Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2099698	09/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Eastern Pathology	3135 S State Street Suite 350t, Ann Arbor, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to retain histopathology slides for 2 (Patients 1 and 2) of 10 patient histopathology slides reviewed. Findings include: 1. The surveyor requested patient histopathology slides for 10 patients on 9/16/20 at 2:33 pm and the following patient slides were not made available during the survey: a. Patient 1 tested on 10/3/18 b. Patient 2 tested on 12/27/18 2. A review of the laboratory's established "Quality Assessment/Assurance Program as it applies to the diagnostic QA program at Eastern Pathology" procedure revealed a section stating, "All slides and reports and requisition forms filed/stored permanently at Eastern Pathology Beckley location are available for review by laboratory accrediting agencies." 3. An interview on 9/16/20 at 4:11 pm with the LD confirmed histopathology slides for the patients listed above were not made available.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to retain requests for patient testing for 2 (Patients 1 and 2) of 9 patient test requests reviewed. Findings include: 1. The surveyor requested patient test requests for 9 patients receiving testing at the laboratory and the following were not made available during the survey: a. Patient 1 tested on 10/3/18 b. Patient 2 tested on 12/27 /18 2. A review of the laboratory's established "Quality Control and Quality Assurance" procedure revealed a section stating, "All information pertaining to specimen collection, preservation and rejection are covered in the procedure manual. All patient test information will be maintained in the appropriate logs in documented in the patient's chart." 3. A review of the laboratory's established "Quality Assessment /Assurance Program as it applies to the diagnostic QA program at Eastern Pathology" procedure revealed a section stating, "All slides and reports and requisition forms filed /stored permanently at Eastern Pathology Beckley location are available for review by laboratory accrediting agencies." 4. An interview on 9/16/20 at 4:11 pm with the LD confirmed the laboratory did not make the patient test requests available.
D5403	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). (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 record review and interview with the Laboratory Director, the laboratory failed to establish a procedure to perform microscopic tissue examinations in histopathology and oral pathology for 2 (2018 to 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's established procedure manual revealed a lack of procedure to perform microscopic tissue examinations in specialties histopathology and oral pathology. 2. An interview on 9/16/20 at 2:10 pm with the LD confirmed the laboratory did not establish procedures to perform microscopic tissue examinations.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to include the correct address of the laboratory location where the microscopic tissue examinations were performed on the test report for 1 (Patient 5) of 9 patient test reports reviewed. Findings include: 1. A review of 9 patient test reports revealed a report for Patient 5 tested on 6/28/19 listed "CLIA: 51D2047184 Eastern Pathology 94 Brookshire Ln Beckley, WV 25801" as the laboratory performing testing. 2. An interview on 9/16/20 at 4:03 pm with the LD confirmed the address listed on the test report was not accurate. ***This is a repeat deficiency from the 8/17 /16 and 2/6/18 surveys***