

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2012057	<b>(X3) Date Survey Completed</b>  10/04/2019
<b>Name of Provider or Supplier</b>  Precise Pathology Associates, PLLC	<b>Street Address, City, State</b>  10847 Kuykendahl Rd Suite 200, The Woodlands, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 2 tests in 2017 and 2018. (grossing) Findings were: 1. A review of laboratory testing records from 2017 and 2018 revealed no documentation of the laboratory verifying the accuracy for grossing. 2. An interview with laboratory director on 10/4/19 at 0950 hours in the office confirmed the above findings.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedures, laboratory records, and confirmed in interview, the laboratory failed to establish a policy for the twice annual accuracy assessment for the special stains performed. Findings were: 1. Review of laboratory records from 2017 through 2019 revealed documentation of the laboratory verifying the accuracy of the following special stains used in histopathology: AFB, Alcian Blue/ PAS without diastase, Alcian Blue/ PAS, PAS with diastase, PAS without diastase, Giemsa, GMS, Iron, Trichrome. 2. Review of the laboratory procedures revealed no documentation of a procedure for how the laboratory performed and assessed the twice annual accuracy assessment of the above stains. 3. An interview with the laboratory director on 10/4/19 at 1110 hours in the office confirmed the above findings.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory policy, laboratory personnel records and interview, the technical supervisor failed to document annual competency evaluations for testing person (TP) # 2. Findings were: 1. Review of the laboratory policy Competency Evaluation (GEN-03) revealed "all employees are required to participate in the program annually and new employees semi-annually." 2. Review of the facility's personnel files revealed no documentation for 1 of 4 testing personnel (TP) of an annual competency evaluation in 2018 relating to laboratory testing for macroscopic (grossing) and microscopic examination. 3. An interview of the lab director on 10/4/19 at 0940 hours in the office confirmed the above findings. She was unaware that pathologists were required to have competencies also.

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**  
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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 or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a

general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on review of the patient test reports and interview the laboratory failed to review within 24 hours of all physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures. Finding were: 1. A random review of the patient reports, whose grossing was performed by a testing person (not qualified as a technical supervisor) from August 2019 and September 2019 revealed 2 of 10 test reports which did not document review of the grossing by the technical supervisor (TS) within 24 hours. Case # SP19-000541-SE Case # SP19-000654-SE 2. An interview with the laboratory director on 10/4/19 at 1040 hours in the office confirmed that there is no review of the grossing.