

# Subpart M—Personnel for Nonwaived Testing

Source: [57 FR 7172](#), Feb. 28, 1992, unless otherwise noted.

 by Fertility Guidance Technologies



## § 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

[[60 FR 20049](#), Apr. 24, 1995]

## Laboratories Performing Provider-Performed Microscopy (PPM) Procedures

**Source:** [60 FR 20049](#), Apr. 24, 1995, unless otherwise noted.

## § 493.1353 Scope.

In accordance with [§ 493.19\(b\)](#), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in [§§ 493.1355](#) through [493.1365](#).

## § 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of [§ 493.1357](#) and provides overall management and direction in accordance with [§ 493.1359](#).

## § 493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in [§ 493.19\(c\)](#) and must be eligible to be an operator of a laboratory within the requirements of [subpart R of this part](#).

### (a) State Licensing

The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

### (b) Qualification Requirements

The laboratory director must meet one of the following requirements:

Be a physician, as defined in [§ 493.2](#).

Be a midlevel practitioner, as defined in [§ 493.2](#), authorized by a State to practice independently in the State in which the laboratory is located.

Be a dentist, as defined in [§ 493.2](#).



## § 493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

- 1 Direct no more than five laboratories;
- 2 Ensure that any procedure listed under [§ 493.19\(c\)](#)—  
  
Is personally performed by an individual who meets the qualification requirements in [§ 493.1363](#); and  
  
Is performed in accordance with applicable requirements in this subpart and [subparts H, I, and K of this part](#);
- 3 Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—
  1. Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing;
  2. Monitoring the recording and reporting of test results;
  3. Review of test results or worksheets;
  4. Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and
  5. Assessment of problem solving skills;
- 4 Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

## § 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of [§ 493.1363](#) to perform the functions specified in [§ 493.1365](#) for the volume and complexity of testing performed.

## § 493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must—

### (a) State Licensing

Possess a current license issued by the State in which the laboratory is located if the licensing is required;

### (b) Qualification Requirements

Meet one of the following requirements:

Be a physician, as defined in [§ 493.2](#).

Be a midlevel practitioner, as defined in [§ 493.2](#), under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

Be a dentist as defined in [§ 493.2 of this part](#).

## § 493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—

### **(a) Personally performed by one of the following practitioners:**

1. A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.
2. A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.
3. A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee;

### **(b) Microscope Requirements**

Performed using a microscope limited to a brightfield or a phase/contrast microscope.

## **Laboratories Performing Moderate Complexity Testing**

## § 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of [§ 493.1405 of this subpart](#) and provides overall management and direction in accordance with [§ 493.1407 of this subpart](#).

## § 493.1405 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of [subpart R of this part](#).

### (a) State Licensing

The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required;

### (b) Qualification Requirements

The laboratory director must meet one of several qualification pathways, including:

- MD/DO with pathology certification
- MD/DO/DPM with laboratory training/experience
- Doctoral degree holders with specific laboratory science education
- Master's degree holders with specific laboratory science education and experience
- Bachelor's degree holders with specific laboratory science education and experience
- Individuals qualified and serving as laboratory directors as of December 28, 2024

Each pathway has specific requirements for education, training, experience, and continuing education.



# § 493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

## Delegation of Duties

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of [§§ 493.1409, 493.1415](#), and [493.1421](#), respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

## On-site Requirements

(c) The laboratory director must:

1. Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed;
2. Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

(d) Each individual may direct no more than five laboratories.

## Core Responsibilities

(e) The laboratory director must ensure quality laboratory services, appropriate physical environment, test methodology selection, verification procedures, proficiency testing, quality control, quality assessment, and proper reporting of results.



## **§ 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.**

The laboratory must have a technical consultant who meets the qualification requirements of [§ 493.1411 of this subpart](#) and provides technical oversight in accordance with [§ 493.1413 of this subpart](#).

## § 493.1411 Standard; Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

### (a) State Licensing

The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

### (b) Qualification Pathways

The technical consultant must meet one of several qualification pathways, including:

- MD/DO with pathology certification
- MD/DO/DPM with laboratory training/experience
- Doctoral/Master's degree holders with laboratory training/experience
- Bachelor's degree holders with laboratory training/experience
- Associate degree holders with laboratory training/experience
- Special qualifications for blood gas analysis
- Individuals qualified and serving as technical consultants as of December 28, 2024

## § 493.1413 Standard; Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in [paragraph \(a\)](#) of this section.

### Accessibility

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation;

### Key Responsibilities

(b) The technical consultant is responsible for:

1. Selection of test methodology
2. Verification of test procedures
3. Enrollment in proficiency testing
4. Establishing quality control program
5. Resolving technical problems
6. Ensuring proper test system function
7. Identifying training needs
8. Evaluating competency of testing personnel
9. Evaluating and documenting performance of testing personnel

# § 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of [§ 493.1417 of this part](#) and provides clinical consultation in accordance with [§ 493.1419 of this part](#).

## § 493.1417 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

<p><b>(a) Laboratory Director Qualification</b></p> <p>Be qualified as a laboratory director under <a href="#">§ 493.1405(b)(1), (2), or (3)</a>; or</p>	<p><b>(b) Medical Licensure</b></p> <p>Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

[[57 FR 7172](#), Feb. 28, 1992, as amended at [58 FR 5234](#), Jan. 19, 1993; [88 FR 90040](#), Dec. 28, 2023]

## § 493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

<p>Be available to provide clinical consultation to the laboratory's clients;</p> <p>Ensure that reports of test results include pertinent information required for specific patient interpretation;</p>	<p>Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;</p> <p>Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.</p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------



## § 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of [§ 493.1423](#), to perform the functions specified in [§ 493.1425](#) for the volume and complexity of tests performed.

## § 493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must—

### (a) State Licensing

Possess a current license issued by the State in which the laboratory is located, if such licensing is required;

### (b) Qualification Requirements

Meet one of the following requirements:

1. Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located;
2. Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; Meet the requirements in [§ 493.1405\(b\)\(3\)\(i\)\(B\)](#), [\(b\)\(4\)\(i\)\(B\)](#) or [\(C\)](#), or [\(b\)\(5\)\(i\)\(B\)](#);
4. Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution;
5. Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);
6. Have earned a high school diploma or equivalent with specific laboratory training;
7. Meet special qualifications for blood gas analysis;
8. Be qualified and serving as testing personnel as of December 28, 2024.

## § 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

### (a) Authorized Testing

Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

### (b) Testing Personnel Requirements

Each individual performing moderate complexity testing must:

1. Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;
2. Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;
3. Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;
4. Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
5. Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director;
6. Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

## Laboratories Performing High Complexity Testing

## § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of [§ 493.1443 of this subpart](#) and provides overall management and direction in accordance with [§ 493.1445 of this subpart](#).

## § 493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

### (a) State Licensing

The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required;

### (b) Qualification Requirements

The laboratory director must meet one of the following requirements:

1. MD/DO with anatomic or clinical pathology certification
2. MD/DO/DPM with experience directing/supervising high complexity testing
3. Doctoral degree holders with specific laboratory science education and certification
4. Individuals qualified and serving as laboratory directors as of December 28, 2024
5. For oral pathology subspecialty, certification by specific pathology boards

[57 FR 7172, Feb. 28, 1992, as amended at [58 FR 5234](#), Jan. 19, 1993; [59 FR 62609](#), Dec. 6, 1994; [62 FR 25858](#), May 12, 1997; [63 FR 55034](#), Oct. 14, 1998; [65 FR 82944](#), Dec. 29, 2000; [68 FR 3713](#), Jan. 24, 2003; [88 FR 90041](#), Dec. 28, 2023]

# § 493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

## Delegation of Duties

- (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§ 493.1447, 493.1453, 493.1459, and 493.1487, respectively.
- (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

## On-site Requirements

- (c) The laboratory director must:
  - 1. Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed.
  - 2. Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.
- (d) Each individual may direct no more than five laboratories.

## Core Responsibilities

- (e) The laboratory director must ensure quality laboratory services, appropriate physical environment, test methodology selection, verification procedures, proficiency testing, quality control, quality assessment, proper reporting of results, and proper supervision of personnel.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003; 88 FR 90041, Dec. 28, 2023]



# § 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of [§ 493.1449 of this subpart](#) and provides technical supervision in accordance with [§ 493.1451 of this subpart](#).

## § 493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

### General Requirements

- (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required;
- (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor meets specific qualifications.

### Specialty-Specific Requirements

The regulation specifies detailed qualification requirements for technical supervisors in various specialties and subspecialties:

- Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology
- Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunochemistry
- Cytology
- Histopathology (including dermatopathology and ophthalmic pathology)
- Oral Pathology
- Histocompatibility
- Clinical cytogenetics

Each specialty has specific education, training, and experience requirements.

## § 493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in [\(a\)](#) of this section.

### Accessibility

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation;

### General Responsibilities

(b) The technical supervisor is responsible for:

1. Selection of test methodology
2. Verification of test procedures
3. Enrollment in proficiency testing
4. Establishing quality control program
5. Resolving technical problems
6. Ensuring proper test system function
7. Identifying training needs
8. Evaluating competency of testing personnel
9. Evaluating and documenting performance of testing personnel

### Cytology-Specific Responsibilities

(c) In cytology, the technical supervisor or qualified individual:

1. May perform duties of cytology general supervisor and cytotechnologist
2. Must establish workload limits
3. Must reassess workload limits every 6 months
4. Must perform specific functions related to cytology
5. Must ensure participation in proficiency testing
6. Must document cytology slide screening activities

§ 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of § 493.1455 of this subpart and provides clinical consultation in accordance with § 493.1457 of this subpart.

§ 493.1455 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Laboratory Director Qualification

Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, § 493.1443(b)(5);

(b) Medical Licensure

Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 88 FR 90043, Dec. 28, 2023]

§ 493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

Be available to provide consultation to the laboratory's clients;

Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

Ensure that reports of test results include pertinent information required for specific patient interpretation;

Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§ 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under § 493.1461 of this subpart to provide general supervision in accordance with § 493.1463 of this subpart.

§ 493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

Basic Requirements

- (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required;
- (b) The general supervisor must be qualified as a laboratory director or technical supervisor;

Alternative Qualifications

- (c) If the requirements of paragraph (b)(1) or (2) are not met, the individual functioning as the general supervisor must meet alternative qualification pathways;
- (d) For blood gas analysis, specific qualifications apply;
- (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology through qualified technical supervisors.

§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (e), or—

(a) State Licensing

Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required;

(b) Qualification Requirements

Meet one of the following requirements:

- 1. Have graduated from a school of cytotechnology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP);
- 2. Be certified in cytotechnology by a certifying agency approved by HHS;
- 3. Be qualified and serving as a cytotechnologist in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since then.

§ 493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed;

For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer;

The number of hours spent examining slides in each 24-hour period.

§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

§ 493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

(a) State Licensing

Possess a current license issued by the State in which the laboratory is located, if such licensing is required;

(b) Qualification Requirements

Meet one of the following requirements:

- 1. Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located;
- 2. Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution;
- 3. Have earned an associate degree in a laboratory science or medical laboratory technology or equivalent education and training;
- 4. Have completed military medical laboratory procedures training;