23-A	X GP15-A2 GP23-A	GP15-A2 GP23-A			

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

Related NCCLS Publications*

GP15-A2 **Papanicolaou Technique; Approved Guideline—Second Edition (2001)**. GP15-A2 gives recommendations on how to collect and process a quality Pap smear specimen for analysis. The document offers practical recommendations on patient preparation; collection of exocervical and endocervical specimens, including a discussion of collection devices and anatomical illustrations; the design of a test requisition form with a sample form included; slide preparation and fixation; staining methods and techniques, including preparation, storage, safe use, and maintenance of reagents; and mounting, storage, and retention of slides. GP15-A2 is a vital educational and procedural resource for hospital and referral laboratories, cytopathologists, family practitioners, obstetrician/gynecologists, and cytotechnologists.

GP23-A **Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (1999).** This document provides recommended procedures for the collection, handling, transport, and processing of cytologic specimens from nongynecologic sources.

M29-A2 **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (2001)**. 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- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 **Toll Free (US):** 877.447.1888 **F:** +1.610.688.0700

E: customerservice@clsi.org **www.clsi.org**

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