Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0957969	12/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jeff P Young Md Pa	2011 Moores Ln, Texarkana, TX	

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
D0000	The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D5217	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 laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to verify the accuracy of potassium hydroxinde (KOH) for two of two years (2019 and 2020). 1. Review of the laboratory 'Quality Assurance Procedures', subsection KOH states: "At least twice annually, the lab director will verify the accuracy of KOH by peer review. The lab Tech will keep a KOH log in the lab and the Lab Director will monitor it quarterly." 2. Based on review of the laboratory quality assurance logs, the laboratory failed to verify the accuracy of the PPM test KOH twice annually in 2019 and 2020. 3. In an interview at 13:10 hours on 12/2/2021, the laboratory personnel confirmed the above stating that they just don't perform that many KOH's. Key: KOH - potassium hydroxide PPM - Provider performed microscopy .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . I. Based on surveyor observation, review of laboratory environmental logs, and confirmed in interview, the laboratory failed to have a system in place to monitor the temperature for four of four reagents stored for histopathology. 1. During the tour of the facilities at 09:10 hours on 12/2/2021 the surveyor observed the following reagents in a flammable cabinet, in a closet, in a patient exam room. Eosin Y Hematoxylin 7211 Clear-Rite 3 PolarStat - Frozen Embedding Material 2. Based on review of laboratory environmental records the laboratory failed to have a temperature monitor in place for storage area for above reagents. 3. In an interview at 09:15 hours on 12/2/2021, in the patient exam room, the laboratory personnel confirmed that there was no temperature monitor in place for the storage of the above reagents. II. Based on review of the instrument instruction manual, laboratory environmental logs, and confirmed in interview, the laboratory failed to monitor humidity for the Leica CM1510S Cryostat, for eleven of eleven months reviewed. 1. Review of the instruction manual for the Leica CM1510S Cryostat (V1.4) Section 4. 'Setup', subsection 4.1 'Installation site requirements' lists the following humidity installations requirements that must be met. "relative humidity max. 60%" With an informational note stating, "high room temperature and excessive air humidity at the installation site affect the cooling capacity of the cryostat." 2. Based on review of the laboratory's 'Temperature Monitor Log - Refrigerator, Freezer, Cryostat' for January through November 2021 the laboratory failed to monitor the humidity for the Leica CM1510S Cyrostat for eleven of the eleven months reviewed. 3. In an interview at 11:30 hours on 12/2/2021 with laboratory personnel at confirmed that the laboratory did not record the relative humidity for the Leica CM1510S Cryostat. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on surveyor observation, review of patient records, and confirmed in interview, the laboratory failed to ensure expired potassium hydroxide (KOH) reagent was not in use in patient testing for seven of seven patients tested between June 2020 and August 2021. 1. During a tour of the facility with the primary laboratory personnel at 09:10 hour on 12/2/2021 surveyor observed the following expired reagent next to the providers microscope. HealthLink KOH 10% - Lot 1914004 EXP 2020-05-20 2. Review of patient records for June 2020, September 2020, June 2021, and August 2021 lists the following 7 patients tested: June 2020 - 2 Patients 6/25/2020 - 5860 6/30/2020 - 9456 September 2020 - 2 Patients 9/2/2020 - 42909 9/2/2020 - 65256 June 2021 - 2 Patients 6/3/2021 - See Patient KOH Worksheet 1 6/4/2021 - 63544 August 2021 - 1 Patient 8/1/2021 - See Patient KOH Worksheet 2 3. During an interview at 09:10 hours on 12/2/2021 with the laboratory personnel confirmed that the expired 10% KOH reagent located next to the provider's microscope was the one used for the PPM KOH test, and that no other non-expired KOH was available for testing. Key: KOH - potassium hydroxide PPM: Provider performed microscopy .

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 review patient test records and confirmed in interview, the laboratory failed to have the name and address of the laboratory location where the test was performed, for one of one PPM testing performed; KOH. 1. Based on review of five PPM patient test reports for KOH, the laboratory failed to include the name and address of the laboratory location where the test was performed. 2. In an interview at 11:00 hours on 12/2/2021 with the practice manager confirmed that the provided patient records were the only place in which the PPM test KOH was reported. .