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D5217 610H 630H	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing and lack of twice yearly accuracy verification records for 2016, 2017, 2018 and to date April 25, 2019, and interview with the histopathology manager, the laboratory failed to establish a means to verify the accuracy of histopathology testing (reading of slides) twice a year. Findings: 1. Review of proficiency testing and a lack of twice yearly accuracy verification records for 2016, 2017, 2018, and to date April 25, 2019, revealed a lack of documentation to verify accuracy two times a year for histopathology slide examination. 2. Interview with the histopathology manager on April 25, 2019 at 12:00 PM confirmed the laboratory failed to verify the accuracy of the nonregulated histopathology slide examination testing twice annually since 2016.	D5217		
D5400 610H	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in §493.1289 for each specialty and subspecialty of testing	D5400		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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D5400	Continued From page 1 performed. This CONDITION is not met as evidenced by: Based on review of grossing procedures and interview with testing personnel #5, the laboratory failed to have a step by step procedure for grossing "Products of Conception" (refer to D5403).	D5400		
D5403 610H	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in §493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values).	D5403		

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D5403	Continued From page 2 (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the histopathology grossing procedures and interview with testing personnel (TP) #5, the laboratory failed to have a step-by-step procedure for the special procedure of "Products of Conception." Findings: 1. Review of the procedure manual located in the grossing room showed a lack of a step-by-step procedure for grossing of the special procedure, "Products of Conception." 2. Interview with TP #5 on April 25, 2019 at 12:30 PM confirmed, "We do not have a step-by-step procedure for Products of Conception."	D5403		
D5800 610H	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.	D5800		

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D5800	Continued From page 3 This CONDITION is not met as evidenced by: Based on review of histopathology grossing procedures and interview with testing personnel #5, the laboratory failed to have a procedure to monitor, assess and correct problems identified in the postanalytic system (refer to D5891).	D5800		
D5891 610H	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) 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 postanalytic systems specified in §493.1291. This STANDARD is not met as evidenced by: Based on review of histopathology grossing procedures and interview with testing personnel (TP) # 5, the laboratory failed to have a procedure to monitor, assess and correct problems identified in the postanalytic system. Findings: 1. Review of the procedure manual located in the grossing room revealed a lack of procedure to monitor, assess, and correct problems identified in the postanalytic system. 2. Interview with TP # 5 on April 25, 2019 at 1:00 PM confirmed the laboratory failed to have procedures for the postanalytic system process.	D5891		
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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	D6076		

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D6076	Continued From page 4 this subpart. This CONDITION is not met as evidenced by: Based on review of procedures and personnel documentation and interview with testing personnel (TP) #5 and the laboratory director, the laboratory director failed to ensure the QA programs are established and maintained (refer to D6094); failed to ensure two of six TP performing histopathology testing had the appropriate education and one of six TP performing histopathology testing had the appropriate training (refer to D6102).	D6076		
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) policy, the "Communication of unexpected findings with delay of final pathology report" policy, patient reports, and interview with testing personnel (TP) #7, #5, and the histopathology manager, the laboratory director failed to ensure the QA program was maintained to assure the quality of services and identify failures. Findings: 1. Review of "Anatomic Pathology Quality Assurance Procedures Specific Guidelines" procedure revealed the instructions "correlate current biopsy diagnosis with previous histological and cytological diagnosis". 2. Review of "Communicating unexpected findings with delay of final pathology report" policy	D6094		

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D6094	Continued From page 5	D6094		

revealed the instructions "when the pathologist in charge of the surgical pathology case finds the diagnosis is clinically significant or unexpected, these findings should be communicated to the clinician as soon as possible."
3. Review of patient A's final report collected 5/26/2018 showed on the gross description "placenta and fetal parts are grossly identified" and the microscopic exam revealed "the section demonstrated immature chorionic villi, placental membrane and decidua". Review of patient A's report labeled as a "re-aspiration" sample collected on 6/30/2018 showed on the gross description "placenta and fetal parts are grossly identified" and the microscopic exam revealed "the section demonstrates immature chorionic villi, placental membrane and decidua."
4. Interview with the histopathology manager on April 25, 2019 at 9:00 AM stated "on previous cases, the pathologists can pull up the previous diagnosis, compare and amend the report if needed."
5. Interview with TP #5 on April 25, 2019 at 12:00 PM confirmed he/she saw and reported "placenta and fetal parts are grossly identified" on both specimens collected May 26, 2018 and June 30, 2018.
6. Interview with TP #7 on April 25, 2019 at 9:30 AM stated "it is common practice to pull up previous reports on patients." TP #7 confirmed the knowledge of the second specimen collected on June 30, 2018 as a re-aspiration and confirmed "I did not check the patient's previous history." TP #7 did not contact the physician to discuss the second sample received on patient A.
7. Interview with the laboratory director on April 25, 2019 at 11:30 AM stated "the pathologists do not routinely pull up previous reports for Products of Conception." "If there is a question about the

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D6094	Continued From page 6 sample, the expectation of the pathologist is to contact the physician." The laboratory director confirmed the pathologist did not contact the physician.	D6094		
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documentation for histopathology testing and interview with TP #5, the laboratory director failed to ensure two of six TP had appropriate education for histopathology testing and one of six TP received appropriate training for histopathology testing. Findings: 1. Review of TP education documentation showed the laboratory director failed to provide documentation (academic credentials) to show TP #4 and #6 were qualified to perform high complexity testing. 2. Review of 2019 histopathology TP training revealed the laboratory director failed to ensure appropriate histopathology training for TP #6. 3. Interview with TP #5 on April 25, 2019 at 1:00 PM confirmed the laboratory director failed to ensure TP #4 and #6 had appropriate education for histopathology testing and that TP #6 received appropriate training for histopathology testing.	D6102		
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES	D6128		

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D6128	Continued From page 7 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 review of personnel documentation and interview with testing personnel (TP) #5, the technical supervisor (TS)failed to perform one of six competency assessment evaluations for 2018. Findings: 1. Review of 2018 TP competencies revealed the TS failed to perform TP #6 competency for high complexity testing. 2. Interview with TP #5 on April 25, 2019 at 1:00 PM confirmed the TS failed to perform TP #6's annual competency assessment for 2018.	D6128		
D6168	TESTING PERSONNEL CFR(s): 493.1487 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. This CONDITION is not met as evidenced by: Review of personnel records revealed and interview with testing personnel (TP) #5 confirmed, two of six TP did not have academic	D6168		

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D6168	Continued From page 8 qualifications required to perform high complexity testing. (Refer to # 6171)	D6168		
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(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 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the	D6171		

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D6171	Continued From page 9	D6171		

ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)
(b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.
(b)(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;
(b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either--
(b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or
(b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);
(b)(5)(i) Until September 1, 1997--
(b)(5)(i)(A) Have earned a high school diploma or equivalent; and
(b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has--
(b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
(b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures;
(b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use;

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D6171	Continued From page 10 (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of §493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of academic credentials and interview with testing personnel (TP) #5, the laboratory failed to provide academic credentials to qualify two of six TP.	D6171		

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D6171	Continued From page 11 Findings: 1. Review of academic credentials showed laboratory could not provide documentation (academic credentials) to show TP #4 and #6 were qualified to perform high complexity testing. 2. Interview with TP #5 on April 25, 2019 at 1:00 PM confirmed the documents needed to qualify TP #4 and #6 were not available for review.	D6171		