Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2061921	03/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mid-Florida Pathology - Mobile Unit 2	2100 Prevatt Street, Eustis, FL	

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	A Recertification survey was conducted on March 5, 2021. Mid-Florida Pathology - Mobile Unit 2 clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document all the quality control information for the Hematoxylin & Eosin (H&E) stain performed for 5 of 24 months (August 2020, September 2020, October 2020, January 2021, February 2021) from March 5, 2019 to March 5, 2021. Findings: Review of the "Frozen Section H/E Stain Quality Control Log" showed the forms did not contain the lot numbers and the expirations of all the reagents used for August 2020, September 2020, October 2020, January 2021, and February 2021. Review of the "Frozen Section H/E Stain Quality Control Log" showed the form for February 2021 was not filled out. Comparison of the two logs showed dates patients were tested where the H/E log was not filled out, and dates no patients were tested where the H/E log was filled out. The "Frozen Section Log" showed patient testing was done on the following dates: August 10, 20, 24, 27, 2020 September 14, 15, 16, 17, 18, 21, 23, 2020 October 2, 7, 8, 12, 16, 19, 20, 22, 27, 2020 January 4, 6, 11, 13, 21, 25, 26, 27, 2021 February 8, 15, 18, 23, 25, 26, 2021 The "Frozen Section H/E Stain Quality Control Log" showed the reagents were checked, filtered or changed on the following dates: August 7, 10, 20, 24, 25, 26, 27, 28, 2020 September 7, 8, 9, 10, 21, 22, 23, 24, 25, 2020 October 5, 6,

	7, 8, 9, 12, 16, 19, 20, 22, 23, 27, 30, 2020 January 1, 4, 6, 8, 11, 13, 15, 18, 21, 22, 26, 2021 During an interview on 03/05/2021 at 11:35 AM, the Quality Assurance Coordinator stated the H/E log was not filled out completely.
D6081	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(d) Each individual may direct no more than five laboratories. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director was the director of six (#1, #2, #3, #4, #5, #6) laboratories. Findings: Review of Center for Medicare and Medicare Services Aspen website, showed the Laboratory Director as being the director for six laboratories. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/03/2021 for laboratory #4, listed the Laboratory Director as being the director for laboratories #2, #3, #5, and #6. During an interview on 03/05/2021 at 12: 37 PM, Laboratory Director stated he was unaware that he was listed as the laboratory directory for laboratory #1, and that he would contact the accreditation agency to get the laboratory director changed to the acting director.